

Denial of Food and Medicine

The Impact of the

U.S. Embargo on

Health & Nutrition

in Cuba



A Report from the American Association for World Health

March 1997



Denial of Food and Medicine

THE IMPACT OF THE U.S. EMBARGO ON HEALTH AND NUTRITION IN CUBA

This study was made possible through the generous support of

**The Arca Foundation, the General Services Foundation, the Christopher Reynolds Foundation,
and the John D. and Catherine T. MacArthur Foundation**

THE AMERICAN ASSOCIATION FOR WORLD HEALTH

The American Association for World Health (AAWH) was founded in 1953 as a private, nonprofit charitable and educational organization and serves as the U.S. Committee for the World Health Organization (WHO) and the Pan American Health Organization (PAHO). Its purposes are to inform the American public about major health challenges that affect people both here and abroad, and to promote cooperative solutions that emphasize grassroots involvement. In carrying out its mission, AAWH works with a variety of public and private health-related organizations, including the Department of Health and Human Services/Centers for Disease Control and Prevention, as well as with WHO and PAHO. AAWH's work is supported by dues payments from institutional and personal members, by charitable contributions from corporate sponsors, and by foundation grants. Guidance is provided by the association's officers and board of directors.



AMERICAN ASSOCIATION FOR WORLD HEALTH
1825 K St., NW, Suite 1208 • Washington, DC 20006 • Telephone 202-466-5883

President Jimmy Carter
Honorary Chairman

Peter G. Bourne, M.D.
Chairman of the Board

Richard L. Wittenberg
President and Chief Executive Officer

Dennis F. Keller, J.D.
General Counsel
board of directors

Elizabeth Frawley Bagley, J.D.
U.S. Ambassador to Portugal
Lisbon, Portugal

Larry Baum
Senior Vice President,
Community Relations
Cedars-Sinai Medical Center
Los Angeles, California

Charles H. Epps, Jr., M.D.
Vice President for Health Affairs
Howard Univ. College of Medicine
Washington, D.C.

Mary Joy Jameson
Vice President, Communications
American Forest & Paper Association
Washington, D.C.

Lucinda Eyster Long
Director, Public Policy
Wyeth-Ayerst Laboratories
St. Davids, Pennsylvania

Joseph L. Motter
Vice President
Macro International
Calverton, Maryland

J. Patrick Nicholson
Chief Executive
N-Viro Energy Systems, Ltd.
Toledo, Ohio

Artemis P. Simopoulos, M.D.
President
Center for Genetics, Nutrition & Health
Washington, D.C.

Eliot Sorel, M.D.
President
World Association for Social Psychiatry
Washington, D.C.

Elisabeth A. Squeglia, J.D.
Attorney
Bricker & Eckler
Columbus, Ohio

Stephen L. Ummel
National Advisor on Integrated
Delivery Systems, Ernst & Young LLP
Chicago, Illinois

The U.S. embargo against Cuba has been in place since the early 1960s. It is one of the few embargoes of recent years (Iraq, Iran, Libya, South Africa, and Bosnia) that explicitly includes foods and medicines in its virtual ban on bilateral commercial ties. Prompted by our 40-year commitment to international health, especially in the developing world, and by the tightening of the embargo since 1992, the American Association of World Health (AAWH) launched a study of the impact of U.S. policy on the health of the Cuban population.

Over a twelve-month period between 1995 and 1996, a multi-disciplinary research team traced the implications of embargo restrictions on health care delivery and food security in Cuba. The team reviewed key U.S. regulations and their implementation, conducted a survey of 12 American medical and pharmaceutical companies and documented the experience of Cuban import firms with the embargo. The team assessed the impact of U.S. sanctions on health in Cuba through on-site visits to 46 treatment centers and related facilities; it conducted 160 interviews with medical professionals and other specialists, government officials, representatives of non-governmental organizations, churches and international aid agencies. In October 1996, the AAWH sent a delegation of distinguished medical experts to Cuba to validate the findings of the draft report through first-hand observation.

This full report of more than 300 pages is the first comprehensive study of its kind. We are pleased to make it available to those who wish more detailed information than the Executive Summary offers. Neither document includes specific policy recommendations. Both are intended to provide a factual basis for informed decision-making on Cuba, and indeed on the wisdom of including food and medicine in any embargo as a means to achieve foreign policy objectives. The AAWH hopes that our findings will temper debate and enhance public knowledge and policy.

Peter G. Bourne, M.D.
Chairman of the Board
American Association for World Health
January 15, 1997

TABLE OF CONTENTS

	Preface	
	Summary of Findings	
	Methodology	
Chapter One	The Embargo	1
	History and Overview	
	The U.S. Role in Pharmaceutical Development & Patent Law	
	Effects of the Embargo	
Chapter Two	Cuban Health Care in the Nineties	31
Chapter Three	Medical Exports to Cuba	43
	U.S. Leadership & the Embargo Restrictions	
	Cuban Importers & Their Trading Partners	
	The Licensing Process	
	Financial & Medical Impact of Embargo Restrictions	
Chapter Four	Medical Testing, Research & the Pharmaceutical Industry	75
	Diagnostic Testing & Protection of the Blood Supply	
	Vaccines & Biotechnology	
	The Pharmaceutical Industry	
Chapter Five	Selected Aspects of Health & Welfare	119
	Food Security & Nutrition	
	Women's Health	
	Water Resources	
	Children's Health	
	Family Relations	
	National Health Emergencies	
	Hospital Care	
Chapter Six	Prevention, Diagnosis & Treatment of Disease	215
	Oncology	
	Cardiology	
	The HIV/AIDS Program	
	Nephrology	
	Endocrinology	
	Ophthalmology	
	Treatment of Foreign Patients	
Chapter Seven	Continuing Medical Education & Exchange of Scientific Information	265
Chapter Eight	Humanitarian Donations & International Cooperation	279
Chapter Nine	International Law & the Embargo	293
	Appendices	
	A. AAWH Delegates to Cuba	
	B. Sites Visited and Persons Interviewed	
	C. About the Authors	

Summary of Findings

After a year-long investigation, the American Association for World Health has determined that the U.S. embargo of Cuba has dramatically harmed the health and nutrition of large numbers of ordinary Cuban citizens. As documented by the attached report, it is our expert medical opinion that the U.S. embargo has caused a significant rise in suffering-and even deaths-in Cuba. For several decades the U.S. embargo has imposed significant financial burdens on the Cuban health care system. But since 1992 the number of unmet medical needs-patients going without essential drugs or doctors performing medical procedures without adequate equipment-has sharply accelerated. This trend is directly linked to the fact that in 1992 the U.S. trade embargo--one of the most stringent embargoes of its kind, prohibiting the sale of food and sharply restricting the sale of medicines and medical equipment--was further tightened by the 1992 Cuban Democracy Act.

A humanitarian catastrophe has been averted only because the Cuban government has maintained a high level of budgetary support for a health care system designed to deliver primary and preventive health care to all of its citizens. Cuba still has an infant mortality rate half that of the city of Washington, D.C. Even so, the U.S. embargo of food and the de facto embargo on medical supplies has wreaked havoc with the island's model primary health care system. The crisis has been compounded by the country's generally weak economic resources and by the loss of trade with the Soviet bloc.

Recently four factors have dangerously exacerbated the human effects of this 37-year-old trade embargo. All four factors stem from little-understood provisions of the U.S. Congress' 1992 Cuban Democracy Act (CDA):

- 1) **A Ban** on Subsidiary Trade-Beginning in 1992, the Cuban Democracy Act imposed a ban on subsidiary trade with Cuba. This ban has severely constrained Cuba's ability to import medicines and medical supplies from third-country sources. Moreover, recent corporate buy-outs and mergers between major U.S. and European pharmaceutical companies have further reduced the number of companies permitted to do business with Cuba.
- 2) **Licensing**-Under the Cuban Democracy Act, the U.S. Treasury and Commerce Departments are allowed in principle to license individual sales of medicines and medical supplies, ostensibly for humanitarian reasons to mitigate the embargo's impact on health care delivery. In practice, according to U.S. corporate executives, the licensing provisions are so arduous as to have had the opposite effect. As implemented, the licensing provisions actively discourage any medical commerce. The number of such licenses granted-or even applied for since 1992-is minuscule. Numerous licenses for medical equipment and medicines have been denied on the grounds that these exports "would be detrimental to U.S. foreign policy interests."
- 3) **Shipping**-Since 1992, the embargo has prohibited ships from loading or unloading cargo in U.S. ports for 180 days after delivering cargo to Cuba. This provision has strongly discouraged shippers from delivering medical equipment to Cuba. Consequently shipping costs have risen dramatically and further constricted the flow of food, medicines, medical supplies and even gasoline for ambulances. From 1993 to 1996, Cuban companies spent an additional \$8.7 million on shipping medical imports from Asia, Europe and South America rather than from the neighboring United States.
- 4) **Humanitarian** Aid-Charity is an inadequate alternative to free trade in medicines, medical supplies and food. Donations from U.S. non-governmental organizations and international agencies do not begin to compensate for the hardships inflicted by the embargo on the Cuban public health system, in any case, delays in licensing and other restrictions have severely discouraged charitable contributions from the U.S.

Taken together, these four factors have placed severe strains on the Cuban health system. The declining availability of foodstuffs, medicines and such basic medical supplies as replacement parts for thirty-year-old X-ray machines is taking a tragic human toll. The embargo has closed so many windows that in some instances Cuban physicians have found it impossible to obtain life-saving medicines from any source, under any circumstances. Patients have died. In general, a relatively sophisticated and comprehensive public health system is being systematically stripped of essential resources. High-technology hospital wards devoted to cardiology and nephrology are particularly under siege. But so too are such basic aspects of the health system as water quality and food security.

Specifically, the AAWH's team of nine medical experts identified the following health problems affected by the embargo:

- 1) **Malnutrition-**The outright ban on the sale of American foodstuffs has contributed to serious nutritional deficits, particularly among pregnant women, leading to an increase in low birth-weight babies. In addition, food shortages were linked to a devastating outbreak of neuropathy numbering in the tens of thousands. By one estimate, daily caloric intake dropped 33 percent between 1989 and 1993.
- 2) **Water Quality-**The embargo is severely restricting Cuba's access to water treatment chemicals and spare-parts for the island's water supply system. This has led to serious cutbacks in supplies of safe drinking water, which in turn has become a factor in the rising incidence of morbidity and mortality rates from water-borne diseases.
- 3) **Medicines & Equipment-**Of the 1,297 medications available in Cuba in 1991, physicians now have access to only 889 of these same medicines- and many of these are available only intermittently. Because most major new drugs are developed by U.S. pharmaceuticals, Cuban physicians have access to less than 50 percent of the new medicines available on the world market. Due to the direct or indirect effects of the embargo, the most routine medical supplies are in short supply or entirely absent from some Cuban clinics.
- 4) **Medical Information-**Though information materials have been exempt from the U.S. trade embargo since 1988, the AAWH study concludes that in practice very little of such information goes into Cuba or comes out of the island due to travel restrictions, currency regulations and shipping difficulties. Scientists and citizens of both countries suffer as a result. Paradoxically, the embargo harms some U.S. citizens by denying them access to the latest advances in Cuban medical research, including such products as Meningitis B vaccine, cheaply produced interferon and streptokinase, and an AIDS vaccine currently undergoing clinical trials with human volunteers.

Finally, the AAWH wishes to emphasize the stringent nature of the U.S. trade embargo against Cuba. Few other embargoes in recent history-including those targeting Iran, Libya, South Africa, Southern Rhodesia, Chile or Iraq-have included an outright ban on the sale of food. Few other embargoes have so restricted medical commerce as to deny the availability of life-saving medicines to ordinary citizens. Such an embargo appears to violate the most basic international charters and conventions governing human rights, including the United Nations charter, the charter of the Organization of American States, and the articles of the Geneva Convention governing the treatment of civilians during wartime.

Methodology

A multi-disciplinary team conducted research for this report between August, 1995 and July 1996, guided by the following concepts:

- 1) The purpose of this study is to assess whether U. S. embargo restrictions jeopardize the health of the Cuban population. Put more specifically: does the policy present a barrier to programs for health care delivery, sanitation and food security?
- 2) The research design calls for tracing the practical application of U.S. regulations and their implications for the health status of the Cuban population; not for policy recommendations, or evaluating the effectiveness of the embargo as a foreign policy option.
- 3) The investigation, although referencing embargo implications over its nearly 40-year history, concentrates on the period 1989, for which original documents and data are more readily available. The economically precarious nineties in Cuba also coincides with a strengthening of the embargo in 1992 and again in 1996.

Evolution of Research

- 1) During the first three months of the study, the team reviewed legal documentation, the scope of current U. S. regulations on trade with Cuba, and attempted to procure information from the Treasury and Commerce Departments concerning licensing procedures and the record of licensed sales to Cuba since 1989 (especially concerning medicines, medical supplies and equipment.) During the same period, they scrutinized documents made available by the Cuban Ministry of Foreign Relations and international agencies on the alleged effects of the embargo on the Cuban population.
- 2) A survey of 12 pharmaceutical companies and medical supply firms was conducted to determine their perception of and experience with embargo regulations.
- 3) A study of international patent law was undertaken to assess its implications for U. S. exports to Cuba.
- 4) With basic information gleaned in the United States, the team proceeded to trace the experience of Cuban import firms in areas especially relevant to health and welfare, agriculture, the food industry, water resources and treatment, medicines, medical supplies, and equipment. The primary research was conducted through interviews and document reviews, including correspondence from U. S. firms, their subsidiaries abroad and other foreign companies, in which the U. S. embargo was referenced. This phrase also included scrutiny of shipping records and freight documents to establish comparative data with World Scale rates, shipping from specified countries, etc.
- 5) In Cuba, representatives of international aid and development agencies were interviewed to ascertain whether the embargo has impacted external cooperation in implementing humanitarian programs on the island. Non-governmental Cuban organizations and churches involved in social services were surveyed with the same objective. (See Appendix for full list of interviews.)
- 6) With the assistance of the Ministry of Public Health, an epidemiological review was undertaken of basic health indicators and health problems throughout the island since 1935.

The validity of Cuban health statistics was validated by the Pan American Health Organization representative in Cuba., on the basis of PAHO's regular reviews of data-gathering methodology.

- 7) On-site visits were made to 32 patient care facilities in Havana City and Pinar del Rio provinces. The provinces represent two poles of Cuban society; the capital is the most highly populated urban center in the country with over two million inhabitants; and Pinar del Rio is one of the rural provinces, which at the same time approximates the average for the country in terms of health and living standards.- Time and financial constraints did not allow for extensive follow up in other regions, although telephone interviews were conducted with hospitals and institutions in five other provinces to investigate specific embargo-related difficulties.

The team visited primary care facilities (family doctors' offices and community clinics), and a series of general, maternity, and pediatric hospitals. The institutions were chosen because their records indicated that they represented the norm of treatment available to the general population, and not "showcase" facilities.

Several tertiary treatment centers and institutes were visited, in which we were able to define more explicitly the impact of U. S. embargo regulations on patient care in specialized fields.

In all on-site visits, the directors of major services were interviewed, as well as other physicians and specialists. The team visited a number of units and wards in each hospital, speaking with patients as well as staff.

While a general questionnaire was developed for these visits, it was adapted considerably to the nature of each institution. In all cases, the objective was to determine the correlation between the application of embargo restrictions and limitations on medical care offered and epidemiological patterns observed.

- 8) Researchers conducted interviews and reviewed documentation at a number of research centers, pharmaceutical production plants, food industry facilities, biotechnology institutes and medical schools, for detailed information to enhance specific sections of this report.

In all, some 170 interviews were conducted in Cuba with medical professionals and other specialists, government officials, representatives of non-governmental organizations, churches, and international aid agencies. (See Appendix for the complete list of interviewees and institutions visited.)

- 9) In October 1996, AAWH sent a delegation of distinguished medical experts to Cuba to validate the findings of the draft report through first-hand observation. (See attached list of participants.)

CHAPTER ONE

THE EMBARGO

History and Overview

Recent U.S. laws seeking to bring about political change in Cuba by exerting economic pressure are not new. Economic sanctions against the island were adopted in 1962 and, other than the ebb and flow of their severity brought on by various gestures toward Castro by intervening administrations, the embargo has intensified in its severity and scope. The bulk of U.S. prohibitions against trade with Cuba are set forth in the regulations of the U.S. Department of the Treasury's Cuban Assets -Control Regulations (31 C.F.R. Part 515) and the Commerce Department's Export Administration Regulations (15 C.R.F. Parts 770 through 785). Federal law provides that civil penalties may be imposed for any violation of these regulations and that knowing violations are also punishable as criminal offenses, incurring substantial fines and possible prison terms of up to ten years. Property involved in such violations of the U.S. embargo regulations is subject to forfeiture.¹

The passage of the Cuban Democracy Act (CDA) sponsored by Congressman Robert Torricelli (D-New Jersey) and the Cuban Liberty Act (Helms-Burton) have, in practice, resulted in a severe tightening of the embargo, specifically impacting medicines and medical equipment. The CDA was originally publicized as offering a loosening of the restrictions on trade in these goods through the licensing provisions it included. However, these were more than offset by other aspects of the legislation, creating a net effect that was the opposite of what was claimed.

Since its formalized institution in 1962, the U.S. embargo against Cuba has become ever more comprehensive. The key elements of the embargo, as it now stands, include the following general prohibitions:

Imports: U.S. law prohibits any imports from Cuba into the United States.

Exports: U.S. law prohibits any exports to Cuba from the United States.

Travel: U.S. law severely restricts the freedom of U.S. citizens and residents to travel to Cuba. This is achieved by regulations which prohibit U.S. persons from paying Cuba or Cuban nationals for travel-related expenses such as hotels. There are exceptions for certain persons, such as those visiting close relatives in Cuba, journalists, academics, and persons traveling on official business for the U.S. government, foreign governments, or international organizations. Even persons in these excepted categories are subject to severe restrictions, including a \$100 per day limit on travel expenses in Cuba. Special restrictions apply to Cuban-Americans seeking to visit family members in Cuba. Under regulations published in October 1995, persons currently wishing to visit close relatives in Cuba "in circumstances of extreme humanitarian need" must apply for a license from the Treasury Department, and such licenses can be issued only for one trip per year, per person.

Transfer of money or property. The United States prohibits any U.S. person from transferring money or property of any nature to Cuban nationals. There are exceptions for family remittances, but these are limited to \$300 every three months to the household of a close relative in Cuba.

Receiving property: U.S. law prohibits any U.S. person from receiving property from Cuba or a Cuban national.

Technical data: The prohibition on transfers of property also includes the transfer of technical data.

Aircraft: U.S. law prohibits any aircraft from departing from the U.S. for Cuba and any aircraft owned or controlled by U.S. persons from departing for Cuba, regardless of departure point.

Vessels: U.S. law prohibits any third-country vessel from entering a U.S. port for a 180-day period following the vessel's entry into Cuba. This provision was included in the CDA and has been one of the most objectionable aspects of the embargo to other nations; as it dramatically impacts foreign nations' freedom of trade.²

Penalties against other nations: The United States may cut off aid and credits to countries which give preferential treatment to Cuba. The United States also maintains veto power within several international financial...institutions over loans and credits to Cuba and nations that trade with Cuba.

- MARCH~1960:** President Eisenhower approves a plan of covert action and economic sabotage against Cuba. In the first months of 1960 the U. S. government waged a campaign to prevent Cuba from receiving loans and credits from Western European and Canadian institutions. A consortium of European banks, under pressure from the U.S., canceled plans to negotiate a \$100 million loan to Cuba.
- July -1960:** President Eisenhower cancels the unfulfilled balance of the Cuban Sugar Quota to the U. S. for 1960.
- AUGUST 1960:** Cuba issues Resolution Number 1 under Law 651, which ordered the expropriation of 26 of the largest U.S. companies operating in Cuba.
- OCTOBER 1960:** In what the media describe as a "quarantine" of Cuba, the Eisenhower Administration bans U.S. exports to that country, except for foodstuffs, medicines and medical and hospital supplies. Companies wishing to sell such goods to Cuba can do so under a "general" license; no specific license is required. Imports from Cuba continue to be allowed.
- JANUARY~1961_** The U.S. severs diplomatic relations with Cuba.
- APRIL 1961:** The Bay of Pigs invasion is launched.
- SEPTEMBER~1961** The Foreign Assistance Act of 1961 authorizes the President to establish and maintain a "total embargo upon all trade between Cuba and the U.S."
- FEBRUARY 1962:** The Kennedy Administration extends the embargo to prohibit Cuban imports into the U.S.
- MARCH 1962:** The embargo is further tightened to prohibit imports into the U.S. from third countries of goods made from or containing Cuban materials.
- AUGUST 1962:** In order to dissuade third countries, Congress amends The Foreign Assistance Act of 1961 to prohibit U.S. assistance to any country which furnished assistance to the Present government of Cuba."
- FEBRUARY 1963:** President Kennedy prohibits U.S. government -purchased cargoes from being transported on foreign flag vessels which had called at a Cuban port after January 1,1963.
- JULY 1963:** The Treasury Department produces the Cuban Assets Control Regulations, which embody the essential features of the U.S. economic embargo against Cuba. These regulations have been in effect ever since, including a freeze of all Cuban-owned assets in the United States, a prohibition on all

nonlicensed financial and commercial transactions between Cuba and the United States and between Cuba and U.S. nationals and a prohibition on the spending of money by U.S. citizens in the course of travel to Cuba.

- MAY 1964:** The Commerce Department revokes its prior general license policy for export to Cuba of foods, medicines and medical supplies. Instead, it adopts a broad policy of denying requests for such commercial sales and permits only limited humanitarian donations.
- JULY 1964:** The Organization of American States (OAS) passes a resolution obliging its members to enforce a collective trade embargo on Cuba. The resolution excludes sales of foodstuffs, medicines and medical equipment. The United States, however, continues its policy of denying licenses for such sales.
- JULY 1974:** The Treasury Department liberalizes its Cuban regulations, to allow, among other things, the importation of Cuban books and records and also lessens restrictions on travel to Cuba by scholars and journalists.
- JULY 1975:** The OAS repeals its regional trade embargo against Cuba, prompting the Ford Administration to end the ban on third-country subsidiary trade with Cuba, instead requiring only that U.S. companies obtain individual licenses for transactions involving their overseas subsidiaries.
- MARCH 1977:** The Carter Administration removes restrictions on the travel of U.S. citizens to Cuba.
- APRIL 1992:** The Reagan Administration severely restricts the travel of U.S. citizens to Cuba.
- OCTOBER 1992:** President Bush signs the Cuban Democracy Act (CDA), which outlaws subsidiary trade with Cuba and imposes severe restrictions on foreign ships that visit Cuba before attempting to enter U. S. ports. The CDA also grants to the Treasury Department, for the first time, the authority to levy civil fines of up to \$50,000 for violations of the embargo.
- MARCH 1996:** The Cuba Liberty and Democratic Solidarity Act (the "Helms-Burton Act") becomes law. It seeks to impede economic recovery under the present Cuban government by deterring foreign investment. Among other measures, the Helms-Burton Act allows foreign companies to be taken to court in the United States if they are "trafficking" in former U.S. citizen-owned properties nationalized by the Castro government in Cuba. ("Trafficking" is expansively defined to include not only direct investment in such properties, but also any activities involving such properties that benefit the "trafficker.") In addition, the Act codifies the existing Cuban Asset Control Regulations. Henceforth, any modification of those regulations will require an act of Congress.

Following the collapse of the Soviet Union in 1989 and the resulting loss of Soviet subsidies, Cuban trade with U.S. corporate subsidiaries rose dramatically. In the year prior to the October 1992 passage of the CDA, subsidiary sales to Cuba totaled between \$400-700 million.⁹ With the CDA's tightening of the embargo to include subsidiary sales (which had been licensed on a liberal basis prior to 1992) this growing trade was cut off almost overnight.

Perhaps the most onerous of the CDA's provisions, and that which is the focus of this report, are those restricting the sale of medicines and medical equipment to Cuba. The CDA provides, in relevant part:

Section 1705(c) **Exports of Medicine and Medical** supplies -Exports of medicines or medical supplies, instruments, or equipment to Cuba shall not be restricted —

- (1) except to the extent such restrictions would be permitted under section 5(m) of the Export Administration Act of 1979 or section 203(b)(2) of the International Emergency Economic Powers Act;
- (2) except in a case in which there is a reasonable likelihood that the item to be exported will be used for purposes of torture or other human rights abuses;
- (3) except in a case in which there is a reasonable likelihood that the item to be exported will be reexported; and
- (4) except in a case in which the item to be exported could be used in the production of any biotechnological product.

(d) Requirements for Certain Exports —

(1) On Site Verifications —

- (A) Subject to subparagraph (B), an export may be made under subsection (c) only if the President determines that the United States Government is able to verify, by on-site inspections and other appropriate means, that the exported item is to be used for the purposes for which it was intended and only for the use and benefit of the Cuban people.
- (B) Subparagraph (A) does not apply to donations to non-governmental organizations in Cuba of medicines for humanitarian purposes.

Licenses -Exports permitted under subsection (c) shall be made pursuant to specific licenses issued by the United States Government.

The CDA's Restrictions on the Sale of Medicines

On its face, the language of the Cuban Democracy Act regarding exports of medicines and medical supplies to Cuba seems to create a liberal policy of granting licenses for such sales. The CDA's literal wording grants exceptions for medical and humanitarian aid. Section 1705 exempts "donations of food to non-governmental organizations MGOs...[and] individuals in Cuba." The act further exempts "exports of medicines or medical supplies, instruments, or equipment," except where "restrictions would be permitted" under the Export Administration Act of 1979 or the International Emergency Economic Powers Act. The Act also restricts the export of medical materials where there is a "reasonable likelihood" of the Cuban government's misuse of such aid for reexport, human rights violations, or biotechnology.

The restrictions the CDA imposes on the delivery of medicines, however, subvert the spirit of such exceptions by making Cuba's access to such materials nearly impossible. The result is a de facto ban on critical medical and other assistance. For example, the medical supplies exemption does not seem so generous when one reads that commercial export of such supplies is subject to the issuance of "specific licenses." Permission for commercial (i.e., nonhumanitarian) export of medical materials also hinges on the President's determination "that the U.S. Government is able to verify by on site inspections" that the items will be put to their intended use to benefit Cuban citizens.

CDA § 1706(a) further limits the shipment of medical supplies to Cuba by prohibiting the issuance of licenses "for any transaction described in section 515.559 of title 31, Code of Federal Regulations"

(part of the Department of the Treasury's regulations). Section 515.559 of the Code states that "no specific licenses [which are always required in this context] will be issued...for [commercial] transactions between U.S.-owned or U.S.-controlled firms in third countries and Cuba."⁴

The U.S. government will consider license applications where certain exceptions apply. Commercial "exportation of medicine or medical supplies from a third country to Cuba"⁵ is one such exception. However, a U.S.-owned or U.S.-controlled firm must still apply for and receive a special license from the U.S. government. Even then, such exported goods are subject to the same burdensome -verification and on-site inspection- procedure⁸ as those imposed by the CDA. The result is that Cuban citizens must wait and languish while U.S. companies and/or their subsidiaries endure the lengthy (and often fruitless) license application process, await word as to whether the U.S. government can "verify" that the exported medical items will be put to their intended use, and then submit to on-site inspection procedures.

Finally, the Treasury regulations act in concert with Department of Commerce regulations to require "U.S.-owned or controlled firms" overseas to obtain Department of Commerce permission to export goods (medical and otherwise) containing U.S.-origin materials. Broad in scope, the Commerce Department regulations encompass foreign firms that are not related to U.S. companies but that merely incorporate "U.S.-origin materials, parts, or components."⁸ The Commerce Department will then only favorably consider foreign firms' request for authorization to use "an insubstantial proportion"⁹ of U.S.-origin matter in "nonstrategic, foreign-made products."¹⁰ To qualify as insubstantial, U.S.-origin matter incorporated into a foreign-made product can amount to no more than "20 per cent...of the value of the product to be exported from the third country."¹¹ The likelihood of favorable treatment is doubtful, however, since "the general policy is to deny all applications or requests to export or reexport U.S.-origin commodities and technical data" to Cuba.¹²

Of the requirements necessary for obtaining a license to sell medicines to Cuba, that of "on-site verification" provides the U.S. Treasury and Commerce Departments with an effective weapon in discouraging and denying requests for licenses. In fact, both of these departments openly state that it is their general policy to deny all applications. For example, in its 1994-1995 Annual Report, the Bureau of Export Administration (BXA) states that "[Applications for validated licenses will generally be denied, except on a case-by-case basis for...exports to Cuba of medicines and medical items that satisfy the requirements of the CDA]"¹³

Like Commerce, the Treasury Department also uses the authority and discretion granted it by the CDA to discourage and deny requests for licenses to sell to Cuba. Testifying before Congress in 1993 on the one-year anniversary of the passage of the CDA, Richard Newcomb, Director of the Office of Foreign Assets Control, boasted that the CDA had virtually cut off all sales to Cuba and stated that it was the agency's intention to see the number of licenses issued fall to zero:

The CDA prohibits the issuance of licenses pursuant to section 559 of our regulations allowing offshore transactions by Cuba with foreign subsidiaries of U.S. firms. The prohibition against issuing licenses was softened slightly, however, in that the CDA provides that the provision shall not affect contracts entered into before the enactment of the CDA.. In 1993 [Cuban trade with U.S. subsidiaries] was down to \$1.6 million. The \$16 million is accounted for by approximately 15 or 1.6 licenses which were pre-CDA contracts. We go over these [license applications] very, very carefully and only grant those that absolutely qualify. Frankly, I anticipate the number next year to be even less, falling ultimately to zero.¹⁴

In his statement before Congress, Mr. Newcomb wrongly stated that the CDA only allowed for the completion of pre-CDA contracts. His statement that the number of licenses would ultimately fall to zero either indicated his mistaken belief that once pre-CDA contracts had been completed no further licenses could be issued, or his intention that, notwithstanding the CDA's provisions for the future licensing of medical sales, the agency would not approve any additional licenses. His confusing comments with regard to the CDA's provisions are echoed throughout his agency and in his counterpart agency within the Department of Commerce, the BXA

A phone call to the Department of Commerce, Bureau of Export Administration, sums up the similar confusion encountered in trying to obtain a license from that agency to sell medicine to Cuba. In a telephone interview conducted by the authors of this report, we asked a BXA information officer to provide us with an overview of the licensing procedures for sales of medicine to Cuba. The officer responded, incorrectly, that the BXA does not license sales to Cuba, only donations. We responded that the CDA provides for licensing procedures for sales. The officer then consulted an agency manual and responded that this was indeed correct, but that the requesting company must list on the application "how it will provide for on-site inspection, and also that the goods would be for the benefit of the Cuban people." She then commented, after reading these requirements, "I doubt very seriously that a license to sell medicines to Cuba would be approved; it would be very difficult to satisfy those two criteria."¹⁵ When asked what the term "on-site verification meant" she was unable to offer an explanation. In short, the reply we received appears quite typical of those given pharmaceutical companies seeking to obtain licenses from BXA or OFAC.

In the course of preparing this report, the authors conducted an informal survey of U.S. pharmaceutical companies to inquire about their efforts in obtaining licenses for the sale of medicines to Cuba. In addition, the authors contacted the Office of Foreign Assets Control with the Department of the Treasury and the Bureau of Export Administration (BXA) within the Commerce Department, the two offices responsible for the processing of applications for licenses to sell medicines to Cuba.

In our interviews with pharmaceutical company representatives, we were told the same thing repeatedly: All inquiries to the U.S. government regarding the possibility of obtaining licenses to sell medicine to Cuba are met with confusing, sometimes hostile replies, all designed to discourage the company from even initiating the licensing process. Of the seven companies that agreed to participate in our survey, only one stated that it had successfully obtained licenses to sell to Cuba since 1992 and then only for a few specific items. This company indicated that it continued to seek to sell medicines to Cuba due to humanitarian concerns, as applying for the licenses "is more trouble than it is worth."¹⁶

We also filed requests with both the BXA and OFAC under the Freedom of Information Act (FOIA) seeking "all applications submitted to and approved licenses from" each agency regarding "subsidiary trade and/or sales of medicines, pharmaceuticals and medical supplies to Cuba" during the period 1990-1995.¹⁷ The request for information from the Commerce Department was denied for "national security reasons." The FOIA request to Treasury was also denied, but information was obtained from the Department through other channels.¹⁸

According to the information provided by the Treasury Department, in the period 1992-1995, only eight licenses were granted for sales of medicines to Cuba; two licenses were denied. Considering the high volume of such sales pre-CDA enactment, one wonders why these total figures are so low. Based solely on these figures, it would appear that only ten applications were filed with OFAC between 1992 and 1995. Pharmaceutical industry members explained to us the reason why so few companies actually file applications for licenses. As one drug company representative put it, when a company calls to informally discuss the possibility of a license with OFAC, they are given confusing information and are generally discouraged from filing a request. Similarly, a representative of OFAC confirmed this, stating that "companies hate to get a denial from the

government for any kind of license. When they phone and are told how difficult it is to comply with the licensing procedures, and are generally discouraged from applying, they usually don't follow up with filing a written application.¹⁹

Of the licensing requirements described to would-be applicants, 'perhaps the most discouraging is that of "on-site verification." Several of the pharmaceutical representatives interviewed mentioned this as an "untenable" requirement. As the CDA states, sales of medical supplies to Cuba may be licensed only if "the President determines that the United States government is able to verify, by on-site inspections-and -other appropriate means,. that the exported item is to be used for the purposes for which it was intended and only for the use and benefit of the Cuban people." Besides being an unprecedented requirement in the history of trade embargoes, neither Treasury nor Commerce has published any regulations making clear the exact meaning of this requirement or how it is to be carried out. As some authors have commented, "[t]hrough the plain language of the Act, the United States is taking upon itself the authority to monitor delivery of medical care [in Cuba]. Carried to its logical extreme, authorities could follow shipments of medicines and medical supplies into the offices of physicians, hospitals and clinics to observe their actual use."²⁰

Of the copies of the OFAC licenses that we obtained, three were able to satisfy the on-site verification requirements by making special arrangements with U.N. agencies, three with the Belgian embassy in Cuba and one with the assistance of the Red Cross. Pharmaceutical company representatives interviewed indicated that the U.S. licensing agencies offer no guidance on interpreting the on-site verification requirement. Further, the ad hoc arrangements made with the above-listed bodies are done out of humanitarian concern but are not satisfactory to those involved since international agencies and foreign embassies do not want to get involved in carrying out actions on behalf of the U.S. government or to appear to approve of the U.S. policies under the CDA. Clearly, the lack of clarity of the term 'on-site verification,' its political offensiveness to the Cuban government and its undesirability to those bodies which may be able to assist in carrying out the "inspection" all serve as a strong deterrent to pharmaceutical companies interested in selling medicine to Cuba.

An examination of the intent of the key architects of the CDA reveals an express desire to dismantle the Cuban health care system. While the creation of its world-class medical capabilities has been called the "prize of the revolution" and Cuba's leaders have been noted as viewing 'health indicators as measures of government efficacy,"²¹ Cuba's advances in medical care have caused Castro's critics to view the system as a political target. During a speech in South Florida in 1995, Richard Nuccio,²² then Special Advisor to the President on Cuba stated: "During the heyday of its \$6 billion annual subsidies from the Soviet Union, the Cuban regime was able to establish a completely government-run, command economy and provide free, universal education and health care. The Government, then, was the only source of everything for the individual, from his job to his home to medicine for his family."²³

The United States' attitude toward the accomplishments of the Castro government in creating a viable, universal health care system is clear. The inclusion of medicines in the embargo, which has had serious effects in Cuba, as examined below, have also been coupled with an increase in support for humanitarian donations of medicine. In explaining how the CDA has cut off trade with Cuba, CDA supporters are usually quick to point out that the amount of donations to Cuba from groups within the U.S. has increased. Richard Nuccio has commented: "Since the enactment of the CDA three years ago, the U.S. government has licensed over \$90 million in private humanitarian aid to Cuba, mostly food and medicine from nongovernmental groups in the U.S. distributed through nongovernmental organizations on the island."²⁴

As discussed below in greater detail, no nation can provide adequate medical care for its population through reliance on donations. The quantity of U.S. donated medical supplies to Cuba falls far below the need of Cuba's residents. Further, the instability and unpredictability of

products donated make it impossible for doctors to properly manage the treatment of certain patients, such as diabetics whose treatment necessitates precise potencies of insulin or other medicine.

The United States' Role as Leader in World Pharmaceutical Development and its Impact on Cuba

U.S. pharmaceutical corporations' large-scale -acquisitions of foreign drug companies, which are taking place at an unprecedented rate, are worsening Cuba's ability to obtain critical pharmaceuticals and medical equipment. These acquisitions trigger a broadening of the reach of U.S. patent protection and the 1992 Cuban Democracy Act's preemptive embargo provisions.

Cuba's ongoing shortage of certain medical materials is linked to the much-heralded globalization of the world economy. Yet in terms of Cuba's access to world-class drugs and high-end medical technology, such globalization is less a result of neighborly cooperation than it is a byproduct of U.S. pharmaceutical companies' mergers and acquisitions and the resulting international reach of U.S. patent and trade law.

For Cuba, pharmaceutical megamergers and the correspondingly broadened scope of U.S. patent law provisions combine with the 1992 Cuban Democracy Act to place top-tier, often unique, medical products out of Cubans' reach. The results are obvious: critical shortages of even the most basic medicines and medical hardware and a serious threat to ordinary Cuban citizens' health and medical care.

Analyzing just how Cuba's medical supply crisis stems from the interrelationship between U.S. patent law, the Cuban Democracy Act, and pharmaceutical industry mergers requires an holistic overview.

An Overview of U.S. Patent Law: Protecting Proprietary Interests

U.S. patent law, codified by the 1952 Patent Act (the Act)²⁵, provides this country's highest level of intellectual property protection. It grants the patentee and his or her successors in title²⁶ a 17-year exclusive right over a patented invention's or process's²⁷ manufacture, use, and sale.²⁸ The Act also bars nonpatentees from actively inducing patent infringement;²⁹ engaging in contributory infringement,³⁰ selling essential components to induce foreign production of a patented invention,³¹ and importing into the United States, or selling or using within this country, any product created through a patented process.²²

In the pharmaceutical arena, an ingenious chemical composition devised to produce a salutary medical result would be patentable, as would the process or processes invented to create such composition.³³ The underlying chemicals themselves may or may not be patentable: man-made chemicals contained in the composition might receive patents, while naturally occurring substances such as oxygen could not.

Of course, different people may hold the respective patents involved in pharmaceuticals. Theoretically, a lone scientist could hold a patent for the process by which a drug is created. Someone else may hold the patent on the drug's actual composition, while a third person may hold a patent for an improved version of the drug's production process, use, or composition.

Drug Patents and the FDA Approval Problem

Drug patents are valid for 17 years. Yet drug manufacturers must get FDA approval after patent issuance and before full-scale marketing. Because FDA approval can take seven to ten years, a manufacturer may only have ten to seven years left on the patent term. Driven to recoup investments and realize maximum profits, the manufacturer must adjust supplies and prices accordingly to compensate for the marketing and sales opportunities lost to the shortening of the patent's useful life. To address this, Congress used Patent Act § 1.56 to permit patent term extensions for certain products requiring FDA approval before sale.³⁴

U.S. Patents and the International Arena

The Paris Convention. U.S. patent rights are viable only within U.S. borders. Inventors desiring patent protection overseas can use the Paris Convention for the Protection of Industrial Property (the Paris Convention) to obtain intellectual property rights in member countries.

With over 100 members, the Paris Convention provides that “[n]ationals of any country of the Union shall...enjoy in all the other countries of the Union the advantages that their respective laws now grant, or may hereafter grant, to nationals.”³⁵ This means that all patents within the same country receive the same rights.³⁶ Thus, an inventor who patents his or her product in a member country receives the same patent protection as that country's citizens.

Convention Article 4 states that “[a]ny filing...equivalent to a regular national filing under...[any Union member's] domestic legislation... shall be recognized as giving rise to the right of priority.”³⁷ Under the Convention the priority right for patents is 12 months.³⁶ Working in conjunction with Patent Act §§ 119³⁹ and 365, this means that one who files a patent application in one member country within 12 months of filing for the same invention in another member nation can assign the earlier filing date to the second application. The inventor thus gets the benefit of the earlier filing date in the event of patent disputes.

The Patent Cooperation Treaty The Patent Cooperation Treaty (PCT), adopted by the United States through Patent Act §§ 3513⁷⁶, attempts to streamline international patent procedures. Under the PCT, a patent applicant files an international application with a member country's Receiving Office (usually that country's domestic patent review office). The applicant indicates on the application the member countries from which he or she seeks patent protection.⁴⁰ Each signatory's Receiving Office ensures that the applications it receives satisfy all formalities. Receiving Offices then send copies of the applications to an International Searching Authority (ISA) and the International Bureau (IB) (the latter serving as an application storehouse). At present, the U.S. Patent Office (PTO) and other nations' patent offices serve as ISAs. The current IB is the World Intellectual Property Organization in Switzerland.⁴¹

After an ISA receives an application, it “conducts an international search aimed at discovering prior art that may be relevant in determining whether the invention is new and nonobvious.”⁴² The ISA then submits a Search Report to both the applicant and the IB. The applicant can then request the IB to forward the application and the Search Report to all countries listed on the application. If so, these countries then assess patentability according to their respective laws.⁴³

The applicant can opt instead to have the IB send the application to an International Preliminary Examining Authority (usually a state party's domestic patent office). The Authority then performs an International Preliminary Examination culminating in “a written opinion as to whether each claim is novel, involves an inventive step, and is industrially applicable.”⁴⁴ The Authority sends the opinion to the IB, the applicant, and each listed nation's patent office. Because every patent

office is free to disregard the opinion, each will apply its own country's law in assessing patentability.

Patent Infringement

A patent is a 17-year,⁴⁵ exclusive right to manufacture, use, and sell the patented product in the United States. According to Patent Act § 271, anyone exercising that right without the patentee's permission is guilty of infringement.⁴⁶ A patentee, however, also has a cause of action against anyone inducing patent infringement⁴⁷ and anyone contributing to another's infringement in the United States.⁴⁸ Patentees may also act to bar importation of goods into the United States that were made using a U.S.-patented process.⁴⁹ Finally, a patentee can recover for another's distribution of parts for overseas assembly of a U.S.-patented product.⁵⁰

Use Infringement for Drug Testing

A drug patent, valid for 17 years, grants an exclusive right over domestic use, manufacture, and sale. Of course, a patented drug manufacturer's competitors will use that 17-year period to analyze, test, and replicate the drug to ready themselves to market the drug once the patent expires.

Under *Roche Products, Inc. v. Bolar Pharmaceuticals Co., Inc.*,⁵¹ however, a company (or person) infringes a drug patent if it fails to obtain a patent license before engaging in "testing and investigation strictly related to FDA drug approval requirements during the...patent [term]."⁵² Such unlicensed testing and investigation constitutes infringing use in violation of Patent Act § 271 by clearly being geared toward generating future profits from the sale of the tested drug following patent termination.⁵³ Such profit-oriented use falls outside the traditional experimental use exception and therefore gives rise to a cause of action.⁵⁴

Congress partially nullified the *Bolar* decision's effect by enacting Patent Act § 271 (e). This section states that "it shall not be an act of infringement to make, use, or sell a patented invention...primarily manufactured using...processes involving site specific genetic manipulation...solely for use reasonably related to the development and submission of information under a Federal law...regulat[ing] the manufacture, use, or sale of drugs" ⁵⁵ Although the Supreme Court extended this exemption to "medical device[s] requiring FDA approval,"⁵⁶ the wording of § 271 (e)'s affords relatively limited application. *Thus, the Bolar* decision holds for drugs outside 271 (e)'s boundaries and for medical devices not needing FDA sanction.

U.S. Patents and the CDA: Merging with Megamergers to Fuel Cuba's Medical Shortages

Worldwide mergers among large-scale pharmaceutical companies, particularly between U.S. and foreign corporations, make first-rate drugs and medical technology progressively less accessible to Cuba's needy population. U.S. drug companies' acquisitions of foreign counterparts extend the reach of U.S. patent protection and bring acquired companies under the CDA's discouraging, time-consuming, and often bewildering licensing requirements.

In medicine, time is critical where lives are at stake. For Cuba's medical establishment, precious time is lost trying to identify a shrinking number of sources for alternatives to the drugs and technology made increasingly out of reach due to megamergers that only lengthen the shadow cast by U.S. patent protection and CDA restrictions.

The Megamerger Trend among U.S. and Foreign Pharmaceutical Companies

The past few years have witnessed large-scale pharmaceutical industry mergers and acquisitions. These include drug company purchases of competitors as well as strategic pharmaceutical buys of key drug distributors.

In 1993, for example, Merck & Co., an industry giant, acquired distributor Medco Containment Services, Inc.⁵⁷ On May 2, 1994, Boche Holding Ltd., another main industry player, agreed to pay \$5.3 billion for Syntex Corp., a commercial counterpart.⁵⁸ Just four years earlier, Roche purchased 66% of Genentech, Inc., a leading biotechnology concern.⁵⁹ Around the time of the Syntex acquisition, SmithKline Beecham PLC outlined an agreement to buy distributor Diversified Pharmaceutical Services, Inc. for \$23 billion "and to ally with Diversified's parent, powerhouse health maintenance organization United HealthCare Corp."⁶⁰

In 1995, Upjohn Co. and Swedish firm Pharmacia, two respected pharmaceutical entities, engaged in a 7 billion-dollar stock-swap merger.⁶¹ That same year, Britain's Glaxo Holdings PIC paid \$14 billion for Burroughs-Wellcome, and Hoechst acquired Marion Merrell Dow for \$7.1 billion.⁶²

In February 1996, Johnson & Johnson acquired cardio-technology manufacturer Cordis Corp. for \$1.8 billion.⁶³ Finally, St. Jude Medical, Inc., looks forward to a 1996 finalized acquisition of Daig Corporation and Cyberonics, Inc., companies that will "provide St. Jude Medical entry into two additional therapeutic markets-interventional cardiology and interventional neurology."⁶⁴ Early in 1996, speculation regarding future acquisitions included Bristol-Myers Squibb Co. and Eli Lilly & Co. as possible buyers of such companies as Searle & Co. and Warner-Lambert Co.⁶⁵

Mergers and Broadened U.S. World Market Share

Industry mergers and acquisitions are radically reshaping the medical product landscape "as giant multinational producers search for new products and wider distribution."⁶⁶ In time, "the way pharmaceuticals are invented, made, and sold will bear little resemblance to the methods of a decade ago."⁶⁷ While industry consolidation will slow in pace, "the merger trend among drug companies... [is not] over... [C]ombinations... [will] continue until only 10 or 15 giants are left."⁶⁸

U.S. pharmaceutical companies are rapidly growing in their percentages of global market share. For example, Merck, one of the industry's largest members, "controls about 5% of the worldwide market."⁶⁹ Glaxo Wellcome, the largest pharmaceutical manufacturer formed by the merger of Glaxo Holdings and Burroughs Wellcome, held 6% of the world market as of January 1996.⁴⁰ Yet during 1975-1989, 47 of 97 world-class drugs originated in the United States.⁷¹ And in 1994 alone, U.S. patents accounted for 78% — 109 out of 140 — of "new genetic engineering patents for health-care products issued by the U.S. Patent and Trademark Office."⁷²

U.S. pharmaceutical megamergers give U.S. corporations and their exclusive patents greater control of global market share. Roche's acquisitions, for example, "will give... [the company] a broader product line to sell [to] big customers in the U.S."⁷³ and presumably abroad. Johnson & Johnson's purchase of Cordis has already yielded J&J "about one-third of the worldwide market for heart intervention products."⁷⁴

To secure global market control and increase revenue, "the big [pharmaceutical] producers are scrambling to build market share by selling more products. To fight the growing might of [pharmaceutical] distributors, they're buying the distributors."⁷⁵ The acquisition of distributors will eliminate "the middlemen that have forced... [drug companies' profit] margins down."⁷⁶

That will affect pricing, market distribution, gross sales, and even health-care plan administration, including insured individuals' drug choices.⁷⁷

Joining Forces: Megamergers, U.S. Patents, and the CDA

Megamergers mean the global marketplace features fewer, bigger, and more powerful providers of world-class drugs and technology. Fewer competitors may mean higher prices, less consumer freedom of choice, and less industry scrutiny -or accountability. More importantly, because many of these commercial titans are U.S. companies, the extraterritorial reach of U.S. patent protection and CDA trade restrictions removes the best medicines and medical equipment from Cuba's reach.

The reasons are clear: as foreign pharmaceutical firms and distributors become part of U.S. entities, they fall under the Cuban Democracy Act's burdensome licensing provisions. Prospective targets of acquisition thus face a difficult choice. They can pursue sales contracts with Cuba and forgo a potentially lucrative merger with a U.S. company, or they can complete a merger and sever possibly profitable ties with Cuba. Once acquired by a U.S. firm, the formerly independent foreign corporation must avoid, cancel, or decline to renew commercial sales contracts with Cuba. Megamergers are therefore quickly shutting off Cuba's access to non-U.S. sources of important drugs and medical technology.

As importantly, acquired companies are likely to work with the patented drugs and technology of their U.S. parent company. Respecting the parent company's U.S. patents would mean not competing with or illicitly pirating such patents. Additionally, powerful U.S. pharmaceutical companies, made even larger through mergers and acquisitions, would have the resources to seek patent protection in as many countries as possible. Because U.S.-patented items fall under the Cuban Democracy Act's licensing provisions, the effect is to cut Cuba off -company by acquired company -from its non-US. medical suppliers.

Goods under exclusive U.S. patents are only available from U.S.-owned or -controlled sources and thus are inaccessible to Cuba. Alternative, parallel products available from third countries are often inferior or (in the case of drugs) inflict undesirable side effects.⁷⁸ Finally, because some Cuban medical professionals deem other countries' pharmaceutical testing standards to be lower than those of the U.S. Food and Drug Administration, Cuban doctors have less confidence in the quality, safety, and effectiveness of third-country drugs and other goods.⁷⁹

Lack of drugs of guaranteed reliability may ultimately degrade patient care and damage the Cuban medical system's world-renowned reputation. It may also erode the faith of Cuban citizens' in the adequacy of their country's health care, prompting both ill and healthy Cubans to forgo preventive and diagnostic care by shying away from a medical system the competence of which they may have come to doubt.⁸⁰ Obviously this would lead to greater health problems among the Cuban populace.

With fewer options and sources for the best medical goods, Cuba must resort to non-U.S. products, whether under foreign patents or pirated abroad or in Cuba. Resorting to pirated products (inexpensive copies of patented drugs, produced without patentees' permission), however, would only compromise already strained political relations between the United States and Cuba, making political and economic rapprochement less likely.¹⁸¹

The Effort to Protect U.S. Patent Interests

U.S. pharmaceutical companies are, of course, actively seeking to confirm treaty-based patent extensions and to secure greater worldwide protection against foreign pirating of U.S.-origin items patented in the United States and elsewhere. Patent extensions are under debate as drug companies and legislators ponder whether the 1994 General Agreement on Tariffs and Trade (GATT) trumps a 1984 law regulating Food and Drug Administration (FDA) approval of generic drugs.

Under GATT, U.S. patent terms are 20 years from the initial filing date rather than 17 years from the date on which the patent is granted.⁸² That effectively grants months — and in some cases, years — of extended patent protection against generic-drug manufacturers.⁸³ An exception under GATT, however, permits a competitor to “introduce a competing product on the original patent expiration date if the company had made significant prior investments and if it paid the patent holder a royalty or some other form of ‘equitable remuneration.’”⁸⁴ The 1984 law, however, bars FDA approval of generics until a name-brand patent expires. According to some U.S. drug companies, the GATT exception should not apply to pharmaceuticals because of conflict with the 1984 law. If these companies prevail, patent extensions will delay the domestic and overseas production and marketing of generic and alternative drugs. That can only impede Cuba’s access to these often-critical products.

Members of the U.S. pharmaceutical industry also actively oppose foreign patent piracy. According to some industry members, foreign “copying [of] patented drugs without permission”⁸⁵ steals “billions of dollars worth of intellectual property a year from pharmaceutical firms.”⁸⁶ Such “losses to patent piracy discourage [patent holders’] investment in research and development.”⁸⁷ Industry members making these claims assert that foreign governments permitting such piracy “discourage the development of indigenous research-based drug industries...[and]...endanger the health of their own people by creating an environment conducive to the production of substandard or counterfeit drugs.”⁸⁸

To address the piracy problem, a number of U.S. pharmaceutical companies support “appropriate worldwide protection of intellectual property, both through international agreements and unilateral action.”⁸⁹ The North American Free Trade Agreement (NAFTA) is one such international accord. NAFTA bars signatory states from discriminating against other signatories in granting government contracts.⁹⁰ It also requires signatories to afford equal treatment to both foreign and domestic companies that make pharmaceutical investments in those signatory countries.⁹¹ NAFTA also restricts compulsory licensing and affords protection to products “patented in one country but not [as] yet in another.”⁹²

Appropriate U.S. unilateral actions include “withdrawing trade concessions and placing duties and other restrictions on goods and services from offending nations.”⁹³ The United States could also use the threat of suspending foreign aid and technology agreements to demand from offending nations greater intellectual property safeguards and adherence to existing intellectual property norms and accords.⁹⁴

NOTES

1 50 U.S.C. app. & 16.

2 As is discussed elsewhere in this report, this provision also causes grave impact on the price of any goods imported into Cuba, as ships from as far away as Europe and Asia are prohibited from visiting the U.S., and thus, the increased shipping costs are passed on to Cuban consumers.

3 U.S. Government -officials have -cited various figures. In a Special Report, *An Analysis of Licensed Trade with Cuba by Foreign Subsidiaries of U.S. Companies*, July 1993, published by the Office of Foreign Assets Control, U.S. Dept. of the Treasury, the figure of \$407 million in subsidiary trade for 1992 is cited. Peter Tarnoff, Undersecretary for Political Affairs, has cited the amount as over \$700 million in 1992. See testimony before the Foreign Relations Committee, Western Hemisphere Subcommittee, U.S. Senate, May 22, 1995. Richard Newcomb, Director of the Office of Foreign Assets Control, Dept. of the Treasury, has put the 1992 figure at \$336 million. See testimony before the Committee on Foreign Affairs, U.S. House of Representatives, November 18, 1993.

4 31 C.F.R. § 515.559 (a) (1993).

5 *Id.* at § 515.559 (a) (2).

6 *Id.* at § 515.559 (a) (2) (v).

7 *Id.* at § 515.559 (a). The Department of Commerce Regulations do not clearly state which entity (the U.S. parent or the foreign subsidiary) must obtain Commerce permission to export materials containing U.S.-origin matter to Cuba. Section 515.559 of the Treasury regulations covers "transactions between U.S.-owned or controlled firms in third countries and Cuba" and specifically states that, given other factors listed in § 515.559 (b), licenses will issue for goods containing 'U.S.-origin parts and components' where "such inclusion has been authorized by the Department of Commerce" (§ 515.559 [b] [1] [iii]). Reading the Commerce regulation (15 C.F.R. § 785.1) in tandem with 31 C.F.R. § 515.559 (a), we can reasonably conclude *that the subsidiary* must obtain Commerce permission.

8 15 C.F.R. § 785.1 (c).

9 *Id.*

10 *Id.*

11 *Id.*

12 *Id.* at § 785.1 (a) (1).

13 Bureau of Export Administration, U.S. Dep't Com., 1994 Export Administration Annual Report and 1995 Report on Foreign Policy Export Controls 111-18.

14 Richard Newcomb, Director, Off. of Foreign Assets Control, U.S. Dep't of the Treasury, testimony of November 18, 1993, before a joint hearing of the Subcomm. on Econ. Pol'y, Trade and Env't, W. Hemisphere Aff and Int'l Cooperation of the Comm. on Foreign Aff, U.S. House of Representatives, at 21,37.

15 Telephone interview with Tracy O'Donald, Dept. of Commerce, Bureau of Export Admin., Feb. 20, 1996.

16 A list of companies surveyed is attached at Exhibit XX. At the request of those interviewed, we are not providing names of individuals quoted.

17 The FOIA requests were filed by the National Security Archives, an independent nongovernmental institute and library located in Washington, D.C.

18 The department provided information regarding licenses it had granted for medical sales in the 1992-1995 period to the office of Rep. Charles Rangel (D-NY) upon his request.

19 Interview with Clara David, OFAC, April 18, 1996.

20) Anthony F. Kirkpatrick, M.D., Ph.D., et al., *The Time Has Come to Lift the Economic Embargo Against Cuba*, 81 J. Fla. Med. Ass'n 681(1994).

21 Julie Feinsilver, *Healing the Masses: Cuban Health Politics at Home and Abroad* -(1993).

22 During the same 1995 address, Nuccio, one of the drafters of the CDA stated, "Immodestly, I believe that the most effective role for the United States in promoting a democratic transition in

Cuba is outlined in the Cuban Democracy Act, legislation I helped draft as an advisor to Congressman Bob Torricelli in 1992 and which President Clinton endorsed when he was still a candidate for office.”

23 Richard A. Nuccio, *Prospects for a Peaceful, Democratic Transition in Cuba: A U.S. Perspective*, Remarks to the West Point Society of South Florida (Sept. 8, 1995) [hereinafter Nuccio].

24 Nuccio, *supra* note 23.

25 35 U.S.C. §§ 1-376.

26 *Id.* at § 100 (d).

27 See *Id.* at § 100 (a), (b).

28 *Id.* at § 271 (a).

29 *Id.* at § 271 (b).

30 *Id.* at § 271 (c).

31 *Id.* at § 271 (f).

32 35 U.S.C. § 271 (g).

33 This assumes the Patent and Trademark Office determines that the product or process meets the statutory standards for novelty, utility, nonobviousness, and originality.

34 R. Dreyfuss & R Kwall, *Intellectual Property 247* (Foundation Press 1994); see also 35 U.S.C. § 156.

35 Paris Convention for the Protection of Industrial Property, art. 2, § 1 hereinafter Paris Conventionl.

36 Dreyfuss & Kwall, *supra* note 34, at 16.

37 Paris Convention, *supra* note 35, at art. 4, § A (2).

38 *Id.* at art. 4, § C (1).

39 35 USC. § 119 reads: “An application for patent for an invention filed in this country by any person who has . . . previously . . . filed an application . . . for the same invention in a foreign country . . . shall . . . [retain] the date on which the application . . . was first filed in such foreign country, if the application in this country is filed within twelve months from the earliest date on which such foreign application was filed.”

40 Dreyfuss & Kwall, *supm* note 34, at 18.

41 *Id.*

42 Dreyfuss & Kwall, *supm* note 34, at 18.

43 *Id.*

44 *Id.*

45 Design patents, lasting only 14 years, are an exception.

46 35 U.S.C. § 271 (a); see also Dreyfuss & Kwall, *supra* note 34, at 203.

47 *Id.* at § 271 (b); see also Dreyfuss & Kwall, *supra* note 34, at 203.

48 35 U.S.C. § 271 (c); see also Dreyfuss & Kwall, *supm* note 34, at 203.

49 *Id.* at § 271 (g); see also Dreyfuss & Kwall, *supra* note 34, at 203.

50 *Id.* at § 271 (f) see also Dreyfuss & Kwall, *supra* note 34, at 203.

51 *Roche Products, Inc. v. Bolar Pharmaceuticals Co., Inc.*, 733 F.2d 858 (Fed. Cir. 1984) [hereinafter *Roche*].

52 *Roche*, *supra* note 51, at 861.

53 Dreyfuss & Kwall, *supra* note 34, at 243-245; see also *Roche*, *supra* note 51, at 863.

54 *Roche*, *supra* note 51, at 863.

55 35 U.S.C. § 271 (e).

56 Dreyfuss & Kwall, *supra* note 34, at 247 (citing *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 110 S.Ct. 2683, 110 L.Ed.2d 605 (1990))

57 Joseph Weber *et al.*, *Drug-Merger Mania*, Bus. Wk., May 16, 1994 thereinafter *Drug Merger Manial*.

58 *Id.*

59 *Id.*

60 *Id.*

-
- 61 Joseph Weber, *Robust and Ready to Brawl*, Bus. Wk., Jan. 8, 1996 [hereinafter *Robust and Ready to Brawl*].
- 62 *Id.*; see also Joan Warner & Heidi Dawley, *Drug Stocks to Watch in '96*, Bus. Wk., Jan. 22, 1996.
- 63 Richard Jacobson, Reuters, Apr. 16, 1996.
- 64 PRNewswire, Apr. 17, 1996.
- 65 *Robust and Ready to Brawl*, *supra* note 61.
- 66 *Drug-Merger Mania*, *supra* note 57.
- 67 *Id.*
- 68 Warner & Dawley, *supra* note 62.
- 69 *Drug-Merger Mania*, *supra* note 57.
- 70 Warner & Dawley, *supra* note 62.
- 71 Pharmaceutical Research and Manufacturers of America, *World Class Drugs: Origin of 97 "Globalized" Drugs 1975-1989* (citing P. E. Barral, *Fifteen Years of Results of Pharmaceutical Research in the World*, Perspective et Sante Publique, (Paris: 1985; updated 1990).
- 72 Pharmaceutical Research and Manufacturers of America, *1994 Patent Analysis Results: U.S. Pharmaceutical Industry Continues Leadership in Biotechnology Research* (Mar. 1995).
- 73 *Drug-Merger Mania*, *supra* note 57.
- 74 Jacobson, *supra* note 63.
- 75 *Drug-Merger Mania*, *supra* note 57.
- 76 *Id.*
- 77 *Id.*
- 78 Aff. of Anthony F. Kirkpatrick, M.D., Ph.D., at 2-3, 4, 8, in Anthony F. Kirkpatrick, M.D., Ph.D., *Adverse Effects of the U.S. Economic Embargo on the Health of Cuba's Children* (Feb. 3, 1995) (presented before the Inter-Am. C.H.R.); see also *Emergency Petition Requesting a Declaration that the U.S. Trade Embargo against Cuba Has Resulted in a Medical Crisis in Cuba and Requesting a Declaration that Said Embargo Violates International Human Rights Laws 6-7* (Oct. 4, 1994) (filed with the Inter-Am. C.H.R.); interview with Senovio González de León, Director of Public Relations, Hospital Nacional Hermanos Ameijeiras, Centro Habana, Havana, Cuba (Mar. 27, 1995).
- 79 Interview *with* Senovio Gonzalez de León, *supra* note 78.
- 80 *Id.*
- 81
- 82 John Carey, *A Patent Medicine Called GATT*, Bus. Wk., Apr. 5, 1995.
- 83 *Id.*
- 84 *Id.*
- 85 Pharmaceutical Research and Manufacturers of America, *Intellectual Property* (July 1, 1995) [hereinafter *Intellectual Property*].
- 86 *Intellectual Property*, *supra* note 83.
- 87 *Id.*
- 88 *Id.*
- 89 *Id.*
- 90 *Id.*
- 91 *Id.*
- 92 *Id.*
- 93 *Intellectual Property*, *supra* note 83.
- 94 *Id.*

35 Years of U.S. Economic Sanctions

Since 1961, the United States has imposed a virtually complete economic embargo on commercial relations with Cuba. The immediate impact of these extensive sanctions was the loss of Cuba's traditional trading partners. In 1959, Cuba did more than 75% of its trade with its closest and most natural trading partner, the United States. The magnitude of this rupture to the Cuban economy has been widely held responsible for Cuba's resulting economic dependence on the Soviet Union and the Eastern European socialist market.

From the beginning, the U.S. sanctions not only prohibited all trade between Cuba and the United States with minimal exceptions, but also significantly impeded Cuba's exports to third countries, because no product produced in a third country which has any Cuban-origin content, even a trace amount, may be imported into the United States. Furthermore, U.S. regulations prohibit the re-export of U.S. products to Cuba from a third country, and even the export of third-country products to Cuba if those products are composed of more than 29% U.S.-origin components. In addition, the regulations during most of the past 35 years have closed U.S. ports to vessels carrying goods to or from Cuba.

The intent and natural consequence of these measures have been to impede the development of the Cuban economy. Our findings show that the impact has been particularly harsh in the areas of food security and public health. The United States was by far the largest supplier of food products to Cuba before 1959. Its proximity and close commercial relations provided significant cost and trade advantages. Also of great importance is the fact that United States pharmaceutical companies and their subsidiaries were the sole source for many critical medical supplies. Moreover, spare parts for equipment purchased prior to the U.S. embargo were no longer accessible, increasing the cost of maintenance and in many cases forcing substitution.

Despite the hardship caused by these measures, Cuba's economic relationship with the former Soviet Union and the former socialist market, known as the Council for Mutual Economic Assistance (CMEA), enabled the island to develop its own agricultural resources and import sufficient quantities of food to provide an adequate diet for its population by the 1980s, and to develop an internationally recognized and universal public health care system. However, the collapse of the former Soviet Union in 1989 and the dissolution of CMEA triggered an economic crisis in Cuba of profound proportions, which put in jeopardy the lives and health of Cuban citizens. Although U.S. government sources cite the Cold War as the primary and most consistently upheld justification for sanctions against Cuba, the U.S. did not relax the economic pressure when the Cold War ended, but rather tightened and expanded the sanctions. Our research indicates this only deepened the hardships for the Cuban population.

Roots and Extent of Cuba's Current Economic Crisis

Of all the countries tied to the former socialist camp, observers believe Cuba was hit the hardest with the collapse of the Soviet Union—largely because it did not have the option of turning to its closest and most obvious trading partner, the United States. As a result of this impact, Cuba's economy tumbled in a free fall that hit bottom in 1993⁹⁴. This crisis rocked the economic foundations of the island, sparing no industry or productive sector. The socialist countries of Eastern Europe had accounted for over three fourths of Cuban trade and development assistance. With the disappearance of these vital commercial relations, the U.S. embargo and domestic inefficiencies became a graver threat to Cuba's economic survival.

Prior to 1989, Cuba's economy registered a national average growth rate of 4.3% annually. The Soviet Union and the CMEA had evolved over three decades into Cuba's number one trading

partners, accounting by 1989 for 85% of Cuba's \$13.5 billion trade. This preferential trade relationship ceased when the Soviet Union collapsed, abruptly ending some \$21 billion in aid and trade credits the Cuban government reports it received from the Soviet Union from 1960 to 1989. By 1990, between 50 and 75% of Cuba's industrial output had been paralyzed

CMEA Trade Losses to the Cuban Economy (1989-1991)	
Food and Raw Material imports	63%
Machinery and Equipment imports	80%
Fuel Imports	98%
Sugar Exports	63%
Nickel Exports	73%
Citrus Exports	95%

Source: *Oswaldo Martínez, Director of the Center for the Study of the World Economy. November, 1995.*

The loss of Soviet trade took an immediate toll on both the economy and quality of life. Between 1989 and 1994, the GNP plunged 35%. In 1994, even with a 7.6% increase in industrial production and a GNP growth of 0.7%, the GNP remained at just 60% of 1989 levels.

CUBA'S GROSS NATIONAL PRODUCT		
Year	Billions of Pesos (at constant 1981 prices)	Growth/Decline
1989	19.6	0.7%
1990	19.0	-2.9%
1991	17.0	-10.7%
1992	15.0	-11.6%
1993	12.8	-14.9%
1994	12.9	0.7%
1995	13.2	2.5%

Source: *Cuba: Inversiones y Negocios, WNAS, Havana, 1995.*

A critical loss to the Cuban economy included some 13 million tons of Soviet fuel, received each year in a barter agreement for sugar and used primarily for domestic industry, national transport and electricity, with a portion being sold on the world market for significant hard currency returns. At the same time, sugar-Cuba's main industry and key export crop-suffered from a lack of inputs (fertilizers, pesticides, spare parts and machinery for the highly-mechanized harvest) that had traditionally arrived from Eastern Europe. The result was a sharp drop in raw production from average levels of 7.5 million tons between 1987-1991 to 4 million tons in 1993-1994, and 3.3 million tons in 1994-95. Non-sugar agriculture suffered much the same fate, and together with hunting, forestry and fishing, declined 55% between 1989 and 1994. Construction dropped 72% in the same period; passenger transportation declined 79.3%; freight transportation, 60%; electricity, gas and water dropped 23%.

Inefficient organization of many Cuban facilities added to problems caused by the abrupt disappearance of imported inputs for industries geared for export to the socialist bloc, with no time and often no domestic raw materials to convert production to other uses. Locked in an acute hard currency shortfall, both import and export trade were severely curtailed. The social consequences of the recession have been harsh, producing widespread unemployment and under-employment for the first time in thirty years, lengthy power cuts, reduced public transport, stringent food rationing and shortages of medicines and medical equipment.

The U.S. embargo has seriously impeded Cuba's ability to find substitute markets and sources of essential goods and has severely limited access to financing and commercial credit, critical for recovery. Moreover, in 1992, with the express intent of preventing Cuba's recovery, the United States imposed new measures to further extend the territorial reach of its economic sanctions against Cuba and to tighten its enforcement mechanisms. Thus, the Torricelli Act (Cuban Democracy Act) of 1992 prohibited trade with Cuba by subsidiaries of United States companies, incorporated and located in third countries. In addition, the prohibitions on access to U.S. ports by third-country vessels carrying products to and from Cuba were made more rigid. The law also denies U.S. aid to any third country that extends loans or credits to Cuba. And finally, in March 1996, President Clinton signed into law the Helms-Burton Act which, among other things, provides for punitive measures against third-country companies that invest in Cuban property formerly owned by U.S. citizens.

To deal with the crisis, the Cuban government reorganized its foreign commerce and undertook a variety of economic reform measures. By the end of 1994, Cuban government figures were registering a modest, tentative recovery for the country's state-oriented economy. Planners predicted the process would be slow and tedious and cautioned the nation to brace itself against upheavals yet to come for an open economy beset by evolving market influences and challenged to attract foreign investors and trade partners.

Recovery Plan

In November 1990, the Cuban government officially enacted an economic state of emergency known as 'Special Period in Peacetime,' initiating a series of structural reforms aimed at amending its economic model. The long-term recovery strategy aimed to boost the island's access to hard currency, put national industries back on track, generate new areas of employment and preserve Cuba's social programs.

Major reforms enacted after 1992 modified the following aspects of the Cuban economy, its internal mechanisms and its productive structure:

- | | |
|--------------------|---|
| July 1992 | Cuban Parliament enacts important modifications to the Cuban Constitution permitting new forms of property relations. |
| July 26, 1993 | Cuban Parliament enacts law #140, legalizing the holding and use of hard currency on the domestic market. The measure has three principal objectives: to surface the dollars circulating in the informal market, expand the country's hard currency reserve, and give Cuban consumers access to imported products. |
| September 8, 1993 | Cuban Council of Ministers approves law #141, legalizing self-employment except in the health and education sectors. By 1995, some 203,009 Cubans were self-employed in 160 types of licensed jobs, including small family businesses. |
| September 15, 1993 | The government restructures state farms aiming to increase agricultural output and stimulate private initiative. A measure is enacted to approve subdividing the country's huge state farms into small cooperatives. By 1995, this had radically changed patterns of land use: 5% of the land was cooperativized (compared to 10% in 1992); 33% remained in state hands (compared to 75% in 1992); and 15% belonged to small, private farmers. In |

- 1995, agricultural production also registered its first growth since 1990, at 4%.
- April 21, 1994 Law #147 is enacted, drastically trimming and restructuring the state apparatus, with greater autonomy in decision-making for ministries and state enterprises. The number of government bodies is reduced from 50 to 33, with significantly fewer employees. (Those laid off, as in other state agencies, receive 60% of monthly salary, until such time as they are offered three new job possibilities, which they may choose to accept or to decline without compensation.) This measure gave additional impetus to the decentralization of foreign trade: in 1989, 50 state corporations were authorized to trade abroad; by 1995, 250 state companies, corporations and joint ventures carried on foreign commerce.*
- May 2, 1994 In an emergency session, Parliament adopts a packet of economic reforms designed to absorb excess money circulating in the market and to reduce the national budget deficit. Measures include new taxes on the self-employed and corporate hard currency earnings; reducing or eliminating government subsidies to state companies and enterprises; price hikes for electricity, water, transport and non-essentials such as tobacco, liquor and gasoline; and stiff penalties for illicit profiteering.
- August 4, 1994 Parliament approves a sweeping income tax law, as well as taxes on sales and certain properties, slated to go into effect the following year.
- October 1, 1994 The government opens free farmers markets, where both private and state farmers are authorized to sell produce and meat at unsubsidized and unregulated prices. This measure both alleviates food shortages and collects millions of excess pesos circulating in the country. For instance, during the first six months of operation, consumers spent some 904 million pesos, and the government brought in approximately 64 million pesos from tax revenues and service charges.
- January 23, 1995 A new mining law is enacted, giving guarantees to foreign investors and bringing Cuban mining regulations in line with international standards. National Office of Mining Resources is established with the authority to engage in transactions with foreign partners.
- July, 1995 Government opens official peso-dollar exchange centers.
- September 5, 1995 Parliament approves new Investment Law, opening all sectors of the Cuban economy to foreign investment with the exception of defense, health services and education. Allows up to 100% foreign operation and ownership.
- November 25, 1995 The government announces a new tax on all personal dollar income, exempting dollar remittances sent from families and friends abroad.*

According to Cuba's Ministry of the Economy and Planning, the government undertook this series of calculated reform measures in order to liberalize Cuba's state-run economy, encourage foreign investment and ease social hardship. It appears that the measures have worked to some degree: the economy clearly hit bottom in 1994, but modest economic growth has resumed since then, registering a 2.5% increase in 1995 and 7.8% in 1996. The Ministry announced its view on February 4, 1996: the reforms have taken hold and successfully revived all key industrial sectors, except sugar production, which nevertheless grew modestly, reaching 4.4 million tons in 1995-96.

Speaking before the World Economic Forum in Switzerland, Jose Luis Rodriguez, the Cuban Minister of the Economy and Planning, stated, 'It will take a certain period to re-establish a normal situation, but we have put the worse behind us and are now on the right path.' He verified that foreign investors have pledged some \$2.1 billion over the last three years. In addition, the Cuban peso's purchasing power has grown and strengthened against the U.S. dollar in the informal domestic market, averaging 32.1 pesos to the dollar in 1995 and 19.2 in 1996. The boost in domestic production gave a well-needed nudge to overall trade: 1995 exports increased some 20%-from \$1.3 billion (U. S.) in 1994 to \$1.56 billion, and imports grew 21%-from \$1.9 billion to nearly \$2.3 billion (still just 30% of 1989 levels). In 1996, figures were 33% and 33.3% respectively.

At the same time, strengthened were the Cuban peso and the purchasing power of government salaries. The average wage grew some 3.8% in 1995, to 193 pesos a month while prices of non-rationed food products declined some 10%. In addition, production bonuses in both Cuban pesos and U.S. dollars have been extended to growing numbers of government workers--from 100,000 in 1994 to 600,000 in 1995. In 1996, an estimated one million out of Cuba's 3.5 million government workforce became part of the bonus program. Furthermore, Minister Rodriguez asserted that the number of Cubans with some type of access to U. S dollars rose from 21% in 1994 to 45% in 1995.

The Cuban Parliament also forecast a 5% increase in the Gross National Product in its "1996 Social and Economic Plan" adopted in December 1995.' It was the first such plan developed in five years, and is based on a 35% increase in sugar production--a goal met by the 1995-96 harvest. The Parliament predicted a 27% increase in foreign investment--chiefly in tourism, nickel, fishing and energy. Exports were expected to increase more than 20% and imports some 15%. Nickel production, which grew from 27,900 to 43,500 tons in 1995, was foreseen to increase an additional 25%; tourism, 20% (similar to 1995); steel production, 50% (as compared to 45.7% in 1995); cement, 24%; rice, 100%; tobacco, 50% (52% in 1995); power, 10%; oil, 7% (16.7% in 1995); and agriculture somewhat above 1995's 4.2% spurt'

In June 1995, Cuba's National Bank released the first comprehensive economic round-up since the crisis began. Prepared for western creditors, the CNB report illustrates official optimism that economic recovery is underway while underscoring the need to find a solution to lingering problems such as Cuba's national deficit, import shortfalls, foreign debt and the U. S trade embargo, if recovery is to proceed. The report illustrates diversification of exports and trading partners. Sugar, nickel, sea food products and tobacco constituted Cuba's principal exports in 1989. In 1994, they were replaced as the island's top currency earners by tourism, sugar, nickel and biotechnology products.

Trade, long directed almost exclusively towards the Soviet Union and Eastern Europe, has been redirected towards Western Europe, Latin America, and Canada. Cuba's former trading partners accounted for less than 20% of trade in 1994, while Western Europe and Latin America garnered over 30% each; China and Canada combined to some 20%, and the remaining 20% was accounted for by other regions, principally in Asia.

Hard Currency: Despite the slight recovery and increased export earnings, Cuba continues to suffer from severe shortfalls in hard currency, restricting imports to 30% of 1989 levels. The U.S. embargo increases this difficulty, by denying credits to Cuba through U.S. veto power in major international lending institutions. Further, as the Cuban Democracy Act and the Helms-Burton Act require the United States to deny aid to any country which trades with Cuba on the basis of credits or even long-term payments, Cuba is forced to pay cash for imports, thus putting the country in a uniquely disadvantaged position with respect to international trade.

CUBAN TRADE (Billions Of U.S. Dollars)			
Year	Imports	Exports	Total Trade
-1989	8.1	5.4	13.5
1990	7.4	5.4	12.8
1991	4.2	3.0	7.2
1992	2.3	1.8	4.1
1993	2.0	1.1	3.1
1994	1.9	1.3	3.2
1995	2.1	1.5	3.6

The hard currency shortage has restricted Cuba to the most essential purchases. For example, although fuel imports accounted for 40% of the island's total purchases in 1994, they barely met 50% of the nation's basic energy needs. This, coupled with difficulties in other foreign inputs, has kept much of the island's industry paralyzed. The CNB report states:

Although foodstuffs and fuel in 1990 accounted for 39% of imports, they jumped to 63% in 1994. Raw materials hold little weight in the total (2.5%), illustrating how import shortages are adversely affecting the country's productive capacity. Likewise, the significant decline in imports of machinery and equipment (from 37% in 1990 to 6% in 1994) reflects the sharp reduction in new, renovated or expanded investments.

CUBAN IMPORTS					
	1990	1991	1992	1993	1994
in billions of U.S. dollars	7.4	4.2	2.3	2.0	1.9
Percentile Breakdown by Sector:					
Foodstuffs	12	20	25	26	23
Raw Materials	4	3	2	3	2
Fuels & Lubricants	27	30	36	37	39
Chemicals	6	7	9	10	7
Machinery & Equipment	37	31	19	12	6
Other Products	14	9	9	12	23

The Budget Deficit: Cuba's deficit ballooned to 5.05 billion pesos in 1993, but was reduced sharply by 1994 to 1.4 and in 1995 to .7 billion pesos. According to the Finance Ministry, Cuba's budget deficit represented some 4% of the Gross Domestic Product in 1995. The Ministry states that the steady reduction since 1994 is due in large measure to revenues from higher sales and profit taxes, a severe reduction in subsidies covering state company losses, and reductions in state subsidies for consumer goods. Since June 1994, a restrictive monetary policy has been in effect-aimed at both strengthening the peso and lowering the national deficit.

Foreign Debt: A great obstacle to economic recovery is Cuba's hard currency foreign debt. The most recent figures released by the CNB indicate the debt at the equivalent of \$9.1 billion for 1994, up \$298 million from the year before and some \$2 billion over 1989 figures (the only previous ones available). The debt is projected to rise somewhere between 1-3% in 1996 or between \$91 and \$270

million. (The CNB figures do not include debts owed to the former Soviet Republics, Russia, China, Vietnam or North Korea.)

Official creditors are owed 49.5% of the debt and private lenders 50.5%. Some 77.6% (\$7.1 billion) is principal owed, while 22.4% (\$2 billion) is interest. Japan is Cuba's largest creditor, at 25% of the total debt; Spain follows with 13%; France, 12%; Argentina, 9%; United Kingdom, 8%; Italy, 5%; Switzerland, 2%; Germany, 2%; Austria, 2%; and others, 22%.

Over the last two years, Cuba has sought to resolve its obligations with a number of Latin American countries through equity swaps and payment through furnishing a percentage of new trade. For instance, Cuba liquidated most of a \$500 million debt to Mexico largely through telecommunications and cement deals. Havana has also negotiated a settlement on a \$50 million debt to Colombia by redirecting 10% of export earnings with Bogota to debt payments.

Cuba's foreign debt is an issue that must be resolved to the satisfaction of Western creditors before the island can be granted any substantial medium or long-term financing—a key to sustained economic recovery. The Cuban government argues that external factors, principally the 35-year U.S. trade embargo, are largely to blame for the country's debt problems, including the fact that Cuba canceled principal and interests payments in 1996 and broke off formal talks with creditors three years later. By virtue of the U.S. embargo, the country has been barred from membership in both the International Monetary Fund and the World Bank. Moreover, and as we have noted, recent United States legislation also targets for reprisals countries which engage in debt swaps and other credit arrangements with Havana.

Obstacle to Recovery: U.S. Trade Sanctions on Cuba

Despite this modest recovery in the face of serious odds, observers warn that the persistence of U.S. trade sanctions hampers Cuba's continued economic recovery. Jose Luis Rodriguez, Cuban Minister of the Economy, told the World Economic Forum in Switzerland on February 4, 1996:

The embargo is a major obstacle to our development and causes additional difficulties because it creates risk factors that make the credits we need more expensive... People who want to invest encounter hostility from the U. S... .But all signs are that this is a policy that will remain. We do not expect it to change, and in our strategic planning, we are not counting on the embargo being lifted in the short run.

For the past seven years, the Cuban government has actively pursued Western investment and trade credits to fill the void left by the Soviet Union. The Cuban Ministry of Foreign Trade reports that 613 foreign firms were operating in Cuba by 1995. By early 1996, there were 230 economic associations, including joint ventures, between foreign partners and Cuban state-run companies, according to Minister of the Economy Rodriguez. In addition, these joint ventures have somewhat eased Cuba's unemployment problem by providing jobs to over 250,000 skilled and professional workers.

The recently enacted Helms-Burton Act seeks to prevent foreign investment in Cuba and, thus, to scuttle Cuba's reconstruction program. The law tightens the embargo by enhancing enforcement mechanisms and permits presidential authorization for private claims in U.S. courts against third-country firms that invest in property in Cuba which was formerly owned by U.S. citizens. It also denies entry into the United States of the officials of such firms, their spouses and minor children. And finally, it imposes stringent requisites for any future moderation of the embargo, thus signaling to would-be investors that the U.S. market will not be open to trade with Cuba for many years to come.

The Helms-Burton Act came on the heels of another embargo-tightening piece of legislation. Enacted in 1992, the Cuban Democracy Act (CDA) precluded U.S. subsidiary trade with Cuba. Such trade was fast becoming vital to the Cuban economy, most notably as a lever to ease some of the island's severest shortages during the first years of the 'economic crisis, when Cuba was scrambling to find new trade partners. In 1990, for instance, U.S. Treasury Department figures illustrated that U.S. subsidiary trade with Cuba had more than doubled in the two brief years after the disbanding of the Soviet Union-up from \$332 million in 1989 to \$705 million during 1990. The increase continued through 1991, with U.S. subsidiary sales to Cuba registering \$718 million.

It was for this precise reason that the bill's sponsor, Representative Robert Torricelli, argued to extend the trade embargo beyond U.S. shores and companies:

Several measures in the bill discourage other countries...from filling in the gap in Cuba's trade and investment requirements. Inclusion of the so-called Mack amendment shuts off the previously permitted trade of U.S. foreign subsidiaries with Cuba. Over the last three years, foreign subsidiary trade with Cuba has grown dramatically. This provision will place foreign subsidiaries under the same prohibition on trade that applies to their parent corporations.

Licensed U.S. Foreign Subsidiary Trade With Cuba					
	1980	1985	1988	1989	1990
Number of Approved License Applications	164	256	215	233	321
Total Exports to Cuba (millions of U. S dollars)	206	162	97	169	533
Total Imports from Cuba (millions of U. S dollars)	86	126	149	162	172
Total Exports & Imports (millions of U. S dollars)	292	288	246	331	705

Source: New Opportunities for U. S-Cuban Trade, Donna Rich Kaplowitz and Michael Kaplowitz Johns Hopkins University, 1992,

U.S. Subsidiary Goods Purchased by Cuba (Millions of U. S dollars)					
	1980	1985	1988	1989	1990
Grain, Wheat and other Consumables	192	109	56	114	500
Industrial and non-Consumables	14	53	41	55	33
Percentage of Consumables in Subsidiary purchases by Cuba	93.20	67.28	57.73	67.46	93.81

Source NEW Opportunities for U. S-Cuban Trade, 1992.

Both the Cuban Democracy Act introduced by Congressman Torricelli and the Helms-Burton Act extend the extraterritorial application of U.S. embargo policy. Serious protests over this extension

have been voiced by the European Union and other U.S. allies in numerous communications with the U.S. government and at the World Trade Organization.

The CDA has taken its toll on the Cuban economy. A list published by Cuba's Ministry of Foreign Trade asserts that, during the CDA's first two years on the books, 'Cuba's bilateral trade with some 26 countries other than the United States was adversely impacted. They were: Antigua, Argentina, Belgium, Brazil, Canada, Czechoslovakia, Chile, China, Colombia, France, Germany, Guyana, Holland, Italy, Jamaica, Japan, Mexico, New Zealand, Nicaragua, South Africa, Spain, Sweden, Switzerland, Trinidad & Tobago, the-united Kingdom and Venezuela.

Because of fear of U. S. government reprisals under the CDA, dozens of U.S. subsidiaries canceled trade deals with Cuba, especially in the months following the signing of the new embargo regulations. A large portion of these were important to Cuba's public health program (see chapters on Medical Exports to Cuba and Selected Aspects of Health & Welfare, Nutrition). In the realm of public health, Cuba's Public Health Ministry calculates that the CDA embargo restrictions claim some 30 cents on every dollar's worth of medicines and medical supplies the country purchases abroad.

The U.S. Embargo: Shipping Costs and Shortages

One of the greatest burdens imposed by the Torricelli regulations is to impede normal commercial shipping to the island. Under CDA provisions, all ships docking in Cuban ports or carrying Cuban nationals and/or goods are prevented from trading in U.S. ports for six months or face a \$50,000 fine. This risk factor causes some shippers to charge Cuban buyers significantly more than the World Scale rate, exacerbating shortages on the island. Considering Cuba's hard currency limitations, every extra dollar paid towards shipping is one less dollar for imported food, medicines and basic supplies.

Before becoming law, these specific restrictions ran into considerable opposition from the international maritime community. For instance, on October 19, 1992, the Maritime Federation of Canada distributed CIRCULAR #5383, which warned that the proposed U.S. law would clearly increase the cost of Canadian shipping to Cuba, limit the selection of ships available to Canadian merchants exporting to the island and, in turn, make Canadian exports to Cuba generally more difficult.

Another objection was logged by the Union of Greek Ship Owners in the summer of 1992. In a demarche addressed to the U.S. State Department and a letter sent to the Council of European and Japanese National Shipowners' Associations, the Union contended that the bill would create serious operational, problems and consequences for ships trading with Cuba and therefore interfere with right of free trade. The Canadians as well as the European Community also filed official protests with the U.S. government.

As the U.S. government began enforcing the CDA late in 1992, the Cuban Ministry of Foreign Trade began experiencing the following shipping-related difficulties:

- Some shippers flatly refused to consider sailing to Cuba.
- Other shippers refused to send any freighter to Cuba which meets U.S. Coast Guard and Federal Maritime Certificate of Financial Responsibility requirements and, thus, is acceptable for docking in U.S. ports. That leaves just 12 to 15 of the world's tankers able to call at Cuban ports.
- Shipping charges to the island fluctuated between 15 and 30% above World Scale rates between shipping regions.

- Some suppliers eliminated the shipping clauses from their sales contracts with Cuban importers, thereby making the client the responsible party for shipping the merchandise. Other suppliers refused credit to Cuban importers unless Cuba either shipped the merchandise itself or found a shipper willing to transport the cargo.

In general, all the shipping problems **have** led to frequent delivery delays.

The CDA and Critical Imports to Cuba

Problems with the following commodities began just weeks after the Torricelli bill became law:

Soap: In late 1992, Cuba tried to import 1,500 metric tons of tallow from Argentina. Normally under these contracts, the supplier arranges shipping. But this contract was subsequently canceled after the Argentinean company failed to find a tanker willing to sail to Cuba. This in turn, sparked severe soap shortages on the island for several months.

Fuel and Fuel Products: When Cuba asked for bids to ship 15,000 metric tons of gasoline from Marc Rich & Co. of Antigua in January, 1993, the country received just one offer. The company would ship at \$309,000, even though the World Scale rate should not have exceeded \$210,000. For this particular fuel shipment, the country paid 43% over the World Scale, and for 1992 post-Torricelli fuel transport, Cuba paid average rates of more than 25% over World Scale. By 1993, Cuban importers were paying an additional 35 cents a barrel for transporting fuel and fuel products.

powdered Milk: The Cuban ration system assures a liter of milk a day to all children through agesix, and to pregnant women every other day. When Germany canceled the powdered milk contracts with Cuba signed by the former GDR, the island became a regular customer of the New Zealand Dairy Board. The milk was delivered to Cuban ports on board Greek Armada freighters, under contract to the Dairy Board. However, in December 1992, Armada refused to take aboard some 1,500 metric tons of powdered milk bound for Cuba, and the New Zealanders canceled the contract with the Cubans. The island then found alternative milk supplies in Europe, but that supplier also refused to take responsibility for shipping the merchandise. Eventually the Cubans found a shipper but paid dearly for both the transportation and the milk. In addition, back in Cuba, the delay caused milk shortages for more than a month.

Basic Foodstuffs: Before the ink had dried on the new Torricelli law, the captain of a freighter at an Italian port was refusing to load 9,009 metric tons of soy oil Cuba had purchased from the Italgrani Company. It took two more months before the exporters could find a replacement tanker willing to sail to Cuba. The additional shipping costs were passed on to Cuba. Similar scenarios were unfolding elsewhere: first, at a French port where the Souflet Company was attempting to ship 25,000 metric tons of wheat to Cuba; and second, at a Chinese port ready to load 20,000 metric tons of beans that finally arrived 6 months later, in late April.

As a freighter from the MN Trade Master Company was crossing the oceans with 16,660 metric tons of China Cereal Foods rice, the company changed their minds and decided they didn't want to risk going to Cuba. For 15 days, while the ship sat at sea, the Chinese exporters renegotiated the contract and agreed to the following terms: (1) the Chinese would compensate the shipper for any damages (fines) it might incur as a result of traveling to a Cuban port; (2) shipping costs would be increased to \$600,000; (3) the demurrage or delay charges of \$8,000 daily would begin on day six after arrival even though the actual unloading time was estimated at 15 days. As a result, an additional \$72,000 was paid to the shipper.

Kraft Cardboard Liner: When the Canadian office of the Dutch Shipper, Spliethoff Bevrachtingskantoor B.V., agreed to transport 3,960 metric tons of Kraft cardboard liner to Cuba, the bill included an extra \$50,000 in the event that the vessel might need to enter a U.S. port within the Torricelli-imposed 180-day limit and might be fined by the U. S government. The Cuban importers finally accepted these conditions on their purchase from Eurocan Pulp and Paper Co. of Canada, since the goods were urgently needed.

Conclusion

Although Cuba's economic reform program designed to reconstruct its economy has stemmed the economic decline experienced between 1989 and 1994, recovery is seriously hampered by the continuation of the U.S. embargo and its extraterritorial extension through the Cuban Democracy Act of 1992 and the 1996 Helms-Burton legislation. The sweeping effect of these measures denies Cuba access to important markets, increases Cuba's cost of trade to well above international market prices, and prevents Cuba from obtaining needed hard currency to invest in its domestic recovery. This, not to mention denying the country access to its most natural trading partner for over 35 years.

Even aid to Cuban families struggling to meet basic needs such as food and clothing is severely restricted. In September 1994, President Clinton cut off the limited remittance individuals in the U.S. could send to relatives in Cuba. Until that time, a modest \$500 was permitted to be sent by close U.S. relatives every three months to a family unit in Cuba.

The U.S. sanctions have had a particularly harsh impact on the Cuban government's ability to provide food to its population and to maintain health services at an adequate level. Even when Cuba faced a serious neuropathy epidemic in 1993, the cause of which was related to dietary deficiencies, the U.S. took no steps to ease its restrictions. Sales of foodstuffs remain strictly prohibited for U.S. companies and their subsidiaries, and sales by third-country companies may run afoul of U.S. legislation if they contain U.S. components or are sold to Cuba on credit. In addition, exports of medicine and medical equipment remain tightly restricted, so much so that pharmaceutical and medical supply manufacturers in the USA themselves consider the embargo the main obstacle for sales to Cuba.

The application of the embargo to foodstuffs and medicines make the U.S. -measures more restrictive than any other international trade sanctions, since no others deny access to such humanitarian goods. The UN Security Council has recently decided to relax some multilateral trade sanctions against the government of Iraq. Yet, no such moves have been forthcoming from Washington with respect to its bilateral embargo on Cuba. Just the opposite has been the case.

NOTES

Comments by Jose Luis Rodriguez, Minister of the Economy and Planning, comments to visiting delegation, June 12, 1996.

²Sources for this section: Osvaldo Martinez, Director, Center for the Study of the World Economy, November, 1995; Cuba, hechos y cifras, published by the Institute for European-Latin American Relations, of the European Commission in cooperation with the Spanish Presidency of the Council of the European Union, December 1995; and Minister of the Economy and Planning Jose Luis Rodriguez, April 3, 1996.

³The main, and until recently, the only employer in Cuba is the government.

⁴Cuban think tanks also assert that recovery has taken hold. Juan Triana Cordoví, director of Havana University's Center for the Study of the Cuban Economy, foresees between 5 and 8% overall growth in 1996. His remarks at a news conference, Havana, Jan. 23, 1995.

⁵Minister of the Economy and Planning, Jose Luis Rodriguez figures, and La Gaceta Oficial de la Republica references to parliamentary proceedings, January 15, 1996.

⁶Testimony of Rep. Robert Torricelli (D-NJ) on August 6, 1992 before the Subcommittee on Western Hemisphere and Peace Corps Affairs of the Committee on Foreign Relations, U.S. Senate.

⁷ Afectaciones por el bloqueo y la puesta en vigor de la Ley Torricelli, Informe 4, Ministry of Foreign Trade, June, 1994.

⁸Comments by Ramón Díaz Vallina, Vice Minister for Economics, Ministry of Public Health, 1995

CHAPTER Two

CUBAN HEALTH CARE IN THE NINETIES

Background

The Cuban Constitution makes health care a right of citizens and the responsibility of government. The public health system, which emerged in the early 1960s, is based on universal coverage and comprehensive care, offered essentially free to the population.¹² Over the past three decades, the following major developments have made their mark on the system:

In the 1960s: The former Health -Department was given -ministerial ranking and reorganized to take up the task of providing universal health care. Pharmaceutical production and private health facilities were nationalized, with few exceptions. A Rural Medical Service recruited physicians who were dispatched to care for patients in remote areas, and 50 local hospitals and dozens of medical posts were hastily constructed in the countryside. By 1962, 161 neighborhood polyclinics were in operation in urban areas. The National Immunization Program was initiated, relying heavily on community participation, as were programs to control such diseases as tuberculosis, leprosy and the diarrheas. During this decade, approximately half the physicians in Cuba emigrated to the United States and elsewhere, leaving the country with 3,000 doctors and 16 full professors at the medical school. Training of new doctors became a priority. Margaret Gilpin comments in the *Journal of Public Health Policy*, "By the end of the first decade, a unified Cuban national health care system had been created and was firmly in place. The efforts paid off in changes in major health indicators, reductions of infectious diseases, and improved hygienic and environmental conditions."³

In the 1970s: In this decade, the polyclinic model of primary care was reinforced and expanded, taking on health education, prevention and environmental monitoring. In general, responsibility for direct health management was transferred to the provincial and municipal levels. The School of Medicine was brought under the Ministry of Public Health, and residency programs were revised. As the numbers of graduates rose, more Cuban health professionals joined the program for "internationalist service" abroad, which began in Algeria in 1961. By the end of the next decade, the total number of Cuban health workers who had spent one or two years in Africa, Asia or Latin America was close to 20,000.

The Maternal-Child Program evolved as a way of giving priority to these sectors of the population. The first major investments were made in new health facilities and pharmaceutical production. Today Cuba has 284 hospitals and 440 polyclinics, among other institutions within Ministry of Public Health authority.

HEALTH FACILITIES IN CUBA (1995)	
FACILITY	NUMBER
HOSPITALS	284
POLYCLINICS	440
RESEARCH INSTITUTES	11
DENTAL CLINICS	168
MEDICAL POSTS	165
MATERNITY HOMES	208
BLOOD BANKS	25
SENIOR CITIZEN HOMES	182
HOMES FOR DISABLED	26
FAMILY DOCTOR-NURSE OFFICES	18,471 .

. Does not include these teams in clinics, workplaces, schools and other institutions.
Source: Ministry of Public Health, Havana , 1996.

In the 1980s "with a consolidated, nationwide health care system, Cuba entered the third decade fully committed to becoming a potent force in world medicine and health care," states Gilpin.⁴ At the level of tertiary care, modern techniques were introduced in virtually all 54 fields of medicine practiced in the country, with specialized institutes acting as national reference centers. This included national programs for prenatal screening, installation of the first nuclear magnetic resonance equipment in Latin America, and an organ transplant program.

Schools of medicine multiplied in each province, and Cuba began the nineties with 28 medical school campuses. By 1995, this country of 11 million people had 57,000 physicians (25,000 of them specialists), 9,000 dentists and 72,000 nurses, although this last number was considered insufficient by health officials.

PHYSICIANS IN CUBA			
YEAR	TOTAL	DOCTORS PER 10,000 INHABITANTS	INHABITANTS PER DOCTOR
1970	6,152	7.2	1,393
1980	15,247	15.6	641
1985	22,910	22.8	439
1990	38,690	36.5	274
1991	42,634	39.9	251
1992	46,860	43.3	231
1993	51,045	46.7	214
1994	54,065	49.1	204
1995 *	56,925	51.2	195

. Provisional. Source: Ministry of Public Health, Havana, 1996.

The 1980s was also the decade for two decisive developments, which became hallmarks of Cuban medicine: the first was the takeoff of the biotechnology industry, which would put Cuba in the front ranks of research in a number of important fields; and the second, the introduction of the Family Doctor Program in 1986, which gave new impetus to primary care. By 1995, 96% of the Cuban population was attended by physician-and-nurse teams living in the neighborhoods they served, each assigned the care of approximately 150 families.

From 1960 through 1990: Cuba's indicators registered consistent improvement in the health of the population, and won praise from international agencies such as the World Health Organization, the Pan American Health Organization and UNICEF. By 1995, Cuba was free of polio, measles and diphtheria, and its immunization program covered 11 infectious diseases. Cuba emerged at the forefront of the developing countries, and began to reflect patterns that more closely resembled the nations of Western Europe and North America.⁵

SELECTED HEALTH INDICATORS		
	Cuba	Latin America*
Life Expectancy (1994)	75 years	68 years
Infant mortality (1994)	9.4/1,000 live births	38
Under Five Mortality (1994)	12/1,000 live births	47
Maternal mortality (1980-92)	39/100,000 live births	178
Access to health services	98% of population	73%

*22 countries of the region. Source: State of the World's Children, 1996, UNICEF.

The Economic Crisis and Health Care

In the early nineties, the tidal wave of socialist Europe's collapse hit Cuba, leaving the economy in shambles and threatening to wash away the gains of the island's government-funded universal health care program. With the disappearance of aid and preferential terms offered by socialist partners, virtually all of Cuba's commerce was now carried out under the shadow of U.S. embargo restrictions limiting international loans, credits, dollar transactions, technology transfers, U.S.-component purchases, third-country exports to the USA of goods with Cuban elements, and so on. Up to 1939, the embargo placed conditions on the 15% of Cuba's international trade which fell outside the socialist market; after 1991, the embargo had a restrictive influence on more than 90% of that trade.

The result was to accelerate Cuba's economic contraction, which may be the U.S. policy's single most deleterious effect on the health care sector and its financial underpinning. This effect was multiplied with the passage of the Cuban Democracy Act (CDA) of 1992, whose express purpose was to cut critical remaining funds, and furnish the coup de grace for the Cuban government. However, since the government was paying the bill for health care, this move necessarily put the population's health in jeopardy.

As noted in other chapters of this study, the CDA eliminated U.S. subsidiary exports to Cuba, over 90% of which were food. And the shipping nightmare that ensued with the virtual reinstatement of the blacklist for vessels traveling to Cuba has added millions to freight costs and months to delays in delivery of vital goods to the island.

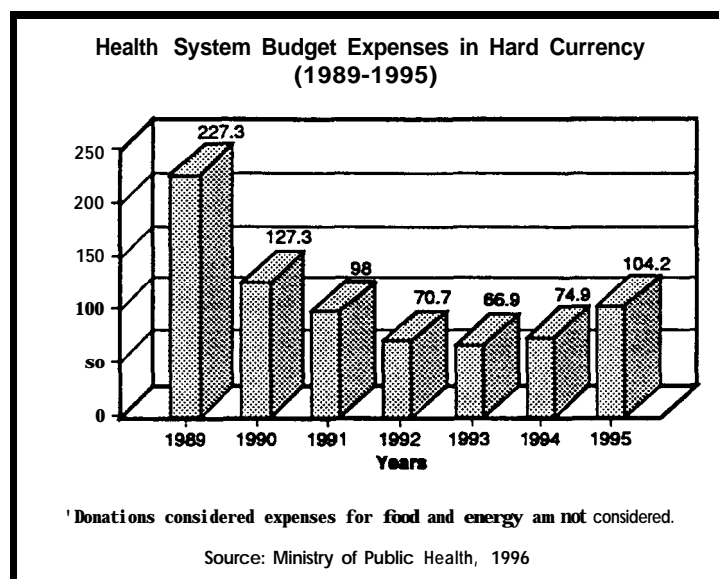
In 1996, the Helms-Burton Act was passed, aiming to scuttle Cuba's pretensions of economic recovery by discouraging foreign investment. While it is too early to measure results, Cuban government officials admit the law has slowed economic recovery. It could stall investment in industries that produce essential goods for the Cuban population, or that bring in dollar earnings directly to the health sector.

Higher Priority, Fewer Resources for Health

As a result of the double drain of disappeared socialist allies and the hostile U.S. embargo, resources vanished overnight that had gone into housing, water resources, sanitation, the environment, food security, education, transportation, and communications—all with serious repercussions for health and welfare. While the priority accorded the health care budget was boosted another notch, up to 7.6% of the total in 1995—the devaluation of the Cuban peso and the shortfall in hard currency reduced dollars for the health sector to 30% of 1989 levels by 1993.

HEALTH CARE SHARE OF CUBA'S STATE BUDGET							
YEAR	11989	1990	1991	1992	1993	1994	1995
% OF TOTAL	15.8	6.0	6.3	6.6	7.4	7.5	7.6

Source: Ministry of Public Health, Vice Minister of Economics Ramón Díaz Vallina, 1996.



The following chart illustrates the priority given health care expenditures in the national budget, increased in the nineties mainly at the expense of shrinking outlays for defense and government management.

THE CUBAN NATIONAL BUDGET: KEY EXPENDITURES											
(in millions of pesos)											
	1986	1987	1988	1989	1990	1991	1992	1993	1994	1995*	1996**
Education	1,640.2	1,600.0	1,651.6	1,650.6	1,619.5	1,504.0	1,426.7	1,384.9	1,334.4	1,370.0	1,430.0
Health	769.7	810.2	872.6	904.5	937.4	924.9	938.3	1,076.6	1,061.1	1,100.0	1,180.0
Defense	1,268.2	1,241.7	1,273.9	1,259.4	1,149.0	882.2	736.4	712.8	651.2	632.0	602.0
Social Security	896.5	961.2	1,031.5	1,093.9	1,164.1	1,225.7	1,348.0	1,452.3	1,532.4	1,585.0	1,630.0
Administration	530.2	495.1	495.0	489.9	453.1	400.2	365.8	413.3	354.2	365.0	357.0
Housing, City. Serv.	443.7	415.9	395.6	406.4	382.7	280.2	247.5	260.0	316.1	400.0	470.0
Culture and Arts	185.2	171.2	173.3	191.4	200.6	203.0	177.6	173.2	159.9	157.0	150.0
Science and Technology	126.6	120.1	121.1	124.4	123.7	126.0	121.6	125.0	121.4	133.0	133.0
Sports	105.4	106.8	114.9	116.2	117.1	124.5	99.5	103.6	105.6	111.0	115.0
Welfare	83.3	93.1	97.0	101.1	95.6	86.4	98.2	94.2	93.7	110.0	150.0

* Estimate . * Planned. Source: *Ministry of Finance and Prices, Havana, 1996.*

Cuba's general economic trauma has had broad impact on the health of the population, and has shaken the medical system's ability to respond to the crisis. Some examples:

Fuel Shortages: With only half the **1989** oil supplies available to the island, blackouts suddenly cut power, industries shut down, public buses are overcrowded and infrequent, and the traffic of cars and trucks thinned on the highways. The implications for health and hygiene are legion: power

outages stop pumping operations, and whole cities go for hours every day without water. The blackouts cause food spoilage in homes, lunchrooms and industrial kitchens, while there is little cooking gas or electricity to boil water, and so more danger of contamination. Households turn to alternative cooking fuels, some of which have noxious effects for asthmatics, and all of which present greater risk of burns. More pedestrians and (inexperienced) cyclists are on the road, but street lighting is at a minimum, so consequently traffic accidents are more common. Dimmed illumination at workplaces causes eyestrain and leads to more accidents on-the-job, and the list goes on.

In the health system, ambulances are idle for lack of gas and tires, and patients have less alternative emergency transport, mobile mammography units face the same fate. Medical equipment runs overtime during hours when electricity is on, and is at risk for damage with unstable voltage. Hospital air conditioning units are shut down, pharmaceutical plants produce a third of what they did in the eighties, and power outages threaten to ruin medications and vaccines in refrigerated warehouses and hospital storerooms.

ENERGY AVAILABLE FOR CUBAN HEALTH FACILITIES (1994-1 996)				
SOURCE	UNIT	1994 REAL	1995 ESTIMATE	1996 PLAN
Electricity	GWH	56.5	55.1	60.7
Oil	TON	3418	3666	3874
Diesel	TON	2637	2560	2830
Gasoline	TON	1947	1637	1800

Source: Ministry of Public Health, Havana , 1996.

Shortages of Hygienic Products: The increase in untreated water correlates directly to increases in water-borne diseases, with mortality climbing seriously among the elderly. Household, school and personal hygiene slacken without adequate supplies of cleaning agents, leading to outbreaks of scabies and other dermatological disorders. The use of corrosive homemade cleansers leads to a rise in household accidents, especially among children under five. Women have neither enough sanitary napkins nor cotton for their monthly needs.

In health care facilities, these same shortages have been blamed for the increase in hospital infections and sepsis; and in institutions such as senior citizens' and maternity homes, the health of vulnerable populations is also endangered.

Food Shortages: Decreased nutritional levels have been registered as a result of plummeting food imports and purchases of vital inputs for agriculture and the food industry. In 1993, sudden drops in nutrition were blamed for an epidemic that debilitated the eyesight and motor function of over 50,006 people. Workplace and school lunchrooms and boarding school dining halls are serving fewer calories and proteins on their trays. The daily liter of milk once assured to all children up to 13 is now limited to children through six; and people over 65 no longer receive special supplements.

Patients in hospitals, and residents in senior citizen homes and other facilities are not assured consistent good diets either. The general limitations on food have also made it more difficult to guarantee reinforced meals to those who most need them, such as pregnant women and patients with HIV and AIDS, not to mention those who require special diets, such as diabetics.

Shortages of Medical Products: Most sensitive for the population is the lack of medicines and medical equipment. of the 1297 medicines circulating in the country in 1991, only 889 can be obtained today, and then on an irregular basis. This presents special problems for critical and chronic patients, as we will see in this study. Equipment repairs have slowed, units lie broken in hospital corridors, and equipment parts take their place behind vital drugs in the wait for a share of the hard currency budget. The Ministry of Public Health reports 13% of x-ray machines are out of commission, as well as 21% of cobalt therapy units⁶

Even paper, imported at rising world prices from Asia, Canada and Europe, is scarce. In hospitals, its absence has led to difficulties in keeping proper case histories, while in medical schools, where texts and journals are few, photocopies can bring only a partial solution. Lack of specialized paper for medical equipment read-outs or sterilization have been known to shut down hospital departments.

The Current Health Picture in Cuba

The presence of family doctors in the community, and the broad hospital system which makes secondary care generally accessible throughout the island, are credited with keeping basic indicators stable in such a precarious environment. Some of these indicators have actually improved, reflecting, specialists contend, both prioritized attention and the incidence of the "human factor," the dedication of medical personnel. Not only do they work long hours for a peso-devaluated paycheck, but nurses, family doctors, pediatricians, cardiologists, and surgeons we spoke with were bicycling from home to hospital and clinic. They described the frustration of seasoned clinicians who know the right therapy, but no longer have the resources to apply it.

The Ministry of Public Health evaluates the health situation measuring a series of broad epidemiological factors, which reflect the following priority areas:

Maternal and Child Health: Infant mortality continues to decline, with the goal at keeping it below 10 per 1,000 live births for the coming five years. Maternal mortality, which reached 44 in 1994, dipped to 33 in 1995. Low birth weight has shown a predominantly increasing tendency since 1969, with some improvement over the last year. Incidence and deaths from household accidents are increasing in children under five.

Infectious Diseases: These are on the rise in the nineties, mainly those transmitted orally, through contaminated food or water. This includes the Acute Diarrheal Diseases (ADD), typhoid fever, and viral hepatitis, for which mortality rates have also jumped. The incidence of sexually transmitted diseases (STDs), including syphilis and gonorrhea, is climbing as well as that of scabies, head lice and especially leptospirosis (this last a severe affliction affecting primarily agricultural workers). Slight increases in tuberculosis have also been reported, and marked increases in TB mortality. Mortality figures from influenza and pneumonia are increasing. Since 1990, pneumonia and influenza have become more prominent as a cause of death among people over 15.

Noncommunicable Chronic Diseases: These conditions are responsible for over 70% of deaths in Cuba. Heart disease is the number one cause of death, with mortality rising in the nineties, registering a slight dip in 1995. Control of risk factors at the primary level has influenced the declining mortality rates for hypertension. Fatalities from asthma, diabetes, renal failure and accidents have all increased. As with infectious diseases, **most** of the reasons are associated with the decline of living standards and deteriorating environmental factors. Asthma now accounts for 60% of chronic obstructive lung disease.'

Attention to the Elderly: Life expectancy now reaches 75 in Cuba, comparable to industrialized nations. Under current conditions, however, the elderly are particularly vulnerable to disease,

and mortality rates for acute diarrheas and pneumonia are of particular concern in the nineties. New emphasis is being placed on preventive care for this generation, especially through the family doctor program.

Cuban health care authorities have developed a package of strategies designed to mitigate the effects of the economic crisis-including those of the embargo-and to place prevention squarely at the center of a system which must rely more on its human resources than any others. While these strategies are pro-active and intended to generate community participation as well as new financing for the sector, the course ahead is uncertain and also marked by economic obstacles. Among the key directions:

The Primary Care Model: This system is to be reinforced by strengthening the preventive role of Family Doctor-and-Nurse Teams, and adding services to local polyclinics to bring effective emergency attention into communities to take pressures off hospital facilities. This is also an attempt to turn around the emphasis on curative procedures at the expense of health education, priorities forced on the system as the logical result of scarce resources being prioritized for the sick. Anchoring the Teams in community education and participation projects is also expected to make them a more consistent source of epidemiological information, vital to predicting health tendencies and pinpointing areas for preventive campaigns. Yet, as with all the strategies outlined here, beefing up this capacity depends not only on redirecting funds, but on finding new ones: doctors' offices need re-equipping, their medicine cabinets restocking, their transportation maintained; education requires teaching aids, tapes and literature; and epidemiological networking requires significant computer hardware.

Revitalize Hospital Care: Instituting more efficient organization and utilization of resources, including human resources, is to boost this arena. Surgical services will need major inputs: by 1993 operations were reduced to less than half of the number carried out in 1990. The Ministry of Public Health also cited adverse economic factors as the main reason for the deterioration of efficient use of hospital facilities, such as the decline in hospitalizations per bed (from 25.4 to 21.4 from 1990 to 1994) and the number of consultations per doctor (from 1763 to 1247 in the same period.)

However, the most pressing problems facing hospitals certainly require more available funding: replacement of outdated and worn-out equipment; purchases of repair parts, accessories and patient kits, x-ray film and air conditioners; guaranteeing sufficient water supplies, cleaning agents and sterilization equipment and supplies.

Streamline MedicalSupply Sources: Programs will be consolidated to guarantee the most vital medications to the population, through imports, national production and alternative medicine. Soon after the economic crisis hit, the Ministry of Public Health developed a nationwide plan for distributing medicines, in an effort to guarantee consistent medication for the chronically ill and critical medications for medical emergencies. Medical prescriptions were limited, and patients with chronic conditions were authorized ongoing drug purchases by a card filed at their local pharmacy. This system has gone a long way to assuring that medications get to the patients who most need them.

But it does not solve the problem of the global supply of medicines. Now, the Ministry hopes to tackle this by boosting domestic production, discreetly increasing imports, maintaining priority medications on continual request from international donors, and turning to alternative medicine where possible.

In this study, we will examine the limitations on purchases of medications abroad and on the pharmaceutical industry, which has the capacity to produce nearly 80% of the medicines needed in the country but today turns out little over half because of economic constraints on inputs.

Guarantee Rational and Sustained Use of Modern Medical Technologies: Introduced in Cuba in the 1980s, the utilization of some technologies has seriously eroded during this decade. The Ministry proposes to refurbish its own equipment and promote domestic research and production of the same.

Bring special attention to bear on programs particularly weakened by general shortages, among these dentistry, medical transportation, and optics, as well social service institutions under the Ministry's guidance.

Seek hard ~~currency contributions~~ to the public health sector, releasing it from total dependence on the central budget and bring in new revenues. The Ministry plans to finance some of its projects through cooperation from other government institutions and from international agencies. It should be noted that municipal government budgets in national currency finance over 90% of health care expenditures. In all but a few cases, the administration of health care facilities falls under the aegis of the provincial and municipal governments.

Promote community participation in the identification and solution of local health problems, primarily with local resources. The Community Health Councils have been set up for this purpose, to work in close collaboration with the neighborhood physician and nurse team, and they are considered key to promoting a return to a broad preventive emphasis at the local level.

Conclusions

After three decades of what international public health experts and organizations consider remarkable results, it is clear that the problem of health care delivery in Cuba today is not a lack of good ideas, competent and committed professionals or national programs with sufficient community outreach. The central problem in the nineties remains one of financial resources- and especially hard currency- to make these programs and ideas work.

After a week of immersion in Cuban health care delivery-its achievements, failures and dilemmas, U.S. cardiologist Dr. Stephen Ayres described the medical system as a giant tree, its roots and trunk intact, but its branches without leaves. A system essentially sound, but without the resources to flourish.

After one year of research, it is our assessment that economic revival is decisive to the vitality of Cuban health care, and to sustaining the welfare of the Cuban people. To the extent that the U.S. embargo successfully blocks this broad recovery-its stated intention-the policy also bears responsibility for undermining public health care strategies to respond to the urgent and long-term needs of the Cuban population.

NOTES

1 "Análisis del Sector Salud en Cuba: Informe de Avance," Ministry of Public Health, Havana, in collaboration with PAHO/VHO, Nov. 21, 1995, p. 1.

2 "Análisis del Sector Salud en Cuba: Informe de Avance," Ministry of Public Health, Havana, in collaboration with PAHO/WHO, Nov. 21, 1995, p. 1.

3 "Cuba: On the Road to a Family Medicine Nation," by Margaret Gilpin, in the Journal of Public Health Policy, Vol.-12, No. 1; 1991, p. 87.

⁴ Ibid.

5 Praise from these quarters has come on the basis of what they consider to be highly reliable methodologies for compiling statistics, and forthright use of findings by Cuba's Ministry of Public Health. Dr. Miguel Márquez, who until 1996 represented PAHO in Havana. Dr. Márquez reports that, on the Cuban government's request, PAHO teams of experts have traveled to the island to review data collection and calculation. Looking at sensitive indicators such as infant mortality and maternal mortality, he noted that the team "concluded by verifying as correct the figures published by Cuba." The same, he stated, was the case for studies of malaria and polio data released by the Ministry of Public Health. See his comments in *Contrapunto*, May, '1993, pp. 41-42. Marta Maurás, UNICEF Director for Latin America, declared in December, 1993: "It is a source of enormous satisfaction to observe the great dedication with which Cuba examines its indicators and puts its statistical information systems to work, making perfectly clear the progress and difficulties..." See her speech at the Presentation of the Second Follow-Up Report on Cuba's National Program of Action for Children, Havana, December 1, 1993.

6 Analysis of the Health Sector in Cuba, Executive Summary, April, 1996, prepared in cooperation with WHO/PAHO, P. 12.

⁷ Ibid., p. 7.

CHAPTER THREE

MEDICAL EXPORTS TO CUBA

Relevance to Cuba of U.S. Research, Development and Production

We have singled out medical imports for special consideration, since this is an arena where our findings indicate that the embargo has had significant health-specific impact, with implications for the medical system as a whole and patient care in particular.

In recent years, United States pharmaceutical and medical supply and equipment manufacturers have consolidated their dominant position in the international market. In the pharmaceutical industry, no other country compares to the United States in terms of the sheer variety, quantities and marketing of medications, with PhRMA member sales up to \$56.6 billion in the United States and \$30.5 billion abroad in 1995.¹ U.S. pharmaceutical manufacturers are also the world's number one in research and development: company-financed RandD expenditures by PhRMA members were projected at \$14.9 billion in 1995, up 7.9 percent from 1994.²

U.S. giants hold a strong 25-year lead over European and Japanese competitors in medical product breakthroughs, for the introduction of new world-class drugs marketed internationally. A recent study published in Britain concludes:

The American pharmaceutical industry has a clear and outstanding lead in discovering and developing major, medically innovative, globally competitive, and therapeutically accepted new drugs.

The American lead in origination has been continuous, with an average score of 43% of all "Major Global Drugs" during the 22-year-period (the 265 major global drugs developed from 1970 through May, 1992). This compares with average scores of 31% for the European Community, 13% for "Other West Europe," 11% for Japan, and 2% for East Europe.

The most recent period (1990-May 1992) shows the American share of "Major Global Drugs" at its highest (47%), with a surge from Japan to 21%, and a serious decline of the European Community to 19%.³

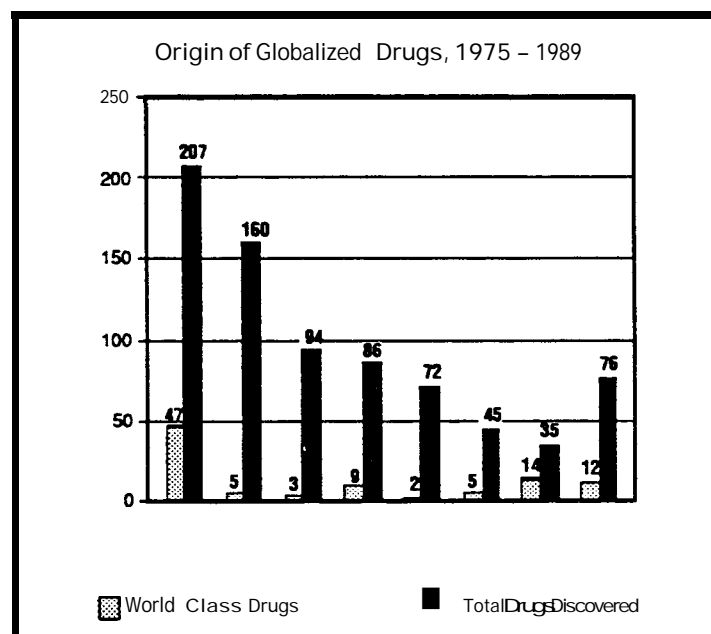
Due to U.S. and international patent law and practice, this means that a host of newly discovered medications are only available from U.S. pharmaceutical manufacturers, during the life of their 17-year patent. Since drugs are patented before they begin the FDA approval process, this means that a U.S. developer is guaranteed exclusive production and sales in the USA for an average of 8 to 10 years, once the new drug emerges onto the market with FDA authorization. International patent practice will guarantee these firms similar rights in other countries. Therefore, all medicines internationally patented by U.S. pharmaceutical companies since 1979 are still exclusively produced by these manufacturers, and thus only available from them directly or under licensed production agreements.⁴ The U.S. embargo's virtual ban on such sales to Cuba, as we will see throughout this study, has had a serious impact on the Cuban population's access to new cures for illnesses, more effective treatments, and alternative therapies.

In Cuba's case, access to the results of U.S. research, development and production takes on additional importance for several reasons:

1. United States suppliers not only occupy the largest share of the international market, but are also the closest to the island, making Cuban importers a "natural" for U.S. firms. Indeed, this was the case prior to the embargo, when most medications were imported from the United States, even to the detriment of developing a domestic pharmaceutical production capability. According to the Cuban Ministry of Public Health, 40,000 medical products were registered in Cuba in 1959 (including medicines, reagents, instruments, accessories, etc.), of which 80% came from foreign firms, mainly those of the United States.⁵ Access to close-at-hand U.S.

suppliers would translate into reduced freight, immediate delivery, less moneys tied up in bulk purchases for the long term, and reduced inventories and warehouse needs.

2. Since the United States manufacturers are often among the strongest in their respective lines of production, they are able to offer more competitive prices, underbidding suppliers elsewhere. This is especially true in terms of their efforts to guarantee maintenance of a major presence in the Latin American and Caribbean markets.
3. New U.S. "state of the art" equipment, supplies and pharmaceuticals are well assimilated by the Cuban health system, both because of its internationally recognized level of development, and because the tradition of Cuban medicine has followed closely in the path of United States medical practice. Thus, many Cuban physicians and specialists told us they often prefer to work with U.S. products because they trust the credibility of FDA and manufacturing standards.



Orlando Romero is General Manager of MEDICUBA, Cuba's government-owned import-export firm for medicines, pharmaceutical raw materials and reagents, medical equipment, supplies, parts and accessories. The company is primarily funded by the government, but derives some of its operating budget from exports. According to Romero, all profits from exports are reinvested in the company or go directly to purchasing medical imports.

During the economic crisis of the past five years, exacerbated by the embargo as noted earlier in this report, the purchasing power of MEDICUBA has plummeted. Despite attempts at import substitution by domestic production (see chapter on the Pharmaceutical Industry) and the adoption of complementary alternative medicine approaches, hard currency budget reductions have drastically diminished supplies of medications and equipment. MEDICUBA is the supplier of 95% of the medical imports for the country's health system, but Romero calculates that the firm's current import budget only covers 40% of the country's needs.⁶

At the height of purchases in the 1980s, he estimates, the company annually spent some \$200 million. But by 1992-the most serious year of MEDICUBA's budget crisis-the firm's import capabilities constituted only a fraction of this figure.

CUBAN MEDICAL IMPORTS .	
Years	Reduction in Imports
1989 to 1990	12 %
1990 to 1991	18 %
1991 to 1992	38 %
1992 to 1993	5 %
1993 to 1994	8 %

'Includes medicines, reagents, raw materials for pharmaceuticals equipment, accessories and parts.

Source: MEDICUBA, November 24, 1995

However, by 1995 the hard currency budget slide had been halted, and Romero predicted an increase in medical imports for 1996, the first time in the last seven years. Even in such depressed times, the MEDICUBA manager calculates that his company would spend \$50-\$60 million annually in the U.S. marketplace if the embargo were lifted on medicines and medical supplies, and he estimates that amount would reach \$150 million under conditions of relative economic recovery.⁷

Application of U.S. Embargo Restrictions on Medical Exports to Cuba

As noted in previous chapters, the U.S. government has levied a series of restrictions on medical exports to Cuba. These apply to all products from U.S. pharmaceutical and medical supply houses, subsidiaries of these firms in third countries, and third-country firms **with** a substantial percentage of U.S. ownership. They also apply to the goods themselves, regardless of nationality or ownership of the manufacturer, when U.S.-origin components, U.S. patents or technology are implicated in the manufacturing process. And finally, these suppliers are subject to U.S. government requirements to certify specific end-use of pharmaceuticals and medical equipment in Cuba, requiring detailed distribution information and the possibility of on-site verification of the information provided.

The regulations governing export of medications and medical supplies to Cuba have changed a number of times since the full U.S. embargo was imposed in 1962. Although we make a general chronological review of U.S. embargo legislation in an earlier chapter, it is useful to look at modifications which have specific relevance to sales for medical purposes.

Until 1964, medicines were exempted from the embargo altogether, and their export to Cuba was permitted. However, on May 14, 1964, the Commerce Department revoked the general license for foods and medicines and indicated that henceforth policy would be to deny such sales, and permit only limited humanitarian donations.* From 1964 until October 1975, no sales to Cuba of medications, medical equipment or supplies containing any U.S. components or technology were permitted, including those by companies in third countries.

In 1975, U.S. Treasury Department regulations *were* liberalized, to permit case-by-case licensing to foreign firms owned or controlled by U.S. nationals, yet limited to those which did not share a substantial number of officers or directors with the parent firm in the United States. This change affected all exports to Cuba, not only those in the health field. The Commerce Department also relaxed its regulations to allow for exports by third countries of foreign-made products containing "an insubstantial proportion of U.S.-origin materials, parts or components." Special licenses could be granted where the U.S. parts or components amounted to 20 percent or less of the value of the product; licenses were less likely to be granted for larger proportions. The government also

took the first steps to eliminate the so-called blacklist of foreign ships, which had prohibited foreign assistance to third countries that permitted their vessels to carry goods to or from Cuba.⁹

From 1977 to 1982, travel restrictions were lifted for the first time, allowing representatives of U.S. firms to explore the Cuban market. However, the prohibition on such trips was reinstated on April 20, 1982. (And it was not until November, 1994, that efficient telephone communication was resumed between the United States and Cuba.)

In 1988, the Treasury Department's Office of Foreign Assets Control (OFAC) embarked on a stepped-up drive to more closely monitor Cuba's international trading ties and "bear most effectively on the key vulnerabilities of the Cuban economy and its embargo circumvention attempts." As a result, by August 2, 1989, OFAC had compiled a list of 258 names of third-country companies or persons considered "Cuban nationals" by the U.S. government, and thus barred from entering into any commercial transactions with the United States.

Finally, on October 28, 1992, the Cuban Democracy Act (CDA) was signed into law, reversing the 1975 decision to allow third-country companies owned or controlled by U.S. firms to engage in licensed trade with Cuba. An exception allowed special licenses to be granted for the sale of medicines or medical equipment by these firms or their parent companies in the USA provided that a number of prerequisites were met to the satisfaction of the U.S. government." These include: that there is no reasonable likelihood that the item exported will be used for the purposes of torture or human rights abuses, that it will be reexported, or that it could be used in the production of any biotechnology product. The law also provides that medical exports can only be authorized if the President determines that the U.S. government is able to verify, by on-site inspection and other appropriate means, that the exported item is to be used for the purposes for which it was intended and only for the use and benefit of the Cuban people.**

In addition, the CDA prohibits foreign ships which have docked in Cuba from entering U.S. ports for the next 180 days, partially reinstating the blacklist.

Also in October 1992, the U.S. Congress increased criminal penalties for those who knowingly violate the embargo. The new regulations allow for a maximum of \$1 million in fines to be levied on corporations and \$100,000 for individuals, ten years in prison and forfeiture of properties involved in the violation.¹² The Helms-Burton Act, enacted on March 12, 1998, mandates full enforcement of these penalties and permits administrative fines to be levied without going to court.

U.S. Exporters and Embargo Laws

Despite the fact that sales to Cuba of medicines and medical equipment may be authorized by the U.S. government, we find that major medical manufacturers in the USA do not in fact export their products to Cuba. Indeed, they report various "chill factors" that keep them from taking advantage of this possibility. Among these are the labyrinth of changing U.S. regulations and their interpretation, licensing requirements and the complex application process, time lags, the uncertainty of final authorization, often based on active discouragement by government offices, and stiffened penalties for embargo violations. We also observed considerable confusion among United States manufacturers in the medical supply field about current U.S. legislation, and a unanimous reluctance to engage Cuban import firms in conversation, much less contracts.

In a survey conducted for this study among 12 pharmaceutical and medical equipment manufacturers in the United States, we found that none sells or had recently sold products directly to Cuba and that none had ever applied for a license to do so. In the vast majority of cases respondents stated that it was their understanding that the U.S. embargo either prevented or

discouraged sale to Cuba. In fact, representatives of six of these companies had the mistaken understanding that the U.S. embargo prohibits all medical sales to Cuba.

The results of our interviews:13

My company sells or has recently sold its products directly to Cuba...

<i>Baxter Healthcare Corporation</i>	NO
<i>Bristol-Myers Squibb</i>	NO
<i>Eli Lilly and Company</i>	NO
<i>Johnson and Johnson</i>	NO
<i>Merck and Company</i>	NO
<i>Ohmeda Pharmaceutical Products</i>	NO
<i>Schering-Plough Corporation</i>	NO
<i>Searle</i>	NO
<i>Siemens, USA</i>	NO
<i>SmithKline Beecham Pharmaceuticals</i>	NO
<i>TPLC Pacemakers</i>	NO
<i>Wyeth-Ayerst Laboratories</i>	NO

My company has applied for a US. government license to sell directly to Cuba

<i>Baxter Healthcare Corporation</i>	NO
<i>Bristol-Myers Squibb</i>	NO
<i>Eli Lilly and Company</i>	NO
<i>Johnson and Johnson</i>	NO
<i>Merck and Company</i>	NO
<i>Ohmeda Pharmaceutical Products</i>	NO
<i>Schering-Plough Corporation</i>	NO
<i>Searle</i>	NO
<i>Siemens, USA</i>	NO
<i>SmithKline Beecham Pharmaceuticals</i>	NO
<i>TPLC Pacemakers</i>	NO
<i>Wyeth-Ayerst Laboratories</i>	NO

The barriers to direct sale are...

- The U.S. embargo prevents sales (they are illegal).
- The U.S. embargo discourages sales.
- The company does not sell to Cuba for political reasons.
- The company has not received a request from Cuban purchasing agents.
- The company's organizational structure does not permit direct sales to the Caribbean.
- Indicates uncertain response.

<i>Baxter Healthcare Corporation</i>	<i>A and C</i>
<i>Bristol-Myers Squibb</i>	<i>E and F</i>
<i>Eli Lilly and Company</i>	<i>B</i>
<i>Johnson and Johnson</i>	<i>A</i>
<i>Merck and Company</i>	<i>A</i>
<i>Ohmeda Pharmaceutical Products</i>	<i>A and B</i>
<i>Schering-Plough Corporation</i>	<i>B</i>

<i>Searle</i>	<i>A and B</i>
<i>Siemens, USA</i>	<i>E</i>
<i>SmithKline Beecham Pharmaceuticals</i>	<i>B and D</i>
<i>TPLC Pacemakers</i>	<i>A and C</i>
<i>Wyeth-Ayerst Laboratories</i>	<i>B</i>

Several companies had two responses, either because one person offered two reasons or because two representatives were contacted, and offered different—even somewhat contradictory—reasons. For example, in the case of Ohmeda Pharmaceutical Products, Judy Klön in International Sales said she thought, "the U.S. embargo makes sales to Cuba illegal." Yet, in-house Counsel Donna Boehme was aware of the licensing options for sales to Cuba, but said she nevertheless had advised the company not to take any action with regard to Cuba which might "incur any risk of government action" (a statement which implies that the embargo discourages, but does not prevent, sales to Cuba). 14

In the case of Searle, Export Manager Diana Smith did not wish to be directly quoted, but her answers indicate that, while she was aware that licensing procedures were in place, it was her understanding that it is not possible to sell to Cuba at the present time.¹⁵

In Summary- All ten of the U.S. manufacturers whose organizational structure would normally permit them to export directly to Cuba cited the U.S. embargo as either preventing or discouraging such sales. (Siemens, USA and Bristol-Myers Squibb said their U.S.-based operations would not be the ones to export to Cuba, and hence, regulations pursuant to such direct exports do not affect them.)

Six of the ten companies citing the embargo mistakenly perceive that it prevents sales to Cuba, and there is obviously confusion among them about the regulations now in place. Nelson Baker, General Counsel for Johnson and Johnson, despite his considerable knowledge and experience in applying for licenses for subsidiary sales and donations to Cuba, stated that it was his understanding that the Cuban Democracy Act permitted donations but not direct sales to the island.¹⁶ However, in retrospect, this may not be surprising: Tracy O'Donald at the Cuba Exports Desk of the Department of Commerce first told us that only donations were permitted, and only later corrected this statement to include the possibility of sales.¹⁷

Other firms' representatives simply stated, as did Robert Lively, Director of Legislative Affairs for Schering-Plough, that the U.S. embargo has a "discouraging effect on any thought of seeking such business sales to Cuba."¹⁸

Two companies contacted cited political reasons for not selling to Cuba: Michele Lockwood in International Sales at Baxter Healthcare Corporation (major distributors of dialysis and blood supply equipment and accessories) told us the company "respects the boycott of Cuba for political reasons".¹⁹ And Bill Nealon, Counsel for TPLC Pacemakers, said he had advised against using the Teletronics pacemaker trademark, licensed by TPLC, for sales to Cuba to avoid legal liabilities. He said top corporate executives at the Hialeah, Florida, offices had followed his recommendation, in order to stay within the law, and with an eye to the sensibilities of the largely Cuban-American workforce at the Hialeah plant.²⁰

Additional survey item included the following:

My company has made verbal inquiries to the U.S. government about applying for licenses to permit direct sales to Cuba..

<i>Baxter Healthcare Corporation</i>	<i>nla</i>
<i>Bristol-Myers Squibb</i>	<i>nla</i>

<i>Eli Lilly and Company</i>	<i>YES. UTo my recollection, we have never received order for Cuba where we have received a license fo sale."</i>
<i>Johnson and Johnson</i>	<i>NO</i>
<i>Merck and Company</i>	<i>YES; not a positive experience</i>
<i>Ohmeda Pharmaceutical Products</i>	<i>Did not want to say</i>
<i>S&ring-Plough Corporation</i>	<i>Did not want to say</i>
<i>Searle</i>	<i>YES, a long time ago; the govenament was helpful, is not possible to sell to Cuba</i>
<i>Siemens, USA</i>	<i>nla</i>
<i>SmithKline Beecham</i>	<i>NO</i>
<i>Pharmaceuticals</i>	
<i>TPLC Pacemakers</i>	<i>nla</i>
<i>Wyeth-Ayerst Laboratories</i>	<i>YES; told not possible to sell</i>

Jaime Esteves, Director of Distribution for Wyeth-Ayerst Laboratories, reports that he received a hand-delivered request from Cuban importers to purchase \$6 million in antibiotics, but that the company's legal department advised him, based on their experience, that it would be "futile" to pursue licensing for the sale. Esteves said he is well aware that Cuba is interested in many Wyeth-Ayerst products, including antibiotics and cardiology medications, which the country has difficulty obtaining elsewhere.²¹

Experience with Subsidiary trade

<i>Baxter Heal thcare Corpomtion</i>	<i>Has a policy that subsidiaries do not sell to Cuba.</i>
<i>Bristol-Myers Squibb</i>	<i>Not mentioned.</i>
<i>Eli Lilly and Company</i>	<i>States CDA prohibits subsidiary trade..</i>
<i>Johnson and Johnson</i>	<i>Received licenses, but refers to process as discouraging.</i>
<i>Merck and Company</i>	<i>Not mentioned</i>
<i>Ohmeda Pharmaceutical Products</i>	<i>Not mentioned</i>
<i>Schering-Plough Corporation</i>	<i>Not mentioned</i>
<i>Searle</i>	<i>Not mentioned.</i>
<i>Siemens, USA</i>	<i>(see quotes below)</i>
<i>SmithKline Beecham</i>	<i>Not mentioned</i>
<i>TPLC Pacemakers</i>	<i>Not mentioned</i>
<i>Wyeth-Ayerst Laboratories</i>	<i>Law discourages such a process</i>

Keven *Krambeer*, in charge of Eli Lilly's International Corporate Affairs for Latin America, states that his company, a major supplier of insulin, sold to Cuba through subsidiaries before 1992 (when the CDA went into effect). But, he says, "Now, the Office of Foreign Assets Control (OFAC) and further restrictions forbid this." ¶In actual fact, the CDA opens the door to subsidiary sales, based on prior approval of individual licenses for each sale.

Nelson Baker of Johnson and Johnson said the CDA has virtually cut off the flow of medicines from U.S. companies to Cuba. He calls the licensing requirements for their subsidiaries a "major deterrent" to companies wanting to sell to Cuba. "You make the calls to OFAC to inquire about a license, and when you finally get someone to talk with you about filing a new application for something, they strongly discourage you, emphasizing how difficult the on-site inspection requirement is to meet."

His words coincide with comments from Clara David, Licensing Officer for OFAC, who said that since passage of the CDA, only a handful of licenses have been approved for subsidiary sales, and

no denials have been issued. She stated that the reason for no denials is that many companies phone to inquire about the application procedures, and when they learn how difficult it is to meet the on-site inspection requirement, they don't apply, as "companies don't like to receive a negative determination from the federal government on anything."²³

Baker reports that Johnson and Johnson has applied for licenses for the anesthesia *thalamonal*, and does so mainly for humanitarian reasons, since the company does not make serious financial gains on the sales and the licensing procedures "are not worth all the trouble." He said he has made many inquiries to OFAC about possible license-applications for other products, but was told before applying that these would be denied.

Siemens, USA states that it has no manufacturing plants in the United States and sales to Cuba are made through their parent company in Germany, where the plants are located. However, R. John Larson of Siemens' Licensing Department notes that a U.S. (Commerce Department) license is required, when the equipment exported to Cuba from Germany contains a part shipped from the United States (that is, when the German warehouse is out of stock and must reclaim a part from warehouses in the USA). He notes that this has made a license necessary to re-export a filter for a Servo lung ventilator, even when that filter was originally manufactured in Germany and is to be shipped from Germany to Cuba. He says this process usually has a turnaround time of three to six months. He speculated that Siemens, USA would have great difficulty in obtaining licenses to sell directly to Cuba, should it attempt to do so.²⁴

Finally, Wyeth-Ayerst Laboratories (which also owns Lederle Laboratories) reports that they have made repeated inquiries to OFAC to attempt to obtain licenses to sell various pharmaceuticals to Cuba. Each time, they have been told "not to bother" making a formal application, since they could expect the licenses to be denied, according to Jaime Esteves, Director of Distribution. He said the company has been repeatedly discouraged (by OFAC) from pursuing subsidiary sales to Cuba.²⁵

Experience with donations

<i>Baxter Healthcare Corporation</i>	<i>Not mentioned</i>
<i>Bristol-Myers Squibb</i>	<i>Not mentioned</i>
<i>Eli Lilly and Company</i>	<i>Yes, understands companies can donate, and has done so.</i>
<i>Johnson and Johnson</i>	<i>Yes, understands companies can donate and has done so.</i>
<i>Merck and Company</i>	<i>Yes, but understands even donations to be impossible for Merck now.</i>
<i>Ohmeda Pharmaceutical Products</i>	<i>Not mentioned.</i>
<i>Schering-Plough Corporation</i>	<i>Not mentioned.</i>
<i>Searle</i>	<i>Not mentioned.</i>
<i>Siemens, USA</i>	<i>Not mentioned</i>
<i>SmithKline Beecham Pharmaceuticals</i>	<i>Not mentioned</i>
<i>TPLC Pacemakers</i>	<i>Not mentioned</i>
<i>Wyeth-Ayerst Laboratories</i>	<i>Not mentioned</i>

Susan Crowley, Director of International Relations for Merck, discussed the U.S. government fine levied on the pharmaceutical giant for violating the embargo. "We wanted an information exchange and to do donations, and even this is apparently not allowed," she told us. "Basically we have been fined for indicating an interest in building a health bridge to Cuba. And just exploring the possibilities and talking about doing something within the law is criticized.*"

Her comments leave no doubt that hefty fines (Merck was charged \$127,500) are another deterrent to companies already hesitant to make their way through the legal labyrinth of licensing

procedures. Merck was fined in October 1995, accused of hiring a Cuban laboratory for testing services, sending company officials to the island, and bringing Cuban products into the United States. The company said at the time that the embargo violation arose out of a trip to Cuba by Merck scientists at the request of the Pan American Health Organization in 1993.²⁷ A Treasury Department statement said the fine was not higher because of the "high level of cooperation" provided by Merck. Merck believed that the scientists' activities were permitted by a general license under the U.S. Cuban Assets Control Regulations," noted a release from Merck itself. It said the violations were "inadvertent and technical" and "resulted in no payment of any kind to Cuba".²⁸

Merck and Eli Lilly were later also threatened with Congressional investigations, apparently as a result of publicity surrounding major donations they made to Cuban nongovernmental organizations. There is no doubt that ~~the~~ subject has become highly charged in political terms for some sectors in the United States, beyond the legal questions involved. Companies like Merck perceive this as an additional obstacle to both donations and sales.

Cuban Importers and The U.S. Embargo

Cuban importers in the medical field also report that the embargo has discouraged them from exploring purchases from U.S. firms, even during the years of liberalized legislation. MEDICUBA's Orlando Romero cited the absolute prohibition on medical sales for over a decade (including from U.S. subsidiaries abroad), the ban on sales by U.S.-based firms for 28 years, subsequent ups and downs in U.S. policy, and other embargo regulations that "tend to hinder transactions." These, he said, are the reasons why "we have spent over 30 years looking for products to substitute those from the United States, manufacturers to substitute U.S. producers".²⁹

Yet, even when inquiries have been made by MEDICUBA to U.S. firms (not an easy initiative in itself, given the communications difficulties between the two countries for nearly three decades), they have been largely "unwelcome," according to Nancy Blanco, Deputy Manager for Pharmaceuticals at MEDICUBA. She contends that requests for catalogs, price quotations and other basic information "are met with no reply at all, or with a negative response." She says she does not remember a single case where a U.S. firm was contacted and decided to pursue a license application to the U.S. government.⁹⁰ Rolando Díaz, Deputy Manager for Medical Equipment, concurs.³¹ They cite several of the most recent examples in which companies have denied information or sale on the basis of the notion that the embargo prohibits transactions with Cuba. Among these:

Thomas Compressors and Vacuum Pumps (Sheboygan, WI): A July 20, 1995, letter from MEDICUBA requesting catalogs, brochures and price lists was answered by Diana Popp, Latin American Marketing Specialist for Thomas, on July 28, 1995. "Due to the embargo between the United States and Cuba, we are unable to conduct any commercial transactions with your company."

Vitalmex Interamericana, S.A. de C.V., Latin American distributors for the U.S.-manufactured Cobe dialysis equipment, (Mexico, D.F.): A June 21 fax from MEDICUBA requested prices for purchase of 20 Cobe dialysis machines. This communication was answered by Jaime A. Cervantes of Vitalmex on July 11, 1995, asserting that since Vitalmex is "associated with" a U.S. company, "we cannot supply the Cobe equipment . . . since I am not authorized lby Cobe in the USA1 to sell equipment or supplies to your country."

DuPont Merck, Manufacturing Division (Wilmington, DE): A fax from Gemex GmbH of Frankfurt, Germany (which represents MEDICUBA) dated 29 March, 1995, requested purchase of warfarin sodium, a pharmaceutical component for an anti-coagulant medication, that had

formerly been supplied to Cuba by the Swedish firm Chemoswed. Dr. John C. Budxinski, Warfarin Sodium Business Manager for DuPont-Merck replied on April 24, 1995, that DuPont-Merck "has acquired the rights to the warfarin sodium technology from Chemoswed . . . I regret to inform you that we will not be able to provide warfarin sodium."

Telectronics (Denver, CO and Hialeah, FL) and St. Jude Medical (St. Paul, MN): Both of these enterprises are manufacturers of pacemakers. In 1993, Telectronics of Australia, a major supplier of pacemakers to Cuba, shut down its pacemaker manufacturing, and transferred both sales and production to the United States. As we noted earlier, legal counsel advised TPLC of Florida (which produces Telectronics pacemakers under patent license) not to pursue sales to Cuba, in order to "stay within the law" and 'with an eye to the sensibilities of the largely Cuban-American workforce" at the Hialeah plant, where executives agreed with his recommendation. It should be noted that in May, 1993, the Florida state legislature passed a law sanctioning companies in the state that maintain economic or trade ties to Cuba.³²

On June 27, 1994, Siemens-Elema of Sweden, another major supplier of pacemakers to Cuba, sold its pacemaker division to St. Jude Medical, and informed MEDICUBA of the sale.³³ According to a telephone interview by Dr. Anthony Kirkpatrick, St. Jude's legal director Kevin O'Malley, told him that he twice attempted to convince the U.S. government to allow export to Cuba of the pacemakers for humanitarian reasons, but was "decidedly rejected." (Refer to the section on Cardiology in 'Selected Aspects of Health & Welfare.')

According to Rolando Díaz, Drake-Whillock, manufacturer of dialysis equipment, has told MEDICUBA that U.S. embargo laws have made it unable to send equipment to Cuba for trials, to allow company technicians to travel to Cuba, or to sell to the island."

Blanco reports what she terms a new phenomenon: approaches and visits to MEDICUBA by numerous persons representing themselves as sales agents for U.S. firms. But, she says she seriously questions their credibility because, among other reasons, "the prices they quote are off the charts, often 200% or more than current market prices."³⁶

Firms Abroad Reluctant to do Business with Cuba

Our research shows that the U.S. embargo also discourages companies in third countries from attempting to sell medical supplies to Cuba. Such companies share many of the misconceptions voiced by U.S.-headquartered firms. Among the problems:

A number of foreign medical firms have apparently assumed that U.S.-origin components or technology makes their equipment automatically out-of-bounds for sale to Cuba, when, in fact, a license could be sought from the U.S. Commerce Department.

Some U.S. subsidiaries abroad have received word from their U.S. headquarters that sales to Cuba are not permitted, when, in fact, licenses could be requested from the U.S. Treasury Department.

And finally, foreign firms that have merged or been purchased by U.S. companies have interrupted sales to Cuba, because they also mistakenly understand that they are no longer permitted under any circumstances.

Examples of these three cases include:

Jena (Germany): A May 1995 inquiry from MEDICUBA for the purchase of an autorefractometer was answered by a June 6, 1995 fax from VL Munkelt advising that "according to embargo (law) an autorefractometer cannot be ordered for MEDICUBA"

Gummi: This company informed Gemex (MEDICUBA's representative in Germany) that it cannot sell aluminum seals to Cuba for domestically-produced medications, since it has been purchased by a United States firm.³⁷

Jbhnson & Johnson Iudustria e Comercio Ltda. (Brazil), a subsidiary of Johnson & Johnson, USA: Cuban importers Consumimport attempted to purchase toothbrushes, on the basis of price offers from the Brazilian company in June, 1993, but was informed that the company's headquarters had advised against the sale.⁹⁸

Latin American subsidiaries of Barter Healthcare Corporation USA: This company is a leader in the Latin American market in dialysis accessories, blood collection bags, and related equipment and supplies. Rolando Díaz of MEDICUBA reports that a number of Baxter's regional subsidiaries have been contacted, and the reply in each case is that they are "not permitted to sell to Cuba." According to Díaz, MEDICUBA has also been rebuffed by wholesalers carrying Baxter products.³⁹ This coincides with the information provided to us by the parent company in the United States.

Eli Lilly (Canada): In 1993, executives of the company informed Cuba that as a result of the prohibition on subsidiary trade with Cuba (the CDA), they would not be able to export medicines to the island. Lilly is the world's number one producer of insulin, among other products." Again, this coincides with the parent company's understanding of U.S. law, as noted in our survey.

Pharmacia (Sweden): Beginning in 1970, this company sold Cuba sophisticated protein purifying and other equipment and reagents for clinical laboratories and production plants, as well as chemotherapy drugs, growth hormone and other medicines. It is the number one supplier of reagents for vaccines and certain blood tests. In 1989, Pharmacia opened an office in Cuba and in 1991-92 sold over \$3 million to the island. In August, 1995, the Havana offices informed MEDICUBA that Pharmacia had merged with the U.S. giant Upjohn, and that this "might lead to a suspension of sales to Cuba.*' The new company, Pharmacia. and Upjohn, Inc., ranks ninth in world drug sales. Because of the U.S. embargo, it pulled up stakes in Cuba on November 2, 1995, leaving some merchandise undelivered and contracts canceled. In the case of equipment and reagents, this has caused major delays in research, production and laboratory analyses, as it takes four to six months to put a new line of reagents through quality control performance tests, assuming it can be identified as suitable for the existing Pharmacia equipment.⁴² (See sections on Vaccines and Biotechnology Research, Development and Production; Diagnostic Testing and Protection of the Blood Supply; the Pharmaceutical Industry; and Hospital Care for impact on the health system and patient care.)

Nunc (Denmark): Supplied plates for HIV-tests and diagnostic kits to screen for hepatitis B and C and congenital malformations, as well as to certify the purity of blood donations. The company was also in the blueprint stage for production of a Cuban-designed plate. However, on August 9, 1995, Nunc notified Cuba by fax: Much to our regret we have to inform you that unfortunately our cooperation of many years has to be terminated. The reason is that as of 1 August, 1995, BTR has sold Nunc A/5, Nunc GmbH and Nunc Inc. to Sybron International Corporation, USA In future, we therefore have to follow the directions laid down by the US Government in relation to Cuba. . .We hope that the political situation will be normalized so that again we will be able to supply our loyal customers in Cuba with our products." (See chapters on AIDS, Women's Health, Children's Health, and Diagnostic Testing and the Blood Supply for implications of this cutoff.>

Wellcome Diagnostic Division (**formerly** of the UK): This division was taken over by Wellcome's U.S. branch, and Cuba was no longer offered Wellcome's products."

Editorial Interamericana, S. A (Spain): This is one of many cases in which products may not fall under the strict category of medical exports, but where refusal to sell to Cuba nevertheless directly impacts the health system. This firm supplied medical textbooks to Cuba until 1990, when it was purchased by McGraw-Hill of the USA "McGraw-Hill advised the Spanish company that since it now was the subsidiary of a United States corporation, its -personnel could not attend the Cuban book fair in Havana and the subsidiary could not make any future sales to Cuba. These instructions were not required by United States law: employees of third-country subsidiaries are permitted to travel to Cuba under Treasury Department regulations, . . . and Congress exempted the sale of books from the United States prohibitions against trade with Cuba (in 1988)."⁴⁴

Analysts advise that the rate of mergers and takeovers involving U.S. companies and manufacturers abroad is accelerating, especially in the pharmaceutical and medical equipment industries. "Mergers have reshaped the industry, and more may be on the way," comments Joseph Weber in a *Business Week* Industry Outlook early in 1996. He calculates that by mid-December 1995, the industry had chalked up \$41.2 billion in deals, up from the 1994 record of \$36.1 billion.⁴⁵ As it stands, this can only have a negative impact on Cuba's access to medical products.

The Recent Licensing Record

While there is ample evidence of reluctance to apply for authorization to export to Cuba, a number of firms-both U.S. subsidiaries and foreign companies manufacturing with U.S. components-have opted to request licenses under the conditions of the CDA of 1992, which provided for case-by-case decisions on medical sales.

However, the number of licenses approved for such transactions since enactment of the CDA has been impossible to ascertain from the U.S. Treasury and Commerce Departments. In summary information provided on June 14, 1995 to Rep. Charles Rangel by R Richard Newcomb, Director of the Office of Foreign Assets Control (OFAC), it is stated that 82 licenses have been issued (total value \$62,888,513) by the U.S. Commerce Department, and two denied (total value: \$23,031,580), between October 23, 1992 (when the CDA became effective) to May 3, 1995. However, Newcomb notes that the licenses do not distinguish between food, agricultural supplies, medicines and medical equipment, nor between purchases and donations. The dollar value of the licenses represents only the permission granted, and not the actual value of the shipments, which he notes was not readily available from the Commerce Department.

It should be clarified here that the Commerce Department is charged with licensing shipment of goods of U.S. origin or a percentage of U.S. composition, or those being re-exported from the United States to Cuba. The Treasury Department's OFAC is charged with licensing exports when they are made from U.S. foreign subsidiaries to Cuba.

Newcomb's letter reports that the OFAC itself has issued eight licenses authorizing the export of medicines and medical supplies from third countries by U.S. subsidiaries since the CDA became effective, the total value of which is US\$336,934. His information does not indicate the number of licenses denied. Licensing Officer Clara David reported to us that no licenses were denied in the same period.⁴⁶

The OFAC licenses issued are as follows, according to encloures provided by Newcomb:

The Johnson & Johnson subsidiary Janssen Pharmaceuticals of Belgium: For sale of 200 packs of the anesthesia thalamonal to MEDICUBA License C-15153, dated April 15, 1994, expired April 15, 1995. Subject to certification by the Belgian Embassy in Havana, "confirming that the exported item will be used for the purposes for which it was intended and only for the use and benefit of the Cuban people."

The Upjohn Company subsidiary N.V. Upjohn of Belgium: For sale of 2,000 vials of depo-provera to the United Nations Population Fund Office in Havana. License C-15071 dated February 7, 1994, expired July 31, 1994.

The Johnson & Johnson subsidiary Janssen Pharmaceuticals of Belgium: For sale of 200 packs of the anesthesia thalamonal to MEDICUBA License G14941, dated May 15, 1993, expired January 31, 1994. Subject to certification by the Belgian Embassy in Havana (see above).

The Upjohn Company subsidiary N.V. Upjohn of Belgium: For sale of 57,000 vials of depo-provera to the United Nations Population Fund in Havana. License C-16123, dated October 31, 1994, date of expiration missing on license.

The Becton Dickinson International, N.V., subsidiary of the same name in Belgium: For sale of 175 boxes of syringes to the United Nations Population Fund in Havana. License C-15153, dated April 15, 1994, expired April 15, 1995.

The Johnson & Johnson subsidiary Janssen Pharmaceuticals of Belgium: For sale of 438 packs of the anesthesia thalamonal, 2 ml., and 292 packs of thalamonal, 10 ml. to MEDICUBA. License C-15602, dated October 13, 1994, expired March 31, 1995. Subject to certification by the Belgian Embassy in Havana (see above).

The Johnson & Johnson subsidiary Janssen Pharmaceuticals of Belgium: For sale of 22,000 packs of Imap to MEDICUBA. License C-15154, dated January 31 1995, expired July 31, 1995. Subject to certification by the Belgian Embassy in Havana (see above).

The Johnson & Johnson subsidiary Ortho Diagnostics Systems Ltd. of England: For sale of an ortho cytron absolute flow cytometer system (including computer) to SERVICEX (a state-owned company in Cuba). License C-14942-a dated February 25, 1994, expired September 30, 1994. Notes that a separate license is required from the U.S. Commerce Department for re-export of the 15.9% U.S.-origin parts in the system. Subject to certification from the Pan American Health Organization, the Red Cross or "other appropriate internationally recognized multilateral relief or non-profit organization," that "The exported item is for the purposes for which it was intended and only for the use and benefit of the Cuban people."

U.S. Licenses Denied for Medical Export to Cuba

The following information was gleaned from documents issued by the companies involved, and from interviews with MEDICUBA importers. These are essentially licenses refused by the U.S. Commerce Department, denying authorization to export to Cuba items of U.S. composition or origin. However, in the Fluka, Schubert Seals and Heinrich Mach Nachf. cases, it seems that the U.S. Treasury Department was involved at some level.

Fluka Chemical Co., Ltd. (Switzerland) supplied Cuba with US\$300,000 annually in chemical reagents for laboratory testing. Fluka belongs to the U.S. group Sigma-Aldrich, based in St. Louis, MO. A fax from Fluka's Elisabeth Berger, dated Oct. 16, 1992, notes that the firm has been able to obtain U.S. Treasury licenses for sales to Cuba within 2-3 weeks when there are no U.S. components involved, but that "the big problem, nevertheless, are the products with U.S.-origin

(components).” She asks that MEDICUBA revise its list of purchases accordingly, apologizing for “this difficult situation, which makes life difficult for both of us.” On November 5, 1992, she informs MEDICUBA that five contracts have had to be canceled since Fluka did not receive the necessary U.S. licenses. On January 23, 1993, Berger telexes MEDICUBA that she has been informed that contracts signed before the CDA went into effect on October 23, 1992 are to be exempted from the CDA stipulation on ending U.S.-subsidiary trade with Cuba. She notes, however, “that in practice this is not the case. The U.S. Treasury Dept. does not answer our reclamations.” These contracts remained canceled, despite the fact that subsequent regulations issued under the CDA clarified that sales of medicines and medical supplies were exempted from the prohibition on subsidiary trade.

Schubert Seals (Denmark) sells rubber seals for domestically produced albumin. Schubert, a U.S. subsidiary, has informed MEDICUBA that it is having difficulties with U.S. licensing for a contract signed in 1994. Among other things, according to MEDICUBA’s Rosa Fuentes, this means that the funds transferred for this purchase will have to be recovered, involving a lengthy international process.” This refusal conforms with U.S. government practice not to authorize exports for Cuba’s domestic pharmaceutical industry (see also Heinrich Mack Nachf. case below.)

Siemens (Germany) applied for at least two licenses that were denied: for the sale of a U.S.-manufactured gamma camera (for diagnostic imaging in cancer patients and others) and computers of U.S. origin, for computer assisted tomography (CAT) scans sold by this company to MEDICUBA.⁴⁸

Heinrich Mack Nachf. (a Pfizer subsidiary in Germany) applied for a license to sell MEDICUBA 500 g. (about one pound) of methotrexate, the active ingredient needed to run trials for domestic production of a chemotherapy medication of the same name, as part of Cuba’s efforts at cost-effective import substitution. This drug is used, among other things, to treat childhood leukemia (MEDICUBA contract 30855 of 1993). A July 16, 1993 fax from Monika Biener of the Chemical Sales Division of Heinrich, indicated: “As informed before, we need prior to shipment an approval from American Authorities. Unfortunately, and unexpectedly, this authorisation has not been received from American Foreign Ministry. Therefore, we regret having to inform you that we cannot comply with your wishes to ship material.” (It is not clear whether the methotrexate was of U.S. origin.) > A September 5, 1995, telex from MEDICUBA’s German representative indicates that HMN no longer offers products to Cuba.

Enraf Nonios, Delft Instruments Physical Medicine (Netherlands) supplied Cuba for a decade with physical therapy equipment and parts, accounting for 80% of such equipment in the country. On July 16, 1991, a letter from the firm’s G. v.d. Schouw, Director of Physical Medicine, indicated that they were “restricted in supplying our products to Cuba” due to a “temporary changed policy from the United States government regarding reexportation of original or licensed (U.S.) components.” The company indicated it would proceed with “time-consuming” procedures in an attempt to procure the necessary licenses, but these were apparently never received. The same letter indicated that the firm would be able to supply sports trauma equipment for the July 1991 Pan American Games in Cuba, but only on consignment to an international organization, for their return upon conclusion of the games.

We have found that when a firm is denied a U.S. license to export to Cuba, the decision sometimes appears arbitrary, especially when the products for which licenses are denied are compared to those for which licenses have been granted. This is the situation with a license request pursued by Picker International, Inc. of Canada, a subsidiary of the Cleveland, Ohio company of the same name, manufacturer of x-ray equipment sold to Cuba, primarily between 1975 and 1978.” During that period, according to Cuba’s Medical Supply Company (EMSUME), 101 Picker x-ray machines were purchased, fundamentally model GX-300.⁵⁰

Alfredo Rivero of EMSUME notes that less than one quarter of the original machines are currently functioning, all of these primarily with parts from other companies, except for those for which there are no adequate substitutes-such as parts for the timing device and other accessories unique to the Picker model. When these break, the machines must be placed out of commission.

In April of 1994, MEDICUBA requested a series of spare parts for this x-ray equipment. The total contract amounted to 110 parts, valued at CAN\$705.30. The U.S. content of the parts was CAN\$193.10 (or 27%), and therefore subject to license by the U.S. Commerce Department.

The following chronology describes the licensing process, as pursued by both Picker of Canada and Picker, USA, from April 29, 1994, when the application was first submitted, through December 23, 1994, when MEDICUBA received final notice from Picker, Canada, that all license applications and appeals had been denied.⁵¹

- April 29, 1994 Paula Iseman of Picker International, Inc., Cleveland, Ohio, submits original license application with supporting documentation.
- May 10, 1994 U.S. Dept. of Commerce notifies Iseman that the case must be resubmitted on another form, as it involves reexport from Canada
- The application is resubmitted, with a copy of a previous license granted to Picker for replacement parts for the same equipment (Export License Number D179606, validated August 14, 1992 and expiring August 31, 1994) The new request is given the Department's Application Control Number H015462.
- July 26, 1994 Dr. Eugene W. Lewis, Chief of Capital Goods and Production Materials Branch of the Dept. of Commerce's Office of Export Licensing, informs Iseman of "the intent to deny the referenced application" since such an export would be "detrimental to United States foreign policy." He notes that "it is the policy of the United States not to approved [sic] license applications to Cuba, except for shipments *to meet basic human needs.*" (Italics added.) Lewis informs Iseman that Picker has 45 days to submit rebuttals or comments
- October 26, 1994 Eileen Albanese, Chief of Processing Branch of the Dept. of Commerce Office of Export Licensing, informs Iseman that the license has been denied, noting that "we have reviewed your letter objecting to the rejection of this application, however, we maintain our denial recommendation" on the grounds that "this export would be detrimental to U.S. foreign policy interests."
- December 23, 1994 Bill Dix of Picker International Canada, Inc., relays fax to MEDICUBA, explaining that "we regret to inform that this order has been canceled due to the denial of export license by U.S. Government Agencies. Happy Holidays."

A footnote to this chronology: On August 12, 1994, Bill Dix quoted a series of prices for a new request for purchase received from MEDICUBA of spare parts for x-ray equipment, "subject to availability and receipt of (U.S.) Government Permits". Such licenses had not been received as of January, 1996.⁵²

Our research in Cuba indicates that the parts requested in this application were destined for 20-year-old x-ray equipment in maternity hospitals, pediatric hospitals, rural hospitals, community health clinics, and one general hospital.⁵³ (See section on Hospital Care for the implications for patients of this license denial.)

The U.S. government interpretation of the licensing regulation on the proportion of U.S. composition of goods offered to Cuba by third-country firms has been particularly problematic, and is an example of the extra-territorial nature of the U.S. regulations limiting sales by these firms to Cuba, and reducing the range of suppliers available to Cuban importers. Even though the original piece of equipment may have contained less than 10% U.S. components, any replacement parts which themselves contain more than 10% U.S.-origin components require licenses, since they are considered as separate from the original purchase. In other words, while licensing may not have been necessary for Cuba to import the original piece of equipment, it may still be necessary to obtain a license for replacement parts needed to keep the equipment running. As in the Picker case, this interpretation can have particularly negative effects when applied to parts for third-country equipment in which Cuba has already made a substantial investment.

In addition to the Picker x-ray parts, earlier cases indicate that such an interpretation has been used to deny replacement parts for equipment purchased from third-country firms. One such instance involves the Swedish firm Alfa-Laval, which was unable to obtain permission to export 100% U.S.-origin cartridges for a filtration system manufactured by Alfa-Laval, and used in Cuba's domestic production of medicines. This resulted in the May 1991 cancellation by Alfa-Laval of its 1990 contract 06'772 with MEDICUBA. "We did what we could, but there seems to be nothing we can do in order to obtain the license," noted the May 28 letter from Tina V. Kristensen.⁵⁴

Such was also the fate of a request from MEDICUBA to purchase replacement parts for operating tables originally bought from Amsco of Canada. According to a note dated April 13, 1992, Amsco's Paul Montador declared: "Please he advised that the product in question is of U.S. origin and therefore not acceptable to you.*"

Licenses Approved: Delays in the Process

Even when licenses are granted, we find that the process of application and approval can substantially delay delivery to health institutions and patients. These delays vary considerably—from several weeks, to months, to years. Cases in point are replacement parts for Siemens respirators, used extensively in surgery and intensive care units, and the anesthesia thalamonal, produced by Janssen of Belgium, the Johnson & Johnson subsidiary referred to earlier.

The Life Support Systems Division of Siemens-Elema (Sweden) has sold several models of respirators to Cuba over the years. There are currently 300-350 Servo 900-C units (for long-term ventilation of intensive care patients) and Servo 900-D (used in surgery to administer anesthesia). Licenses were not necessary for original purchases, since the U.S.-origin components constituted less than 10 percent of the respirator's value. Each Servo cost at least US\$15,000 at the time of purchase.⁵⁶ However, as previously noted, the process of purchasing spare parts for this equipment is handled differently.

In the case of Siemens respirator parts, the purchasing process for two contracts involving U.S.-origin components, complicated by the intricacies of licensing, took over two years.

In July, 1995, MEDICUBA received shipment of 49 parts for the Servo respirators (both models), which were on order by virtue of contracts initiated in 1992 and signed in 1993. Nineteen of these parts are crucial to operating the equipment, and without them, the respirators do not function. Most

of this shipment was destined for hospitals in outlying provinces. (Refer to section on Hospital Care for the implications of such a delivery delay.)

Tracing the inquiry, purchase, documentation, licensing and delivery process, we find that a total of seven agencies in four countries were involved: two agencies in Havana (MEDICUBA and EMSUME), one in Germany (Gemex, the MEDICUBA representative), one in Sweden (Siemens-Elema), and three in the United States (Siemens, the U.S. Commerce Department and the U.S. State Department): We had access to full documentation of the following "paper trail":

- June 1992 Siemens-Elema informs Medicuba (directly and via Gemex) that its order for oxygen sensor cells requires export authorization from the United States before it can be sold to Cuba.
- July 1992 Siemens faxes Gemex with request that MEDICUBA fill out attached "Statement of Ultimate Consignee and Purchaser" from U.S. Commerce Department for the oxygen fuel cell, which it notes is manufactured in the United States by Catalyst Research, Owings Mills, MD. Gemex signs contract 26626 on behalf of MEDICUBA, for purchase of 24 test lungs, 2 step motors, 24 oxygen cells, and 6 magnet valves. Siemens-Elema notes transshipments will be made to Cuba via Brussels, Madrid or Paris, and final carrier will be Cubana Airlines, to be delivered collect to Havana. Total value of contract: 63,550.08 Swedish kronas (SEK).
- August 1992 MEDICUBA cancels oxygen cells (after finding another supplier). Contract now stands at 33,179.52 SEK
- March 1993 MEDICUBA transfers full amount for contract 26626 to Gemex for purchase.
- June 1993 Gemex signs contract 36552 on behalf of MEDICUBA, for purchase of 6 screens, 20 bacteria filters, and one airway pressure meter. Total value of contract: SEK 32,556. Notes transshipment points to be Berlin, Madrid or Paris.
- February 1994 Siemens-Elema asks MEDICUBA for "Statement of Ultimate Consignee and Purchaser" for bacteria filters (30% of part is of U.S.-origin); and for magnet valves (part is 100% U.S.-origin), since these require U.S. export authorization.
- March 1994 Gemex telex to MEDICUBA refers to contracts 26626 and 36552, noting that Siemens has sent "statement" forms to MEDICUBA which should be filled out as soon as possible, since Siemens must then send them on to the U.S. government, which decides whether or not to authorize sale to Cuba. "[Siemens-Elema] tells us that there are cases where [this decision] has taken six months." Proposes that bank transfer for contract 36552 be issued after Siemens-Elema informs Gemex that export has been authorized by the United States. Telex same day from Gemex to MEDICUBA confirms that contract 36552 has been reduced to SEK 18,716 (10 bacteria filters were canceled).
- MEDICUBA and EMSUME return "Statement"; form notes that Sylvia Biglin, Siemens Medical Systems, Inc., USA, assisted in preparing statement, on behalf of Siemens-Elema, Sweden. (Note: this statement covers parts ordered in both contracts signed.)

July 1994	Siemens applied for license to U.S. Commerce Dept.
September 1994	<p>Siemens-Elema informs Gemex that the U.S. government has required further information on the parts before a decision can be made. Encloses fax from Siemens USA to Siemens-Elema referring to conversation with State Department, in which the officer requested the names and addresses of hospitals in Cuba where the items will be shipped; asked if any of the hospitals listed are military hospitals, and asked if any-of the hospitals listed are primarily set up for foreigners, where the majority of patients are foreigners and not Cuban citizens.</p> <p>MEDICUBA informs Siemens-Elema via Gemex of specific hospitals where the parts are destined, noting that they also may be sent to "others that eventually need some spare parts like this one." States that these are not military hospitals, and are for the use of Cuban citizens.</p> <p>Siemens-Elema forwards to Gemex fax from Siemens USA, (dated September 14) with additional information requested by the U.S. Commerce Department. This fax notes that the licensing officer stated that the license would not be approved unless all end-users were known beforehand.</p> <p>U.S. Commerce Department faxes Siemens-USA to advise acceptance of the following conditions is necessary for license approval: the medicines and medical supplies will not be used for purposes of torture or other human rights abuses; will not be re-exported; and will not be used in the production of any biotechnological product.</p>
October 1994	Gemex telexes MEDICUBA with faxed request from U.S. Commerce Department.
November 1994	License approved by U.S. Commerce Dept. for both contracts.
July 1995	Parts for contract 26626 and 36552 are received in EMSUME warehouse, for distribution to hospitals.

The Case of Anesthesia Thalamonal

Thalamonal, an anesthesia manufactured by Janssen of Belgium (a subsidiary of Johnson & Johnson in the USA), is widely used in Cuban hospitals, especially for longer operations. Since 1992, MEDICUBA has signed five contracts for thalamonal with Janssen. U.S. government export authorization requires a separate license for each of these orders (even though the product is the same) and each license is valid for only one shipment."

December 17,1992	Contract 21554 signed with Janssen by MEDICUBA for 10,000 10ml vials of thalamonal. Value: \$30,950.
September 19,1993	Shipment of thalamonal received as per contract 21554.
December 7,1993	Contract 31621 signed with Janssen by MEDICUBA for 4,000 10ml. vials and 16,000 2ml. vials of thalamonal. Value: \$21,900.
May 16,1994	Shipment of thalamonal received as per contract 31621.

May 4, 1994	Contract 40725 signed with Janssen by MEDICUBA for 6,000 10ml. vials and 9,000 2ml. vials of thalamonal. Value: \$23,220.
December 25, 1994	Shipment of thalamonal received as per contract 40725.
May 18, 1994	Contract 41421 signed with Janssen by MEDICUBA for 8,600 10ml. vials and 12,900 2ml. vials of thalamonal. Value: \$33,282.
June 15, 1994	MEDICUBA receives request for information from the Belgian Embassy in Cuba on final destination of thalamonal in contract 41421.
June 21, 1994	MEDICUBA supplies information to Belgian Embassy in Cuba on hospitals destined to receive thalamonal as per contract 41421.
December 25, 1994	Shipment of thalamonal received as per contract 41421.
February 25, 1995	Contract 50558 signed with Janssen by MEDICUBA for 2,600 10ml. Vials and 10,900 2ml. vials of thalamonal. Value: \$15,282.
June, 1995	MEDICUBA receives request for information from the Belgian Embassy in Cuba on final destination of thalamonal in contract 50558.
June 19, 1995	MEDICUBA supplies information to Belgian Embassy in Cuba on hospital destined to receive thalamonal as per contract 50558.
December 22, 1995	Janssen informs MEDICUBA that it still has no response from U.S. Treasury Dept. on license request for contract 56558. Meanwhile, Janssen notes, it is returning to MEDICUBA the international narcotics licenses for export of this drug, which have by now expired- because of delays, Cuban importers will have to begin that process again.

According to this data,⁵⁸ an average of over seven months elapses between contract signing and delivery. Nelson Baker, General Counsel for Johnson and Johnson, reports that three to six months of this period is spent waiting for licenses to be approved.⁵⁹

The On-Site Inspection Requirement

Under the CDA, the Government of the United States must be able to verify-by on-site inspection- the end-use of any medication or medical equipment exported to Cuba under U.S. license. This is perhaps the most broadly interpreted stipulation in the CDA regulations. Whatever may have been the original intent of Congress, our research indicates that the provision constitutes a deterrent to medical exports to Cuba for several reasons:

1. Reviewing the CDA, the Congressional Research Service concludes that the on-site inspection requirements "are unlikely to be accepted by Cuba".⁶⁰ Indeed, various representatives of the Cuban Public Health Ministry confirmed that the Cuban Government would not allow U.S. Government inspection of its health facilities, for the purpose of determining end-use of imported medications or equipment.⁶¹
2. However, in the limited experience available for review, Treasury and Commerce Departments' interpretation of on-site inspection has not included inspection by the U.S. Government. It has translated into a requirement that Cuban health authorities provide lists of patient care facilities where medications or equipment are to be used; and that a foreign embassy, international agency or other "suitable" entity certify end-use of the products in

question. (See the case of thalamonal, for example, where the Belgian Embassy provided the requisite certificate for each license granted.) Thus, designation of an appropriate inspector becomes a secondary issue, constituting a further obstacle when one is not available.

3. The requirement has also been used to deter pharmaceutical and medical supply companies in the United States from applying for export licenses, either for their own direct sales to Cuba or on behalf of their subsidiaries abroad pursuing such sales. This practice is amply reflected in comments from company representatives, and from the Treasury Department itself.
- 4 Changes have been made in Government's own interpretation of on-site inspection: the original wording in the CDA states that "the United States Government is able to verify, by on-site inspections and other means, that the exported item is to be used for the purposes for which it was intended and only for the use and benefit of the Cuban people." However, the regulation governing foreign subsidiaries of U.S. corporations is reformulated to state that they can obtain licenses to sell to Cuba "except where it is determined that the United States Government is **unable** to verify, by on-site inspection or other means..." (emphasis added). This same reformulation was applied to direct medical exports to Cuba from the United States, by virtue of new Commerce Department regulations, issued in March, 1996.

In our view, such diverse interpretations and subtle changes only add to the confusion already created around licensing procedures, erecting more obstacles along the export route. In addition, the vague nature of this restriction opens the door to arbitrary decisions.

Conclusions on Licensing

Our investigation leads us to conclude that the U.S. government's complex licensing restrictions and procedures present a serious obstacle to the willingness of U.S. medical firms, their subsidiaries abroad, and even foreign medical companies to attempt exports to Cuba.

Aside from mistaken perceptions that it is simply illegal to trade with Cuba, the process of license application itself confronts sales departments with significant additional red tape, requiring communications among several offices and other agencies in as many as four countries. Not only is this a time-consuming effort, but for a cost-conscious corporation, the volume of trade involved may not be worth the bureaucratic bother-especially when there is no guarantee when or if the licenses will receive final approval from Washington. Indeed, when the U.S. origin of spare parts is over 20% U.S. government practice has been to deny licenses in several instances, even after enactment of the CDA in 1992, which seemed to open the door to more positive consideration of such cases.

For MEDICUBA, the licensing requirements, procedure, and uncertain approval present a special dilemma, according to General Manager Orlando Romero. In addition to the reluctance of U.S. firms to deal with Cuba, he says that the embargo regulations keep the Cuban import firm from seriously exploring long-term purchases in the U.S. market, for fear that critical pharmaceuticals and equipment would be held hostage to the decisions of the U.S. Treasury and Commerce Departments, or to the inclinations of a given U.S. administration or Congress. On many occasions, and despite higher prices, he says they have purchased U.S.-manufactured products through intermediaries or comparable items from non-U.S. producers, simply to guarantee stable deliveries for patient use.⁶²

Embargo Restrictions: Financial Impact on Cuban Medical Importers

We have found that the U.S. embargo reduces the hard currency funds available for medical imports-both by aggravating the general contraction of the Cuban economy and its access to hard currency, and by measures which specifically reduce the medical import budget. Among the latter:

shipping Costs: During the last three years alone, MEDICUBA calculates that the company has spent an additional \$8.7 million on shipping, due to the necessity of importing from Asian, European and other American markets (as opposed to directly from the USA). Delays in maritime shipping have forced them to use the more expensive air routes, when time is of the essence.

COMPARATIVE COSTS OF MEDICAL SHIPMENTS BY AIR									
	1993			1994			1995		
	Europe	Asia	The Americas	Europe	Asia	The Americas	Europe	Asia	The Americas
Weight (Kg)	868,215	106,677	276,108	658,527	114,578	193,955	374,726	38,029	110,245
Freight Paid (USD)	\$2,691,466	\$746,739	\$383,790	\$1,975,581	\$801,626	\$269,597	\$1,161,650	\$266,203	\$153,240
If Imported from USA (1995 rates)	\$1,007,129	\$123,745	\$320,285	\$763,891	\$132,910	\$224,988	\$434,682	\$44,114	\$127,884
Difference	\$1,684,337	\$622,994	\$63,505	\$1,211,690	\$668,716	\$44,609	\$726,968	\$222,089	\$25,356
Total Extra Paid for Year	\$2,370,836			\$1,925,015			\$974,356		
Extra Paid for three years	\$5,270,264								

COMPARATIVE COSTS OF MEDICAL SHIPMENTS BY SEA									
	1993			1994			1995		
	Europe	Asia	The Americas	Europe	Asia	The Americas	Europe	Asia	The Americas
Weight(T)	788.55	4,462.21	608.50	1,650.10	8,542.68	273.10	1,739.61	14,419.84	263.45
Freight Paid (USD)	\$102,511.50	\$763,037.91	\$35,493.80	\$214,513.00	\$1,460,798.20	\$15,929.92	\$226,149.30	\$2,465,792.60	\$15,367.04
If Imported from USA (1995 rates)	\$45,996.12	\$260,280.71	\$35,493.80	\$96,250.33	\$498,294.52	\$15,929.92	\$101,471.45	\$841,109.27	\$15,367.04
Difference	\$56,515.38	\$502,757.20	-	\$118,262.67	\$962,503.68	-	\$124,677.85	\$1,624,683.30	-
Total Extra Paid for Year	\$559,272.58			\$1,080,766.40			\$1,749,361.20		
Extra Paid for three years	\$3,389,400.21								

Shipping and the Cuban Democracy Act: Freight of medicines and medical supplies has also increased in cost due to the fact that the CDA prohibits vessels that deliver goods to Cuba from docking in U.S. ports for the next 180 days. This regulation effectively limits the number of ships willing to travel to Cuba and often makes it necessary for medical supplies to be dropped off at a nearby Caribbean port (adding docking and storage charges), and then picked up by a Cuban vessel (adding more docking costs). Contracts have also stipulated that Cuban importers must provide shipping.

Warehousing Needs: Since imports must come with some delay from far-away ports instead of immediate delivery from the United States-Cuban importers must order more supplies to last them longer. According to both MEDICUBA and EMSUME (the Medical Supply Company in charge of distribution of equipment and materials), this translates into building costs for construction of significant warehouse space over the years, major financial resources tied up in large warehouse inventories, and less efficient use of moneys (since they must be spent towards long-term calculated needs, which are never exact). EMSUME is now carrying \$12 million in inventories, representing 88,000 types of parts and equipment.⁶³ EMSUME's Rivero argues that these moneys could be put to use more rationally, if they could be freed up for shorter term purchases from U.S. suppliers.

U.S. Dollar Purchases: The embargo prohibits Cuba from engaging in international transactions using the U.S. dollar. Thus, even when medical supplies are purchased from wholly-owned foreign companies, this often involves changing currencies, with the consequent banking charges and losses in exchange rates, because of the relative strength of the U.S. dollar. Dr. Jose Luis Fernández Yero, Director of the Immunoassay Center for diagnostic testing, says that he must budget at least an additional 10% for currency changes. He and others interviewed also note that because there are no banking relations with the USA, even though technically Cuban entities can purchase medical literature, in practice they must do so through third countries, at higher prices and with long delivery delays@

U.S. Firms Not in the Bidding. As noted earlier in this section, United States manufacturers tend to be the strongest and often most competitive in pharmaceuticals and medical equipment. Once they are eliminated from the bidding, the remaining companies are not obligated to come down to meet their prices, and consequently Cuba as a rule pays higher prices for comparable European goods?

Intermediary Purchases: When Cuban importers decide to purchase U.S. products through intermediaries or wholesalers, whether because these products are unique or simply of the quality required, the prices paid are often higher, due to the profit margin of the wholesalers or what MEDICUBA's Orlando Romero calls the 'third party risk tax,' charged by intermediaries who maintain they are taking a risk in selling U.S. goods to Cuba. In any case, if these products could be imported directly from the United States, prices would be lower. (See sections on National Health Emergencies and Hospital Care.)

Resources Tied UP Longer: Scarce financial resources are tied up longer as contracts are often closed months before the process of license application is completed (see the cases of thalamonal licenses). This can also result in higher banking fees when letters of credit are issued.

Credits: Long-term or medium-term credits are almost impossible to obtain, according to MEDICUBA General Manager Orlando Romero. Not only does the CDA open the door to sanctions against those who would offer such credits or preferential terms to Cuban customers, but the embargo, which has put a higher price tag on medical imports for the reasons outlined here, has also contributed to the debt of companies like MEDICUBA, which now stands at \$140 million. This has made it necessary for the firm to negotiate new agreements with suppliers, agreeing to pay as much as 40% more for new orders to pay off past debts.⁶⁶

Refurbished Equipment Unavailable: Because of its technological development in the medical field, the United States is virtually the hemisphere's only source of refurbished medical equipment, available for export at a fraction of the cost of new equipment. However, Rivero of EMSUME indicates that the embargo prevents Cuba from accessing this source of reduced-cost equipment. He argues: "Even if we were to find a company who would sell to us, and at least one in Miami has outright refused, and it were to obtain the necessary licenses, we would have the problem of travel, since buying refurbished equipment is rather like buying a used car: you must see it and test it for yourself."⁶⁷

The end result of the embargo's further limitation of funds available for medical imports is that Cuban health authorities have been obligated to reduce their purchases to absolute essentials, often simply products that determine life and death—and then, there are not always enough resources. (See section on Oncology.) As noted, efforts at import substitution by domestic pharmaceutical production have also been hindered by the embargo, and in particular by the U.S. Government practice of refusing to issue export licenses for Cuba's pharmaceutical industry. (See section on the Pharmaceutical Industry.)

Embargo Restrictions: Impact on Quality of Health Care

Cuba is unable to introduce the newest equipment and drugs that are a result of U.S. research and development, which, as we noted, is the most advanced and prolific in the world. As we have seen, several factors are implicated here: some firms simply refuse to offer catalog information on drugs or equipment, let alone the newest generations, so physicians in Cuba are even unaware of the latest developments. If licenses were applied for, there is no guarantee that they would be approved. And finally, if Cuba attempts to purchase these U.S. products through intermediaries, the prices are often out-of-reach for a strapped Cuban economy, since wholesalers' profit margins and increased freight costs from faraway markets are piled on top of an already higher price for a patented drug (as compared to later generic versions).

As we noted earlier, under U.S. patent laws, a company has 17 years exclusive rights on a drug, which turns into 9 to 10 years of marketing opportunities, once FDA approval is granted. However, pharmaceutical companies have recently been successful in extending patents on a number of their top money-makers, effectively putting them out of reach for Cuban patients for at least a decade after they go on the market. In general, we can conclude that any drug patented in the United States since 1979 is unavailable to Cuban patients, except at inflated intermediary prices, and some medications patented before that date as well.

The implications for patient care are discussed in sections on The HIV/AIDS Program, Nephrology, Cardiology, Oncology, and others. Other problems include:

Range of Therapeutic Options: Physicians constantly explained to us that their "therapeutic arsenal" has been seriously affected by the embargo, both because of budget problems, and because of difficulties in accessing U.S. drugs and equipment. This problem has become more serious in recent years for several reasons, among them, the fact that the United States has clinched its lead in the international pharmaceutical industry just at a time when less funds are available for intermediary purchases of such drugs. There are cases in which a patient will respond to one drug but not another, or will be allergic to one drug and not another, or will need a specific combination of medications, some of which may be of U.S. origin and therefore difficult, if not impossible, to obtain.

purchase Through Intermediaries: There are a number of U.S.-manufactured drugs that are still under patent by U.S. firms, and cannot be sold legally to Cuba without a license. Cuba's Deputy

Minister of Public Health for Economics estimates that, even in times of serious economic crisis, Cuba must purchase at least 20 drugs of U.S. origin that have no substitutes.⁶⁸ There is also a range of drugs and equipment manufactured in the United States which Cuban specialists consider to be incomparable in quality to other sources. When these items are purchased through intermediaries-usually with difficulty, given the penalties prescribed by U.S. law-their higher prices automatically translate into smaller amounts contracted, or the contrary occurs, and the higher prices obligate Cuban importers to purchase an alternative of inferior quality.

Repairs of Equipment: As we have seen, in examples related to x-ray equipment, operating tables, pharmaceutical manufacturing equipment and respirators, the embargo has restricted effective repair of medical equipment for patient care. This is also the case with donated items: a humanitarian donation may be approved by the U.S. government, but it may be impossible later to obtain a license to purchase replacement parts. This is the case of a significant number of Cobe dialysis machines. (See section on Nephrology.)

Accessories for Equipment: This category has met with the same fate as equipment repair, since often the disposable accessories are unavailable due to the embargo. This is the case of diagnostic testing, Kodak film for the national breast cancer detection program (see section on Women's Health), and patient circuits for neonatal ventilators (see section on Children's Health).

Ingredients and Equipment for the Pharmaceutical Industry: Practice has indicated that only finished products have received U.S. export licenses, meaning that Cuba must import finished medications at a much higher price. This not only leaves factory space and workforce idle, but limits often to one fourth the amount of a given drug available to the population. In addition, the embargo has made it impossible for Cuba to purchase key equipment for manufacturing and quality control of certain pharmaceuticals, or has made it necessary to purchase these through intermediaries at much higher prices. (See section on the Pharmaceutical Industry.) The CDA also especially targets Cuba's biotechnology research and production, specifically prohibiting any exports for such use. (See section on Biotechnology and Vaccine Research for the implications of this provision.)

Sudden Cutoffs: By virtue of the embargo, Cuba has lost key third-country suppliers when they have been bought out by U.S. firms. The cases of Pharmacia and Nunc have been amply documented, and Cuba suddenly lost its two main sources of pacemakers for this reason as well. (See section on Cardiology).

Delays in Arrivals: Delays in deliveries of medications and equipment are often a result of distance shipping, as well as the CDA regulations, which tend to limit the number of ships willing to travel to Cuba (see above). One example of this problem occurred just after the CDA was enacted, and involved the importation of 1,5 mtm of tallow from Argentina, used to produce soap for hospitals and the general population. Due to the fact that the Cuban fleet has very few ships with the technical requirements for bulk-shipping this product, contracts were usually closed to include shipping by the supplier. However, it took several months to find a tanker willing to transport the tallow to Cuba, and thus, manufacture and distribution of the soap was likewise delayed.⁶⁹ In some cases, suppliers have insisted that Cuban ships be used, again representing delays.

Additionally, as has been noted, the licensing procedures themselves add to the time between contract closure and delivery. All of these embargo-related factors tend to create gaps in supplies of medicines, materials, parts, equipment and related items. In some medical emergencies, this can create life-and-death situations. (See sections on National Health Emergencies and Family Relations and Humanitarian Emergencies.)

No Patient Compensation: If U.S. products are purchased, whether licensed or through third parties, and they prove defective, Cuba has no way to recover monetary compensation for patients

or their families. Even if a case to this effect **were** to be admitted to a U.S. court, and the patient were awarded compensation, none would be forthcoming, since the embargo prohibits transfers of funds to Cuban nationals. The compensation would no doubt be deposited in a blocked U.S. account. (See section on Cardiology, for the situation regarding Telectronics pacemakers.)

Security of Supply vs. Quality: As we have seen, U.S. firms are reticent about attempting exports to Cuba; licensing is by no means guaranteed for direct, subsidiary or U.S.-origin component exports; and foreign firms may be taken over by U.S. companies. Such implications of the embargo mean that U.S. products are-not-a stable source for the Cuban medical system. This, contends Deputy Health Minister Ramón Díaz Vallina, forces Cuban importers to choose stable supply over product quality. "If there is U.S. medication that will cure a patient in seven days, and a European alternative that takes 14, we will choose the European alternative to guarantee availability of the drug," he says.⁷⁰ Cur research has shown that this leads to longer hospital stays, resulting in heavier case loads for doctors and greater hospitalization costs.

In the following chapters, we will explore the embargo's limitations on medical imports as they impact both preventive and curative care throughout the Cuban health system.

NOTES

*Pharmaceutical Research and Manufacturers of America, "U.S. Pharmaceutical RandD and Sales," January, 1995.

²*Ibid.*

³*Price Regulation and Pharmaceutical Research: The Limits of Co-Existence*, by Heinz Redwood, Oldwicks Press, Suffolk, GB,-1993,-p. 21.

'New regulations issued by the U.S. Department of Commerce in March 1996, may open up a loophole in the patent restrictions. According to legal experts, the regulations may allow Cuban buyers to import medications licensed to a foreign firm under a U.S. patent, only **if** the medication is entirely manufactured in the third country, and contains no U.S. ingredients. However, this has yet to be tested, and even if certain, it is not clear what possibilities this would actually open up, since we do not have information on what average percentage of U.S. components or materials such a licensed pharmaceutical might contain.

⁵"Consecuencias adversas que tiene para el disfrute de los derechos humanos del pueblo de Cuba el embargo economico de los Estados Unidos de Norteamerica," mayo 1993, Office of the First Deputy Minister of Public Health, Havana, p. 1.

'Interviews with Orlando Romero, General Manager of MEDICUBA, Havana, 19 Sept1995 and 24 Nov. 1995.

'Interview with O. Romero, MEDICUBA, 19 Sept. 1995.

⁸Michael Krinsky and David Golove, *United States Economic Measures Against Cuba*, Aletheia Press, Northampton, Mass., 1993, p. 114.

⁹Krinsky and Golove, p. 118.

¹⁰In fact, it was not until June 29, 1993, that OFAC amended its regulations to bring them into line with the CDA. As noted in Congressional testimony by Airline Brokers Co., Inc., presented in their outline of "Communications with U.S. Pharmaceutical Companies Concerning the Exportation of Medicine to Cuba and Legislative History of the Cuban Democracy Act," 'OFAC (apparently) had difficulty drafting the amendments and ascertaining the intent of Congress when it enacted the CDA. For example: On the one hand, the CDA prohibited OFAC from issuing licenses to foreign subsidiaries that are owned or controlled by U.S. Arms and that wish in export foreign manufactured goods to Cuba. On the other hand, the CDA permitted U.S. persons to export directly from the United States to Cuba donated or sold medicine, provided certain conditions are met." These provisions were reconciled in July 1993 CDA regulations, which allowed for licensed sale of medicines and medical supplies to Cuba by both U.S. companies and their subsidiaries abroad.

"CDA, Sec. 1705.

¹²Krinsky and Golove, p. 126.

¹³The following interviews were conducted for the survey of pharmaceutical and medical equipment firms in the United States: Michele Lockwood, International Sales, Baxter Healthcare Corporation; Kathy Daniels, International Division, Bristol-Myers Squibb, March 28, 1996; Nelson Baker, General Counsel, Johnson and Johnson, February 20, 1996; Keven Rrambeer, International Corporate Affairs for Latin America, Eli Lilly and Company, March 28, 1996; Susan Crowley, Director of International Relations, Merck and Company, March 29, 1996; Donna Boehme, Legal Department, Judy Klon, International Sales, Peter Flanagan, outside counsel, De Bauer, Distribution, and Judee Shuler, Public Relations, Ohmeda Pharmaceutical Products; Robert Lively, Director of Legislative Affairs, Schering-Plough Corporation, April 4, 1996; Diana Smith, Export Manager, Searle, March 28, 1996; R. John Larson, Licensing Department, Siemens USA, Malcolm Barlow, Public Affairs, SmithKline Beecham Pharmaceuticals; William C. Nealon, Attorney for TPLC Pacemakers, October 27, 1995; Jaime Esteves, Director of Marketing for the Americas, Wyeth-Ayerst Laboratories. (Wyeth-Ayerst also owns Lederle Laboratories).

"Interviews with Donna Boehme and Judy Klon, Ohmeda Pharmaceutical Products.

¹⁵Interview with Diana Smith, Export Manager, Searle, March 28, 1996.

"Interview with Nelson Baker, February 20, 1996.

¹⁷Interview with Tracy O'Donald, U.S. Department of Commerce, Cuba Exports Desk, by Wallie Mason, Feb. 20, 1996. O'Donald told Mason that the Dept. only licenses medical donations, not sales. After being asked to consult the guidelines, she rectified her first statement, and said that licenses for sales were indeed possible. On reading requirements for on-site inspection and that goods be for the benefit of the Cuban people, she said: "I doubt very seriously that a license to sell medicines to Cuba would be approved: it would be very difficult to satisfy these two criteria."

¹⁸Interview with Robert Lively, Director of Legislative Affairs, Schering-Plough Corporation, April 4, 1996.

¹⁹Interview with Michele Lockwood, International Sales, Baxter Healthcare Corporation.

²⁰Interview with William C. Nealon, Attorney, October 27, 1995.

²¹Interview with Jaime Esteves, Director of Distribution, Wyeth-Ayerst Laboratories.

²²Interview with Keven Krambeer, International Corporate Affairs for Latin America, March 28 1996.

²³Interview with Clara David, Licensing Officer, OFAC, February 20, 1996.

"Interview with R. John Larson, Licensing Department, Siemens, USA

²⁵Interview with Jaime Esteves, Director of Distribution, Wyeth-Aye& Laboratories.

²⁶Interview with Susan Crowley, Director of International Relations, Merck and Company, March 29, 1996.

²⁷Responding to an inquiry concerning this issue, Dr. A D. Brandling-Bennett, Deputy Director of the Pan American Health Organization said in a letter to Richard Wittenberg, President of the American Association for World Health: "The Government to Cuba has had a long-standing interest in developing biologicals and vaccines and marketing them internationally. At the request of Cuba and with the approval of U.S. authorities, a technical group from Merck, Inc. visited several biotechnology institutions in Cuba to make an evaluation of their facilities. This assessment did not create any legal difficulties for Merck, and they were not fined for any of the work conducted at PAHO's request. We do not have information about other activities which may have been conducted outside those approved by the U.S. authorities." Communication of February 20, 1996.

²⁸Merck Pays \$127,500 to Settle Cuba Allegations," Bergen Record, October 25, 1995, a story by Bloomberg Business News.

²⁹Interview with O. Romero, MEDICUBA, 19 Sept., 1995.

³⁰Interview with Nancy Blanco, Deputy Manager of MEDICUBA, Havana, 7 September, 1995.

³¹This does not include Picker International, Inc., The Upjohn Company, Johnson Johnson, and Becton and Dickinson, in cases where the licensing process was carried out by these U.S.-based companies on behalf of their foreign subsidiaries, requesting permission to sell to Cuba.

³²Interview by Stephen Kimmerling with William Teletronics legal counsel, October 27, 1995. Also note that according to Dunn and Bradstreet's *America's Corporate Families, the* Teletronics pacemaker manufacturer in Australia was owned by Pacific Dunlop Ltd. of Melbourne, which owns Pacific Dunlop Holdings of Wilmington, DE., whose subsidiary Teletronics Pacing Systems of Englewood, CO, owns TPLC, Inc. of Hialeah, FL, where the pacemakers are manufactured under patent authorization from Australia.

³³Fax from Siemens-Elema, dated June 29, 1994.

³⁴Interview by Dr. Anthony Kirkpatrick with Kevin O'Malley, March 19, 1995.

³⁵Interview with Rolando Díaz, MEDICUBA, November 23, 1995.

³⁶Interview with N. Blanco, MEDICUBA, Sept. 7, 1995.

³⁷Telex dated September 27, 1994.

³⁸*Afectaciones por el bloqueo y la puesta en vigor de la Ley Torricelli*, Ministry of Foreign Trade, Havana, June, 1994, p. 6.

³⁹Interview with R. Díaz, MEDICUBA, Sept. 6, 1995.

"Letter from Cuban Foreign Minister Roberto Robaina to UN Secretary General Boutros Boutros Ghali, June 25, 1993, p. 7.

⁴¹Fax to MEDICUBA and others, from Aldo Galano, representative of Pharmacia, dated August 25,

1995.

⁴²Interview with Leonel Zúñiga, Director, Empresa Nacional de Suministros Medicos, ENSUFARMA. February 7, 1996.

⁴³MEDICUBA report, June, 1994.

⁴⁴Case cited by Krinsky and Golove, p. 103.

⁴⁵Pharmaceuticals: Robust and Ready to Brawl," by Joseph Weber, *Business Week*, January 8, 1996.

⁴⁶Interview with Clara David, February 20, 1996.

⁴⁷Interview with Rosa Fuentes, MEDICUBA purchasing agent, Sept. 7, 1995.

⁴⁸Interview with R. Diaz, MEDICUBA, *Nov. 23, 1995*; and *Business Week* article cited by Krinsky and Golove, p. 103.

⁴⁹Picker "Checklist for License Application," contained in appendix to this chapter, and interview with Juan Suarez, Deputy Director, National Center for Electromedicine, December 8, 1995.

⁵⁰Interview with Alfredo Rivero, Deputy Director for Medical Equipment, EMSUME, 22 December 1995.

⁵¹Authors of this study had access to full documentation of this process. However, Joyce Simon of the U.S. Commerce Department's Bureau of Export Controls (BXA) informed Wallie Mason on Feb. 20, 1996 that information concerning the denial of these licenses to Picker International "is confidential and the government will not comment."

⁵²August 12, 1994 fax from Bill Dix of Picker in Canada to Galax, Inc., Montreal, and interview with R. Díaz, Deputy Director of MEDICUBA for Medical Equipment, January 5, 1996.

⁶³Interview with Juan Suarez, Deputy Director of the National Center for Electromedicine, December 8, 1995.

⁵⁴Letter of May 28, 1991, signed by ALFA LAVAL's Tina V. Kristensen, to MEDICUBA.

⁵⁵Letter of April 13, 1992, signed by AMSCO's Paul Montado.

⁵⁶Interview with R. Díaz, MEDICUBA Sept. 6, 1995.

⁵⁷U.S. Treasury documents conflict with MEDICUBA records and with statements from Janssen itself: Treasury records only three licenses issued for thalamonal, while MEDICUBA records four shipments; and Janssen confirms that it has never shipped without a license. We were unable to obtain further clarification on the thalamonal licenses from Clara David, Licensing Officer for OFAC.

⁵⁸MEDICUBA contracts reviewed by the authors, and summarized in MEDICUBA report, January 16, 1996.

⁵⁹Interview with Nelson Baker, General Counsel for Johnson and Johnson, February 20, 1996.

⁶⁰"Cuba Issues for Congress," Congressional Research Service Issue Brief, May 2, 1994, CRS-7.

*Interviews with Ramón Díaz Vallina, Vice Minister of Public Health; Enrique Comendeiro, Advisor to the Minister of Public Health; and Orlando Romero, Director, MEDICUBA

⁶²Interview with O. Romero, MEDICUBA, Sept. 19, 1995.

⁶³Interview with A Rivero, EMSUME, Dec. 22, 1995.

⁶⁴Interview with Dr. Jose Luis Fernández Yero, Oct. 17, 1995.

⁶⁵Interview with R Díaz, MEDICUBA, Sept. 6, 1995.

⁶⁶Interview with O. Romero, MEDICUBA, Sept. 19, 1995.

⁶⁷Interview with A Rivero, Dec. 22, 1995.

⁶⁸Interview with Ramón Díaz Vallina, August 25, 1995.

⁶⁸Afectaciones por el bloqueo y la puesta en vigor de la Ley Torricelli," Ministry of Foreign Trade, Havana, June, 1994, p. 22.

⁷⁰Interview with R. Diaz Vallina, August

CHAPTER FOUR

MEDICAL TESTING, RESEARCH & THE PHARMACEUTICAL INDUSTRY

introduction

Cuba has developed a national program for diagnostic testing in several fields, most extensively carried out to determine the presence of congenital malformations, congenital hypothyroidism, infant allergy predisposition, HIV 1 & 2, and hepatitis B & C. All of these tests, plus the certification of the purity of the 920,000 annual blood donations, rely on reagents, technology and equipment developed, produced and furnished by the National Immunoassay Center in Havana. Currently, the Center equips 104 laboratories in Cuba. Some eight million tests were carried out with Center support and supplies in 1995.¹

The following table illustrates the results of these nationwide programs since their inception, through July of 1995.

**TECNOSUMA NATIONAL SCREENING PROGRAMS:
Accumulated Results through July, 1995**

CONGENITAL MALFORMATIONS	
Pregnant Women Tested	1,593,798
Neural Tube Defects	2,017
Other Malformations	1,280
Other Problems	10,968
Incidence Per 1,000	2.07

CONGENITAL HYPOTHYROIDISM	
Newborns Tested	1223,098
Hypothyroid Detected	357
Frequency	1: 3,426

ALLERGY-PRONE INFANTS	
Newborns Studied	1,015,359
IGE % 5 and 20 UI/ML	127,142
Percent	12.52%
*IGE > 20 UI/ML	38,037
Percent	3.75%

● IGE is Immunoglobulin E

HIV 1 and 2'	
Number of Tests	4,364,640

'See chapters on AIDS for full information

HEPATITIS B	
Number of Tests	3,233,636.
Positives	61,679
Percent	1.91%.

HEPATITIS C	
Number of Tests	489,588
Positives	4,919
Percent	1.00%

Source: National /immunoassay Center, Havana, September, 7995

The program for detection of congenital malformations began a decade ago and currently tests 95% of pregnant women. The programs for diagnosing congenital hypothyroidism and allergy predisposition were started eight years ago, and now cover over 97% of Cuban newborns.

The Immunoassay Center also supplies the Cuban health system with diagnostic kits for detection of leprosy, meningitis B & C, tetanus, chorionic gonadotropine, immunoglobulin levels, and confirmatory testing for hepatitis B. The Center provides its TECNOSUMA technology and reagents to Cuban hospitals free of charge, by virtue of income generated from exports to 106 laboratories worldwide..

In addition to the diagnostic kits mentioned above, the Center exports kits for detection of HIV 1, chagas, IgG dengue virus, IgM dengue virus, rubella, cytomegalovirus, herpes, total tiroxine in dry blood on paper filters, and fluorescent tests for quantifying phenylalanine in dry blood on paper filters. From January through September of 1995, 1,760,000 kits were sold abroad.²

Beterá Laboratories in Havana also play a pivotal role in diagnostic testing and protection of the blood supply. Installed within the National Blood Bank system, the Beterá produces a series of biological reagents and offers testing services to less well-equipped laboratories. The reagents produced here include those used for: histocompatibility testing, cell cultures, and erythrocyte tipification, among others. The national blood banks use a number of these reagents for blood classifications and reactivity of red blood cells. Therapeutic agents produced by the labs include gamma globulins for anti-tetanus sera and for children and adults with immunodeficiencies. The labs offer testing services for: hematology, microbiology, nephrology, parasitology, medical genetics, gastroenterology, allergies, and immune diseases.

Impact of the U.S. Embargo

The U.S. embargo has negatively impacted Cuba's diagnostic testing programs, and the prognosis is for considerable threat to the country's capabilities to maintain uninterrupted universal screenings in its preventive arsenal for the coming period.

The most sustained effect of the embargo has been to impose increased costs on research and production, and consequently to limit the development and manufacture of diagnostic testing equipment and material. There are a number of chemical products and components of U.S. origin

that the Center must buy through third parties, multiplying costs by 2.5 times in comprehensive terms. For example, analog device components are needed to read results in all the ELISA (Enzyme-linked Immunoabsorbent Assay) system tests, and several of these are only manufactured in the USA.

The Center has also determined that the quality of a number of chemicals used to produce reagents is acceptable only from certain U.S. suppliers. The following table shows the price differentials resulting from necessary U.S.-origin purchases made through European or Asian intermediaries.

Price Comparison Products Purchased Directly from U.S. Companies and through Intermediaries <i>(continued on following page)</i>							
PRODUCT	COMPANY	UNIT	QTY	PRICE	WHOLESALE	DIRECT	DIFFERENCE
MEMBRANE XM-300/150MM	AMICON	BOX/5	4	784.00	3136.00	2195.20	940.80
MEMBRANE YM-30DIA.76MM	AMICON	PKG/10	1	187.00	187.w	130.9	66.10
MEMBRANE XM-300DIA.43MM	AMICON	PKG/10	1	143.00	143.00	100.10	42.90
MEMBRANE XM-300DIA.76MM	AMICON	PKG/10	1	187.W	187.W	130.90	56.10
MEMBRANE YM-100DIA.76MM	AMICON	PKG/10	1	187.00	187.00	130.90	66.10
MEMBRANE YM-100DIA.90MM	AMICON	PKG/5	2	143.00	266.W	200.20	85.80
CONCENTRADOR 8400 CAP.500ML	AMICON	ONE	2	1045.00	2125.w	1463.00	627.00
REPLACEMENT KITS FOR RK8400	AMICON	ONE	1	225.00	225.00	157.50	67.50
FIXED ANGLE ROTOR 18X10 ML	BECKMAN	ONE	1	3354.00	3354.00	2347.m	1006.20
FIXED ANGLE ROTOR 8X50	BECKMAN	ONE	1	3354.00	3354.00	2347.80	1006.20
FIXED ANGLE ROTOR 5x500	BECKMAN	ONE	1	1552.7(3)	552.70	3886.89	1665.81
FIXED ANGLE ROTOR 6X250	BECKMAN	ONE	1	4382.00	4382.00	3067.40	1314.60
CENTRIFUGE REFRIGER J2 HS	BECKMAN	ONE	1	22856.00	22856.00	16999.20	6866.80
CENTRIFUGE REFRIGER J2 MC	BECKMAN	ONE	1	26424.60	26424.60	18497.22	7927.38
IDEM 125 ML	CMS	ONE	50	23.56	1177.60	624.25	353.25
IDEM 260 ML	CMS	ONE	50	36.53	1826.50	1278.66	547.95
SWABS	CMS	ONE	2	19.59	39.18	27.43	11.76
SYRINGES (HAMILTON)	CMS	ONE	2	60.00	120.00	84.00	36.W
IDEM	CMS	ONE	2	63.W	126.00	88.20	37.6
ELECTRIC PIPETTE	CMS	ONE	2	255.00	510.w	357.W	153.00
IDEM	CMS	ONE	3	1688	50.64	35.45	15.19
TRYPSIN 1250	DIFCO	F/100q	2	140.54	281.08	196.76	84.32
FREUND'S ADJUVANT COMPLETE	DIFCO	6x10mL	5	2605.00	13025.w	9117.50	3907.50
FREUND'S ADJUVANT INCOMPLETE	DIFCO	6x10nL	10	1931.00	19310.00	13517.00	5793.00
NERVIS ADJUVANT	DIFCO	F/0.5ml	18		0.00	0.00	0.00
FREUND'S ADJUVANT COMPLETE	DIFCO	6x1 ml	10	69.90	699.00	489.30	209.70
FREUND'S ADJUVANT INCOMPLETE	DIFCO	6x1 ml	50	49.20	2460.00	1722.00	738.00
NONIDET P-40	FLUKA	ONE	1	58.52	58.52	40.96	17.56
ELLMAN REAGENT	FLUKA	F/5q	1	53.20	53.20	37.24	15.96
THIORESOL	FLUKA	F/100q	1	35.75	35.75	25.03	10.73

THIOPHENOL	FLUKA	F/50ml	2	1250	25.00	17.50	7.50
HIDROGEN FLUORIDE	FLUKA	F/5L	1	1849.20	1849.20	1294.44	554.76
L-LEUCIL-L-ALANINE	FLUKA		1	266.52	266.52	186.56	79.96
L-LEUCIL-L-ALANINE	FLUKA	F/250GR	170	16.32	2774.40	1942.08	832.32
PVC	LABCONC O	ONE	3	95.00	285.00	199.50	85.50
FIXTURE KIT	LABCONC O	ONE	3	350.00	1050.00	735.00	315.00
STANDARD SERVICE FIXTURE KIT	LABCONC O	ONE	3	205.00	615.00	430.50	184.50
DUAL EPOXY 6"X3"	LABCONC O	ONE	3	70.00	210.00	147.00	63.00
48" LABORATORY HOOD	LABCONC O	ONE	3	5200.00	15600.00	10920.00	4680.00
SPILL STOPPER WORK	LABCONC O	ONE	3	500.00	1500.00	1050.00	450.00
THERMO PLASTIC DUG	LABCONC O	ONE	8	320.00	2560.00	1792.00	768.00
90° ELBOW	LABCONC O	ONE	9	340.00	3060.00	2142.00	918.00
FEMALE COUPLING DURT	LABCONC O	ONE	9	51.00	459.00	321.30	137.70
48" BASE STAND	LABCONC O	ONE	3	525.00	1575.00	1102.50	472.50
CYTOMEGALOVIRUS	SCRIPPS	mg/ml	5	119.00	595.00	416.50	178.50
HERPES SIMPLEX VIRUS TYPE 1	SCRIPPS	mg/ml	54	119.00	6426.00	4498.20	1927.80
HERPES SIMPLEX VIRUS TYPE 2	SCRIPPS	mg/ml	5	119.00	595.00	416.50	178.50
RUBELLA VIRUS S. STRAIN 77	SCRIPPS	mg/ml	5	119.00	595.00	416.50	178.50
RUBELLA VIRUS S. EDMONTON STR	SCRIPPS	mg/ml	5	137.00	685.00	479.50	205.50
RUBELLA VIRUS	SCRIPPS	ML	50	75.00	3750.00	2625.00	1125.00
EDTA-TETRASODIUM SALT	SIGMA	F/100g	1	34.03	34.03	23.82	10.21
GENTAMICIN SOLUTION	SIGMA	F/10ml	5	87.15	435.75	305.03	130.73
L-GLUTAMINE	SIGMA	F/100g	2	94.21	188.42	131.89	56.53
SODIUM BICARBONATE	SIGMA	F/100g	7	35.69	249.83	174.88	74.95
ACRIFLAVINE HYDROCHLORIDE	SIGMA	F/25g	1	34.50	34.50	24.15	10.35
ERIOGLAUCINE	SIGMA	F/25G	1	37.00	37.00	25.90	11.10
CIPROFLOXACIN	SIGMA	grams	2	58.00	116.00	81.20	34.80
ETHYLENE GLYCOL	SIGMA	F/1L	30	32.85	985.50	689.85	295.85
PROTAMINE SULFATE	SIGMA	GR	1	15.74	15.74	11.02	4.72
PROTAMINE-AGAROSE	SIGMA	F/5ML	1	78.66	78.66	55.06	23.60
HIDROXIBENZOTRAZOL	SIGMA	F/100G	1	138.50	138.50	96.95	41.55
HUMAN IGA REAGENT GRADE	SIGMA	F/10MG	1	300.16	300.16	210.11	90.05
HUMAN IGM REAGENT GRADE	SIGMA	F/10MG	1	554.93	554.93	388.45	166.48
PROTAMINE-AGAROSA	SIGMA	F/10ML	1	201.89	201.89	141.32	60.57
ANTIL-L THYROXINE (T4)	SIGMA	F/1ML	100	71.50	7150.00	5005.00	2145.00
ANSA	SIGMA	F/100gr	1	171.60	171.60	120.12	51.48

Source: National Immunoassay Center, Havana, September, 1995.

However, Immunoassay Director and President of TECNOSUMA, Dr. Jose Fernández Yero says that the purchase of such materials and components has become in itself a laborious, difficult and near-clandestine operation. "We spend our time shrouded in mystery, just to buy reagents for

medical testing; we can't even use e-mail to inquire about prices. We have had a number of unfortunate experiences in which the U.S. government has threatened to cut off trade with wholesalers that supply us." He explains that every time the Center has had to change suppliers for such reasons, this implies adaptations in technology to "fit" the new products, with the resulting additional investments and time lags in production.³

Mergers and buyouts by U.S. corporations of key suppliers to Cuba currently endanger the country's diagnostic testing programs. Two cases in point are those of the Nunc group and Pharmacia.

Nunc (Nunc A/S of Denmark and Nunc GmbH of Germany) is one of the world's five major suppliers of plastic laboratory testing plates, and Cuba purchased some 500,009 plates annually from Nunc, which were used in virtually all diagnostic test kits. In addition, Cuban scientists had successfully developed a 49% more efficient plate, with plans that it be manufactured in a joint production agreement with Nunc, beginning as early as September 1995.

However, in August, the Nunc group was acquired for \$170 million by the U.S. firm Sybron International of Milwaukee, WI, and on August 9, 1995, a fax was received from O. Bjorn Hansen of Nunc A/S, which reads in part: "Much to our regret we have to inform you that unfortunately our cooperation of many years has to be terminated. The reason is that as of 1 August 1995, BTR has sold Nunc A/S, Nunc GmbH and Nunc Inc. to Sybron International Corporation USA. In future we therefore have to follow the directions laid down by the US Government in relation to Cuba. We regret that all the work done by your organisation in having all the quotations finalized into a contract has been in vain and that the comprehensive technical preliminary work involved in creating the basis for SUMA's quotation cannot be followed up by a cooperation concerning this very interesting matter. We hope that the political situation will be normalized so that again we will be able to supply our loyal customers in Cuba with our products."⁴

Dr. Fernández Yero comments that by virtue of the purchase "we have lost a year of scientific research, and now all the technical data is in the hands of this U.S. company." He says that Cuba owns the patent on the new plate design, which should stop Sybron from copying it, but that it would be difficult for Cuba to muster the financial resources to defend its rights in international court.

Dr. Fernández Yero notes that the buyout came as a complete surprise to Cuba, and that in anticipation of production of the new Cuban plates, the Center had stopped buying Nunc's conventional ones. This means, in turn, that some Nunc plates may have to be purchased at considerably higher prices from a third party and that eventually a new supplier must be found. However, he notes that now there are only *one* or two firms in the world that could be potential partners with Cuba, given that the testing process is very complex, in that the plastic itself becomes part of the chemical reaction. Once again, the Center is faced with the specter of technological revamping, delays and new investments.

Consequently, while scientists had hoped to use the more efficient Cuban plates to bring down the production cost of tests such as HIV (currently at 50 cents), and reduce export prices as well, just the opposite is in the offing as a result of the loss of the Nunc partnership.

The case of Pharmacia's merger with Upjohn (see chapter on Medical Exports to Cuba) has potential dramatic implications for diagnostic testing in Cuba. The Center used the company's chromatography columns to purify all reagents for testing. As a result of the cutoff of Pharmacia's sales, Cuba was faced with a critical gap in the availability of reagents for such tests as alpha fetoprotein for congenital malformations (specifically, sepharose 4B-ACT and sephadex to purify proteins from the amniotic fluid). Even a few days lag in supply of these reagents is dangerous for patients, since the testing can only be performed during certain weeks of pregnancy. Afterwards, it is simply too late.

It should be noted that intermediary prices quoted to Cuban importers for the two Pharmacia reagents needed for this important test are significantly higher than when they could buy directly from the Swedish company: DEAE Sephadex (500 g.) was sold to MEDICUBA at \$716.00 in 1995, when purchased directly from Pharmacia, but in June, 1996, offers through a third party trading company put the same amount at \$963.87. CNBR Sepharose (4B, activated) was purchased from Pharmacia at \$187.06 (15 g.), and the June, 1996 price quoted to MEDICUBA through the trading firm was \$269.00—for an average price hike of 40% for these two products alone.⁵ Thus, the embargo has also made it more expensive for the Cuban health system to ensure a woman's right to make an informed decision about the course of her pregnancy (see chapter on Women's Health for more detail).

What's more, says Dr. Fernández Yero, "if we stopped production [of reagents] at any time, the entire blood supply in the country would be threatened. We could not guarantee disease-free blood donations." (A share of these donations have gone abroad to disaster sites over the years as well.)

The final twist in this fateful circle is that with the loss of direct purchases from Nunc and Pharmacia, the Center must pay more for these products through third parties; and must consequently bring in more revenues from exports. However, it was counting on stable prices from Pharmacia and on the more efficient Nunc plate to make the Center's export offers of diagnostic kits more competitive in the international market. At risk are the effectiveness and coverage of Cuba's diagnostic testing programs which depend entirely on these funds.

Dr. Fernández Yero comments: "Cuba is the only country in Latin America that carries out such broad testing for congenital malformations, hepatitis and other diseases. We can only conclude that the United States is making every effort to see these programs eliminated."

For Beterá Laboratories the Pharmacia merger comes on the heels of the buyout of another of their major reagent suppliers: IBF of France, which was taken over by the U.S. firm Sepracor and broke all commercial ties with Beterá as of 1993. The case of Pharmacia was even more alarming. Beterá is one of the few centers in Cuba which has a range of sophisticated laboratory and industrial equipment and corresponding reagents purchased from the Swedish firm six years ago. These include:

- Biopilot, bought at some \$90,000 This unit is a virtual pilot plant for purifying proteins, substances used in turn to produce diagnostic mediums. It is used for cell cultures; manufacture of diagnostic kits for cholesterol, creatinin, glucose, urea and gamma globulin counts; obtention of gamma globulins for children and adults with immunodeficiencies (including AIDS and HIV); and for purification of pigments obtained from marine and fresh water algae used to mark monoclonal antibodies for use in diagnostic testing for malignant cells (cancer) and immune diseases. (
- FPLC (Fast Protein Liquid Chromatography). This unit accomplishes some of the same tasks as the Biopilot, but on a smaller scale. (In addition to Beterá, an FPLC is installed at the Immunoassay Center.)
- Electrophoresis equipment (Multiphor and PHAST) separates proteins, and is used to characterize them and determine possible contamination in the production process.
- Spectrophotometer (Ultraspec), used for metabolism counts in clinical and immunology testing.

This equipment relies on a series of Pharmacia reagents, quite difficult to substitute, which as we have observed, obligates importers to look to higher priced intermediary purchases for the same

items. Moreover, in June 1996, one of the crystal columns broke in Beterá's Biopilot, the only industrial unit at the labs. The broken column in the pump could have been replaced for \$98 when Pharmacia was able to sell to Cuba. However, as of July, the Biopilot was still working at one third capacity, since the part was not yet obtainable from any source. This is the second time after the Pharmacia merger that the Biopilot has been forced to function at reduced capacity: a microchip in the same pump burned out as a result of a power outage, and it took six months to find a new one in Europe. As noted above, the Biopilot is critical to the production of a number of diagnostic tests, as well as the production of therapeutic gamma globulins.⁶

NOTES

-
- 1 Data provided by Dr. José Fernández Yero, Director of the Immunoassay Center, October 18, 1995.
 - 2 Ibid.
 - 3 Interview with Dr. J. Fernández Yero, October 17, 1995.
 - 4 Fax dated August 9, 1995, from O. Bjorn Hansen, Sales Director of Nunc A/S, Denmark.
 - 5 Documentation provided by Reagents Department; MEDICUBA-June 20, 1996.
 - 6 Information on Beterá provided by Dr. José Lagomasino, Chief of Protein Chemistry, Beterá Laboratories, Havana, interviewed June 26 and July 3, 1996.

Introduction

Biotechnology and vaccine research evolved in Cuba in the early 1980s, coupling the island's burgeoning scientific capabilities with efforts to solve domestic health care problems. Thus, the Pedro Kourí Institute for Tropical Medicine was reorganized in 1982, on the heels of the national dengue epidemic and following an increase in diseases imported by Cubans serving abroad. The Center for Biological Research (CIB) was founded the same year to piggyback on international research -into interferons, the "wonder -drug" -of-the eighties; the Finlay Institute for vaccine research and production came into its own in 1991 built around a core team of scientists responsible for successfully curbing the meningitis B epidemic with a vaccine they developed in Cuba; and numerous centers were incorporated into the search for bio-improved farming methods early in this decade, when the economic emergency declared food production a national priority.

In addition to these, today the following medical science institutions participate in biotechnology research and production in Cuba: National Center for Scientific Research (CNICM), Center for Genetic Engineering and Biotechnology (CIGB), successor to CIB, National Reference Laboratories on HIV, National Immunoassay Center, National Center for Bio-Preparations, and the Center for Molecular Immunology (CIM), among others.

The national network extends further afield, with the biotech data base listing close to one hundred research centers, production facilities, biofactories. pharmaceutical plants and other facilities working in agriculture, marine and forestry biotechnology, industry and human medical and pharmaceutical biotechnology, software design, production automation processes, factory and equipment design, and related enterprises.' These institutions engage in research and development projects, both independently and cooperatively.

Cuba now manufactures an array of biotech products in agriculture, many of them bio-fertilizers and pest-control agents; plus some 160 medical-pharmaceutical products, including interferons, recombinant epidermal growth factor, human transfer factor, recombinant streptokinase, reagents and diagnostic systems, enzymes and technologies for industrial use, molecular biology products, 39 monoclonal antibodies, automated programs for biomedical research and production, vaccines (including recombinant hepatitis B, meningococcal B-C, and several traditional vaccines), and products for veterinary medicine.'

Julie Feinsilver, who has written extensively on Cuba's biotechnology capability, observes that "Experts from the United States, Latin America, Spain and international organizations have assessed as excellent Cuban biotechnology and genetic engineering."³ And Harvey Bialy, Research Editor of *Bio /Technology* states: "From its inception, the Cuban biotechnology enterprise was intellectually and technically extremely sophisticated and serious." He goes on to predict that "The future of Cuba does indeed seem to be...in the hands of its young scientists.*

With the crisis of the 1990s, biotechnology development was selected-along with a handful of other key sectors such as food production and tourism-to help get the economy back on its feet. Since then, biotechnology has offered solutions to critical domestic health and agriculture problems, becoming an all-important source of savings as a result of import substitutions; and has pulled in significant hard currency revenues from exports, many of those plowed back into the industry or into the health care delivery system. *Bio/Technology* Editor Bialy comments on the basis of several visits to the island's biotech facilities: ". ..Cuba's biotechnology is now a fully developed, integrated set of industries that last year (1994) generated close to \$200 million from the worldwide sale of its products.⁶ Initial investments in the highly. complex industry have been recovered, according to Dr. Rosa Elena Simeón, Minister of Science, Technology and the Environment ⁶

The U.S. Embargo and Cuban Biotechnology

Just at the time when Cuban biotechnology had come into its own, and when the country was most in need of its contribution, the United States singled out the industry as a specific target for the embargo. In the 1992 Cuban Democracy Act, biotech was the object of a separate clause:

Exports of Medicines and Medical Supplies. Exports of medicines or medical supplies, instruments, or equipment to Cuba shall not be restricted...⁴⁾ except in a case in which the item to be exported could be used in the production of any biotechnological product.'

The vague wording of this section (italics are ours) allows broad interpretation, taking aim at research as well as production, and at agricultural as well as medical biotech investigation and manufacture. According to sponsors of this legislation, this provision was intended to cut Cuban export revenues by crippling Cuba's biotechnology capability.

As a result of on-site visits to a number of biotech facilities in Cuba, detailed interviews with scientists, medical professionals and corporate representatives, it is our judgment that the embargo does indeed have a serious impact on Cuba's ability to realize its potential in this field of research, development and production. We have found that this leads to considerable negative consequences for the right of the Cuban population to benefit from biotechnology advances through their application to health care delivery and agriculture (see also section on Food Supply and Nutrition). And finally, it is our conclusion that not only the Cuban population is deprived of such timely advances, but also the populations of other countries, including the United States.

Particularly eloquent is the case of biotechnology applied to medical-pharmaceutical research, which Feinsilver notes has become the hallmark of Cuban efforts in the field.*

Based on our exploration of the industry in Cuba and the explicit content of the Cuban Democracy Act, we find that the embargo specifically targets the following populations, treated with Cuban biotechnology products in the medical field:

Cuban and other victims of HIV-AIDS, certain other viral infections and cancers, treated with interferons.

The Center for Genetic Engineering and Biotechnology currently produces four interferon products: Alfa N injectable (human leukocyte alpha interferon), Alfa N cream (human leukocyte alpha interferon), Alfa N eye drops (human leukocyte alpha interferon), and Alfa R injectable (alpha 2B recombinant interferon). These are used in the treatment of various viral diseases and tumors, and in particular for maladies such as leukemia, laryngeal papilloma (cancerous tumors), inoperable lung cancer, hepatitis B, the symptoms of dengue fever, plantars' warts, and herpes zoster, among others.

Alpha interferon is also used in delaying the progression to AIDS in asymptomatic HIV-positive patients, and in treating Kaposi's sarcoma, an AIDS-related cancer. HIV treatment with recombinant alpha-2b interferon has yielded the following results: in trials with 66 asymptomatic seropositive persons, after a long-term low-dose treatment (three to 26 months, 3 million IU three times per week) an 11-month delay of the onset of AIDS associated symptoms was registered, as well as a 20-month prolongation of the incubation period, with less opportunistic infections and general complications, as compared to 72 individuals who received no treatment.⁹

From 1986 to May of 1993, 133 HIV-positive patients received interferon in field tests which showed that administration of the medication effectively delayed -AIDS-defining diagnosis and extended patients' lives once they had AIDS. These successful results led specialists to apply domestically produced interferon to approximately 70%-or 840-o-f seropositive patients from 1993 to the present,

giving them as much as an additional seven years of life. A significant share of these patients also received the human transfer factor, also produced in Cuban biotech laboratories.”

Patients suffering from hepatitis B, which affects some 26% of populations in developing nations.” In Cuba, treatment of hepatitis B with interferons has been reported to significantly increase the probability of survival and promote histological cure.¹² By 1986, *Newsweek* reported that Cuba was “the second-largest producer of natural human leukocyte interferon, after Finland.”¹³

Interestingly, alpha interferon was central to the genesis of Cuban biotechnology research, since it was used as a model for subsequent molecular biology and biotechnology development. This strategy, according to many U.S. biotechnology experts and industry analysts, has proven significant, since “alpha interferon almost serves as a paradigm for...biological response modifiers (interferons, interleukins, colony-stimulating factors, etc.).” This places Cuba among those in the forefront of product development in the field¹⁴

Infants, Children and other populations needing vaccine against hepatitis B. In 1992, the Cuban recombinant hepatitis B vaccine had been proven effective in clinical trials in Cuba, Colombia, Venezuela, Russia and Eastern Europe, with results showing good seroconversion and high antibody titers.¹⁵ By 1996, it was registered for use in 28 countries.¹⁶

In Cuba by the early nineties, 1700 to 2000 cases of hepatitis B were being reported annually. Vaccination began in 1991-92 with immunization of infants born to mothers carrying the virus, all patients in dialysis, all personnel and patients in mental hospitals, and all health workers at risk. The vaccine’s effectiveness against hepatitis B has also meant reduced incidence of chronic liver disease and liver cancer associated with the virus.

Later, the vaccine was included in the national children’s immunization program, and by 1995, 98.1% of all newborns; 91% of all third-graders; and 90.3% of all ninth-graders were vaccinated against hepatitis B. Additionally, all public health and medical students were receiving the vaccine.* The Ministry of Public Health includes in its objectives for 1996 immunization of all pregnant women in their third trimester.¹⁹

Cuban experts in the immunization field say such a program would not have been possible if they had to rely on imported hepatitis B vaccines, since the cost rises exponentially for national application seeking broad coverage.

With the opening of a new plant at the National Biopreparations Center (BIOCEN) in 1995, production capabilities for the hepatitis B vaccine have been enhanced. The director of the new installation for recombinant products, Emma Uramis, estimates that the plant will produce 20 million 20-microgram doses of the vaccines annually. Some two million doses had previously been applied in Cuba and sold in 19 other countries, primarily in the developing world.²⁰ According to the WHO, in Latin America alone, some 400,000 persons contract hepatitis annually, requiring expenditures of some \$300 million.²¹ The Cuban hepatitis B vaccine is currently in the final phase of the WHO-PAHO certification process.²²

Cuban and other victims of heart attack, treated with recombinant streptokinase. Recombinant streptokinase (sold by Cuba as *Heberkinasa*) is used to dissolve blood clots during heart attacks (acute myocardial infarction), to prevent cerebral embolisms, and for treatment of deep venous thrombosis, pulmonary embolisms, and dysfunctions of prosthetic heart valves. It has also been found useful in arterial occlusions, hemodialysis, shunt obstructions and intrapleural adhesions.²³

Studies in Cuba carried out in 1992 showed this domestically produced medication to be as effective as natural streptokinase, which physicians note was imported at nearly \$150 per dose. From 1992

95,306 of 712 heart attack patients were treated with recombinant streptokinase at the Cardiology Institute in Havana, reducing the mortality rate at the hospital from 18% to 9.5%. Nationally, results are similar, with mortality now reduced to 10.4% through the application of streptokinase in cases where it is indicated. Dr. Orlando Rucabado, Chief of Coronary Intensive Care at Havana's Cardiology Institute, notes that the sooner the streptokinase is applied after the heart attack, the more effective it is.

Today, the medication is stocked in all Cuban hospitals, and the Ministry of Public Health is examining use at all primary care centers (community polyclinics with emergency facilities). Thus, as with other products obtained domestically, recombinant streptokinase allows for more complete coverage of the Cuban population at substantially lower costs to the health system, and at no cost to patients.

Heberkinusa has been patented in 43 countries, including the United States, preventing any other producer from manufacturing or marketing it in the USA, unless under Cuban license. (The embargo prohibits such licensing, since it would necessarily involve a transfer of funds to Cuban nationals.)

Cuban and other burn patients treated with epidermal growth factor. The Cuban Heberfarma product, **Hebemzin**, is a healing and antiseptic cream containing human recombinant epidermal growth factor and silver sulfadiazine. It is used to stimulate healing and epithelialization, for cell growth regulation, and bactericidal antimicrobial action.

This growth factor, like others in its class, successfully reduces the healing time for burns, achieves a better granulation zone, improves graft acceptance and cicatrization. Further indications are in other surgical or degenerative processes, or whenever cicatrization or tissue regeneration is required, such as ulcers and lesions due to radioepidermitis or radiodermatitis, chemotherapy drug leakage, and ulcers produced by circulatory failure.²⁵

Cuban infants and other young people immunized against meningococcal (meningitis) Band C. In the 1970s, meningitis caused by serogroup B meningococcal had already become a significant health problem in Cuba. And by 1933, the rates of meningitis had reached their highest levels at 1440 cases, or 14.4 per 100,000 inhabitants. The Cuban VA-Mengoc-BC vaccine was obtained in 1987, and Phase III field trials took place in the seven provinces which showed the highest rates of infection, including among some 106,000 junior high school students in boarding schools. These randomized double-blind trials, which concluded in 1989, showed an efficacy of 83%.²⁶

After national applications of the vaccine and its inclusion in the routine immunization program, rates decreased substantially: from 1988 to 1995, the incidence of this child-killer disease was reduced by 93%.²⁷ In 1993, 87 cases were registered, bringing the rate to under one per 160,000 inhabitants for the first time (.79); and in 1995, 61 cases were registered, for a rate of 55 per 100,000 inhabitants, the lowest in the last 20 years. The Cuban vaccine is now applied to virtually all children in their first year (100% of infants in 1994 and 98.5 in 1995, or some 160,000 annually). All Cuban young people under the age of 30 have been immunized.

Epidemiologists caution that should the vaccine become unavailable for any reason, Cuba would "certainly face a new epidemic in a short time," bringing rates similar to 1989, when 130 children died as a result of infectious meningococcal meningitis."

By the end of 1995, the Cuban VA-Mengoc-BC vaccine against meningococcal meningitis types B and C, had been registered by national health authorities for medical use in 10 countries, according to Dr. Lourdes Almeyda of the Finlay Institute. Speaking at the Sixth Congress of the Cuban Society of Pharmaceutical Sciences, Dr. Almeyda said that in addition to Cuba, the vaccine was registered for use in the Dominican Republic, Colombia, Brazil, Mexico, Uruguay, Paraguay,

Argentina, Nicaragua and Russia. To date nearly 38 million doses of the vaccine have been applied in various countries, including Cuba, in both epidemic situations and community outbreaks.²⁹ The Finlay Institute's Catherine Ribas explained that in addition to the countries applying the vaccine, the medical registration and approval process is currently underway in several other countries. VA-Mengoc-BC is patented, or commercially protected, in seventeen countries: Cuba, Argentina, Austria, India, Russia, Israel, Spain, Sweden, Switzerland, Germany, the United Kingdom, Italy, Australia, Holland, France, Luxembourg, and Greece. The patent for this vaccine was awarded the Gold Medal of the World Intellectual Property Organization (WIPO) in 1989. The patent application to the U.S. patent office is still pending, according to Ribas.³⁰

The vaccine is currently undergoing rigorous testing for approval by the World Health Organization and the Pan American Health Organization.

It should be noted that virulent strains of *Neisseria meningitidis* cause sporadic cases and periodic outbreaks of epidemic meningitis throughout the world, with strains belonging to serogroups B and C responsible for the overwhelming majority of cases. According to PAHO, "... Brazil, Colombia, Chile, Argentina, Uruguay, and the Scandinavian countries have experienced increases in serogroup B meningitis"³¹

Cuban and other populations with high blood cholesterol Levels, treated with PPG. Ateromyxol or policosanol, commonly known as PPG, is a derivative of sugarcane. In clinical testing in Cuba, PPG compares favorably to cholesterol reducing agents on the U.S. market. Studies in Cuba indicate that total cholesterol levels are reduced up to 16% with a 5 mg/day dosage, and up to 19% with 10 mg/day. PPG reduces LDL cholesterol levels further still-up to 29%.³²

According to *Harvard International Review* Editors Ryan Bradley and Edy Rim, "An independent assessment by the University of Geneva endorsed PPG as the best anti-cholesterol drug available, thereby removing the international community's doubts about PPG's effects.... Even with international accreditation, however, actual export of PPG encountered several problems with world markets... The large industrial markets were either closed by the U.S. embargo or dominated by pharmaceutical giants with enormous marketing campaigns that push their own anti-cholesterol products."³³

The World Health Organization (WHO) recently announced that the world "is on the brink of a major health crisis" due to the alarming rise in both new and known infectious diseases such as tuberculosis, malaria, hepatitis, AIDS, cholera and many more. In their report on the State of the World's Health released in May 1996, WHO declares that there were 17 million deaths worldwide from infectious diseases in 1995: nine million of these in young children.³⁴

Of the 37 vaccines on the WHO and UNICEF priority list, Cuban scientists are currently working on 28. Their research falls within the National Vaccine Development Program, involving some 3,000 scientists and technicians. Work underway is placing particular emphasis on vaccines against HIV/AIDS, cholera, leptospirosis, and multiple vaccines for infants.

We find that Cuban and other populations are targeted by the embargo's explicit provisions aimed at stalling such vaccine research and other biotechnology products in the pipeline. Specifically:

Cuban and other populations potentially against leptospirosis A trivalent vaccine developed by the Finlay Institute against leptospirosis is now in final testing in Cuba with hopes of curbing the disease, declared epidemic since 1994. Beginning May 21, 1996, 100,000 people in at-risk groups between the ages of 15 and 65 began receiving their first dose of the vaccine, completing Phase III trials in humans.³⁵

This disease, more prevalent in rural areas of Cuba and other developing countries, is transmitted fundamentally by contact with water or soil contaminated with the urine of infected farm animals and rodents. Symptoms include high fever, headache, muscular pain and lethargy. Over 2,000 cases of leptospirosis and 60 fatalities were reported in Cuba in 1995, down from the previous year, but still a major health problem.³⁶ Significant incidence of leptospirosis has been reported in Central America and elsewhere in Latin America.

The spectacular rise in leptospirosis in Cuba is directly related to the five-year economic crisis and the dip in relations with Russia over this period. Specifically, less fieldwork is mechanized, and so more farm labor is used; more people from the cities are in the fields for the first time, and are less resistant to the disease; less protective clothing is available for this growing workforce; and fewer medications can be bought for treatment. Until purchases were stopped in 1991, Cuba imported about 500,000 doses annually of a Russian vaccine, which was applied to the (smaller) population-at-risk, at a cost of \$2.00-2.40 per vaccination. In 1995, Cuba was able for the first time to import the same amount, which was used to immunize some 120,000 people. However, it is the Cuban-produced vaccine which will allow for universal coverage of those currently at risk."

Cuban and other populations potentially protected against cholera While no cases of cholera have so far been reported in Cuba, Dr. Manuel Santin, the country's chief epidemiologist, calls the disease "a constant threat."³⁸ However, in the rest of Latin America, the situation is indeed grave: from 1991 through 1994, 1,061,188 cases of cholera were reported in these countries, with nearly 10,000 deaths. In fact, by early 1996, the only countries of the region which were free from cholera were Uruguay and the Caribbean islands. In Central America and Brazil, the incidence continues to climb.⁹⁹ Cholera is endemic to a great part of Africa.

Cholera vaccines currently in use in the world have not proven to be highly effective, reaching 50% after three years of evaluation. Through genetic engineering, the Finlay Institute and CNIC have isolated several strains as logical "candidates" for a new Cuban vaccine to be tested in human volunteers." These trials were set to begin in July, 1996."

Cuban and other children and elderly potentially protected against haemophilus-b influenza (Hib). Haemophilus-b bacteria do most damage among the most vulnerable: infants, small children and the elderly. Hib can cause meningitis (it is the number one cause of this disease in Cuba), pneumonia, septicemia, throat and skin infections and even arthritis. Last year, 1,119 cases were reported in Cuba, 477 of these in infants under one year of age, including 44 deaths. According to international data, 15%30% of children who survive meningitis Hib will suffer irreversible brain damage."

The head of Cuba's National Vaccination Program points to broad application of a haemophilus-b vaccine as one of the few ways the country could continue to reduce infant mortality, which stood at 9.4 per 1,000 live births in 1995. Dr. Miguel Angel Galindo suggests such a vaccine administered to infants in their first year of life could have saved the lives of the 67 babies that died from the disease since mid-1994, and could bring infant mortality down another 0.3 points in the coming years.⁴³

However, importation of the vaccine for all infants would cost some \$6 million annually; and for coverage of 95% of children under five, another \$36 million, states Dr. Galindo, a sum which he says Cuba simply cannot afford. Hence, the overriding importance of achieving a Cuban vaccine, which could be domestically produced at a fraction of the cost.

In 1993, health authorities began-submitting the haemophilus-b bacteria to strict epidemiological controls, as a prerequisite for testing a Cuban vaccine in development, which could be applied universally once obtained.⁴⁴

Cuban and other populations potentially protected against dengue virus. According to Dr. Rafael Figueredo Gonzalez, who heads the Ministry of Public Health's Vector Control Program, dengue has not been a health problem in Cuba since the 1961 epidemic, due primarily to strict controls on the carrier *Aedes aegypti* mosquito.⁴⁵

However, dengue is a serious threat in Asia and Africa. And there is currently no effective vaccine against dengue in the world. Cuban scientists are involved in a multi-center vaccine research effort in Havana to develop a vaccine against dengue, headed by the Pedro Kouri Institute of Tropical Medicine.⁴⁶

Cuban and other women potentially protected against breast cancer. A therapeutic vaccine-which works by enhancing the body's immune response-is now under development in Cuba against breast cancer and various other forms of malignant tumors. According to Dr. Gustavo Sierra, Vice Director of the Finlay Institute, his research team is working with scientists at other centers on this vaccine, and they have already obtained antigens necessary for its production."

Nearly 1,000 Cuban women die every year from breast cancer, and it is the most frequently found cancer among women in the country, with over 2,000 new cases diagnosed every year. (See section on Oncology for further information.)

Cuban and other populations potentially protected against HIV/AIDS. In Cuba, 1,200 HIV-positive cases have been reported since the virus was first detected on the island in 1986; 446 of these have resulted in AIDS; and 292 persons had died by the end of 1995." Worldwide, over one million cumulative cases of AIDS in adults and children have been reported since the onset of the pandemic; an estimated 4.5 million, if underdiagnosis and incomplete reporting are taken into account.⁴⁹ And in the United States alone, over 290,000 deaths have been reported through June of 1995.⁵⁰

A team of scientists from the Center for Genetic Engineering and Biotechnology, the Pedro Kouri Institute of Tropical Medicine, the Finlay Institute and other Cuban research facilities announced recently that they are gearing up for the first trials in humans of their newly-developed AIDS vaccine." Dr. Manuel Limonta, CIGB Director, told the authors that he expects these to begin in September 1996.⁵² According to Dr. Jorge Perez, human volunteers are being selected and the vaccine continues to undergo tests for toxicity and reactivity.⁵³ Cuban AIDS sufferer Federico Ramos, told us that he is among a group of patients who have already participated in stages of vaccine research, giving blood for laboratory investigations.⁵⁴

Cuban and other populations in need better food supplies Biotechnology and genetic engineering in agriculture is being developed to increase crop yields through the production of disease-resistant seeds and strains of plants, organic biofertilizers, biopesticides, more productive plants, and to improve animal health and milk and meat yields.⁵⁵ In addition, the introduction of genetically engineered industrial enzymes into various production processes has also led to considerable savings and improved output.

Among the results showcased at a UNESCO meeting on biotechnology in Havana in November 1995 were: Gavac (a recombinant vaccine against cattle ticks, purchased by several Latin American countries); progress in improving rice culture through biotechnology; and a genetically-engineered sugar cane plant, Jaronú 60-5, which will serve as a prototype for a new variety of seedling.⁵⁵

Other products include *Rhizobium* bacterial biofertilizer, which reportedly has increased crop yields by as much as 75%, especially among legumes. And, for over two decades, Cuban scientists have been working on a soy development project, "Cubasoy-23," adapting the bean to local climatic conditions.

The CIGB's research in this arena has relevance to the Latin American region, according to a ***Trends in Biotechnology*** article by Clare Robinson. "Sugar still forms a key component of the economy of Cuba and many other Latin American countries," she states. "Hence the recent achievement of obtaining transgenic sugar cane. ..was significant-the eventual goal is the introduction of agronomically important traits. Diagnostics for plant diseases, particularly for major crops, is another focal area: e.g. monoclonal antibody-based ELISA tests for potato viruses, PVX, PVY and potato leaf roll virus (PLRV) have been produced for verifying seed quality. Walled-cell electroporation techniques that have been successful for transforming sugar cane are also being developed for rice, and agroinnoculation is being developed for use in sweet potato and tomato.*"

Given the current economic crisis, the contribution of these biotechnology discoveries cannot be underestimated, both as boosts for food production and as substitutions for costly imports such as nitrate fertilizers and seeds. One example was described to us at the Institute for Plant Biotechnology in Villa Clara Province, central Cuba. Dr. Elio Jiménez reported that the potato seeds developed at his institute will completely substitute imports by 1999: producing the vitroplants at one of Cuba's 19 biofactories costs \$2 million annually, compared to the \$13-15 million spent on certified seeds from abroad.⁵⁸

Dr. Jiménez also referred to research that has implications for the region, such as the insect-resistant coffee plant developed through genetic transformation, biotechnology applied to increase the time between ripening and rotting for banana fruit, and the production of an in-vitro plantain resistant to two diseases which cause half the crop losses of this product worldwide (*micosphaerella fijensis* and *fusarium oxysporum* var *cubense*).

Biotech Research: The Information Embargo

Obtaining details on research in Cuban biotechnology is in itself a challenge: citing the need to maintain discretion in the face of what they term persecution by U.S. embargo enforcers, most scientists and directors in the field were forthright in explaining self-imposed limitations when it came to giving us specific data on suppliers, joint research projects with scientists abroad, visits by U.S. scientists, and the main markets for Cuban products."

They did, however, provide us with ample data on how the embargo has directly and indirectly impacted their research and production pursuits, beginning with the barriers it creates to the flow of scientific information.

It should be noted that information, including public technical information in books, abstracts, journals, etc., is exempted from the embargo restrictions by virtue of an amendment that entered into effect in 1988. Later rulings also exempted from the embargo information transmitted by electronic means, including wire services and electronic mail. However, in the case of biotechnology, the reticence of suppliers in the United States appears to indicate that they are either unaware of these exemptions, or they fear sales to Cuba may be interpreted as assisting biotechnology research and production, and therefore subject to prosecution.

Gilberto Sotolongo, Director for Scientific Information at the Finlay Institute, told us that the embargo and the CDA in particular hamper the free exchange of ideas between Cuban and U.S. scientists and even between Cuban researchers and those in other countries of the world. He prefaced his discussion- by noting that the United States is the-world's number one source for scientific information, whether in the form of books and magazines or more sophisticated computerized networks, publications and data banks. Sotolongo reports that scientific institutions on the island are able to subscribe to scientific literature (magazines) and receive some books

through the Havana-based firm WSP. However, he states that the prices paid are 40-100% above list prices, because WSP must often go through "unusual machinations" in order to obtain the literature for distribution to Cuban biotech researchers.⁶⁰

The Finlay Institute, the CIGB and other Cuban biotech centers also use the Dutch firm SWETS as a purchasing agent for scientific literature. The record indicates no problems when the publisher does not request information on the customer. However, U.S. firms at times inquire, and when the customer is Cuban, they have refused to sell. *Current Contents*, a series of U.S. publications which provide regular updated listings- of new titles in the sciences, is one example: Sotolongo states SWETS has indicated it cannot sell it to Cuba due to client information requirements and U.S. prohibitions in relation to Cuba.⁶¹

It has been the experience of the Finlay Institute, the CIGB and the Immunoassay Center that electronic or computerized information has been particularly difficult to obtain, especially when provided on CD-ROM. Sotolongo spoke to us of the case of the Institute for Scientific Information (ISI), a Philadelphia-based center which produces bibliographical data bases, key to their research. This includes a series called the *Sciences Citation Index*, which is the only one of its kind in the world. The Index lists all articles (title, author, journal, abstract), plus all references for each article as well. This is fundamental for research scientists all over the globe, states Sotolongo.

However, when Cuban research centers pooled resources to pay the \$17,000 annual fee for the *Index* (provided on CD-ROM), ISI refused to sell it through SWETS on the basis that the final destination was Cuba. A letter from SWETS Latin America sales manager Jorge H. Fernandez-Garza explained: "... I have made direct contact with the Institute for Scientific Information, and they have informed me that no publication on disc or tape will be sent to Cuba, given that this medium may be re-recorded for other uses, and this is subject to heavy government restrictions." & In this case, the problem apparently stems from the interpretation that an erased disc is like blank paper, and therefore constitutes a product that does not necessarily fall under the embargo exemption for sale of information.

Yet, language introduced for informational materials in 1994 specifically exempted CD-ROM materials from the embargo, and since the *Index* is public information, its export to Cuba cannot be interpreted to fall under the ban on selling products for the biotechnology industry. We would venture that the ISI case maybe similar to those of U.S. pharmaceutical exporters explored in an earlier chapter, where the intricacies of embargo law plus the stiff penalties for its violation were seen to effectively deter corporations from deciding to sell to Cuba.

Adequate bibliographic research is the starting point for scientific creation: learning what has already been accomplished in a specific line of investigation is essential to building on that body of work. Yet, as is reviewed in the chapter on Continuing Medical Education & Exchange of Scientific Information, the biotech facilities are among the Cuban institutions which have difficulty subscribing to a U.S. magazine or purchasing a U.S. book, even when publishers agree to sell, simply because the embargo has also cut off banking relations between the United States and Cuba. Some scientists have found themselves in the awkward position of being unable to purchase reprints of their own articles, when published in U.S. publications, or available from a U.S. abstract service. And finally, Cuban scientists and institutions in biotechnology have difficulty in maintaining any regular exchange with U.S. colleagues, because of travel restrictions, the ban on making any contribution to biotech development in Cuba, and the embargo clause that prohibits U.S. persons from "providing a service" (including offering a lecture) to any Cuban national. These last obstacles make it difficult for colleagues from the two countries to carry on a conversation, let alone share significant scientific information or participate in joint research projects.

All this makes for a high frustration level among Cuban biotech researchers, especially those working to obtain medical advances. Dr. Jorge Perez, vice director of the Tropical Medicine Institute and Director of the AIDS Program, comments: "It is astonishing to see this small country developing a vaccine against HIV, through sheer dedication and despite the obstacles. We have very qualified scientists and professionals, but because of the embargo, we have little access to specialized scientific information. We have no regular access to U.S. universities and scientific institutions. More resources must be invested and more time spent, just to overcome these barriers, and in particular the provision that aims to paralyze our work on an AIDS vaccine simply because we are using biotechnology to do it. I think any conscious action that holds back the discovery of an AIDS vaccine for even a minute is a criminal act."⁶³

Cuban biotech scientists contend that U.S. visa denials are used to keep them out of the information loop, by barring them from active and consistent participation in many events and seminars in the United States, even when these are sponsored by international organizations. Frequently they cannot attend, even when all expenses are paid by the host, and often despite lobbying efforts on their behalf by prestigious U.S. scientists or institutions. While visa decisions do not fall strictly within the purview of the embargo, we would argue that the negative climate towards Cuba and various travel policy rulings over time do indeed influence the outcome of the visa process. Dr. Jose de la Fuente of the CIGB told us that 51 scientists from his center have been unable to travel to the United States from 1989 through January of 1996. Their visa requests were denied or simply left unanswered, despite repeated inquiries as to their status. Other research institutes assured us they have had the same experience as the one illustrated by the following list provided to us by the CIGB.⁶⁴

CENTER FOR GENETIC ENGINEERING AND BIOTECHNOLOGY (CIGB)
U.S. VISITS CANCELED BY SCIENTISTS BECAUSE NO U.S. VISAS GRANTED

Name	Event, Scholarship or Symposium
<u>1989</u>	
1) Lilia Ana Pereiras Perez	Miami Biotechnology Winter Symposium
Februarv	
<u>March</u>	
2) Sergio Perez Talavera	"Agrotech '89," Arlington, Virginia
JuLy	
3) Maria P. Rodriguez Molto	Shrimp Pathology Short Course, Arizona
<u>September</u>	
4) José Otero Molina	Advisor, PAHO Delegation
Qctober	
5) Hemán Roca Campaña	Scholarship to Penn. State University
<u>November</u>	

6) Carlos Duarte Cano PAHO meeting, Washington, DC

December

7) Luis Herrera Martinez Scientific Workshop, Baltimore

1990

8) Ricardo Leonart Cruz Meeting-on Shrimp Diseases, U. of Arizona

9) Oscar Hernández B. Meeting on Shrimp Diseases, U. of Arizona

10) Carlos Duarte Cano Antibody Engineering Conference, San Diego

1991

January

11) Nelson Santiago Vispo Keystone Symposium, Los Angeles

February

12) Jesus del Valle Rosales 14th Annual Update in Clinical Microbiology and Immunology, Utah

13) Eduardo Pentón Arias 14th Annual Update in Clinical Microbiology and Immunology, Utah

October

14) Alfredo Méndez Alarcón International Marine Biotechnology Conference '91, Baltimore

15) Maria Rodriguez Molto Parenteral Drug Association, Maryland

16) Guillermo Selman-Housein Scientific Conference on Plants

17) Pedro Oramas Frenes Scientific Conference on Plants

18) Gustavo de la Riva Scientific Conference on Plants

1992

January: Miami Biotechnolow Winter Svmnosium/'92

19) Jose Manuel Limonta

20) Rebeca Martínez Rodriguez

21) Fidel Ovidio Castro Reboredo

22) Ricardo Leonart Cruz

23) Manuel Rodriguez Valle

- 24) Lázaro Hernández Garcia
- 25) Rolando Morán Valdivia
- 26) Luis Lago Castro
- 27) Pedro Oramas Frenes
- 28) Yamilet Coll Garcia
- 29) Guillermo Selman-Housein
- 30) Gustavo de la Riva
- 31) Manuel Luis Penichet Prado

February

- 32) Sergio Perez Talavera Course on Pharmaceutical Development Projects, New Jersey

March

- 33) Sergio Perez Talavera ISPE/FDA Forum

September

- 34) Bicardo Leonart Cruz Cold Spring Harbor Laboratory, NY

December

- 35) Marta Ayala Avila IBC Conference on Antibody Engineering, San Diego

1993

June

- 36) Maribel Guerra Vallespi 8th Conversation on Biomolecular Stereodynamics, State U. of N.Y., Albany

September

- 37) Rebeca Martinez Rodríguez Scholarship to Pennsylvania University

1994

Anril

- 38) Violeta Laberta Beceiro 1st World Congress on Computational Medicine and Public Health, U. of Texas

December

- 39) Jose Manuel Limonta VIBC International Antibody Engineering Symposium

1995

April

- 40) Raymundo Ubieta Gómez Keystone Symposium on Molecular and Cellular Biology
 41) Verena Muzio Gonzalez International Congress on' Hepatitis B and C, Sheraton City, Washington

August

- 42) Jose Cremata Alvarez --XIII International Symposium on Glycoconjugates
November

- 43) Eileen Riego Trejo ISICR '95, Baltimore, Maryland

1996

January

- 44) Fidel Castro Reboredo Annual Congress of the International Society of Embryo Transfer, Salt Lake City, Utah and: Seminar on Transgenesis in Cuba, Byron College of Medicine, Houston, Texas
 45) José Manuel Limonta Annual Congress of the International Society of Embryo Transfer, Salt Lake City, Utah

February

- 46) Maribel Guerra Miami Biotech Winter Symposia, Therapeutic Strategies and Molecular Medicine, Miami, Florida
 47) Julio Delgado Exploiting Enzymes Technology for Industrial Application, Florida

March

- 48) Julio Delgado Current Topics in Gene Expression-1996 Piechia Pastories In Vitro Gen, San Diego
 49) Jose Cremata Current Topics Gene Expression-1996 Piechia Patories In Vitro Gen, San Diego
 50) Francisco Alea Tercer Congreso Biotecnología del Caribe, Universidad de Puerto Rico, Mayaguez, P.R.
 51) Jose Fernández de Cossio ASMA course. Utilization of spectrometry. Portland, OR

While many visa requests are denied or never receive a response, some are granted. Yet, these can also be problematic. Gilberto Sotolongo reports that it is not uncommon for scientists at the Finlay Institute to receive their U.S. visas several days or more after the close of the event they were invited to attend.

"The whole visa situation is very uneven," notes Sotolongo, who suggests there may be other factors taken into consideration at the time a visa is granted. "Now someone (from the Finlay Institute) is going for a month to the Centers for Disease Control (CDC) for work related to meningococcal disease and vaccine development. Perhaps it is in U.S. interests now to permit this-we are the only ones with this vaccine." Yet, he points out, on numerous occasions Finlay Institute scientists have been denied visas to the United States, sometimes for international events sponsored by non-U.S. organizations but being held in the U.S. One of those denied is the Institute's director and discoverer of the meningitis vaccine, Dr. Concepción Campa.⁶⁵

Biotechnology Development and Production

Our research indicates that the embargo, and the CDA in particular, directly and indirectly hinders biotechnology development and production in Cuba. An eloquent example can be found in the case of reagents and gels for purification of vaccines. The biotech industry, and the entire health care system, has had to change suppliers twice in the past three years, due to sudden cutoffs resulting from the U.S. embargo.

These chemical supplies are an integral-part-of the production process, and any unforeseen change of manufacturer can shut down the line for as long as six months, while new products (sometimes including new equipment) are rigorously tested and approved, contracts negotiated and finalized, and new shipments received. It should also be noted that in highly complex production processes such as these, lines of production are mounted in accordance with the characteristics of specific equipment, matched with their corresponding gels and reagents. If either are changed, this means remounting the production line. "There is no such thing as a quick substitution when you are working with delicate items like vaccines," says Juan Carlos Leyva of the Finlay Institute's Imports Department. "These products (reagents and gels) are never exactly the same, and an entire series of trials must be set up to carefully test new candidates throughout the whole plant. This is very costly, both in terms of time and money. Taken together, these embargo-provoked delays have inflated our costs of production by as much as two thirds.⁶⁶

Cases in point are those of the Fluka Chemical Company of Switzerland, and Pharmacia of Sweden, both producers of chemical reagents widely used in Cuba.

The Fluka Chemical Company, Ltd., a Swiss company associated with the Sigma-Aldrich group of the United States, supplied Cuba with some \$300,000 annually in laboratory chemical reagents. When the CDA was signed into law in 1992, the firm began to run into problems with its sales to the island. By November 1992, Fluka's Elizabeth Berger informed Cuban purchasers that a series of contracts had to be canceled, because the necessary export licenses had not been received from the United States. In January 1993, Berger reported to Cuban customers that she was informed that contracts signed before the effective date of the CDA (October 23, 1992) were to be exempted from the prohibition on subsidiary sales. But, she noted that her experience was proving otherwise, and the contracts remained canceled. "The treasury department of the U.S. refuses to answer our repeated reclamations," commented Berger in her January communication."

Interviews at the CIGB revealed that research was hampered when Fluka did not receive these licenses and contracts with Cuba were canceled. The Center was a major customer of Fluka's, says Dr. de la Fuente, and the cutoff resulted in research delays, and higher prices paid for substitutions.⁶⁸

But an even greater blow to the biotech and vaccine industry in Cuba came with the merger of the Swedish giant Pharmacia with the U.S. company Upjohn, announced in August, 1995. Pharmacia, which established offices in Havana in 1989, was the number one supplier of the industry's reagents, a significant amount of its equipment, and key chemicals such as gels for the chromatographic purification of vaccines. The offices were closed by November, in such a hurry that some products were undelivered and some payments incomplete for those already in hand.

The disappearance of Pharmacia has sent tremors through a number of Cuba's research, development and production facilities.= CIGB purchased its reagents and key equipment from Pharmacia, equipment for which it now has no source for parts or accessories, unless purchased illegally at significantly higher prices. It should be noted that because of the provision banning exports from any U.S. source for Cuba's biotech industry, there is no use applying for licensing of such sales. Since these units are used across the board-we saw everything from High Performance Liquid Chromatography (HPLC) to gene assemblers-many CIGB projects were

impacted, including the HIV/AIDS vaccine research program, which suffered from shortages and consequent delays until new suppliers could be found.”

We interviewed Dr. Jose Luis Fernández Yero of the Immunoassay Center about two weeks before Pharmacia left Havana, and he told us that the chromatographic columns used to purify all reagents developed at the center were purchased entirely from Pharmacia. And production of the alpha fetoprotein test relies on sephadex and sepharosa (4B-ACT), both from Pharmacia. Without a constant supply, Cuba may be faced with a gap in the availability of the test, used in mass screening- of expectant mothers,- to detect congenital -malformations. This method of analyzing genetic material is safer and less invasive than amniocentesis and has been credited with leading to a further decline in infant mortality in Cuba. A gap in availability can be serious, since alpha fetoprotein can only be performed from week 16 to week 18 of pregnancy. After that, it is too late.⁷¹

At the Finlay Institute, Catherine Ribas, Director of International Relations, and Juan Carlos Leyva of the Imports Department expressed particular concern for the impact the Pharmacia-Upjohn merger will have on their center, the leading producer of vaccines in Cuba. Our first visit to the Institute took place in November 1995, days after the closing of the Havana Pharmacia office. They explained that the Finlay Institute had had significant business dealings with Pharmacia up till that point. At the time of our interviews, the fate was unclear for a number of outstanding contracts; some purchases had already been paid for, others not. In addition, several pieces of equipment already purchased were still awaiting shipment, and it was presumed they would not be received. Leyva told us: ‘We didn’t even have time to close out with them, to liquidate our contracts. This then creates a whole chain reaction-a chain of problems begins that begins now. And the situation also jeopardizes major investments on our part.*

He cited the example of the Pharmacia chromatographs, expensive equipment for vaccine purification, which implied major investments for Finlay. Now, all technical contracts and service agreements have been canceled, prohibited by U.S. law in the future, representing a serious dilemma for the center, which also faces considerable price hikes for parts and accessories through third parties, if it is able to purchase them at all.

Leyva notes that negotiations with such intermediaries is a delicate process: “True negotiations are almost impossible. We have to function in semi-secrecy to protect our suppliers from U.S. reprisals. This just isn’t a normal way of doing business, and we pay for this. What’s more, it is our experience that bringing in products through third parties from various destinations means price hikes of up to 25% for additional shipping alone.⁷³

Dr. Elio Jiménez of the Institute for Plant Biotechnology in Villa Clara Province reported similar price differentials when purchasing Pharmacia parts and reagents for HPLC, electrophoresis and other units through intermediaries-as much as 50% more.”

Instability is one of the main consequences of the embargo for Cuban scientists involved in biotechnology research, development and production. We found that another major difficulty is presented by the . unavailability of U.S.-manufactured equipment. This is of particular importance, since U.S. producers of such sensitive high-tech equipment are among the world’s leaders.

Researchers at the Center for Genetic Engineering and Biotechnology report that it has been impossible for the CIGB to buy a variety of items, such as:

- Equipment for the study of hybridizations through reactive and non-reactive probes. There are only two firms in the world that manufacture this type of equipment, and the Cuban experts

would choose to purchase from Molecular Dynamics of La Jolla, California, but have been unable to do so.

- Systems for information processing, computers for the CIGB's work on protein structure. The most complete systems for the Center's needs, according to these scientists, are the ones sold by Silicon Graphics, Mountain View, California.

Dr. de la Fuente reports that when the CIGB has written to U.S. firms for information on equipment, the answer has invariably been that they are prohibited from selling to Cuba." This problem means limited access to new and more efficient U.S. technologies for Cuban biotech production, in a state-of-the-art industry that relies on constant development.

In addition, once the stronger U.S. companies are out of the bidding, offers from other quarters tend to climb in price. U.S. equipment and products bought out of necessity by the CIGB through third parties carry a higher price tag, further increased by higher freight costs for distance shipping, and because of the shipping restrictions of the CDA, according to Dr. Jose de la Fuente.

This has been the common experience of various biotech centers: "It's not the same to transport a one-ton centrifuge from Japan as it is to bring it a few miles from the USA," notes Dr. Concepción Campa, Director of the Finlay Institute. "And you have to think of parts, reagents, raw materials, and the like. For example, sometimes the reagents must be refrigerated, and it's not the same to guarantee refrigeration over a short distance than to ensure it half-way around the world."⁷⁶

Arrival delays from faraway ports bring on yet another set of problems: Dr. Jiménez of the Institute for Plant Biotechnology reports that his Molecular Biology labs are especially hard hit, because they need fresh chemicals for testing. "If a chemical has a two-week effective lifespan, and you spend seven days getting it, that leaves you only seven to use it in your research."⁷⁷

As we saw with the example of Pharmacia products, the maintenance of U.S.-manufactured equipment is more expensive for Cuban biotech centers, because of the embargo. A centrifuge at the Finlay Institute is U.S.-made and replacement parts have already been a problem, according to Rolando Díaz, vice-director of MEDICUBA for Medical Equipment."

Dr. Fernández Yero, Director of the Immunoassay Center and President of TECNOSUMA International told us that because of the embargo **We** cannot buy near with quick delivery guaranteed, and thus must purchase from afar, with shipments taking two to three months or more to arrive. This then implies the need for bigger purchases, and therefore more money tied up in fewer items, larger storage facilities, greater refrigeration capacity, more money spent on electricity, and so on. Thus production becomes more costly in general."⁷⁹

Quality control is an important area of biotech production which has been adversely affected by the embargo. For example, as we noted in the chapter on Medical Exports, the only quality control gauges approved for use in Cuban laboratories are those made in the United States, according to specifications of the U.S. Pharmacopoeia (USP)⁸⁰

Such testing kits are used for determining the presence of impurities in domestically produced pharmaceuticals. Manufacturers such as Whittaker M.A Bioproducts of Plymouth, MA, are prohibited from selling kits such as the one they produce for determining endotoxins (LAL QCL-1000) in injectables, key for many Cuban productions, including interferons. Only after months of searching was Havana's Medications Research and Development Center (CIDEM) able to purchase the kit at significantly higher than list prices. -(See the section on the Pharmaceutical Industry.)*' CIGB, MEDICUBA and CIDEM experts state that European substitutes for this product do not meet Cuban biotechnology production standards.

In fact, quality control in general, according to Porto, involves equipment and products that often can only be obtained through U.S. manufacturers and especially if the medications to be produced are to be up to U.S. FDA standards. This was reiterated during our visit to the Finlay Institute.”

The Embargo and Biotech Bales

The express purpose of the CDA special provision on Cuban biotechnology was to stall Cuban success in exportation -of its -biotech products, offered at considerably lower prices than those of competitors from the industrialized nations, but nevertheless able to generate profits from sales abroad. Inasmuch as the embargo has increased domestic costs for research and production in the field, the industry must sell more or raise its prices to customers, in order to continue developing Cuba’s biotech capabilities and contribute to the national economy and to the health care budget in particular.

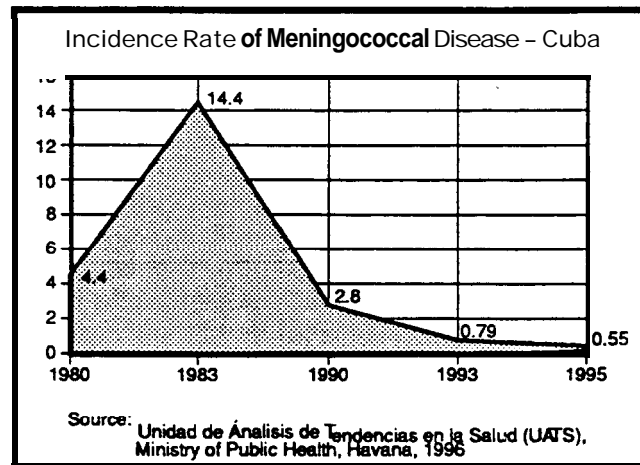
While it is unclear if Cuban products could successfully break into the highly monopolized arena of international pharmaceutical sales, it is certainly clear that the embargo prevents Cuban biotech products from being sold in the United States itself. This is significant for our study for two reasons. First, biotechnology is one field in which Cuba might have a chance to compete in the U.S. market, were it not for the embargo: “loopholes exist in U.S. patent law allowing a company to produce a biotechnology product offshore that is already patented by another company in the United States and to import it into the United States without infringing on patent rights. Unfortunately for Cuba, the trade embargo precludes Cuba’s entry into the U.S. market by this or any other means.”⁸³

And second, most profits in this field are either plowed back into vaccine and other research, or reinvested directly into the Cuban health care delivery system. Thus, an action such as the embargo, which artificially reduces earnings from this sector by prohibiting sales in the United States, effectively limits the development and use of Cuban biotechnology achievements for the Cuban population, and also further restricts resources available for health care in general.

The Embargo in Reverse: The Case of Meningitis B

Dr. Conception Campa and Dr. Gustavo Sierra led the team that developed the Cuban vaccine against meningococcal serogroups B and C, VA-MENGCC-BC. These scientists later formed the Finlay Institute, dedicated to vaccine research and production, which Dr. Campa heads today.

The vaccine, developed after the meningitis B epidemic of the early 1980s, is used in the prevention of serogroups B and C, and was first applied in 1987. The vaccine has been progressively administered throughout the country, and all Cuban children are now vaccinated in their first year as part of the National Immunization Program. All Cubans under the age of 30 have also received the vaccine. By 1995, the Public Health Ministry reported a 9% drop in the incidence of the disease since 1988, and credited this achievement to the vaccine.”



Source: *Unidad de Analisis de Tendencias en la Salud (UATS), Ministry of Public Health. Havana, 1996.*

Dr. Campa reports VA-MENGOC-BC has been 83-93% effective in Cuba, and has shown promising results in massive testing in Brazil. The vaccine is currently undergoing testing sponsored by the World Health Organization, an international umbrella which has also made CDC participation possible, despite the **embargo**.

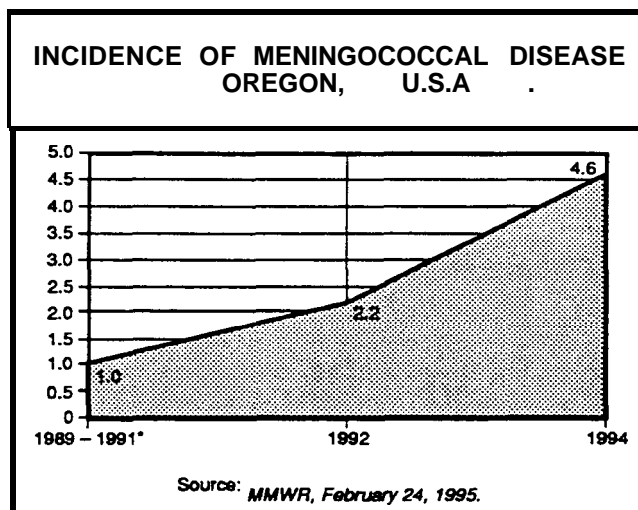
There are two other vaccines in earlier stages of development: One Norwegian and the other produced at Walter Reed Army Research Laboratory. A recent PAHO circular discusses the current status of meningococcal meningitis, paying particular attention to the rise in incidence of outbreaks and epidemics in many countries, and the research on effective vaccines. PAHO describes the most recent efficacy trials, and concludes:

The vaccine produced in Norway is still considered experimental. The vaccine produced at Walter Reed Army Research Laboratory continues to be in the research and development phase. The vaccine produced in Cuba has been registered in... [a number of] countries of Eastern Europe, Africa, and Latin America.

Based on the knowledge and published data **from** the efficacy trials conducted to date, it may be concluded that the vaccine produced in Cuba is efficacious in the aver-4-year-old group. In one of the trials, lower efficacy was observed among... [younger] children... However, these trial results are inconclusive and somewhat contradictory.⁸⁵

The U.S. Department of Health and Human Services/Public Health Service reports outbreaks of serogroup B meningococcal disease in a number of communities and states, along with increasing frequency nationwide since 1991 of serogroups B and C meningococcal disease. A recent CDC Prevention Guidelines publication also reported that community outbreaks of meningococcal disease are increasing, and that approximately 50-55% of all cases in the U.S. are caused by serogroup B, while serogroup C accounts for approximately 20-25% of all cases.⁸⁶

A 1995 CDC *"Morbidity and Mortality Weekly Report"* (MMWR) discusses the rising incidence of meningococcal disease in Oregon, stating that "meningococcal disease has increased substantially, more than doubling from 2.2 cases per 100,000 persons in 1992 to 4.6 per 100,000 in 1994-the highest incidence in Oregon since 1943."⁸⁷



Source: MMWR, February 24, 1995.

The report goes on to state:

This incidence was almost fivefold higher than recent estimates for the United States during 1989-91," with the majority of cases due to serogroup B meningitis (61%), followed by serogroup C disease (35%). "When compared with 1992 and 1993, the serogroup-specific incidence in 1994 was higher for both serogroups B and C... When compared with 1987-1992, the incidence of reported serogroup B disease in 1994 increased modestly among those aged <5 years, approximately 14-fold among those aged 15-19 years, and approximately fourfold among those aged >60 years.⁸⁸

Finally the report notes that, while no vaccine against serogroup B meningococcal disease is currently licensed in the United States:

Three outer-membrane protein-based serogroup B meningococcal vaccines employing two-dose regimens have been effective among older children and young adults in large clinical trials outside the United States [footnotes here reference studies on all three vaccines, including the Cuban one]; estimated efficacies ranged from 57% to 83%. The only vaccine available commercially is not licensed for use in the United States but has been used in some South American countries to control serogroup B meningococcal epidemics. In Sao Paulo, Brazil, approximately 2.4 million children aged three months to six years were vaccinated during 1989 and 1990, and the vaccine was estimated to be 74% effective in children aged 4-6 years [footnote indicates this is the Cuban vaccine]. Efforts to initiate studies in the United States to evaluate available vaccines under an investigational new drug application are in progress."

Here we encounter a compelling, albeit unusual, instance of the impact of the embargo in reverse: the embargo also erects obstacles against Cuban medical discoveries making their way into the United States for the benefit of the American people. It is difficult to imagine that either the Cuban pharmaceutical industry or any U.S. drug manufacturer would take on the multi-million-dollar cost of massive U.S. trials with prospects for future sales registering nil, as a result of embargo prohibitions. At the same time, it is also uncertain whether such trials themselves would be permissible under current U.S. law, and it would be wise to follow the results of efforts to begin studying the vaccines under an 'investigational new drug application,' specifically, whether this initiative includes the Cuban vaccine.

Several times over the past few years, after reports of meningitis outbreaks in the U.S., Dr. Campa has stated that the Finlay Institute was “absolutely willing” to make the vaccine available to communities in the U.S. on whatever basis specialists wished to use it. Besides Oregon and some counties in Washington State, there have been outbreaks in a number of other cities and towns across the U.S., including some of the southwestern states bordering Mexico. Finlay reports Mexican Health Authorities have approached Cuba about the vaccine because of their concern about spread of the infection from neighboring U.S. communities into Mexico.⁸⁹

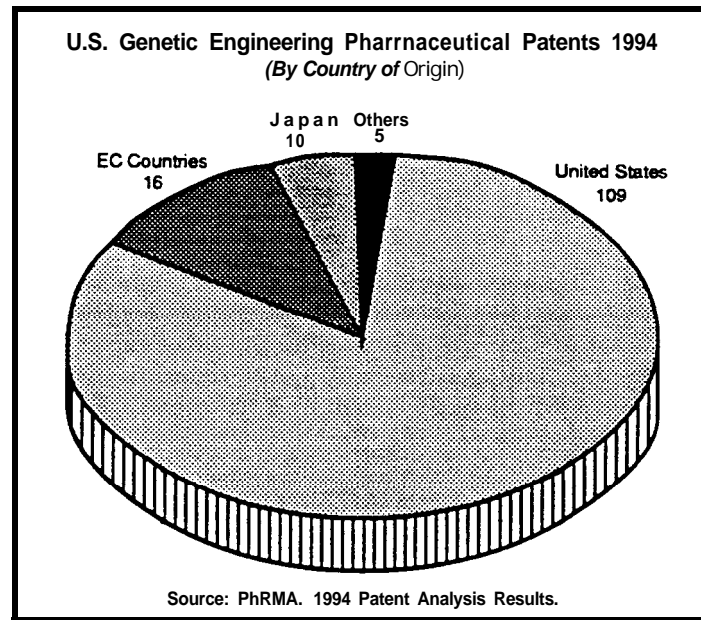
The Embargo and Lost Opportunities

The case of the meningitis B vaccine opens the door to another question made hypothetical by the embargo: the lost opportunities for collaboration and joint research between U.S. and Cuban scientists for the benefit of citizens in both countries, and indeed beyond. Dr. Manuel Limonta is director of the CIGB, the Cuban institution centering work on the HIV/AIDS vaccine. The team has openly expressed a willingness to cooperate with scientists from other countries in this effort, given the proportions of the AIDS pandemic. In particular, they have been open to working with U.S. entities.

In a study entitled *Report on the Capabilities of Cuba To Conduct HIV/AIDS Scientific and Clinical Research*, Drs. Stephen Ayres and Thomas Kerkerling of Virginia concluded that indeed Cuba was well-equipped to enter into joint endeavors in this important field: “The clinical expertise and necessary supporting infrastructure of laboratory, pharmacy and data collection exists in Cuba to carry out any degree of complex study in the area of HIV/AIDS clinical trials.⁹⁰ Other authors, such as Julie Feinsilver, point to the Cuban health infrastructure as a potential bonus for broad biotech research initiatives:

Biotechnology and genetic engineering in Cuba evolved from clinical medicine, which, from the outset... was a key area of development. By the **1980s** . . .with the first major investments in biotechnology and beginning studies of interferons... Cuba already had a national network of health-care delivery facilities, medical schools, research institutes, and pharmaceutical and medical products factories that could be put at the service of this incipient scientific sector.⁹¹

There can be no doubt, of course, that Cuban efforts in the field would potentially be enhanced scientifically and financially through possible partnerships with U.S. scientific institutions and research labs. Fourteen of the 18 AIDS vaccines now being developed are being generated in U.S. laboratories, coinciding with information gathered from a major European study of international markets which shows that for 22 years, U.S. producers have been responsible for 70% of new major global drugs in immunology. The same study extends its findings to biotechnology drugs involving recombinant-DNA techniques and monoclonal antibodies, revealing that the United States “is the originator of 76% of all ‘Major Global Drugs’ developed so far” in the field.⁹² A recent report from PhRMA confirms U.S. leadership in medical biotechnology and genetic engineering research today.⁹³



While our investigation confirms interest in both the United States and Cuba in exploring possibilities for joint research and clinical testing, the embargo specifically outlaws pursuit of such an enterprise. It is our conclusion that by so doing, U.S. policy not only limits Cuban research, development and production capabilities, **b**ut effectively prevents such collaborative initiatives from benefiting the health of persons in Cuba, the United States and elsewhere.

Appendix: Leading Medical Research & Development Facilities

Institute for Tropical Medicine

The Pedro Kouri Institute for Tropical Medicine (IPK) was founded in 1939 by Dr. Pedro Kouri, and was reorganized in 1982 under the direction of Professor Gustavo Kourí with an initial focus on improving the health status of developing countries and protecting the health of Cubans serving in the developing world, particularly in Africa and Latin America. The Institute played a key role in curbing the dengue epidemic of the early 1980s, and Cuba continues to be a leader in control of dengue and other tropical diseases throughout Latin America.

As early as 1982, four years before the first AIDS patient was identified in Cuba, the National Committee for AIDS Prevention was founded under the auspices of the IPK, and today the Institute is the country's premier facility for the clinical management of HIV/AIDS. (See section on AIDS.)

The IPK maintains clinical, diagnostic, inpatient and outpatient services for AIDS under the direction of Dr. Jorge Perez. Dr. Perez is vice-director of the IPK and its chief AIDS clinician, as well as the Director of the AIDS Sanatorium in Santiago de las Vegas, Havana. IPK researchers and physicians, in cooperation with the National Reference Laboratory for HIV, the Finlay Institute and the Center for Genetic Engineering and Biotechnology (CIGB), are currently involved in an HIV vaccine project.

Center for Genetic Engineering and Biotechnology

Organized in 1986, the CIGB is directed by Dr. Manuel Limonta, and occupies several large buildings located over an extensive area in western Havana. More than 800 people work there, the majority being scientists and graduate student researchers. Both pre-doctoral and post-doctoral opportunities are available, making this an important teaching center. The CIGB contains divisions for vaccine development, pharmaceutical development, immunotechnology, industrial biotechnology, animal and plant biotechnology, protein structure and expression, basic biological research, the production of recombinant molecules, quality control, and clinical trials. A new addition in 1995 was opened to produce monoclonal antibodies for diagnostic and human therapeutic purposes. The CIGB also oversees two establishments in other parts of Cuba: a center for agricultural research and another for veterinary development.

CIGB's first export product was alpha interferon which has been widely used in Cuba for the treatment of HIV infection, hepatitis B, and some cancers among other conditions. Other products include various interferon preparations (injection, cream, eyedrops) using both human alpha leukocyte interferon and the alpha 2b recombinant interferon; a recombinant hepatitis B vaccine; epidermal growth factor; human transfer factor; and recombinant streptokinase. Exports to countries in Latin America, Asia, Central Europe and Africa are marketed under the firm name HEBER BIOTEC.⁹⁴ There are various vaccine projects in the pipeline, including the HIV vaccine project mentioned above and work on effective vaccines against cholera and dengue.

The Finlay Institute

The Finlay Institute was founded in 1991 to center vaccine research, development and production in Cuba. With 850 staff the Institute has three research areas completely dedicated to vaccines, an

area for sera and diagnostics and another for basic vaccinology, infectology, molecular biology and immunology. It also has four production plants for bacterial and viral vaccines and high-tech sub-units vaccines, a quality control center and a specialized reference center on vaccines and infectology.⁹⁵

The Research and Development portfolio of the Finlay Institute includes: development of a Cuban vaccine against cholera, a new generation of multiple antimeningococcal vaccines, polyvalent antimeningococcal-antohaemophilus vaccine and others. A trivalent anti-leptospirosis vaccine is now being produced, and the cholera vaccine is scheduled to begin trials in the summer of 1996.⁹⁶

National Immunoassay Center

See section on Diagnostic Testing and Protection of the Blood Supply.

NOTES

- ¹Ministry of Science, Technology and the Environment, Centro de Intercambio Automatizado de Informacion, *Biotech* data base, 1995.
- ²Pharmaceutical Industry and Biotechnology," by Mara Roque Gonzalez in *Business Tips on Cuba*, March 1995.
- ³Cuban Biotechnology: The Strategic-Success-and Commercial Limits of a First World Approach to Development," by Julie M. Feinsilver, in *Biotechnology in Latin America*, 1995, p. 103, and her footnote 31 on p. 122.
- ⁴Harvey Bialy, "Cuba's Biotechnology and the United States Embargo," in *Bio /Technology*, Vol. 13, March 1995.
- ⁵H. Bialy, *Ibid*.
- ⁶Dr. Rosa Elena Simeón, in *Prensa Latina*, Havana, April 12, 1996.
- ⁷Cuban Democracy Act of 1992, as cited by Krinsky et al, *United States Economic Measures*, p. 150.
- ⁸Feinsilver, 'Cuban Biotechnology,' p. 107.
- ⁹CIGB and Heberfarma, "Line of Pharmaceutical Products," 1993-94, p. 16.
- ¹⁰Interview with Dr. Jorge Perez, Director, National AIDS Program and Director of the Havana AIDS Sanatorium, May 21, 1996.
- ¹¹*The New York Times*, Aug. 16, 1990, p. C-1.
- ¹²CIGB and Heberfarma, "Line of Pharmaceutical Products", 1993-94, p. 16.
- ¹³*Newswatch* March 1986, "Cuban-made Interferon Reaches Out for World Markets."
- ¹⁴*The New York Times*, Aug. 16., 1990, p. C-1; and Julie M. Feinsilver interview with Harvey Bialy, February 1991, in *Biotechnology in Latin America*, 1995, Chapter 5, p. 101.
- ¹⁵Feinsilver, p. 108.
- ¹⁶Statements by Dr. Manuel Limonta, Director, CIGB, June 12, 1996.
- ¹⁷Incidencia de hepatitis *segun* tipo", *Anuario Estadfstico del Ministerio de Salud Pública*, 1994, Havana, p. 68.
- ¹⁸*Impacto del Programa Nacional de Inmunización*, Ministry of Public Health, Havana, pp. 5-6.
- ¹⁹*Indicaciones Generates del MINSAP para 1996*, Jan. 25, 1996, p. 90.
- ²⁰Cuba: Inmunizarin contra hepatitis-b a menores de 20 años," IPS and *Prensa Latina News Service*, Havana, Nov. 13, 1995; and remarks by Dr. M. Limonta, Director, CIGB, Feb. 27, 1995.
- ²¹WHO as quoted in "Iniciarán en Cuba campaña de vacunación contra la hepatitis-b," *Prensa Latina News Service*, Havana, Jan. 11, 1996.
- ²²Interview with Catherine Ribas, the Finlay Institute, June 6, 1996.
- ²³Interview with Dr. Orlando Rucabado, Chief of Coronary Intensive Care at the Institute of Cardiology, Havana, June 5, 1996; and Center for Genetic Engineering and Biotechnology and Heber Biotec, S.A., 'Line of Pharmaceutical Products,' 1993-94, p. 25.
- ²⁴Interview with Dr. Rucabado, June 5, 1996.
- ²⁵~~Center~~ Center for Genetic Engineering and Biotechnology, "Line of Pharmaceutical Products," 1993-94, p. 23.
- ²⁶**Incidence** and results provided by the Finlay Institute, Havana, 1996.
- ²⁷*See Impacto del Programa Nacional de Inmunización*, Ministry of Public Health, Havana, p. 5; and *Sindromes neurológicos infecciosos*, Unidad de Analisis de Tendencias de la Salud (UATS), Ministry of Public Health, Havana, March, 1996, pp. 1-2.
- ²⁸*Sindromes*, p. 1.
- "Quote in "Registrada en diez países vacuna antimeningococcica cubana," Havana, *Prensa Latina News Service*, Nov. 30, 1995.
- ³⁰Interview with C. Ribas, the Finlay Institute, Havana, June 6, 1996.
- ³¹Vaccines Against Meningococcal Meningitis: Current Status," 1994 *PAHO Report* prepared collaboratively by the Expanded Program on Immunization, Special Program on Maternal and Child Health and Population, the Division of Communicable Disease Prevention and Control, and the Division of Health and Development of the Pan American Health Organization.

³²PPG: Cuba's Cholesterol Reducer," by Gail Reed, Cuba *Update*, Fall 1992.

³³RBradley and E. Rim, "Loosening the Reins: Autonomy Boosts Cuban Medical Industry." in *Harvard International Review*, Fall 1994, p. 66.

³⁴EFE, Geneva, May 19, 1996, "Anuncia la OMS crisis infecciosa mundial" in *Granma*, May 20, 1996.

³⁵Cuban trials follow the U.S. Food and Drug Administration guidelines and Phase I-IV testing.

³⁶Leptospirosis" National Epidemiology Department, Ministry of Public Health, Havana, February 15,-1996, p. 2.

³⁷Interview with Dr. Manuel Santín, National Epidemiology Director, Ministry of Public Health, Havana, Dec. 12, 1995; and "Leptospirosis", National Epidemiology Dept., Ministry of Public Health, Havana, Feb. 15,1996.

³⁸Interview with Dr. M. Santín, Dec. 12,1995.

³⁹Situación del cólera en las *Américas*, *VacciMonitor*, February 1996, pp. 6-7.

⁴⁰Hacia el desarrollo de una vacuna eficaz contra el cólera," by Luis Garcia Imia and Jorge Benítez Robles, *Vu&Monitor*, February 1996, pp. 2-6.

"Interview with C. Ribas, the Finlay Institute, June 6,1996.

⁴²**VACUNE!**, Health, World Health Day pamphlet, 1995, p. 23.

⁴³Interview with Dr. Miguel Angel Galindo, Director, National Immunization Program, Ministry of Public Health, Nov. 27, 1995.

⁴⁴*Indicaciones Generaks del MINSAP para 1996*, Jan. 25,1996, p. 96.

⁴⁵Interview with Dr. Rafael Figueredo Gonzalez, Vectors Department, Epidemiology, MINSAP, Havana, January 24, 1995; and *Indicaciones Generales del MINSAP para 1996* "Programa de Vigilancia y Lucha Anti-Vectorial," p. 97.

⁴⁶Science at the Service of Health," The Finlay Institute, Havana, 1994, p. 5.

⁴⁷Dr. Gustavo Sierra quoted in 'Cuba trabaja en mas de veinte proyectos de vacunas,' Dec. 16, 1995, Prensa Latina News Service, Havana.

⁴⁸Dr. Jorge Perez, Director, National AIDS Sanatorium, December, 1995.

⁴⁹*AIDS: Shared Rights, Shared Responsibilities*, a pamphlet for World Aids Day, 1995, published by the American Association for World Health, p. 17.

⁵⁰Facts About AIDS" published by PhRMA, Dec. 19,1995.

⁵¹Interview with Dr. J. Perez, 1996.

⁵²Comments by Dr. Manuel Limonta to Gail Reed, June 13,1996.

⁵³Interview with Dr. J. Perez, May 21,1996.

⁵⁴Interview with Federico Ramos, Havana AIDS Sanatorium, May 23, 1996.

⁵⁵*Granma*, Oct. 17, 1991: "Resolución Sobre el Desarrollo Económico del País."

⁵⁶Presenta Cuba logros científicos en industria biotecnológica," Prensa Latina News Service, Havana, Nov. 15, 1995.

⁵⁷"Biotechnolgy in Cuba: Tackling Third-World Problems with Front-line Technology," by Clare Robinson in *Trends in Biotechnology*, March 1993, Vol. 11, p. 80.

⁵⁸Interview with Dr. Elio Jiménez, Institute for Plant Biotechnology, Central University of Las Villas, Santa Clara, June 11, 1996.

⁵⁹Interviews with Dr. José Luis Fernández Yero, President of TECNOSUMA International and Director of the Centro de Inmunoensayo, Havana, October 17, 1995; and Gilberto Sotolongo Aguilar, Director for Scientific Information, the Finlay Institute, Havana, November 17, 1995.

⁶⁰Interview with G. Sotolongo, Finlay Institute, Havana, November 17, 1995.

⁶¹Ibid.

⁶²Letter to the Finlay Institute from Jorge H. Fernández-Garza, Latin American Sales Manager, SWETS Subscription Service, Lisse, Holland, December 22, 1992 [Translated from the Spanish.]; and our own conversations with ISI representatives confirmed that they are unwilling to lease the *Index* to Cuba, citing U.S. embargo restrictions.

⁶³Interview with Dr. J. Perez, Feb. 2,1996.

⁶⁴CIGB International Relations Department, March 1996.

⁶⁵Interview with G. Sotolongo, Nov. 17, 1995.

- ⁶⁶**Interview** with Juan Carlos Leyva, Finlay Institute, Havana, Nov. 17, 1995.
- ⁶⁷**Letter** dated January 21, 1993 to Mr. Corbelo of MEDICUBA from Elisabeth Berger, Fluka Chemical Company, Ltd., Switzerland.
- "Interview with Dr. Jose de la Fuente, CIGB, Havana, December 14, 1995.
- ⁶⁸**A** similar problem occurred with IBF of France, which sold biological reagents to Cuban biotech plants in 1991-93, and was subsequently taken over by the U.S. firm Separcor, according to information provided to the authors by the Beterá Laboratories in Havana, June 26, 1996.
- ⁶⁹**Ibid.**
- ⁷¹**Interview** with Dr. J. Fernández Yero, Immunoassay Center, Havana, October 17, 1995.
- ⁷²**Interview** with J. Carlos Leyva, November 17, 1995.
- ⁷³**Ibid.**
- "Interview with Dr. E. Jiménez, June 11, 1996.
- ⁷⁶**Interview** with Dr. J. de la Fuente, Dec. 14, 1995.
- ⁷⁶**Interview** with Dr. Concepción Campa, Havana, November 1995.
- ⁷⁷**Interview** with Dr. E. Jiménez, June 11, 1996.
- "Interview with Rolando Díaz, MEDICUBA, Havana, Sept. 6, 1995.
- ⁷⁸**Interview** with Dr. J. Fernández Yero, Oct. 17, 1995.
- ⁸⁰**Interview** with Nancy Blanco, MEDICUBA, Havana, September 7, 1995.
- "Interview with Marlene Porto, Director of the Medications Research and Development Center, October 2, 1995.
- ⁸²**Interview** with M. Porto, Oct. 2, 1995; and interviews with specialists from the Finlay Institute during on-site visits, November 1995.
- ⁸³**"Biotechnology,"** *Healing the Masses*, by Julie Feinsilver, University of California Press, 1993, p. 154.
- ⁸⁴**Impacto del Programa Nacional de Inmunización**, Ministry of Public Health, Havana, 1996.
- ⁸⁵**1994 PAHO Report**, *supra* note 31.
- ⁸⁶**CDC Prevention Guidelines**, 1995 and *Morbidity and Mortality Weekly Report (MMWR)*, Vol 48, No. 14., April 1996.
- ⁸⁷**CDC Morbidity and Mortality Weekly Report (MMWR)** "Serogroup B Meningococcal Disease-Oregon, 1994," February 24, 1995, Vol. 44, No. 7.
- ⁸⁸**Ibid.**
- ⁸⁹**Interviews** with G. Sotolongo and C. Ribas, Finlay Institute, Havana, November 17, 1995.
- ⁹⁰ **Report on the Capabilities of Cuba to Conduct HIV/AIDS Scientific & Clinical Research** by Stephen M. Ayres, MD, Dean Emeritus and Director of International Health Programs, Medical College of Virginia/Virginia Commonwealth University (MCV/VCU); and Thomas M. Kerkering, MD, Professor of Medicine, MCV/VCU and Principal Investigator, Richmond AIDS Consortium, March 6, 1995.
- ⁹¹**Julie M. Feinsilver in Biotechnology in Latin America**, 1995; Chapter 5: "Cuban Biotechnology: The Strategic Success and Commercial Limits of a First World Approach to Development," p. 97.
- ⁹²**Price Regulation and Pharmaceutical Research**, by Heinz Redwood, Oldwicks Press, Suffolk, GB, 1993, p. 21.
- ⁹³**See Biotechnology Medicines in Development**, PhRMA, March 30, 1995; and *1994 Patent Analysis Results: U.S. Pharmaceutical Industry Continues Leadership on Biotechnology Research*, March 30, 1995.
- ⁹⁴**Ayres/Kerkering**, *supra* note 90; *Business Tips on Cuba*, March 1995, p. 23; and Heber Biotec, S.A *Heberfarma* pharmaceutical products catalogue, 1993-94.
- ⁹⁵**Interview** with C. Ribas, Nov. 17, 1995.
- ⁹⁶**Interview** with C. Ribas, June 6, 1996; and from *the Research and Development Portfolio* of the Finlay Institute

As a consequence of the economic crisis of the nineties and reduced funds available for imports of all kinds, MEDICURA severely restricted medical purchases abroad. (See chapter on Medical Exports to Cuba.) Of the 1,297 medicines available in Cuba in 1991, only 889 were still circulating by 1995. At the same time, the Ministry of Public Health tightened the reins on distribution of medications and prescriptions, limiting use in many cases to patients in critical or chronic need. Of the 899 medications on the national list at the end of 1995, 94 were designated as Absolute Priority (P-I). However, there were times when assuring adequate supplies of even these drugs was problematic, because of hard currency shortages: according to the National Pharmaceutical Supply Company (ENSUFARMA), at one point the country had just enough insulin for one month.

In such a crisis, boosting domestic pharmaceutical production became not only desirable but imperative for keeping a minimum of drugs on the shelves. On first analysis, industry experts decided to attempt production of 464 of the 889 drugs used in the country. In 1995, plants were turning out 119 of these, while another 49 were awaiting factory equipment installation. These 49 plus an additional 38 were undergoing final testing for approval, 67 were in earlier stages of research, and 80 had been discounted as unfeasible. However, Marlene Porto, Director of the Center for Medication Research and Development (CIDEM), explains 'that research has yet to begin on the remaining 111 designated for national production, primarily because Cuban importers have not been able to purchase the necessary active ingredients.

Research, development and production of pharmaceuticals have been hampered by the same economic constraints that reduced hard currency for health care expenditures from \$227.3 in 1989 to \$74.9 in 1994.' Despite this and other obstacles imposed by the embargo, from 1991 to 1996, the Cuban pharmaceutical industry saved \$45 million for the national health care budget by substituting imports with national production.*

The US. Embargo and Cuban Pharmaceutical Production

While changes in U.S. embargo law over three decades have periodically allowed Cuba to legally import finished medications of U.S. manufacture, embargo restrictions have more effectively prevented Cuba from importing items for domestic pharmaceutical production from U.S. manufacturers or distributors.³ This prohibition now includes active ingredients and other raw materials, reagents, and quality control indicators. It also extends to any laboratory or production equipment built with U.S. technology, accessories or parts; and prevents purchase of U.S.-manufactured packaging for medications. Further CDA provisions fully apply, banning U.S. subsidiary exports of these items to Cuba and barring ships from U.S. ports for six months after they make deliveries to Cuba from any country.

It is our finding that these U.S. embargo restrictions have reduced the medicines available to the Cuban population and negatively impacted the process of import substitution. Specifically:

The embargo adds costs to the production process. Marlene Porto, Director of CIDEM, says her center's market studies show that, on average, Cuba can produce a medication at one third the price of importing the finished product, whatever its country of origin. She argues that this ratio would be more favorable, and thus more medications could be produced for the same investment, were it not for the inflationary pressure the embargo exerts on the cost of production.

She says that in her experience, the price paid by Cuba for equipment, raw materials and packaging is increased by the effects of the embargo, since the industry cannot import from the closer and sometimes more competitive US. market. Moreover, some ingredients are manufactured only by U.S. companies, putting them out-of-reach for Cuba except at higher risk prices offered by third-country wholesalers. The Cuban Democracy Act limits bulk maritime shipping to Cuba of items such as packaging and the powders needed for tablets, and raises the cost

of bringing these items to the island (as we have seen throughout this study).

We find that these observations are correct, and our research reveals additional embargo-specific costs added to production.

Shipping charges are a main factor for this industry, which must import large quantities of excipients (such as talc), glass bottles, jars and ampules, and other packaging materials. The Reynaldo Gutierrez Plant in Havana, which produces some 190 medications, requires 20 tons of excipients every-month-for its line of tablets alone. Most of these are imported from China, with charters running at some \$600,000 per ship. It is estimated that for imports from Asia, up to 30% of the total bill is tied up in freight charges; 10% if the supplier is in Europe; but the cost would be only 5% if the island were able to purchase from U.S. manufacturers.'

For a number of active ingredients, other raw materials and packaging items, the United States also offers a more competitive market. The following table illustrates what MEDICUBA could have saved for other purchases, had it not been barred from U.S. imports of the active ingredients for 24 domestically produced medications.⁵

Price Comparison: Active Ingredients for Pharmaceuticals'				
Item	Quantity (kg.)	Price Paid (Europe)	Tilgrex Quote (USA)	Difference Overpaid (%)
Amikacin Sulfate	5	6,249.15	4,275.-	46
Antipyrine BPC 73	100	1,660.-	1,471.-	13
Atenolol	600	58,800.-	54,720.-	7
Chloramphenicol base	7,000	490,000.-	303,240.-	62
Chloramphenicol Palmitate	200	12,122.-	11,400.-	6
Cimetidine	5,350	267,500.-	237,861.-	12
Diiodohydroxyquin	200	5,142.-	4,788.-	7
Disulfiram	50	1,175.-	900.50	30
Efedrim Gel	1,775	107,387.50	95,104.50	13
Erythromycin Stearate	2,700	260,442.-	190,836.-	36
Griseofulvin microsize	10	747.30	627.-	19
Haloperidol	15	8,850.-	8,379.-	6
Ibuprofen	25	589.25	427.50	38
Indomethacin	3,450	91,425.-	69,207.-	32
Kanamycin Sulfate sterile	300	27,096.-	20,007.-	35
Manitol	5,400	22,140.-	20,304.-	9
Mebendazole	275	12,124.75	10,345.50	17
Methocarbamol	1,175	32,900.-	27,459.75	20
Metronidazol Base	24,175	444,820.-	330,714.-	35
Nifedipine	100	11,167.-	6,156.-	81
Prednisone	132	144,608.64	117,374.40	23
Promazine HCl	60	4,875.60	2,975.40	64
Sulfamethoxazole	39,700	734,450.-	441,464.-	66
Triethanolamine	112	440.16	287.84	53
Total	92,909	2,746,711.35	1,960,324.39	40%

⁵Chart compares actual prices paid by MEDICUBA to European exporters with prices quoted by Tilgrex International Export, Inc., Miami, FL, 1993. Documents provided by MEDICUBA.

The embargo nudges production costs up another notch, since warehouse space and expense must be multiplied. This, since faraway ports and delayed cargo arrivals (complicated by CDA-related difficulties in finding vessels willing to travel to Cuba) force the industry to import bulk

shipments of products to last several months or even a year. As a result, ENSUFARMA expanded its warehouse space to 36 provincial warehouses and seven central warehouses, with 9,000 square meters for raw materials alone.⁶

It should be remembered that these products must be kept under carefully controlled conditions, both en route to Cuba and once stored on the island, and the longer they are in transit or warehoused, the more the industry runs the risk of spoilage and consequent outlays for replacement. More expenditures are also needed to guarantee refrigeration when necessary. It is clear that if smaller shipments could be made from U.S. ports, not only would freight charges be significantly reduced, but these additional costs would become savings as well.

Inflated embargo-related expenditures can influence decisions on which medications to import, and which to produce domestically, obliging the pharmaceutical industry to invest in lines of drugs that, if not for the embargo, might be purchased from U.S. manufacturers for less than the cost of production in Cuba. According to information provided by CIDEM, an end to the embargo might well offer Cuban importers this choice for such medications as:

General anesthetic:	Sodium Thiopental ("Pentothal", Abbott Laboratories)
Antiarrhythmic:	Quinidine (Quinidine Sulfate, Lederle)
Antibiotic:	Sodium cefaxoline ("Kefsol", Eli Lilly)
Antibiotic:	Ciprofloxacin ("Ciproxin", Bayer)
Antibiotic:	Chlorophenicol Succinate ("Chloromycetin", Parke Davis)
Antibiotic:	Vancomycin ("Vancocin", Eli Lilly)
Antimycotic:	Anfotericin B (Fungizone", Bristol-Myers Squibb)
Antidiarrheal:	Difenoxilate and atropine ("Lomotil", Searle)
Vasopressor used in shock:	Dobutamine HCl ("Dobutrex", Eli Lilly)

Source: CIDEM, Oct. 4, 1995.

The embargo - - timely production of quality pharmaceuticals as a result of the combined effects of sheer unavailability, sudden cutoffs in supplies, inflated prices and denial of U.S. government export licenses.

The case of key equipment in Cuban pharmaceutical plants once provided by Pharmacia of Sweden reveals the vulnerability of this industry to the embargo. As reviewed in earlier chapters, Pharmacia merged with Upjohn, of Kalamazoo, MI, in August, 1995. A number of contracts with Havana were left unfulfilled, and from that time forward, Cuban importers have not been able to purchase new Pharmacia equipment, parts, accessories or reagents used in the precision units. Given current economic constraints, national replacement of this entire line of highly technical and costly products with those of another company is for the moment an unfeasible alternative.

Medication production and quality control have been seriously affected by the merger and subsequent ban on sales to Cuba. The industry is dependent on the functioning of HPLC (High Performance Liquid Chromatography) units, as well as gas and other chromatography equipment purchased from Pharmacia-LKB, plus the reagents that match. In particular, at the Reynaldo Gutierrez Pharmaceutical Plant, which turns out 130-170 million tablets each month, both the HPLC and the gas chromatograph from Pharmacia have spent several months broken and without replacement parts, as Cuban importers have been unable to obtain these from any source since the merger.'

According to Haydee Cela, Deputy Director for Quality Control at Reynaldo Gutierrez, the HPLC is vital to certify the purity of raw materials, to guarantee the correct proportions of the active

ingredient in the final product, and to determine a medication's "bioavailability"-the time it takes to dissolve and pass into the bloodstream. Cuban quality standards are guided by the USP (U.S. Pharmacopoeia), and Cela notes that its latest edition (XXIII) requires that "nearly all medications in tablet form be rigorously tested using HPLC equipment." She says that the other Pharmacia unit waiting for parts-a gas chromatograph-is also critical to quality control.

The only functioning HPLCs in the pharmaceutical *sector* are at CIDEM, which has now assumed quality control testing for 15 pharmaceutical plants. 'Without our approval,' says Noelio Flores of CIDEM, 'The medications 'cannot- be released for use.'" He describes double -and triple shifts at CIDEM to keep the units working round the clock, and a special bus service organized to ferry lab workers to and from home.'

Nevertheless, the burden is too much. There are logical bottlenecks and serious delays in medications reaching pharmacies and patients. Cela states that when her plant's HPLC is functioning, testing the required number of samples from each lot is completed the same day tablets are turned out, and thus the seven to 10-day production cycle is respected. However, in the ten months that she has had to send the samples out to CIDEM, HPLC trials have added as much as 15 to 20 days to the production process. Hence, if warehouses should be replenished on a monthly basis with a particular medication, now they are receiving new stock every 45 days.

The resulting gaps in availability are obvious, and have a negative cumulative effect on supplies, already lagging behind demand because of the more general economic limitations facing the industry. The Reynaldo Gutierrez Pharmaceutical Plant is experiencing delays in production and subsequent shortfalls in annual deliveries of most of its medications, among them the following:

CUBAN MEDICATIONS AFFECTED BY PHARMACIA-UPJOHN MERGER		
ITEM	USE	ANNUAL PRODUCTION
Medrone Aminor Etinor	Contraceptive pills	120 million
Magnesium Valproate	Anti-convulsive	8-9 million
Nitroglycerin	Cardiotonic	20 million
Ranitidine HCl	Anti-ulcer	6 million
Trimethoprim, Sulfamethoxazole	Anti-infective	60 million
Prenatal vitamins	Pregnancy vitamin	120 million
Mercaptopurine	Anti-cancer	30,000
Levo Thyroxine Sodium and Lio Thyronine Sodium	Thyroid Hormone Combinations	2 million*
Thyronine	Thyroid hormone	2-3 million*
Levodopa with Benserazida	Anti-Parkinson's	20 million*

'In the case of the hormones. the plant has had to wait up to on8 month for HPLC trials to finish, since these are microdoses, and require special treatment. In the case of Levodopa, 20-day delays are common, also because of specific testing prescribed. Source: Reynaldo Gutierrez Quality Control Division, July 4, 1996.

Cela describes the tensions created by the delays: "I send my chemist to CIDEM every day to check

which lots can be shipped to the warehouses. Some days, we are lucky. Others, we have to take our place in line behind all the injectables, which are logically given priority. It is the patients in either case who are left waiting."⁹

The Carlos J. Finlay Products Plant has also suffered from the breakdown of its HPLC, idle for lack of parts since February, 1996. Finlay produces diagnostic kits for syphilis, leprosy, and glucose tests. And most importantly, it produces the standards by which each of Cuba's clinical laboratories check the validity of their results. In other words, it is in charge of *quality control for all laboratory testing in the country*. However, these standards must in turn be validated with CIDEM's HPLCs, and slowing this process means that laboratory inspections required every three months are now made less frequently, and labwork is more subject to errors in all hospitals and clinics. And finally, this plant manufactures key anesthesia for surgery, a production threatened by the inability to procure parts for the HPLC. "Certain surgeries could be stopped, if at any time we cannot process the anesthesia with our HPLC here at CIDEM," observes Flores."

In addition to the most recent difficulties with Pharmacia, the production of injectables and sera has already felt the impact of the U.S. embargo in other areas. As we noted in the chapter on Medical Exports, two firms which sell aluminum seals and rubber stoppers (Gummi and Schubert Seals of Denmark respectively) reported they were blocked from exporting to Cuba, because they are U.S. subsidiaries. In the case of Gummi, a buyout suddenly shut off supplies. In the case of Shubert, by September of 1995, the amounts contracted in 1994 had not arrived, and MEDICUBA was forced to request that the bank cancel its letter of credit, to begin to look for another supplier. All this shut down production for several months.

Equipment used for producing injectables was also idled when Cuban importers could not replace filtration cartridges used in the system. The Swedish manufacturer, Alfa Laval, explained that they were unable to obtain a license from the U.S. government for export of the 100% U.S.-origin part.

Production of warfarin sodium, one of the most commonly used anti-coagulants, was nearly stalled due to a U.S. buyout: in this case, when DuPont Merck of Wilmington, DE, purchased the rights to the warfarin sodium technology from Chemoswed AR of Sweden (Cuba's supplier of the medication's active ingredient). This was the reason cited for an April 1995 refusal by DuPont to sell its product to MEDICUBA. Cuban importers finally received a quote of \$456.90 per kilo for importation through Germany, stipulating that a U.S. government license would first have to be sought authorizing sale and shipment. However, aware that no licenses had been granted for such pharmaceutical raw materials, and facing the prospect of stopping production altogether, MEDICUBA made an unlicensed purchase through an intermediary at \$1,204.13 per kilo—a price inflated 262% by the embargo, not to mention what might have been saved if imported directly from DuPont in the USA. These obstacles delayed procurement by six months." Since that time, warfarin sodium (active ingredient) purchases from other sources have not measured up to Cuban quality standards, according to Rosa Fuentes of MEDICUBA, so the search for a regular supplier continues.¹²

The U.S. embargo blocks ready access to key quality control gauges and standards for the entire pharmaceutical industry, making this process more difficult, time-consuming, costly and also less reliable. In addition to the Pharmacia problems **described** above, the standards and stability of quality control procedures have been threatened by the U.S. embargo. As mentioned above, Cuban pharmaceutical production norms follow the U.S. Pharmacopoeia, and rely on specific instruments and software.

An example is the Liquidborne Particle Counter, manufactured by Climet Instruments Co. of Redlands, CA, a firm which specializes in this equipment. The Counter (purchased through intermediaries, and including a Russell Sensor, Sampler, Particle Counter, and The Reporter"

and "The Calibrator" software programs) is essential to guarantee the correct number and size of particles suspended in injectables, and to measure how well these dissolve. It was purchased by CIDEM in 1992, and its Sensor has since broken and been repaired by Cuban engineers. However, the instrument must now be re-calibrated and its accuracy re-tested before it can be used. This, in turn, requires the AC Fine Test Dust (ACFTD) Contaminant, produced only by AC Spark Plug (owned by General Motors of Flint, MI). Cuban importers have approached several AC-associated firms abroad, with no answer as of June, 1996.¹³

Noelio Flores of CIDEM notes that with the Counter, testing the three samples per lot required for each injectable solution (in addition to eyewashes and other liquids) is completed in five minutes. However, manually, it cannot be done in less than an hour and relies on a microscope count, more prone to human error. CIDEM labs have no choice until the Counter-itself purchased at nearly \$27,000-can be reintegrated into the process. Thus, a critical aspect of quality control for the country's entire production of injectables is currently endangered by the U.S. embargo."

The U.S.-manufactured standards gauges prescribed by the USP are difficult for Cuba to obtain, again affecting quality control efforts, since these are the only ones approved for use in Cuban laboratories. MEDICUBA's Rosa Fuentes referred to the case of gauges to test the purity of raw materials (active ingredients) in the pharmaceutical industry. She reports that purchase does not present a problem when wholesalers have the gauges in stock. However, if not, Cuba is simply forced to wait until they come in, since MEDICUBA cannot put these items on special order or buy directly from U.S. producers. The result is delays in arrival.

A similar problem has occurred with gauges to test for toxic substances in injectables, which of necessity must be imported through intermediaries. Both Porto of CIDEM and Diana Guzman at MEDICUBA cited delays this has caused in obtaining such tests as the LAL QCL-1000 for determining endotoxins-a test produced by Whittaker Bioproducts of Plymouth, MA Our research also indicates that MEDICUBA paid well above market prices for the kits when finally obtained: for the 120-test kit, \$556.60 (as compared to \$253 quoted to us by Whittaker as the retail price for one kit); and \$902.00 for the 300-test kit (as compared to \$410.00 retail for one kit). Thus, guaranteeing the purity of injectables has also become vulnerable to the U.S. embargo and its implications.¹⁵

Finally, purchases of pharmaceutical literature imperative to quality control have been subjected to embargo restrictions which cut off banking relations between the United States and Cuba, banning Cuba from using the U.S. dollar for international transactions. So, while scientific literature is presumably available directly to Cuba under the 1988 Berman Amendment, practically speaking, Cuban institutions must subscribe through agencies in third countries. The result is more expensive, often with delays in arrival. This is the case of four U.S. publications which CIDEM's Porto considers essential to her Center:

Publication	U.S. Subscription	SWETS Subscription
Drug Development and Industry Pharmacy	\$385.00	\$639.25
Journal of Pharmaceutical Science	\$354.00	\$482.11
Journal of Pharmacy and Pharmacology	\$450.00	\$593.98
U.S. Pharmacopoeia XXIII Edition	\$517.50	\$656.27

Source: CIDEM, 1995 S WETS is the Dutch firm S WETS ZEITLENGER.

The US embargo also acts as a barrier to the development of the pharmaceutical industry and import substitutions. Chemotherapy drug production offers an example of the hurdles throw

up by the U.S. embargo to the expansion of Cuba's pharmaceutical industry into new lines of manufacture. For example, the same obstacles posed by the embargo which have held up quality control testing and production of injectables are now blocking attempts to produce chemotherapy medications.

A host of new embargo-related barriers appears as the industry gears up facilities for these drugs, including methotrexate, vincristine sulfate (the first used in breast cancer, and both used against childhood leukemia), actinomycin D, cisplatin, vinblastine sulfate, and bleomycin sulfate. Such was the case when MEDICUBA attempted to purchase a freeze dryer from the British firm Edwards for CIDEM, equipment which dehydrates these injectable powders to ensure their stability over time. However, since the model needed by Cuba (Lyoflex 16) is only produced in Edwards' U.S. plant, prices could not be obtained from the company, according to Porto of CIDEM. This has held up trial runs for several months, as CIDEM searches for an alternative which offers similar standards of quality.

Trials on methotrexate were further delayed when the U.S. government refused to issue an export license for one pound of the active ingredient, which Cuba attempted to purchase from Pfizer's German subsidiary Heinrich Mack Nachf. in 1993. By 1995, MEDICUBA's German representatives simply stated that the company "no longer sells to Cuba."¹⁶

Thus, the U.S. embargo has been directly responsible for delays in full-scale production of chemotherapy drugs for cancer patients, which are now in chronic short supply (see the section on Oncology), mainly because of the high cost of importing the finished products. According to Porto of CIDEM, chemotherapy agents rank with insulin as the number one priorities for new production.

One last observation is that the embargo also prevents Cuban pharmaceutical plants from producing U.S.-patented drugs under license from the U.S. manufacturer, since Cuba cannot legally pay for such permission, a point of interest since Cuba signed the international patent treaty early in 1996.

NOTES

¹ *Analysis* of the Health Sector in Cuba, Ministry of Public Health, January 1996, p. 14.

² Interviews with Marlene Porto, Director, Center for Medication Research and Development, Havana, Sept. 27 and Oct. 2, 1995; and "Vamos al restate de los aspectos que se deterioraron," interview with Minister of Public Health Dr. Carlos Dotres, *Trabajadores* newspaper, Havana, June 10, 1996, p. 8.

³ In fact, since the embargo was imposed in 1962, U.S. companies have never been authorised to sell such items directly to Cuba, and from 1975 to 1992, only their subsidiaries were allowed to do so, and than only by virtue of a special license. And, since the CDA was passed in 1992, it is our understanding that the U.S. government has not included in medical exemptions from the embargo the export of raw materials or other products used in the pharmaceutical industry. Furthermore, we know of no licenses issued for such exports.

⁴ Interview with Haydee Cela, Deputy Director for Quality Control, Reynaldo Gutierrez Pharmaceutical Plant, Havana, July 4, 1996.

⁵ Some clarifications: Items in this table may be of U.S.-origin or manufactured elsewhere. This chart is intended to illustrate the range of drugs for which one U.S. supplier offered better prices than Cuba was currently paying in Europe. It does not attempt to illustrate an average price offered by a spectrum of U.S. suppliers; nor does it include the prices of active ingredients for which Tilgrex did not offer a lower bid than European exporters.

⁶ Interview with Leonel Zúñiga, Director, ENSUFARMA, Feb. 7, 1996.

⁷ MEDICUBA managed to obtain a first offer for chromatography replacement parts in late May 1996. The prices quoted by a Brazilian firm, acting as intermediary, were 40% higher than those quoted by Pharmacia when the company was able to do business with Cuba. Documentation provided by MEDICUBA's Equipment Division, May 28, 1996.

⁸ Interview with Noelio Flores, CIDEM, June 14, 1996. CIDEM does not do quality control for biotech productions, which have their own equipment.

⁹ Interview with H. Cela, July 4, 1996.

¹⁰ Interview with N. Flores, CIDEM, June 14, 1996.

¹¹ See chapter on Medical Exports for details. Information on sale provided by Noelio Flores, CIDEM, June 14, 1996.

¹² Interview with Rosa Fuentes, MEDICUBA, Sept. 7, 1995.

¹³ The Norm used to calibrate this instrument is ISO 4462, hydraulic fluid power calibration of auto-count instrument for particles suspended in liquid, using AC Fine Test Dust Contaminant. Interview with Noelio Flores, CIDEM, June 14, 1996.

¹⁴ CIDEM tests all injectables and washes, with the exception of those manufactured in the biotechnology plants.

¹⁵ Price quotes from Whittaker provided by Greg Gonzales to Stephen Kimmerling, October 1995; and prices paid by MEDICUBA provided by Diana Guzman, Sept. 7, 1995.

¹⁶ Telex from MEDICUBA representatives, Sept. 5, 1995.

CHAPTER FIVE

SELECTED ASPECTS OF HEALTH & WELFARE

Food Supply and Nutrition

The Cuban population's nutrition and food security have been adversely affected by the U.S. embargo, especially in this decade, when the island has been doubly impacted: first, by the collapse in traditional trade relations with the former Soviet Union and Eastern Europe, and second, by the tightening of the U.S. trade ban through the Cuban Democracy Act (CDA) of 1992.

The embargo's effects have been particularly negative in four areas:

1. Its contribution to the general contraction of the economy, and reduced import capabilities for food, fuel and other commodities key to guaranteeing basic foodstuffs and maintaining nutritional levels. In addition, when the CDA was enacted, its provisions blocking Cuban exports to U.S. subsidiaries cut funds available to Cuba to import prioritized food items—a substantial amount, considering that from 1989 to 1992, Cuba received a total of \$781 million from exports to these companies.¹
2. Higher shipping rates and shipping delays resulting from the CDA's prohibition on entrance to U.S. ports by vessels which have docked in Cuba during the previous 180 days. Economists estimate that if goods could be sent to Cuba from the USA, a savings of \$215,800 could be rung up for each ship replacing a European freighter, and \$516,706 for each replacing an Asian freighter, adding up to millions annually.² Furthermore, as noted in the chapter on the general economic crisis, shipping associations worldwide have notified their members of the risks involved in taking a vessel into Cuba; and several companies have decided not to enter Cuban ports altogether.
3. The sudden cutoff of competitively priced U.S. subsidiary commodities to Cuba, when the CDA became law in October, 1992. This compounded the effect of the three-decade prohibition on direct imports from the United States, Cuba's nearest market.
4. Obstacles created for biotechnology research and production as applied to agriculture, by virtue of the CDA clause specially targeting this industry for embargo enforcement.

We will examine the impact of these factors on the availability of foodstuffs, and, in turn, on the nutritional levels of the Cuban population.

Food Imports

While the Executive Order mandating the embargo was signed in 1962, it was not until 1964 that all food sales to Cuba were prohibited. At that point, the island turned to new allies in Europe. And by the late 1980s, Cuba's was a highly specialized economy within the framework of the socialist bloc's division of production and exports.

Many key food stuffs were imported from these or other sources (including 100% of cereals, 9% of beans and 96% of cooking oil). In 1989, 57% of proteins and 50% of calories came from imported foodstuffs.³ The Council for Mutual Economic Assistance (CMEA) countries accounted for the lion's share of these food imports: 96%-100% of butter, cheese and condensed milk imports, 90-95% of powdered milk, 70-80% of cereals and oils, and 50-60% of canned meats and beans.'

Thus, when trade with these nations was drastically reduced in the early nineties—and along with it, the favorable terms offered—Cuba began to seek suppliers elsewhere. This explains why U.S. subsidiary exports of "grain, wheat and other consumables" to Cuba increased nearly tenfold from 1988 to 1990. For the following two years, when the island was battered full-force by economic

crisis, such imports were slightly reduced but remained well above the levels of the 1980s, constituting a bigger share of total trade between Cuba and U.S. subsidiaries than ever before.

LICENSED EXPORTS TO CUBA BY U.S. FOREIGN SUBSIDIARIES Grain, Wheat and Other Consumables		
Year	Total Exports In Millions of USD	Percent of U.S. - Cuba Trade
1987	\$54	22%
1988	58	23%
1989	114	34%
1990	500	71%
1991	348	48%
1992	363	73%

Source: U.S. Department of the Treasury, 1993 Special Report.

By FY1992 (the last year before the CDA eliminated subsidiary trade) soybean products, wheat, sunflower oil, corn, rice and palm oil constituted 89% of total Cuban imports from U.S. foreign subsidiaries.⁵

The following are some of the U.S. companies whose subsidiary sales in foodstuffs and related products were cut off by the CDA, effective October 23, 1992:

- Cargill
- Central Soya
- Continental Grain
- Del Monte
- Dow Chemical
- J. Heinz
- Hoechst Celanese
- International Multifoods

The canceled contracts ranged from baby foods supplied by H. J. Heinz Co. of Canada, to nearly \$100 million in imports of wheat, soy, beans, peas and lentils from the Argentinean subsidiaries of Continental Grain (New York) and Cargill (Minneapolis, MN).⁶

After the CDA was enacted, documentation indicates that Cuban importers were not able to obtain prices as competitive as those offered by U.S. subsidiaries, and that the CDA shipping restrictions resulted in increased freight costs. According to figures from Cuba's Ministry of Foreign Trade, as early as 1992, when Cuban importers began switching suppliers, higher prices from these new sources resulted in an additional cost of \$41.5 million for cereals, chicken and milk alone. By 1995, average shipping rates for cereals had doubled from their 1991 levels; and shipping rates in general were reported at 15 to 30% higher than the World Scale (the average freight charges along worldwide shipping routes between specified geographic zones).⁷

The premium paid on foodstuffs due to the embargo is much higher, if one compares actual prices and freight costs contracted by Cuban importers with price quotations from U.S. companies and average freight costs from the mainland USA. For example, wheat is currently purchased from the European agro-industry 'at a price of \$25-28 per ton, freight included, but the same quality grain would be available from U.S. suppliers for half that: \$13 per ton (shipping included from a Gulf port). Understood in this light, for 1993, Cuba paid an additional \$34 million for food, and in 1994, an additional \$36 million, due exclusively to the U.S. embargo.*

Inflated Costs of Food Imports to Cuba Due to U.S. Embargo (1994)	
Product	Additional Price and Freight Paid
Wheat Flour	\$ 7,823,920
Soy Flour	\$ 5,403,458
Wheat	\$ 9,441,084
Corn	\$ 1,033,516
Soy Beans	\$ 727,513
Chicken	\$ 718,063
Milk	\$10,734,342
TOTAL	\$35,881,896

Source: *Invoices and other documents from the Ministry of Foreign Trade, Havana, 1996.*

Not only were shipping costs increased as a result of the CDA., but shippers willing to send their vessels to Cuba became harder to find, and consequently vital food imports were delayed in reaching the Cuban population:

- Just weeks after the CDA was enacted, a New Zealand milk producer canceled a long-standing contract to sell Cuba 1,500 metric tons of powdered milk after the supplier's regular shipper refused to carry the Cuba-bound cargo. Months later, a more costly replacement shipment was eventually purchased in Europe.
- An Italian supplier could not find a tanker for some 9,000 metric tons of soy cooking oil. After considerable delay, the company located a shipper at higher rates. The additional costs were passed on to the Cuban importer.
- Some 17,000 metric tons of rice sat at sea while the Chinese supplier re-negotiated higher freight terms with the shipper, who cited risks under the newly-enacted CDA as the reason for increasing his rates.
- Another Chinese shipper tried for seven months to send 90,600 metric tons of beans to Cuba. When all options failed, the Cubans re-directed one of their own few freighters to pick up the cargo.

Food Industry Imports

As many fledgling Cuban industries, food and food processing relied heavily on U.S. imports for decades. When the embargo was imposed in 1962, virtually all of the equipment in this sector was U.S.-manufactured. Among the units that were idled over the following years for lack of embargo-outlawed parts were: refrigerator compressors for the milk products, meat and canning factories; steam boilers for all plants; bottling and sealing units for all plants; and pumps for the milk and soft drink plants. Most of this equipment eventually had to be replaced with Soviet and Eastern European models, which not only required major investments, but also brought into the country outdated energy-gobbling technologies. Some of the U.S.-units-such as the bottling lines-have never been substituted, and have functioned all these years on makeshift parts.⁹

Nevertheless, from the early 1960s and through 1989, the Cuban food and food-processing industry registered increases in production, reflecting government priorities.

GROWTH IN THE CUBAN FOOD INDUSTRY (1963-1 989)	
Item	Production Multiplied by:
Ice Cream	9.2
Pork Meat	7.9
Strained Fruits	7.9
Canned Vegetables	7.0
Milk	4.8
Canned Meats	3.6
Bread	3.4
Wheat Flour	3.0
Pastas	2.6
Fruit Preserves	2.4
Vegetable Cooking Oil	1.9
Tomato Paste	1.7

Source: Cuba's Report to the International *Conference on Nutrition, 1992*

However, by 1993-94, the industry was sorely affected by the general decline in the availability of hard currency for purchases abroad, needed for 7580% of investments in food-processing equipment. Also needed were virtually all the oil to run the plants and a significant share of raw materials and packaging supplies.¹⁰ This situation was further aggravated by delays in arrival of imported merchandise and additional costs (resulting in decreased imports), derived from the U.S. embargo.

Bread is one example of the toll that the embargo has taken on production of basic foodstuffs in Cuba. As noted earlier, if Cuban importers could purchase directly from U.S. suppliers, it is estimated that some \$7.8 million extra paid for wheat flour in 1994 alone could have gone for larger purchases of this basic ingredient. Banned from direct buys from the United States, Cuban importers turned to U.S. subsidiaries: a major part of U.S. subsidiary exports to Cuba were grains, and wheat in particular, until the CDA banned such transactions in 1992. At that time, shippers also became reluctant to send their vessels to Cuban ports, due to CDA sanctions. For example, shortly after the CDA was enacted, the French firm Souflet spent over two months searching for a ship for wheat exports to the island. In late 1992, an Italian shipment of 8,000 metric tons of wheat flour was delayed nearly three months, waiting for a vessel willing to dock in Cuba."

Once these ingredients finally arrived in Cuba, they were subject to the general fuel shortage—slowing down the chain of production, from transportation to the bakery ovens themselves—also exacerbated by the CDA. Documents from the Ministry of Foreign Trade reveal that in the last trimester of 1992, fuel tankers were charging Cuba 25% over World Scale rates: and by 1993, importers were paying as much as 43% over pre-CDA rates. We should note that increased payments for fuel is one reason why many plants in the food industry simply shut down during the worst years of the crisis.¹²

Specialized food productions have also been hit by the U.S. embargo: take sausages. Celanese Mexicana, S.A, a subsidiary of Hoechst Celanese Corporation (Somerville, NJ) reported in December, 1992, that it was unable to continue exporting sausage casings to Cuba, citing the CDA

prohibition on subsidiary trade. When Cuban importers turned to other firms, they continued to receive negative answers: first from Teepak, Inc. of Switzerland (a subsidiary of Teepak, Inc. of Bethlehem, PA); and then from Viskase, SA. of Canada (owned by Emerald Acquisition Corp., of Hinsdale, IL).¹³

Food packaging is another area where imports play an important role, and have thus been vulnerable to CDA and other embargo restrictions: The Celanese Mexicana, S.A. firm also cut off prospective sales to Cuba of cellophane for food items, coffee, and candies. Fyskeby of Sweden, which had been approached by Cuba to buy 25 metric tons of cardboard packaging, informed Havana that it had recently been acquired by a U.S. firm and would have to bow out of the negotiation. Productos Industriales Venezolanos, SA (PIVENSA) told Cuba's Ministry of the Food Industry (MINAL) that it would not be able to continue direct supplies of aluminum canning material, for fear of possible U.S. sanctions against the company, which exports 79% of its production to the USA”

The U.S. embargo recently threw another wrench into the works of the Cuban food industry, when it held up a Swedish donation of some one million kronas in precision equipment, destined for the Center for Testing and Recovery of Factory Parts-key to getting some of the machinery, retooled now for the third time, back into operation. The donation from ICS-SWEDIND has been stalled, since several of the units contain U.S.-manufactured components. Such is the case of two personal computers, a distance temperature detector (relying on infrared rays), visual inspection units, and “metalock” technology for sealing cracks in production machinery equipment.¹⁵

Imports for Agriculture

Since the 1970s and through the eighties, Cuba's national agricultural production inched its way up as a percent of the recommended per capita consumption of calories and proteins: from 22.7% of calories in 1975 to 28% in 1985, and 27.9% of proteins in 1975 to 35.1% a decade later.¹⁶

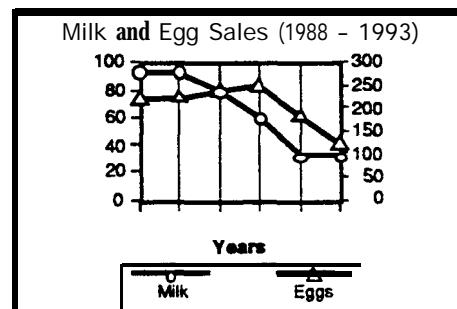
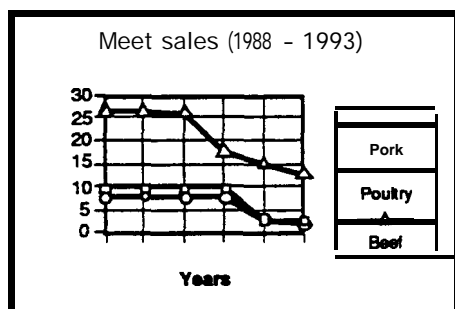
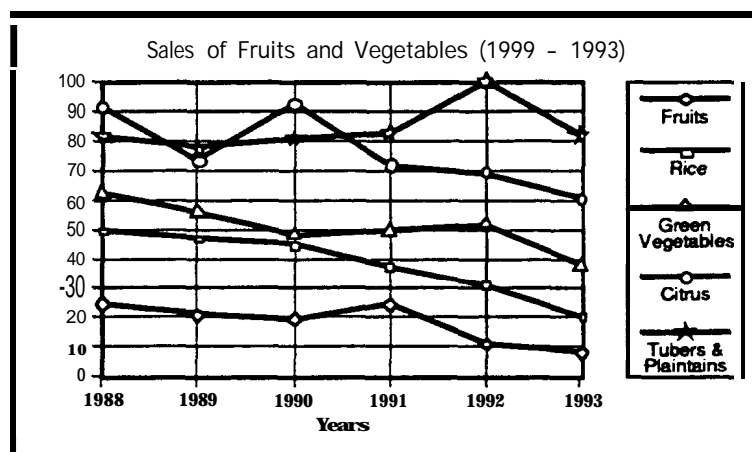
The following chart illustrates absolute growth in several basic items:

Development Of Agricultural Production (Thousand Tons)		
	1969	1989
Tubers, roots and bananas	440.0	972.6
Vegetables	140.8	610.2
Rice	224.6	536.4
Citrus Fruit	159.3	825.7
Eggs	1342.0'	2522.6.
Pork (live)	7.2	110.4
Poultry (live)	20.4	117.8

'In millions of units.

Source: Comité Estatal de Estadísticas, as quoted in the Report to the International Conference on Nutrition, Rome, 1992.

However, the economic crisis of the nineties has taken its toll on harvests, and on dairy and meat yields, weakening domestic production possibilities to compensate for more expensive food imports at the time when this was most needed.



It is our conclusion that the U.S. embargo has contributed to this situation and has seriously affected *Cuba's* ability to increase agricultural production and crop yields. Examples can be found in fertilizers, pesticides, animal feed and fuel.

In September of 1992, Bayer AG (Germany) informed Cuban importers that the firm's 'Sencor' pesticide sales to Cuba were being cut off due to the company's decision to transfer production of the chemical's active ingredient to a Kansas City plant. Since the pesticide had lost its "German origin" in this process, Bayer *noted that* a U.S. license had been sought, without results. Abandoned by this traditional supplier, Cuban buyers turned to other sources, paying a higher price for pesticides that would reach the country's potato fields late.

In November of 1992, Fertran (Trinidad and Tobago) refused to continue sales to Cuba of ammonia (for fertilizers), noting that the company was partially owned by a U.S. corporation (Amoco).

A shipment of 7,000 metric tons of urea, used in fertilizing canefields, was contracted with Helm, AG (Germany). However, shippers cited U.S. legislation against Cuba for their refusal to deliver the product directly, and instead dropped it at a Venezuelan port. This situation, which was repeated twice in 1992, caused considerable delays in arrival and increases in shipping costs."

In general, these and other direct effects of the U.S. embargo further reduced fertilizer and pesticide imports to Cuba during the economic crisis, forcing the country to pay more for less and to delay application of these products to the fields. Faced with the combined impact of the loss of European suppliers and a tightened U.S. embargo, Cuban fertilizer imports alone declined from an average of 829,000 tons a year for 1988-90 to 180,000 for 1992 and 1993.¹⁸

During 1994, Cuban importers calculate they paid an additional \$8.3 million in inflated prices and shipping fees for chemicals used in agriculture, as they redirected purchases in the wake of the Cuban Democracy Act (CDA).¹⁹

Unstable supplies of animal feed components had a drastic effect on milk, meat, poultry and egg supplies, especially in the months following passage of the CDA. It was then that both Cargill and Continental Grain subsidiaries in Argentina cut off cereal shipments to Cuba, which represented cancellation of two of the largest cereal contracts the island had at the time.²⁰

In addition, the CDA shipping regulations threw up serious obstacles to deliveries of animal feed grains. It should be noted that both the Maritime Federation of Canada (circular 5383 of Oct. 19, 1992) and the Union of Greek Shipowners (letter of Aug. 6, 1992, sent to the Anglo Caribbean shippers of London) had warned of serious difficulties that could arise in carrying products to Cuba, as a result of the bill then pending before the U.S. Congress. The Canadian shippers predicted that the 180-day ruling would limit the selection of ships available to Canadian firms for charter to Cuba, and in general, would make Canadian exports to the island more difficult and more costly. The Greeks made specific reference to difficulties that would arise for carrying fuel and grains destined for Havana.²¹

Shipping irregularities began disrupting grain deliveries to Cuba in the weeks following enactment of the CDA. Two shipments of soy flour, a key ingredient for poultry feed, were contracted with Argentinean exporters in October, 1992, for arrival in Cuban ports no later than December, on board ships furnished by the exporters (C and F). However, when no ships were forthcoming, in either case, Cuban vessels had to be sent empty to Argentina to pick up the cargo: a total of 24,500 metric tons of flour. This incident illustrates the chain reaction that results from the shipping ban on Cuba:

Scarce financial resources were unnecessarily tied up in two purchases already made, but which, in fact, did not arrive in time to head off shortages.

- As a result of the delay in delivery--the Cuban ships returned with the cargo at the end of February--Cuban importers (ALIMPORT) were forced to purchase a stopgap lot of 11.8 metric tons in northern Europe, at \$50 per ton over the Argentinean price. The ship carrying the flour had insufficient cargo space for the entire shipment, and thus Cuba paid full freight for only a partial shipment. This factor turned out to cause extra delivery delays, as negotiations proceeded.
- A second lot of 4,060 metric tons was purchased in the Dominican Republic at nearly \$100 per ton over the Argentinean price, for which Cuba had to supply the ship in order to guarantee immediate delivery.
- Nevertheless, an obvious shortfall occurred in soy flour, with the consequent shortage of chicken feed. Egg supplies dipped sharply during the period, and farms were forced to sacrifice thousands of chickens, for lack of feed. The number of eggs rationed to the public declined from the rate of 160 per year in mid-1992 to approximately 125 per year by 1993, partly as a result of such shipping irregularities consistently caused by the U.S. embargo.²²

A similar catastrophe occurred with the country's cattle herd, once fattened on grains imported from the Soviet Union and subsequently from other sources, among them, U.S. subsidiaries. At the height of the economic crisis, feed shortages meant the death of more than 300,000 animals from hunger each year for four years running. By 1992, milk production was barely 45% of what was produced nationally in 1989.²³ To make matters worse, as we saw above, the CDA forced Cuban importers to pay more for powdered milk, and caused delivery delays.²⁷

In 1993, importers estimate that for each ton of powdered milk Cuba procured at inflated purchase and shipping prices, the country could have received 2.6 tons of milk at normal rates.²⁵ By 1994, according to Cuban nutritionists, the most serious deficits for the basic Cuban diet were registered in supplies of milk products, meat and oils, among the basics in the Cuban diet.²⁶

The U.S. embargo has also cut into fuel imports, key to agricultural production. Energy supplies to this sector were reduced sharply between 1989 and 1993, primarily as a result of decreased oil purchases from the former Soviet Union, but also as a result of embargo restrictions which divert a portion of the country's limited hard currency *-reserves* from fuel purchases into inflated freight charges, forcing Cuba to pay more for less.

CUBA's SHRINKING ENERGY SUPPLY FOR AGRICULTURE (1989-1993)	
Diesel Fuel	-47%
Electricity	-45%
Gasoline	-75%

Source: *Plan Nacional de Acción para la Nutrición Havana 1994, p. 48*

Tanker rates for fuel shipments to Cuba have increased dramatically since the CDA was passed in 1992, overcharging importers by an average, economists estimate, of 15-30%, and Cuba has paid as much as 43% over pre-CDA rates. This additional freight overhead-totaling \$11 million in 1993 and **\$8.4** million in 1994-might have been available for more fuel, if it were not for the U.S. embargo.²⁷

Fuel is critical for irrigation, especially during the almost six months of the dry season. By 1969, Cuba had managed to increase ten fold the areas of croplands receiving regular irrigation, but this program has suffered serious setbacks with reduced oil imports in this decade.²⁸ Fuel shortages contribute to inefficiency and make agriculture less productive: mechanization becomes a luxury for most crops, replaced by human labor and animal traction, while transportation shortages delay field-to-market arrivals for consumers. The end result is less food.

Biotechnology Applied to Agriculture

Cuban biotechnology research in agriculture has been dedicated fundamentally to boosting food supplies, improving nutritional content and contributing to a sustainable base for the agro-industry. Scientists are working to achieve organic biofertilizers and biopesticides, climate- and disease-resistant crops, with higher yields and higher protein concentrations, and to accelerate the maturing of freshwater species for higher yields at fish farms. In the latter case, synthetic growth hormone is being applied to tilapia, which doubles the speed of their normal growth cycle, thus generating the same 'catch' in half the time.

Advances already obtained are expected to save Cuba millions in imports: for example, researchers calculate that domestically developed potato seeds should replace imports of certified seeds by 1999, saving the country \$11-13 million annually.²⁹

By virtue of a separate clause, the CDA specifically bans any export to Cuba which would be used in such biotechnology research or production. The obstacles this has created for the industry-and hence for application to agriculture-are detailed in the section on Vaccines and Biotechnology

Research, Development and Production, where we also make broader reference to the projects underway in plant and animal biotechnology for increasing food production.

The Cuban Population's Food Security and Nutrition

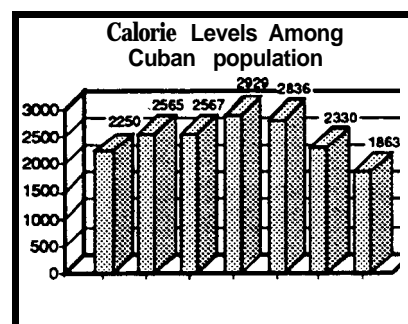
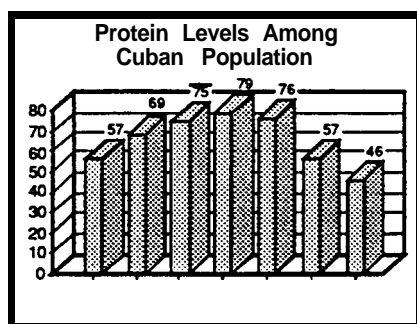
As demonstrated above, the U.S. embargo has siphoned off critical resources for food, and as such represents a drain 'on nutritional levels and food security in Cuba in the economically treacherous nineties. Summarizing the data we have presented above: between 1992 and 1994, \$196.3 million was cut from the food import budget, paid out in inflated prices and freight fees, resulting from the U.S. embargo. For the year 1994 alone, another \$8.3 million extra was paid out for agricultural chemical imports, due to the embargo. This reached a total of \$204.6 million through 1994, without counting inflated prices and shipping costs for numerous other components of the food-import and food-process chain, such as fuel, equipment, and additional purchases for the agricultural sector. This figure constitutes 47% nearly half, of the total food import budget for 1993."

This situation has compounded food shortages. Both quantity and variety have been seriously compromised, and the population's nutrition has suffered as a result.

CUBA'S 1993 AVERAGE DAILY NUTRITIONAL INTAKE			
Nutrients	Actual Intake	Daily	Recommended Requirement
Calories	1863		2400
Protein	46 grams		72 grams
Fats	26 grams		75 grams
Vitamin C	5 mg		57 mg
Vitamin B1	0.91 mg		1.2 mg
Vitamin B2	0.78 mg		1.5 mg
Niacin	7.7 mg		17 mg
Vitamin B6	1.05 mg		1.5 mg
Vitamin B12	1.7 (g		2.8 (g
Folic Acid	152 (g		225 (g
Vitamin A	285 (g		700 (g
Iron	11 mg		14 mg
Calcium	706 mg		850 mg

Source: *Plan Nacional de Acción para la Nutrición Havana, 1994, p. 6.*

The plunge in nutritional levels in the early nineties is better understood in the context of previous years: on average, calorie intake from 1985 through 1989 exceeded 2800 a day, and protein levels stood at 76 grams. By 1993, daily caloric intake had dropped 33%; and protein 39%.³¹ While the FAO recommends 2300 calories a day, Cuban nutrition standards run at 2400 daily, considering that a major share of the country's workforce labors in agriculture, and other high-energy consumption occupations.



By 1993, nutritional deficiencies began to emerge in the general population:

- Under90 age group: A drop in the median weight for both males and females was noted in 1993, using national data gathered in 1982. Adolescents registered a decrease of at least 2 kilograms.
- Children born in 1990 or later (3 years of age or younger) were notably smaller than the same age group measured in 1982. While children 3 years of age or older were larger than those registered in 1982, experts say their growth rate was delayed when compared to growth charts of developed countries.
- The average corporal mass in 1993 was less than that of 1982. In fact, for individuals over 5 years of age, the rates were the lowest since these studies were first carried out in 1972.
- The 1993 study found average muscle density the lowest ever registered.
- Fat density had also dropped when compared to 1982 findings and were the lowest ever registered for males over 6 years of age.
- In adults between 20 and 60 years of age, findings indicated a marked drop in weight for both women and men-especially for individuals above 30.
- The corporal mass index, the arm's circumference and muscle area, decreased for both men and women between 20 and 60 years of age."

In general, the 1993 study concluded that the Cuban economic crisis and shortfalls in food imports were adversely affecting the general population's nutritional health. While the picture had improved discreetly by 1995, the Resident Program Director in Havana for UNICEF, Luis Zúñiga Zárata, was still prompted to call restrictions in food supplies and their nutritional effects "the gravest social problem faced by the Cuban population."³³

The UNICEF Director also makes specific reference to the "lack of foodstuffs for school lunch programs, drop in quality of food for hospital patients, and closings of workplace dining halls."³⁴ Among others, this situation affects children in some 9,000 elementary schools and over 500 boarding schools for junior high and high school students throughout the island.

Low Birth *Weight Babies*

Over the years, iron deficiencies in the Cuban diet have been responsible for a tendency towards anemia in children six months to five years of age, adolescent girls, those in their reproductive

years, and pregnant women. By the 1990s, 30% of pregnant women were diagnosed with iron deficiency.

During this same period, there was also a notable rise in women with deficient nutrition at the beginning of pregnancy, another sign of inadequate food intake and quality of diet. Nutritional deficiencies in expectant mothers often appear in the first months of pregnancy. Despite the fact that the Cuban government has provided additional protein to pregnant women since the early 1960s, the food quota **is** just not enough in the context of reduced availability. (See Appendix to this chapter on the ration system in effect in Cuba.)

DEFICIENT NUTRITIONAL STATUS IN WOMEN BEGINNING PREGNANCY	
1990	0.7%
1991	9.3%
1992	10.0%
1993	10.5%

Source: Plan Nacional de Acción para la Nutrición 1994.

Mothers' nutrition during pregnancy has a serious bearing on the incidence of low birth weight among their newborns. And low birth weight, in turn, is an early warning sign for increases in infant mortality to come, since a baby born under the required 2500 grams is 14 times more likely to die in its first year of life. In Cuba, low birth weight is a factor in one half of infant deaths.³⁵ The low birth weight indicators registered an increase in Cuba in the early nineties, for the first time in 15 years, an increase that reversed slightly in 1994, when the indicator stood at 8.9%.³⁶

(See sections of this chapter on Women's Health and Children's Health for further discussion of nutritional levels and low birth weight.)

LOW BIRTH WEIGHT IN C U B A	
1990	7.6%
1991	7.8%
1992	0.6%
1993	9.0%

Source: National Department of Statistics, Ministry of Public Health, Havana.

Both pregnant women and children have historically received-and continue to receive-extra food from the government rationing card. It is reasonable to assume that, if the embargo were lifted, they would also benefit in greater proportion, given the priority placed on their nutrition.

Neuropathy Epidemic

During 1992 and 1993, over 50,000 Cubans were afflicted with neuropathy, constituting an epidemic among men and women primarily between 25 and 64 years of age."

Both Cuban and international doctors and specialists,-after carrying out exhaustive research, concluded that the nation's food shortages had been a main cause of the epidemic, most likely complicated by the presence of an environmental toxin. Overnight, they concluded, the Cuban

consumer experienced a sharp drop in calories and nutrients which affected the body's natural ability to purge toxins.³⁸

Researchers also concluded that the reason certain population groups had not been affected by the epidemic was because they receive extra nutrients under the government food distribution system: children, pregnant women and the elderly. The higher energy expenditure and exposure to toxins of active adults were believed to have aggravated the effect of nutritional deficiencies-leaving this sector more vulnerable to neuropathy.³⁹

Investigators from the United States and elsewhere also concluded that the U.S. embargo had significantly contributed to the appearance of this nutrition-related epidemic, by leading to further cuts in foodstuffs and other key imports which seriously affected the lives of Cuban families. (See the section on National Health Emergencies for a more detailed discussion.)

Appendix

The rationing system for food, which was designed in the early sixties to help offset the negative effect of the U.S. embargo and allow for a basically equitable allotment of basic products, was relaxed in the early 1980s. By then, supplies had become sufficiently abundant to freely sell a variety of products once rationed, and sell additional quotas of rationed items at slightly higher prices. By later in the decade, nearly 20% of household food purchases were made outside the ration system.

By 1990, however, food shortages emerged with the general economic crisis, and the havoc the U.S. embargo caused when Cuba looked to new suppliers for its import needs after the CDA was enacted. All basic products were returned to the ration system, and supplies of many became highly unstable.

The following table illustrates what the government ration supplied to the average food basket for one person in Havana in 1995.

1995 CUBAN FOOD RATION FOR CITY OF HAVANA		
Food Product	Yearly Total Amount	Frequency
Beef	0.60 lb.	0.26 lb. twice during year
Beef (for pregnant women)	18 lb.	3 lb. during last 6 months of pregnancy
Soy-enriched ground beef	7.5 lb.	0.75 for 10 months
Poultry Paté	4 lb.	0.50 lb. eight times during year
Bread	73 lb.	3 oz. daily
Chicken	1.75 lb.	Portioned in July and December
Chicken (for children up to 13 years)	6.75 lb.	0.75 lb. nine times during year
Cooking Oil or Lard	2.75 lb.	Varied amounts during 6 months
Corn Meal	3 lb.	0.50 lb. six times during year
Dried Beans	24 lb.	1.25 lb. each month
Eggs	119	Varied amounts during 12 months
Fish	24 lb.	2 lb. monthly
Milk for pregnant women	16.88 lb.	45 oz. every month from the 3rd to 9th month

1995 CUBAN FOOD RATION FOR CITY OF.HAVANA		
Food Product	Yearly Total Amount	Frequency
Milk (for children up to 6 years)	365 qt.	1 qt. daily
Soy Yogurt (7-13 years)	60 qt	5 qt. monthly
Soy Cereal (7-13 years and 65 and over)	26.25 lb.	2.2 lb. monthly
Rice	72 lb.	6 lb. monthly
Sausage	2.5	0.50 lb. five times during year
Spaghetti	6 lb.	0.50 lb. monthly
Sugar	72 lb.	6 lb. monthly

In late 1994, the ration system was supplemented by the creation of farmers' markets across the island, where produce and meats are freely sold by family farms and cooperatives. While this has alleviated the situation for many families, the prices at the markets do not receive the same state subsidies as do those for rationed items, and consequently access depends on family earning power.

By 1995, it was estimated that rationed items covered some 1,300 calories daily; workplace and school lunchrooms another 300. Between rationing, lunchrooms and the farmers' markets, some two thirds of the Cuban population **was** able to obtain foodstuffs sufficient for 2,000 calories consumption per day, but approximately 3.5 million did not have the resources to guarantee even this level."

N O T E S

- ¹ U.S. Treasury Dept., Licensed U.S. Foreign Subsidiary Trade with Cuba.
- ² Documents provided by the Ministry of Foreign Relations, Havana, and letter from the Cuban Foreign Minister to the Secretary General of the United Nations, June 9, 1995.
- ³ Plan Nacional de Acción para la Nutrición, Havana, 1994, p. 5.
- ⁴ Anuario Estadístico de Cuba, -Comitk-Estatal de Estadísticas, 1989; and Resumen Estadístico del Comercio Exterior, Ministry of Foreign Trade, 1989.
- U.S. Treasury Department, Summary Data of Licensed Trade with Cuba by Foreign Subsidiaries of U.S. Companies in FY1992, which stipulates that the figures extend to the signing of the CDA on October 23, 1992.
- ⁶ Cuban Ministry of Foreign Trade documents furnished to the authors.
- ⁷ Documents provided to the authors by the Ministry of Foreign Trade, Havana.
- ⁸ Ibid.
- ⁹ Interview with Mabel Balbín, specialist, Ministry of the Food Industry, June 9, 1996.
- ¹⁰ Plan Nacional de Acción, 1994, p. 5.
- ¹¹ Documents provided to the authors by the Ministry of Foreign Trade, Havana, 1996.
- ¹² Ministry of Foreign Trade invoices and other documents furnished to the authors, 1996.
- ¹³ Ibid.
- ¹⁴ Documents provided to the authors by the Cuban Ministries of Foreign Trade and the Food Industry, 1996.
- ¹⁵ Interview with M., Balbin, June 9, 1996.
- ¹⁶ Plan Nacional, 1994, p. 46.
- ¹⁷ Documents provided to the authors by the Ministry of Foreign Trade, Havana, 1996.
- ¹⁸ Plan Nacional, 1994.
- ¹⁹ Ministry of Foreign Trade, Havana, 1996.
- ²⁰ See press reports in the Argentine newspapers Cronista, Nov. 2, 1992 and Pagina 12, Nov. 1, 1992, for statements by company executives.
- ²¹ Documents furnished to the authors by the Ministry of Foreign Trade, Havana, 1996.
- ²² Plan Nacional, Havana, 1994, p. 49, and documents from the Ministry of Foreign Trade, Havana, 1996.
- ²³ It was reduced from 740 million liters to 335 million liters. Presentation by Luis Zúñiga Zárate, Resident Program Director, UNICEF-Cuba, to UN Meeting, Cartagena, Colombia, October, 1995.
- ²⁴ "Cattle Raising The Thin Cow Epidemic," *Cuban Review*, June, 1996, p. 3.
- ²⁵ Letters from the Cuban Foreign Minister to the Secretary General of the United Nations, July 22, 1994 and June 9, 1995.
- ²⁶ Plan Nacional, Havana, 1994, p. 5.
- ²⁷ Ministry of Foreign Trade documents and letters from the Cuban Foreign Minister to the UN Secretary General, July 22, 1994 and June 9, 1995.
- ²⁸ Plan Nacional, Havana, 1994, pp. 51-53.
- *Interview with Dr. Elio Jiménez, Institute for Plant Biotechnology, Central University of Las Villas, Santa Clara, June 11, 1996.
- ³⁰ Presentation by Luis Zúñiga Zárate, Resident Program Director, UNICEF-Cuba, at meeting of UN Agencies in Cartagena, Colombia, October, 1995, p. 4.
- ³¹ 'Food, Nutrition and Health in Cuba,' by Professor Manuel Amador, MD, Ph.D., SV International Congress on Nutrition, Adelaide, Australia, 1993, p. 5. In 1994, a discreet improvement was registered: 1948 calories, 47.7 grams of protein, and 28.7 grams of fat, according to the Ministry of Public Health.
- ³² Plan Nacional, Havana, 1994.
- ³³ Presentation by L Zúñiga Zárate, October, 1995.
- ³⁴ Ibid.

³⁵ **Interview** with Dr. Francisco Valdes Lazo, National Maternal-Child Division, Ministry of Public Health, Havana, Nov. 10, 1995.

³⁶ Measures credited by UNICEF and the Ministry of Public Health with the turnaround included the implementation of a national program to promote exclusive breast-feeding, through the “Baby and Mot&-Friendly Hospital” distinction; provision of prenatal vitamin supplements to all pregnant women with a UNICEF grant, beginning in 1993, and the revitalización of nearly 200 maternity homes, which serve as live-in residences for women with high-risk pregnancies, and meal centers to provide supplemental nutrition for ~~expectant~~ surrounding community.

³⁷ “Food Nutrition Studies,” presented by the Cuban Institute of Nutrition and Food Hygiene to an International workshop on the Cuban Neuropathy Epidemic, held in Havana in July, 1994.

³⁸ **Ibid.**

³⁹ **Ibid.**

⁴⁰ **Mercado Agropecuario: Apertura o Limitación?**, Departamento Agroindustrial, Instituto Nacional Investigaciones Económicas, June, 1995, p. 36.

Introduction

Women in Cuba receive special attention and protection within the legal framework of the Constitution, the Family Code, labor laws which provide for maternity leave with pay and make other allowances for mothers who work and study, and legislation which acknowledges equal status for women under the law.

However, in practical terms, the economic tailspin of the last five years has had devastating consequences for Cuban women, and for programs allowing for greater female participation in the workforce and society at large. For example, in the nineties there have been serious cutbacks in programs which once alleviated women's disproportionate share of family and household responsibilities: expanding childcare and after-school facilities, inexpensive workers' dining halls, accessible fast and easy-to-prepare foods, laundromats, dry cleaners and a host of other services.

As a result, as UNICEF regional Director Dr. Marta Maurás put it, 'Cuban women are those making the greatest sacrifice in handling daily problems, dealing each day with an infinity of difficulties appearing at work, problems emerging at home and the shortages that affect home life and even personal well-being.'¹

Stress is the common denominator of Cuban families during the crisis of the nineties, with cultural legacy dictating that women bear the brunt of the burden. They are the care-givers, the home educators, the endless inventors of recipes based entirely on substitutes, the stand-in-line shoppers, and soothers of nerves and spirits. They are also 40% of the Cuban workforce, constituting 57% of the country's university graduates. Their days grind into operation in the early hours of the morning, often lighting a candle in the pre-dawn blackouts to put a dwindling breakfast on the table. Once the children are off to school, working mothers take as many as two to three hours to get to their jobs (in Havana City alone, bus runs have been cut by two thirds). On arrival, more often than not, their work and creativity are hampered by shortages of all kinds, their eyesight dulled by lack of proper illumination.

Facing public transit buses that cram over 300 people on board, these women make their way home, stopping to pick up rationed items at the store. Many days, there is nothing to buy. Children burst in from school, hungrier than ever before, since the lunch programs are putting less on their noontime plates, and if they've already eaten their rationed bread roll for breakfast, the mother will part with her own for their after-school snack. Dinner starts, with the added tension of wondering if a blackout will suddenly shut off electric burners, if the gas main will eke out enough to get the beans done, or if charcoal will have to finish the job. Add to this picture the fact that it does not describe a "pocket of poverty," but life for the majority of Cuban women today.

In the midst of this tension, public health continues to prioritize women and children, through the National Maternal-Child Program, the Family Doctor Program, the National Immunization Program, the Early Detection Program for Breast and Cervical Cancer, among others. These are credited with mobilizing scarce resources for attention to these sectors of the population, within the universal health care model. As a result, indicators such as infant mortality, under-five mortality, and maternal mortality are among the best in Latin America, and comparable to industrialized nations. (See Appendix.)

Making attention to women and children the top priority for public health in Cuba has shielded their essential well-being from the harsher realities of the economic emergency declared early in the decade and from the sharpest blows of the U.S. embargo, even after tougher sanctions were imposed in 1992. However, as discussed above, women's lives are exposed to such a myriad of detrimental factors that the prioritized protection granted them in health care cannot offer

sufficient protection. Dr. Cristina Valdivia, National Director for Ambulatory Care, told us that family doctors in communities across the country are dealing increasingly with family destabilization and dysfunction, due to the high levels of stress that come to bear first and foremost on women.²

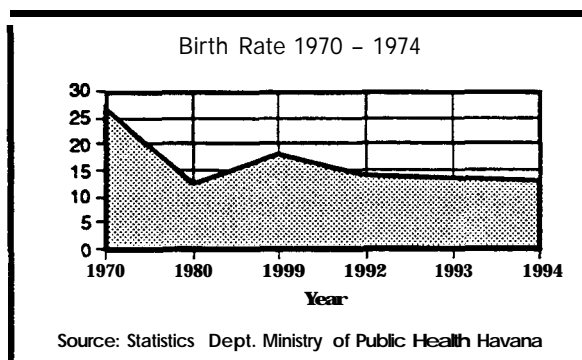
While this dilemma is not an outcome exclusively of the embargo, as a result of our research, we have come to share the opinion of UNICEF's Resident Program Director Luis Zúñiga Zárate, who commented: "Discussion of political regimes and strategies aside, the reality is that the [U.S.] embargo [against Cuba] is one of the key factors in the deterioration of the quality of daily life for children, for families and particularly for Cuban women."³

The limitations of this study do not allow us to explore the entire range of U.S. embargo implications for women's lives in Cuba: therefore, in this chapter we will concentrate on fundamental aspects of reproductive health and nutrition, followed by a detailed review of the embargo's effect on programs to prevent and treat breast cancer, since we found this a particularly striking example of the policy's impact on a life-threatening condition.

Family Planning, Sex Education and Birth Rates

For two decades, Cuba has had a community-based family planning program, reinforced in the 1980s with the participation of the neighborhood doctor and nurse teams which now dispense primary care for over 95% of the Cuban population. Written information and seminars at doctors' offices are complemented with conferences at schools, television and radio shows, regular columns in the press, etc.

As a result of these efforts, the numbers of women incorporated into the workforce, and the general educational level in the country, the birth rate most clearly reflects *couples' individual choices* in the timing and size of their families. By virtue of these decisions, more than any other factor, the birth rates have gone up and down with the country's economic situation: in the 1970s, a dip; a slight rise during the prosperous eighties; and another dip since the beginning of the nineties.



However, the current economic situation has also created substantial difficulties for educational work, and for effective birth control in general, with scarce resources siphoned off to critical, life-and-death programs. This in turn makes it harder for couples, and women in particular, to make a thorough exploration of choices, and to implement their decisions once made.

For example, availability and alternatives for contraception -have become a critical problem in Cuba during the last five years, due both to the economic situation and the U.S. embargo. We learned that Cuba has been able to produce only minimal stocks of birth control pills in this period (120 million of the 400 million needed annually), and their formulas are limited by not having

access to U.S.-patented ingredients. Dr. Miguel Sosa, President of the Cuban Society for Family Planning and Education (SOCUDEF), notes that there are some ten to twelve basic "mixes" of pills on the market, and by virtue of U.S. origin of some of the compounds, Cuba has access only to two. Both of these, he contends, are outdated and last choice in terms of risk factors for the women taking them.⁴

Production is complicated by two main factors: first, and most directly related to the embargo is the breakdown of Pharmacia-LRB lab equipment at the pharmaceutical plant where the tablets are produced. In addition, there are the bans on Cuba's purchase of parts needed to repair it, as a result of this Swedish company's merger with the U.S. firm Upjohn. This has backed up the release of millions of these tablets, pending the required quality control checks, now bottlenecked at another center where Pharmacia's High Performance Liquid Chromatography (HPLC) unit is still functioning, and, where all such testing is now being rerouted. (See details in the section on the Pharmaceutical Industry.)

Second, due to the general economic crisis exacerbated by the embargo, construction on a new plant for producing contraceptive tablets was paralyzed earlier in the decade. With funding from the Cuban government, and additional financing from the UN Population Fund, it was hoped that production would begin late in 1996. This should alleviate the situation, since the factory has a capacity of 500 million pills annually, and is equipped with precision technology from a manufacturer other than Pharmacia. In the meantime, workers at the Reynaldo Gutierrez Pharmaceutical Plant rotated through the birth control pill production line, their permanence limited by regular physicals to pull them out before their hormone levels become too high, due to exposure to the formulas. The new plant is completely automated and would not have these drawbacks for worker safety or for timely production.⁵

Birth control pills are another donation which is welcomed, but which presents its own problems: brands and dosages differ, notes Dr. Sosa, and so women are subjected to one brand one month and another brand and even dosage the next month—a far from ideal situation. Women in Cuba are mistreated when it comes to contraceptives," comments Dr. Sosa.⁶

Add to this the situation with condoms: In 1994, budget restrictions limited purchases to 49% of the island's needs. A year later, only 16.6 million were bought, with another seven million in donations, for a country which needs 120 million optimally and 60 million minimally. While most of these were imported from China, Dr. Sosa recalls that emergency purchases of U.S.-origin condoms were made through third parties in India, at "200% over the average wholesale price," due to bigger markups and shipping charges.⁷

There is generally a low acceptance rate among Cuban women for the diaphragm, and virtually no creams or jellies available. Due to all these factors, the primary form of contraception used in Cuba today is the intra-uterine device, or IUD. We end up using IUDs for everyone, when they are only indicated for a limited number of women, We were told by Dr. Francisco Valdes Lazo and Dr. Otto Machado of the Ministry of Public Health's National Maternal-Child Division.⁸ Indeed, this observation was repeated in virtually all our interviews with specialists in the maternity hospitals and primary care units. The IUDs can be dangerous for some women and are in part to blame for the high rate of pelvic inflammatory disease (PID) seen in Cuban women as well as for a share of ectopic pregnancies.⁹

However, Dr. Sosa informed us that even IUDs were at one time difficult to obtain because of the embargo, since DuPont held the patent for a plastic component used which enabled visualization by ultrasound.¹⁰

The specialists we interviewed estimate that approximately 25% of the abortions performed in Cuba today are a result of contraceptive failure, with another significant proportion a result of the use of abortion as a means of contraception.

ABORTION RATES IN CUBA	
Year	Rate*
1970	24.2
1980	43.2
1989	44.7
1992	41.1
1' 993	36.0
1994	37.4

**Per 100 pregnancies*

Source: Ministry of Public Health, Havana.

The Cuban Public Health Ministry has also recorded a rising incidence of sexually transmitted diseases (STDs) in the last few years, due in large part to shortages of condoms and medications. This increase applies to most STDs—gonorrhea, syphilis and condyloma, in particular.”

Pregnancy

Due to the presence of family doctors in virtually every Cuban neighborhood, 90% of pregnant women receive prenatal care beginning in the first trimester. In healthy women, prenatal care includes an average of 12 appointments with the family doctor, several of these jointly with a specialist in obstetrics and gynecology present. Pregnant women with risk factors are seen more frequently, and the family doctor is responsible for home visits if necessary. In addition, the Cuban program calls for all pregnant women to receive a series of prenatal tests and at least one ultrasound examination for the diagnosis of congenital malformations and disease.

From the beginning, however, specialists face a shortage of reagents for all kinds of testing: reagents for pregnancy testing, specifically determining levels of chorionic gonadotropin, are often lacking, requiring heavy dependence on clinical diagnosis. There are no home pregnancy testing kits available in Cuba, although Dr. Manuel Limonta, director of the CIGB told the authors that they are working on the development of such a kit. This work, however, is targeted by the CDA since it is a biotechnology project.¹² These shortages, in which the U.S. embargo plays a direct role, can be life-threatening when it comes to extra-uterine or ectopic pregnancies and molar pregnancies.

The reagent kits for chorionic gonadotropin are produced at the National Immunoassay Center, another of Cuba's biotechnology facilities. During the last period in particular, the Center has felt the full impact of embargo restrictions, including: purchase of U.S. chemicals and reagents through third parties at inflated prices and additional shipping fees, because comparable materials are not available elsewhere; and threatened cutoffs of critical supplies due to mergers and buyouts by U.S. corporations of key third-country exporters to the Center, such as Nunc GmbH (Germany) which was acquired in July 1995 by Sybron International (USA) and Pharmacia (Sweden), which merged with Upjohn (USA) in August 1995.

Thus, due to the Upjohn-Pharmacia merger, for example, key equipment and chemicals used for chorionic gonadotropin kit can no longer be purchased directly, nor at reasonable prices, and stable supplies have not been assured since Pharmacia closed its Havana offices in November,

The specialists we interviewed estimate that approximately 25% of the abortions performed in Cuba today are a result of contraceptive failure, with another significant proportion a result of the use of abortion as a means of contraception.

ABORTION RATES IN CUBA	
Year	Rate*
1970	24.2
1980	43.2
1989	44.7
1992	41.1
1' 993	36.0
1994	37.4

**Per 100 pregnancies*

Source: Ministry of Public Health, Havana.

The Cuban Public Health Ministry has also recorded a rising incidence of sexually transmitted diseases (STDs) in the last few years, due in large part to shortages of condoms and medications. This increase applies to most STDs—gonorrhea, syphilis and condyloma, in particular.”

Pregnancy

Due to the presence of family doctors in virtually every Cuban neighborhood, 90% of pregnant women receive prenatal care beginning in the first trimester. In healthy women, prenatal care includes an average of 12 appointments with the family doctor, several of these jointly with a specialist in obstetrics and gynecology present. Pregnant women with risk factors are seen more frequently, and the family doctor is responsible for home visits if necessary. In addition, the Cuban program calls for all pregnant women to receive a series of prenatal tests and at least one ultrasound examination for the diagnosis of congenital malformations and disease.

From the beginning, however, specialists face a shortage of reagents for all kinds of testing: reagents for pregnancy testing, specifically determining levels of chorionic gonadotropin, are often lacking, requiring heavy dependence on clinical diagnosis. There are no home pregnancy testing kits available in Cuba, although Dr. Manuel Limonta, director of the CIGB told the authors that they are working on the development of such a kit. This work, however, is targeted by the CDA since it is a biotechnology project.¹² These shortages, in which the U.S. embargo plays a direct role, can be life-threatening when it comes to extra-uterine or ectopic pregnancies and molar pregnancies.

The reagent kits for chorionic gonadotropin are produced at the National Immunoassay Center, another of Cuba's biotechnology facilities. During the last period in particular, the Center has felt the full impact of embargo restrictions, including: purchase of U.S. chemicals and reagents through third parties at inflated prices and additional shipping fees, because comparable materials are not available elsewhere; and threatened cutoffs of critical supplies due to mergers and buyouts by U.S. corporations of key third-country exporters to the Center, such as Nunc GmbH (Germany) which was acquired in July 1995 by Sybron International (USA) and Pharmacia (Sweden), which merged with Upjohn (USA) in August 1995.

Thus, due to the Upjohn-Pharmacia merger, for example, key equipment and chemicals used for chorionic gonadotropin kit can no longer be purchased directly, nor at reasonable prices, and stable supplies have not been assured since Pharmacia closed its Havana offices in November,

1995. The chorionic gonadotropin test is critical to women with ectopic pregnancies, which cannot be detected early through clinical exam, and can have serious and permanent consequences for health if not found in time. As the rest of the world, Cuba is experiencing a rise in the rate of ectopic pregnancies. In a study of 39 hospitals, a 53% increase was registered in the last five years." Such tendencies are most commonly associated with the use of IUDs, abortions and other complications.

In the case of molar pregnancies, the rate is less (one for every 1500 pregnancies), but the consequences can be dangerous. A molar pregnancy involves the growth of cancerous cells within the fetal tissue. These --elaborate-a unique and characteristic tumor marker, human chorionic gonadotropin (hCG)" end are highly curable with chemotherapy. The hydatidiform mole is the most common, and studies show the highest incidence among women whose diets are deficient in protein, folic acid and vitamin A Careful monitoring of beta-hCG levels is necessary for diagnosis, treatment and follow-up in these cases, especially to avoid metastases, which can develop into a life-threatening condition."

Thus testing for levels of chorionic gonadotropin in the blood is an absolute requirement for these patients. Yet, we encountered shortages of the reagents needed for these tests at many of the hospitals we visited, in good measure due to problems triggered by the sudden application of U.S. embargo restrictions on key Cuban suppliers which have entered into partnerships with U.S. companies. "This is of great concern to us, as these women who have had a molar pregnancy are placed at significant risk."¹⁵

In the case of molar pregnancies, women are also affected by the lack of chemotherapy drugs, despite the A-1 Priority status accorded these medications on the list currently circulating in Cuba. Treatment generally calls for chemotherapy with methotrexate and/or dactinomycin. Other protocols add cisplatin, chlorambucil or cyclophosphamide, leucovorin calcium, hydroxyurea, vincristine, vinblastine and/or etoposide.¹⁶ During an on-site visit to the Provincial Maternity Hospital in Pinar del Río, we encountered three patients hospitalised for molar pregnancies who were about to be released without the required chemotherapy treatment, since no methotrexate was available.

As will be discussed in the section on breast cancer, and as is covered in the section on the Pharmaceutical Industry, not only does the embargo significantly add to the price of imported chemotherapy drugs some of the most expensive on the international market-but it has also directly sabotaged Cuba's domestic production of these medications, which represented a fraction of the cost. As a result of the embargo, then, these life-saving medicines are not available for all patients who need them.

In 1985, Cuba initiated a comprehensive testing program for detecting congenital malformations, relying on alpha fetoprotein and corollary analysis, a program which currently covers 95% of pregnant women. Among other conditions, tests determine the presence of congenital hypothyroidism, infant allergy predisposition, HIV 1 and 2 viruses, and hepatitis B and C. The program uses reagents and kits produced by the National Immunoassay Center, which is responsible for some 8 million laboratory diagnostic tests every year, and for supplying reagents, technology and equipment for over 100 Cuban laboratories. ¹⁷(See sections on Diagnostic Testing and Protection of the Blood Supply).

The U.S. embargo has negatively impacted Cuba's testing program, and poses a considerable **threat to the country's** capabilities to maintain uninterrupted screenings for pregnant women in the coming period. This is due to the decisions by key suppliers to become associated with U.S. firms: Pharmacia and Nunc are the most recent examples, and similar problems of supply occurred earlier with the Swedish reagent producer Fluka. The result in each of these cases is that Cuban importers must find quality substitutes for the products, provide samples to laboratories for quality control testing, sign new contracts and ensure the speediest delivery possible of the

substitute items. The following reagents used in the genetics program were regularly bought from Pharmacia prior to the August 1995 merger: Ficoll-400, Ficoll Paque, Deae Sephacel, Sephadex Deae, Sepharosa 4B Lentil Lectin, CNBR Sepharosa UB ACT and Proteina A Sepharosa Cl 4B. Dr. Manuel Garcia of the Gonzalez Coro Maternity Hospital confirmed that all were used by the Genetics department but were difficult or impossible to obtain by the time of our 1996 interview.**

To make the switchover complete, reports Dr. José Fernández Yero, Director of the Immunoassay Center, adaptations in technology may be necessary to "fit" the new line of reagents. An alternative solution sought by MEDICUBA is to continue purchasing reagents, parts and equipment from Pharmacia, through third parties. In this case, significant delays and price hikes have also been the norm: the firm reports it took at least six months to obtain a first quote from an intermediary willing to sell Cuba parts for a broken HPLC unit (used in genetics testing as well as in production), originally purchased from Pharmacia-LRB. However, the wholesaler wanted 40% more than the part had previously cost when bought directly from Pharmacia.

The outcome of either of these options is higher prices and freight costs, delays in shipping, and ultimately a period of depleted stocks. In fact, more acute shortages of reagents have been registered since the Pharmacia merger, posing special problems for genetics testing during pregnancy due to the narrow time frame for such tests.¹⁹

For example, alpha fetoprotein (AFP) testing, is routinely carried out in Cuban women during their 16th to 18th week of pregnancy. If positive, the test is normally repeated, and should a second positive be registered, the patient is referred for amniocentesis before confirming diagnosis. Each of these steps must be performed within a period of approximately two weeks, and each requires rapid determination, since a decision to terminate pregnancy at this late juncture is difficult both psychologically and physically. However, the U.S. embargo's implications for the program described above include tightening of the economic and logistical limitations, and it is no longer possible to guarantee the sequence of testing for all women who need it.

Complicating this situation, as we have seen in the section on Diagnostic Testing, is the fact that there are equipment components and reagents which are produced with acceptable quality standards only in the USA, according to Cuban specialists. These items are legally unavailable to Cuba and once again their acquisition means extra time and money—the extra expense often prohibitive.²⁰ Dr. Manuel Garcia, Director of the Gonzalez Coro Maternity Hospital in Havana, reported this to be the case at his genetics department: "We try to get the [U.S.] products through third countries when we can, but sometimes the price is just too high." He says that in this regard the U.S. embargo has compounded the program's already substantial problems. "The result is that genetics testing is being done less and less here. There have been months and months when we were not able to do any amniocentesis, and many women who should have had that test did not."²¹ This is the situation encountered at the Gonzalez Coro Hospital's Genetics Department which doubles as the center for the National Genetics Program. Generally we found a worse situation at other institutions which at one time had the capacity for genetics testing. Only 500 amniocentesis tests were carried out in 1995, one fifth the number done in 1989.²²

Specialists from the National Maternal-Infant Division of the Ministry of Public Health confirmed that the amniocentesis and cytogenetics programs have been severely affected, primarily due to the absence of necessary reagents. Cytogenetics stopped service in 1995 for nearly the entire year. One reason cited was problems in procuring the 25 components for cellular culture mediums, at a reasonable price. All are complex to produce, and Merck holds many of the patents.²³

Nutrition in Pregnancy

Since the U.S. embargo was imposed in 1962, it has tended to reduce the food available for the Cuban population, bearing down more forcefully with the Cuban Democracy Act (CDA) of 1992, which eliminated multi-million-dollar Cuban imports from U.S. food subsidiaries abroad. In addition, as outlined in the section on The Food Supply and Nutrition, the embargo has severely restricted Cuba's ability to purchase fuel, fertilizers, pesticides and seeds; and to buy ingredients, parts and equipment for the domestic food processing industry. Further prohibitions dictated by the CDA target Cuba's efforts in biotechnology research, which is directed at increasing crop yields, planting disease-resistant crops, achieving quality seedlings through genetic engineering, and multiplying growth rates of certain species such as the freshwater fish, tilapia.

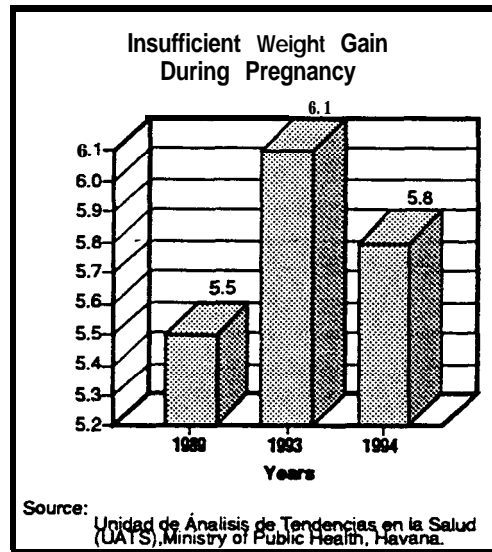
As a result of these influences, and the general economic crisis aggravated by the embargo, food security has been seriously affected in the nineties. A 1996 report from the Ministry of Public Health states that food security in Cuba "has been precarious since 1992... and by 1993 a substantial deterioration in the nutritional status of the Cuban population could be observed."²⁴

Slight improvements were noted in 1995, but average consumption was still below the recommended 2400 calories per day for women in general, and 2800 for pregnant women. In fact, some specialists suggest that actual caloric needs may be higher during the economic crisis, because people are expending extra energy: transportation problems lead to more bicycling and walking long stretches; increased difficulties with water supplies mean regular carrying of buckets, sometimes for quite some distances and up several flights of stairs; and shortages of cooking fuels translates into hauling wood or charcoal as alternatives. The close to 50% of Cuban women, wives and mothers, who currently work outside the home, and who shoulder the primary burden of a "second shift" to keep the household running, are particularly affected.

Nutritional deficits have had particular impact in pregnancy, complicated by the fact that in response to the crisis, many women disburse much of their rationed food allotment, particularly the protein, to their children. In fact, most Cuban families have prioritized children and the elderly in the household, so that women and men of reproductive age tend to be hardest hit by food shortages.²⁵

More women now are beginning pregnancy with deficient nutritional status than at the beginning of the decade, with the greatest problems showing up in the eastern provinces. In 1989, 8.8% of women beginning pregnancy were undernourished; by 1994, that figure had climbed to 10.48." A mother's pre-pregnancy nutrition is an important factor in the development of the infant's metabolic pathways and future well-being, and lack of proper diet at the start of pregnancy does not bode well for the full term. Moreover, because of economic limitations, once again impacted by the embargo, the extra rations allocated to pregnant women do not begin until the end of week 12 of pregnancy. Each woman receives one half-liter of milk daily, plus three pounds of beef per month, in addition to her regular rations, listed in the appendix to the section on The Food Supply and Nutrition.

Pregnant women have special dietary needs, including increased calories, protein, iron, folic acid, calcium and zinc. Consumption of inadequate calories during pregnancy can lead to inadequate intake of other essential nutrients. Most women should gain an average of 10-12 kg during pregnancy, and underweight women need to gain more. In the last several years, Cuban specialists estimate that pregnant women in Cuba have been receiving as few as 60% of the calories and protein they need. This situation has been remedied to a certain extent with the expansion of live-in maternity homes for high-risk women, which also serve as meal centers for pregnant women in the surrounding community. Even so, the homes cannot always provide the diet required.



Inadequate weight gain is associated with the higher rates of premature births and low birth weights registered in the early nineties.²⁷

Luis Zúñiga Zárate, Resident Program Director for UNICEF-Cuba, noted that by 1991, iron deficiencies could be detected in nearly one third of pregnant women in the country, another contributing factor to the sustained rise in low birth weight through 1993. Zúñiga estimated that about 30% of pregnant women (about 45,000) fell into a high risk category, due to insufficient weight gain and/or low hemoglobin counts.²⁸

Since 1993, UNICEF has sponsored prenatal vitamin supplements of iron, folic acid, Vitamin C and Vitamin A, produced at the Reynaldo Gutierrez Pharmaceutical Plant in Havana, and provided to all pregnant women in Cuba (170,600 annually). However, as we note in the section on the Pharmaceutical Industry, timely production of this vital supplement is now being held up, as key U.S.-origin equipment at the plant is in disrepair, with no immediate likelihood of obtaining parts.²⁹

Premature births and low birth weight-associated in Cuba's case with poor nutrition, anemia, hypertensive states of pregnancy, infection, and stress-are in turn major causes of infant mortality. In one hospital, we were told that 63.3% of infant deaths were infants who had been born premature.³⁰

Medications and Pregnancy

We encountered embargo-related deficits in a number of important medications related to pregnancy.

Prostin E2 and Prostin F2 Alpha (prostaglandins) are considered to be drugs of choice for inducing labor. Dr. Alejandro Velazco, Director of the Eusebio Hernández Maternity Hospital, comments that "Prostaglandin has no substitute. It is truly superior for inducing labor, and for use in abortions. If we had the prostaglandins we would not have to use oxytocins, which carry greater risks for the mother and child, increasing the chances of uterine rupture, amniotic fluid embolism, and fetal distress or fetal compromise³¹ His situation was repeated at other maternity hospitals we visited both in Havana City and Pinar del Rio provinces.

These products are manufactured by the U.S. firm Upjohn, and are listed by the manufacturer as exclusively for hospital use. This creates problems, however, for Cuban hospitals, which do not have normal direct access to Upjohn because of the embargo, and must depend on trading houses or other intermediaries. In this instance, a notification of destination is required, thus blocking Cuban hospitals from obtaining the prostaglandins even by end-running the embargo through third parties. Thus, in this situation the U.S. embargo presents a barrier to the quality of care for expectant mothers.³²

Insulin. Diabetes during pregnancy presents a complicated medical management problem for insulin dependent women and their doctors. These women should be initiated on human insulin or changed from animal products for reduction in antibody formation, according to relevant literature in this field.³³ However, human insulin is not currently available in Cuba, and, in fact, there have been problems with the stability of the supply of insulin in general, with hospital stocks often being supplemented by donations.

In 1993, executives of Eli Lilly (Canada) informed Cuba that as a result of the prohibition on subsidiary trade with Cuba dictated by the CDA, they would not be able to sell insulin to Cuban buyers as before. Lilly is the world's number one producer of insulin. While this is a mistaken conception, it illustrates the extent to which the embargo discourages companies from applying for requisite export licenses, and coincides with the parent company's understanding of U.S. law, as noted in the survey described earlier in this study. (See chapter on Medical Exports to Cuba.) Cuban importers are currently buying from Europe, at significantly higher rates for air shipments, a cost that could logically have been applied to human insulin purchases from Lilly or another competitive U.S. supplier in quantities enough to cover the needs of diabetic women during pregnancy.

Vaginal Suppositories. Medications for sexually transmitted diseases (STDs) and vaginal candidiasis, or yeast infections, should be administered to pregnant women as vaginal suppositories or creams. Literally every women's health specialist and family physician contacted told us that these were in extremely short supply, constituting a serious problem for the pregnant woman with an infection. Without such suppositories, both she and her fetus can be at risk of contracting a number of perinatal complications. Dr. Manuel Garcia, Director of the González Coro Maternity Hospital in Havana reported that his institution does not have a stable supply of vaginal suppositories and that the necessary variety is also missing. "These are really very important in pregnancy...vaginal yeast infections (candidiasis), for example, should be treated before birth to avoid the risk of serious lung infection in the newborn."³⁵ At the national level, specialists from the Maternal-Child Division of the Ministry of Public Health confirmed that indeed this is the case, due to economic limitations on medical imports.

Asthma Medications. The incidence of illness and deaths from asthma are both on the rise. Among the factors influencing this trend is the unstable supply of asthma medications, with a patient sometimes required to change a medication he or she is accustomed to, or go without the most effective drugs for their particular case. In a meeting with specialists from the National Asthma Commission, we learned that women are particularly affected by these problems, since they are more subject to worsening household environmental conditions which can provoke recurring attacks. These include the use of homemade alternative cleansers and paints, and prolonged exposure to charcoal, firewood or kerosene fumes, which were being substituted by gas until the recent economic crisis.

Here, again, if medications could be bought from the U.S.; significant savings could be achieved and used to offset shortages, particularly of inter-crisis inhalers. Yet, even limited additional purchases of steroid inhalers could make a difference for pregnant women who need them, since this form is considered safer than oral administration for both mother and unborn child.³⁶ Cuba is

spending hundreds of thousands of dollars extra in air-cargo to bring asthma medicines from Asia and Europe, due to difficulties finding less expensive maritime transport, primarily because of the CDA shipping restrictions. For example, in 1993, two million bottles of salbutamol were flown to Cuba from Asia at \$7.00 a kg. Cuban economists estimate that for every 5 dollars spent shipping by air from Europe, 4 could be saved if shipped from the U.S.³⁷

Due primarily to economic constraints aggravated by the embargo, several more medication shortages are of special concern to obstetricians and gynecologists. These include: hormonal medications which have been severely cut back during the last five years; antibiotics, particularly the antibiotic of choice in any given situation; medications for gestational hypertension (preeclampsia and eclampsia), which is a factor in low birth weight and premature births; medications to stop bleeding after birth; and anesthetics, including thalamonal (see chapter on Medical Exports for delays caused by U.S. licensing requirements for this product).³⁸

Hospital Conditions for Pregnancy and Delivery

Over 99% of births in Cuba take place in hospitals. This fact has been credited with helping to reduce infant mortality over the years, which in 1996, stood at 7.9 per 1,000 live births, or the lowest rate in Latin America. Yet, hospitals are now experiencing a series of problems due to the economic crisis and the U.S. embargo: hygiene, equipment repair and maintenance, shortages of basic supplies ranging from soap and disinfectants to Kraft paper for sterilization, sheets and surgical greens, and sanitary napkins or cotton wadding for women in post-partum. Transportation limitations to the hospital are an extra burden for pregnant women and their families.

Dr. Manuel Garcia, Director of the Gonzalez Coro Maternity Hospital, painted a stressful picture for patients and staff:

We have daily crises--of looking high and low for a medication, or doctors who perform heroics to save a life under especially **difficult** conditions-but we can't **say we** have had a woman die in our care because of the embargo. We struggle against the odds so that will not happen. However, what is truly dramatic is the alarming rise in risk factors expectant mothers bring into our hospital--such as insufficient weight gain, inadequate solutions for illnesses during pregnancy, stress and hypertension, and so on. On top of this, we now have a situation where hospitalization itself constitutes a risk, because of increased possibilities of infection. Yet, this still does not compare to the dangers inherent in not bringing in women who need to be here. And there are more of them, so the hospital is always full: we are hospitalizing more women than ever, earlier in their pregnancies than ever.³⁹

As we have seen, one of the threats to hospital hygiene and care is the lack of water supply and clean drinking water for many of these institutions, a crisis which is a direct result of the U.S. embargo and the obstacles it has presented for repairs to the essentially U.S.-origin water system throughout the country, particularly after the CDA cut off subsidiary trade in 1992. (See section on Water Resources for details.) As we note elsewhere, the lack of water and clean water play a significant role in hospital infections and sepsis.

In fact, physicians and administrators we spoke to at maternity hospitals concurred that infection was the common, complicating element in maternal mortality. Specialists from the Maternal-Infant Care Division of the Ministry of Health state that "In 1995, as in 1994, sepsis was an important factor in -maternal mortality in a significant number of cases."⁴⁰

Cuban maternal mortality indices climbed from 29.2 per 100,000 live births in 1989 to 44.1 1994. In addition to home and hospital infections, the Ministry of Public Health attributes this rise to factors

correlated to poor health and nutritional status and lack of medications for infections." Maternal mortality declined in 1995 and is expected to dip further in 1996, as a result of a special mobilization of personnel and resources to curb the increases.

For example, although it does not appear as a specific cause of maternal mortality, the Ministry of Health has issued an alert and guidelines for reducing the rate of Cesarean births, since specialists estimate that approximately 30% of maternal deaths are associated with complications arising from this procedure, including post-operative infections." Currently, the Cesarean rate in Cuba is 22%, and 15% for first births. It is still common practice in Cuba to deliver all subsequent newborns by Cesarean, once a woman has had one Cesarean delivery. Other factors contributing to maternal mortality rates include preeclampsia-eclampsia and hemorrhage (refer to medicine shortages listed above).

In general, it is our finding that while the Cuban health care system places a priority on women's reproductive health, professionals in the sector face an uphill battle to improve nutritional and health levels before and during pregnancy, and to keep maternal mortality, low birthweights and infant mortality down. The U.S. embargo, directly or indirectly, by siphoning off precious resources for shipping and higher-priced inputs, constitutes a hindrance to these efforts.

Infertility Programs and Counseling

Some 10-15% of Cuban couples of childbearing age are faced with fertility problems, of which approximately 5-10% would be eligible for in-vitro fertilization/embryo transfer (IVF-ET) programs, and a larger share of whom would benefit from other therapies.

In the late eighties, Cuba developed a fully equipped infertility program, including IVF-ET. Nine healthy babies were born through IVF. However, by 1992, the service, headquartered at the Gonzalez Coro Maternity Hospital in Havana, was essentially shut down.

Many of the reagents needed for standard genetics testing for at-risk couples were simply in too short supply, their purchase reduced and later eliminated for the reasons outlined above. Diagnostic workups and treatment programs for infertile couples have experienced even more severe shortages of reagents, hormones and other medications. Specialists say that in the short term, there is little hope of revitalizing the program, especially in view of the added costs and limitations posed by the U.S. embargo, as we have noted. Laboratory heads indicated, among other things, that a number of the Pharmacia chemicals and equipment no longer available to Cuba had been used to isolate purified proteins to determine hormone levels, just one series of tests important in infertility investigations.⁴⁴

In addition, a number of important medications and hormones necessary for both diagnosis and treatment of infertility are no longer stocked. Currently, there is no medication for the stimulation of ovulation available in Cuba, primarily due to the economic situation, exacerbated by the embargo, which forces priority to be placed on purchases for more critical conditions.⁴⁵ Nor will new U.S. drugs for infertility—a field in which the United States takes the lead—be available to Cuban patients.

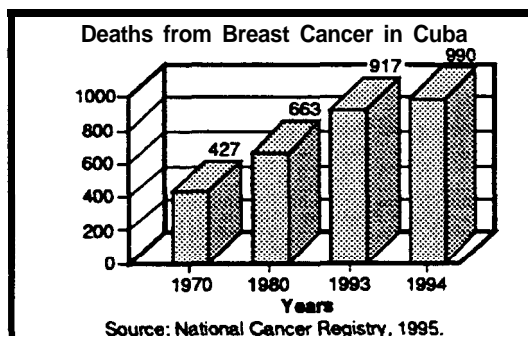
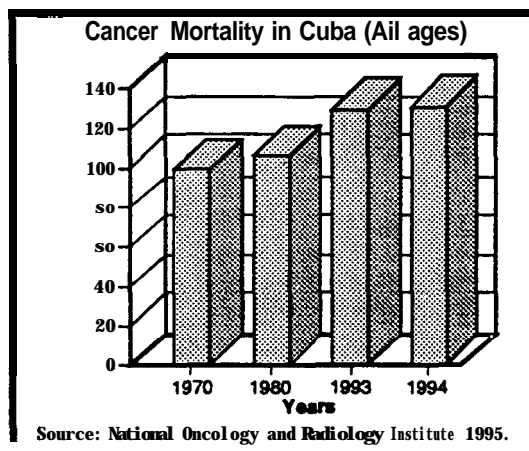
Dr. Manuel Garcia, Director of the Gonzalez Coro Hospital, stated, "There is not much we can do for infertile couples today. The testing is quite complex, and requires step-by-step procedures which are almost impossible, since every other step, some key product is missing⁴⁶

Waiting, for those who can, seems to be the only option: "There is no hope, other than to wait, if the couple is young enough, in hopes that we can re-establish the program," says Dr. Evelio Cabezas, Chief of the National Obstetrics and Gynecology Program.⁴⁷

But some cannot wait. Dr. Luis Heredero, Director of the National Center of Medical Genetics, admits: "In our context, the infertility program had to take a back seat. But as a result, there are couples who very much want children who will not be able to have them, especially older couples who have less time to wait for the economic situation to improve."⁴⁸

Breast Cancer

Malignant neoplasms or cancer are second only to cardiovascular disease as the leading cause of death in Cuba, and it is the leading cause of death in people between the ages of 50 and 64. Both cancer incidence and mortality are on the rise.⁴⁹ (See section on Oncology.)



The ten most common malignancies in Cuban women, listed by site, show breast cancer to be both the most prevalent form of cancer in women, as well as the principal cause of death by cancer in women. 990 women with breast cancer died in 1994, and the tendency is ascending.⁵⁰

Cuban scientific literature and the specialists consulted **estimate** that effective education, prevention and early detection programs, along with consistently applied treatment protocols, would reduce the current mortality rates by 20% or more.⁵¹

However, our research indicates that the embargo impacts virtually all aspects of cancer management, either directly or indirectly, by its incidence in the current economic crisis in Cuba. (See section on Oncology.) As a result of on-site visits to public health facilities at the primary, secondary and tertiary care levels and interviews with specialists, family doctors, community activists and women with cancer, we have found breast cancer to be an example of the pervasive

nature of the embargo as it plays a role along the chain from prevention and early diagnosis to treatment and research and development of new products in the fight against this leading cause of death in Cuban women.

Cuba has developed national programs for the prevention and early detection of breast and cervical cancers. These, among others, are community-based programs supported by the media, local organizations and the neighborhood doctor-nurse teams. They have been in place in one form or another since the 1960s, and are based on WHO guidelines.⁵²

According to Dr. Rolando Camacho Rodriguez, Resident of the National Cancer Prevention and Control Commission and Director of the National Oncology and Radiology Institute, these programs-which apart from educational components include diagnostic workups-are costly and have been particularly vulnerable to the country's economic free fall since the beginning of the nineties, with extra limitations imposed by the U.S. embargo and the CDA of 1992. In the field of oncology, Dr. Camacho asserts that preventive strategies have been weakened by the crisis, since scarce resources have had to be prioritized for costly life-and-death curative procedures and treatment.⁵³

His comments were borne out by our observation of the national mammography program, where economic and embargo-specific obstacles combine to spell severe setbacks. Specialists in general, including the Cubans, accept WHO guidelines and American Cancer Society Recommendations for screening of asymptomatic women. These prescribe a baseline mammography at age 35, and decide the earlier use or frequency of later mammographies on the basis of family and individual histories. Generally, it is recommended that mammograms be repeated every two years from ages 40 to 50 and annually thereafter. However, due to economic restraints, mammography is available in Cuba today only to those considered high risk, and is not a routine preventive procedure for other women over 35.⁵⁴

The Cuban screening program relies on one mammography unit at the National Oncology Institute and one at the Hermanos Ameijeiras Hospital (the two national reference centers for breast cancer), plus 15 mobile units in the country-two for the city of Havana and one each for the other provinces. Each unit, when functioning, can carry out approximately 400 mammograms a week, including post-operative mammography.⁵⁵ Dr. Orlando Valls, head of the Cuban Radiology Society and Chief of Radiology at the Hermanos Ameijeiras Hospital, says that historically about 2% of these tests show some indication of pathology, and are referred for further studies.⁵⁶

However, the units have been working at far from optimum levels over the past five years: shortage of hard currency to purchase spare parts for the mammography equipment and the mobile unit vehicles causes delays in repairs and makes routine maintenance difficult at best. In 1994, the whole program shut down for two months because there was no x-ray film available. In the first part of 1995, the program was shut down again, this time for one month, since stocks of developer had run out. On any given day, in any given province, a myriad of economic obstacles frustrate the planned functioning of the mobile units, says Dr. Maria Luisa Buch, Chief of the National Program for Early Detection of Breast Cancer.⁵⁷

Fuel shortages also impose serious obstacles to the operation of the centers and equipment. Each of the mobile units functions with a generator which can run the equipment for some four to six hours a day. However, fuel is often simply not available, since the oil supply for the island has been cut in half from 1989 levels, and only 12 to 15 of the world's tankers now travel to Cuba, as a result of CDA shipping restrictions imposed in 1992, and then at exorbitant freight rates, running at least 25% over World Scale. (See chapter on The -Embargo in the context of the current economic crisis.)

In addition, the U.S. embargo bans the use in Cuba of the x-ray film specifically recommended by the WHO to expose women to the least possible radiation: Kodak Mini-R film for mammography,

produced in the USA⁵⁸ Both Dr. Buch and Dr. Valls expressed concern that Cuban women were being exposed to higher radiation levels, because under the embargo Cuban importers do not have ready access to this more sensitive film.⁵⁹ Dr. Valls reported that they have approached third-party trading companies, but without success: the markup through such intermediaries puts the price out of range, and even so, reluctance was encountered on the part of these trading companies, who expressed fears that the large quantities required by Cuba to cover its national screening program might call U.S. government attention to the illegal sale, and expose them to reprisals in the form of elevated fines.

These difficulties prompted Luis Zúñiga Zate, Resident Program Director for UNICEF, to comment on the cause. 'One could say that the chain of scarce resources and limitations affecting the early detection program derives from the U.S. embargo,' he said in a meeting of UN agencies in 1995.⁶⁰

The results for women and their doctors are both frustrating and frightening. From 1990 to 1994 in Havana City, a well below capacity number of 42,000 mammograms were done. Of these, 185 registered positive, with 43 of these zero lesions (before the invasive stage), while another 58 were pre-malignant lesions. It is doubtful that at this early stage--the ideal for fully eliminating the breast cancer risk through effective treatment--these lesions would have been detected by physical examination. These 100 women were lucky to have had a mammogram, but hundreds more like them did not.⁶¹

Dr. Ana Isabel Valdés, a family doctor in a community to the east of Havana, reports that 44 women in her care were classified as high risk for breast cancer and thus eligible for mammography when the mobile unit came to her municipality. The classification system organizes women over age 35 into high risk, medium risk and low risk categories. However, many women must be eliminated who under normal circumstance would qualify for a mammogram under the guidelines of the original Cuban program. Thus, Dr. Valdés' caseload includes 164 women over 85, each of whom should have had a baseline mammogram; 53 women between 40 and 50, each of whom should have mammograms every two years; and a smaller number over 50, each of whom should have a yearly mammogram. But in fact, most of these women have never **had** a mammogram.&

Ideally, treatment for breast cancer should be instituted following early detection. Because of the problems with the mammography program described above, Cuban women with breast cancer often begin treatment late, with the consequent impact on prognosis. The therapeutic options available to Cuban physicians, including surgery, chemotherapy and other medications, and radiation therapy, are all affected to at least some degree by the U.S. embargo.

Surgery for breast cancer is impacted in several ways. Anesthesia is affected by serious problems with operating room equipment and repairs, plus other difficulties faced by surgical services nationwide (see section on Hospital Care). Dr. Lorenzo Anasagasti, Technical Vice-Director at the Oncology and Radiology Institute, told us that U.S. firms have the best quality equipment but since they are out of the bidding, the Cubans must buy what they consider to be generally inferior equipment at higher prices. He also reports delays in arrivals of spare parts for equipment when a U.S. partnership is involved.⁶³

At various hospitals visited, we encountered waiting lists for surgery. In fact, the number of surgical interventions performed over the past five years has seriously declined throughout the Cuban hospital system. (See section on Hospital Care.) At the Eusebio Hanandez Maternity Hospital, a major OB-GYN teaching- hospital in Havana, we were told that an average of 15 gynecological surgical interventions were performed daily in the 1980s, but that currently they are only able to perform two or three a day. At the time of our visit, there was a back-up of 60 days, with more than 100 women waiting, most with breast or uterine cancers since these cases are prioritized

for surgery.⁶⁴ Dr Manuel Garcia, director of the González Coro Maternity Hospital likewise told us that 1,000 fewer surgeries had been performed in 1995.⁶⁵

Intra- and post-operative tissue analysis and mammograms often present problems as well. It is standard procedure to review tissue during surgery to guide further intervention or to know when to close the wound. There have been times when relatives of patients on the operating table have had to take tissue samples to another hospital for inspection, often requiring completion of the operation before all the results are in. Sometimes, post-operative mammograms cannot be performed, thus leaving doubt as to the efficacy of the surgical procedure. There is only one mammography machine at the Institute, which is not always functioning. When these mammograms are performed, it is with film that exposes the patient to higher doses of radiation, as noted above, since the Mini-R film from Kodak is not available.⁶⁶

In breast cancer, the Cubans normally apply a protocol which includes cyclophosphamide and 5-fluorouracil, combined with either methotrexate or adriamycin. These drugs are not always in sufficient stock. During an October, 1995 visit to the National Oncology and Radiology Institute, we found, only one of these (cyclophosphamide) in the hospital pharmacy. We were told of the anguish this causes to patients, their families and physicians, especially since this treatment must be started two to three weeks following surgery to achieve maximum effectiveness and the best prognosis. The shortages of anti-cancer agents were even more acute at virtually every other hospital we visited. For example, at the González Coro Maternity Hospital in Havana, physicians reported that cisplatin for gynecological cancers, methotrexate for breast cancer and in general most of the medications needed for cancer treatment are very difficult to guarantee.⁶⁷

Likewise, at the Abel Santamaría Provincial General Hospital in Pinar del Río, physicians noted gaps in the availability of anti-cancer drugs, including medications used for the treatment of breast cancer.⁶⁸ In 1995, the economic difficulties exacerbated by the embargo created a continuing shortage of anti-cancer drugs. If these could be purchased directly from the U.S., as we have seen across-the-board, significant savings could be achieved by lower freight costs and in many cases more competitive prices, allowing the budget for these medicines to go further.⁶⁹

At the Oncology Institute, we found a chemotherapy waiting list for breast cancer patients. During our October 1995 visit, Dr. Barroso reported that "For the last two weeks, we have not been able to accept any new patients for chemotherapy because of drug shortages. They must postpone treatment." At that time, ten patients were on the waiting list, but she said this number was actually considerably higher since physicians had been advised to hold up referrals. These were all women whose disease-free survival time was evaporating with each day of waiting.⁷⁰

In addition to chemotherapy drugs, the national cancer program also experiences shortages in commonly used hormones for therapy. There are gaps in the supply and thus, for example, the hormone medication, tamoxifen, used in one half of breast cancer patients is frequently not available for a patient at the time she needs it.⁷¹ Tamoxifen is used in adjuvant therapy to delay recurrence of breast cancer following surgery and/or radiation therapy, and is also used for advanced disease in the treatment of metastatic breast cancer.⁷²

Hilda Guadarrama is a 60 year old Havana woman whose condition and course of treatment illustrate the cumulative impact of these difficulties for patients: she was diagnosed with breast cancer in early 1996, when she decided to see a specialist at the Oncology Institute because of an abnormal growth in one of her breasts, detected by self examination. She had never had a mammogram. After a relatively short time on the waiting list for surgery, in her case approximately six weeks, she was successfully operated on (mastectomy) without complications, but was not able to get any tamoxifen, prescribed by her physician. Approximately two months after surgery the Oncology Institute was able to guarantee her regularly needed supply of the medication, but only on a month-by-month basis. At no time was she able to obtain analgesics to

relieve post-operative pain, which, she describes as particularly severe during the first week after surgery.⁷³

It is noteworthy that the U.S. embargo bans U.S.-manufactured drugs for breast cancer from Cuba. These are not readily available to Cuban patients from the time they are patented, and for approximately a decade after they are first sold on the international market. This has a devastating impact on the ability of Cuban physicians to prescribe the latest, most effective medications of choice for this condition: U.S. medicines developed for breast cancer therapy as far back as 1979 cannot be freely purchased for Cuban patients until 1997, when generics can be produced by firms in other nations. Similarly, those discovered in 1996 are not legally an option for these patients, should they still be alive, until the year 2013

This problem brings double trouble, since the United States is the world's leader in cancer research. According to a British report, U.S. labs developed five of the 16 Major Global Drugs against cancer which were discovered in the 22-year period between 1970 and 1992. (The EC countries taken together were responsible for eight, and other Western European countries for the remaining three.) In addition, the U.S. lead is overwhelming among other cancer-effective agents such as biotechnology products, including monoclonal antibodies.⁷⁴

In its 1995 fifth survey of "New Medicines in Development for Cancer," the Pharmaceutical Research and Manufacturers of America report that 215 new medications were in Phase I-III FDA trials at the time. By far, the largest number—48—were being developed against breast cancer. A total of 72% of these drugs are intended for use in the five main cancer sites among Cuban women, for whom none will be fully accessible as long as the embargo is in place.⁷⁵

In addition to the embargo's obstacles to acquiring important cancer medications, the embargo also directly interferes with Cuba's ability to produce some of these drugs domestically. In the case of methotrexate, in 1993, the German subsidiary of Pfizer, Heinrich Mach Nachf., reported they had not received a U.S. license for sale to Cuba of a pound of the active ingredient needed for trial runs of this important anti-cancer agent. (See the chapter Medical Exports, section on the Pharmaceutical Industry.) As a result, tests were stalled, and full-scale manufacture delayed.⁷⁶ As a result of the shortages of chemotherapy drugs, Dr. Camacho of the Oncology Institute says that not only are therapeutic options seriously restricted, but disease-free survival times are reduced.⁷⁷

The production of methotrexate has also been held up by another embargo prohibition, this time barring purchase of key U.S.-origin equipment. In fact, domestic manufacture of a number of chemotherapy drugs (such as cisplatin, for use in ovarian cancer) has been hampered by embargo restrictions preventing Cuba from buying a freeze dryer for dehydration of injectable chemotherapy compounds necessary to ensure their long-term stability. According to Marlene Porto, Director of Cuba's Center for Medication Research and Development (CIDEM), this unit is sold by the British firm Edwards, but produced in the United States. She says the Center has not even been able to obtain a quotation for the unit, which she asserts is a very difficult piece of equipment to substitute, because of quality control requirements in Cuba.⁷⁸ (See section on the Pharmaceutical Industry.)

The impact of the embargo on pharmaceutical development is not limited to blocking sales of raw materials and equipment to Cuba. The CDA dedicates a separate clause to prohibiting any exports to Cuba which might be used in the Cuban biotechnology industry. Thus, advances in this arena, which include efforts to develop products for use in breast cancer, must first clear the hurdle of the U.S. embargo.

Currently Cuba uses domestically produced interferons in cancer treatment. In addition, the Center for Molecular Immunology has developed two monoclonal antibodies with a high specificity for the detection of malignant neoplasms. These antibodies are used for diagnostic

purposes in tumors of the lung, breast, and colon, and can also be used for the detection of newly forming malignant cells after surgery or radiation therapy.⁷⁹

Dr. Gustavo Sierra of the Finlay Institute reports that Cuba is far along in developing a therapeutic vaccine for breast cancer, also relying on biotechnology. "We have achieved various important antigens for several malignant neoplasms, including breast tumors," he said at a National Science and Technology Forum held in Havana in late 1994.⁸⁰

In conclusion, we find that the U.S. embargo prevents comprehensive screening for breast cancer, contributes to the serious limitations on surgery for this condition, effectively bans use by Cuban physicians for their breast cancer patients of U.S.-developed and manufactured drugs to treat their life-threatening condition, denies them access to new drugs in the pipeline for at least a decade to come, and frustrates domestic production of chemotherapy and other anti-cancer agents in Cuba.

NOTES

- ¹ Speech by Dr. Marta Maurás, Regional Director of UNICEF, at presentation of the Second Follow-Up and Evaluation Report of the National Program of Action for Children, Dec. 1, 1993.
- ² Interview with Dr. Cristina Valdivia, National Director for Ambulatory Care, MINSAP, January 20, 1996.
- ³ "Nota sobre el embargo a Cuba" - Luis Zúñiga-Zárate, - Resident -Program Director, UNICEF-Cuba, August, 1994.
- ⁴ Interview with Dr. Miguel Sosa, President of the Cuban Society for Family Education, Havana, November 27, 1995, and "UN agency will help with completion of plant for birth control pills," *EFE*, May 19, 1995.
- ⁵ Interview with Haydee Cela, Deputy Director for Quality Control, Reynaldo Gutierrez Pharmaceutical Plant, Havana, July 4, 1996, and "Cuba will be able to eliminate its deficit of birth control pills," NOTIMEX, May 23, 1995.
- ⁶ Interview with Dr. M. Sosa, Nov. 27, 1995.
- ⁷ Ibid.
- ⁸ Interview with Dr. Francisco Valdes Lazo, and Dr. Otto Machado, National Maternal-Child Division, Ministry of Public Health, Havana, November 27, 1995.
- ⁹ Interview with Dr. Ana Isabel Valdés, Specialist in General Comprehensive Medicine, East Havana, June 4, 1996.
- ¹⁰ Interview with Dr. M. Sosa, Nov. 27, 1995.
- ¹¹ Interview with Dr. Manuel Santín, Epidemiology Department, Ministry of Public Health, Havana, December 12, 1995.
- ¹² Dr. Manuel Limonta, Havana, June 12, 1996.
- ¹³ Interview with Dr. Evelio Cabezas, Chief of the National Obstetrics and Gynecology Program, Havana, July 15, 1996.
- "Current Obstetric and Gynecologic Diagnosis and Treatment*, edited by Alan H. De Chemey, MD and Martin L. Pemoll, MD, Appleton and Lange, Norwalk, CT, 1994, page 967.
- ¹⁵ Interview with Dr. Carlos Brown, first Vice-Director, "Justo Legón Padilla" Provincial Maternity Hospital, Pinar del Rio, November 29, 1995. NOTE: From this point, we will refer to these hospitals as Maternity Hospitals, however, in Cuba, they are called Maternal-Infant/Gynecology and Obstetrics Hospitals, since the services offered include Obstetrics, Neonatology and Gynecology.
- ¹⁶ *Current Obstetric and Gynecologic Diagnosis and Treatment*, pages 971- 976.
- ¹⁷ Interview with Dr. Jose Fernández Yero, Director of the Immunoassay Center, Havana, October 18, 1995.
- ¹⁸ Interview with Nancy Blanco, Deputy Manager of MEDICUBA, Havana, September 7, 1995; and with Dr. Manuel García. Domínguez, Director of the González Coro Maternity Hospital, Havana, November 2, 1995.
- ¹⁹ Interview with Dr. J. Fernández Yero, October 17, 1995.
- ²⁰ Ibid.
- ²¹ Interview with Dr. M. García, November 2, 1995.
- ²² Interviews with Dr. Luis Heredero, Director of the National Center of Medical Genetics, and Dr. Jorge Quintana, Chief of Cytogenetic Laboratories at the Center, July 10, 1996.
- ²³ Interview with Dr. F. Valdes Lazo Dr. O. November 27, 1995.
- ²⁴ : "Relación de Situaciones Ambientales Monitoreadas por el MINSAP. Análisis Epidemiológico 1990-1995", Unidad de Análisis de Tendencias en la Salud (UATS), Ministry of Public Health, Havana, Feb. 15, 1996; p. 9.
- ²⁵ Dr C. Valdivia, Havana, January 20, 1996; and Dr. Ana Isabel Valdes, June 4, 1996.
- ²⁶ UATS Report, Feb. 15, 1995, p. 10.
- ²⁷ "Pregnanancy weight, weight gain, and birth weight," by Abrams, BF, Laros RR Jr, in *American Journal of Obstetrics and Gynecology*, 1986; vol. 154, page 503.

- ²⁸ "Nota sobre el embargo a Cuba", L. Zuriiga, August, 1994.
- ²⁹ Interview with H: Cela, July 4, 1996.
- ³⁰ Dr. Reinaldo Menéndez, Director, and Dr. Carlos Brown, First Vice Director, "Justo Legón Padilla" Provincial Maternity Hospital, Pinar del Rio, November 29, 1995; and interview with specialists at other Maternity Hospitals.
- ³¹ Interview with Dr. Alejandro Velazco, director, "Eusebio Hernández" Maternity Hospital, December 14, 1995.) However, Dr. Manuel Garcia Dominguez, Director of the "Gonzalez Coro" Maternity Hospital said his facility simply has no access to this medication for patients.
- ³² Interview with N. September 7, 1995.
- ³³ *Current Obstetric and Gynecologic Diagnosis and Treatment, 1994*, p. 372.
- ³⁴ Letter from Cuban Foreign Minister Roberto Robaina to UN Secretary General Boutros Boutros Ghali, June 25, 1993, p. 7.
- ³⁵ Interview with Dr. M. Garcia, November 2, 1995.
- ³⁶ Interview with Dr. Fidel Rodriguez Calla, National Asthma Commission, Havana, December, 1995.
- ³⁷ MINREX report to the UN General Assembly, July 29, 1994, and interviews at the National Pharmaceutical Supply Company, Dec., 1995.
- ³⁸ Observations of the authors during on-site visits to maternity hospitals cited here and listed in the general appendix, interviews with their medical staff and with specialists from the National Maternal-Child Division of the Ministry of Public Health.
- ³⁹ Interview with Dr. M. Garcia.
- ⁴⁰ Interview with Dr. F. Valdes Lazo, Dr. O. Machado, Nov. 27, 1995.
- ⁴¹ Ministry of Public Health Statistics Department, Havana, 1995.
- ⁴² "Indicaciones Generales del MINSAP para 1996", Ministry of Public Health, January 25, 1996.
- ⁴³ Ibid.
- ⁴⁴ Interviews with Dr. Celso Cruz Rodriguez, head of Laboratories at the Ameijeiras Hospital and Dr. Wilfredo Tones, Chief of the National Laboratory Group of the Ministry of Public Health, Havana, June 5, 1996.
- ⁴⁵ Interviews with Dr. F. Valdes Lazo and Dr. O. Machado, Nov. 27, 1995.
- ⁴⁶ Interview with Dr. M. Garcia.
- ⁴⁷ Interview with Dr. E. Cabezas, July 15, 1996.
- ⁴⁸ Interview with Dr. Luis Heredero, July 10, 1996.
- ⁴⁹ *Anuario Estadístico*: 1994, Ministry of Public Health, Havana, 1995, pp. 4346; *Informe Anual*: Cuba 1990, Ministry of Public Health, Havana, 1991; and Fernández, L., Caraballoso, M., et al, *National Cancer Registry of Cuba* in Parkin DM, et al, eds., "Cancer Incidence in Five Continents", International Agency for Cancer Research IACR Scientific Publications, No. 120, 1993.
- ⁵⁰ *Registro Nacional de Cancer, 1991-1994*: National Oncology and Radiology Institute, Havana, May, 1996; and *Anuario Estadístico*: 1994, Ministry of Public Health, p. 51.
- ⁵¹ Camacho RR, Garrote, L.F., et al, "The National Program for the Control of Cancer in Cuba," in *Revista Cubana de Medicina General Integral*, Vol. 10, No. 3, July-September, 1994; and interviews at the National Oncology Institute, Havana, October 16, 1995.
- ⁵² *National Cancer Control Programmes. Policies and Managerial Guidelines*: Handbook produced by the World Health Organization Global Programme for Cancer Control, Geneva, 1993; and Camacho, R.R., Garrote, L.F., etc al, "The National Program for the Control of Cancer in Cuba", in *Revista Cubana de Medicina General Integral*, Vol. 10, No. 3, July-September, 1994.
- ⁵³ Interview with Dr. Rolando Camacho, Director, National Oncology and Radiology Institute, Havana, Oct. 16, 1995.
- ⁵⁴ Interview with Dr. R. Camacho, October 16, 1995; and *Current Obstetric and Gynecologic Diagnosis and Treatment*, edited by Alan H. De Chemey, MD and Marin L. Pemoll, MD, Appleton and Lange, Norwalk, CT, 1994, page 616; and *Cecil Essentials of Medicine*, edited by Thomas E. Andreoli, MD, Charles C.J. Carpenter, MD, Fred Plum, MD and Lloyd H. Smith, Jr., MD, W.B. Saunders Company, Philadelphia, PA, 1986, p. 410.

- rs Interview with Dr. Maria Luisa Buch, Chief of the National Program for Early Detection of Breast Cancer, Havana, October 16, 1995.
- ⁵⁶ Interview with Dr. Orlando Valls, Chief of Radiology, Ameijeiras Hospital, Havana, December 15, 1995.
- ⁵⁷ Interview with Dr. Maria Luisa Buch, Oct. 16, 1995.
- ⁵⁸ **National Cancer Control Programmes. Policies and managerial guidelines., WHO**, 1993, and interviews with specialists at the National Oncology and Radiology Institute, Oct. 16, 1995.
- ⁵⁹ Interviews with Dr. M. Buch, Oct. 16, 1995 and Dr. O. Valls, Dec. 15, 1995.
- ⁶⁰ "The challenge to sustain the level of equality and other achievements related to the well being of [Cuban] women," from a presentation by Luis Zúñiga Zárate, Resident Program Director, UNICEF-Cuba, meeting of UN Agencies in Cartagena, Colombia, October, 1995.
- ⁶¹ Interview with Dr. M. Buch, Oct. 16, 1995.
- ⁶² Interview with Dr. A Valdés, Specialist in General Comprehensive Medicine, East Havana, June 4, 1996.
- ⁶³ **Interview** with Dr. Lorenzo Anasagasti, National Oncology and Radiology Institute, Havana, Oct. 16, 1995.
- ⁶⁴ Interview with Dr. A Velásco November 3, 1995.
- ⁶⁵ Interview with Dr. M. García, Nov. 2, 1995.
- ⁶⁶ Interview with Dr. M. Buch, Ha-, Oct. 16, 1995.
- ⁶⁷ Interview with Dr. M. García, Nov. 2, 1995.
- ⁶⁸ Visit and interviews with the director and other specialists at the "Abel Santamaria" Provincial Hospital, Pinar del Rio, Nov. 27, 1995.
- ⁶⁹ Interview with Dr. Maria del Carmen Barroso, National Oncology and Radiology Institute, Oct. 16, 1995.
- ⁷⁰ Ibid.
- ⁷¹ Ibid.
- ⁷² **Physicians' Desk Reference, 47th Edition**, 1993, p. 1126.
- ⁷³ Interview with Hilda Guadarrama, Havana, June 4, 1996.
- ⁷⁴ "Price Regulation and Pharmaceutical F&search" by Heinz Redwood, Oldwicks Press Ltd., Suffolk, England, 1993, p. 77.
- ⁷⁵ "1995 Survey: Over 200 Medicines in Testing for Cancer -- The Number Two Killer of Americans." published by Pharma Pharmaceutical Research and Manufacturers of American, May 12, 1995.
- ⁷⁶ **Interview** with N. Blanco, September 7, 1995, and supporting documentation from the German firm.
- ⁷⁷ Interview with Dr. R Camacho, Oct. 16, 1995.
- ⁷⁸ Interview with Marlene Porto, Havana, October 2, 1995.
- ⁷⁹ "New Monoclonal Antibodies Achieved in Cuba" **PL**, Havana, March 2, 1995.
- ⁸⁰ **"Cuba Working on More than 20 Vaccine Projects"**, EFE, Havana, December 16, 1995.) See chapter on Vaccines and Biotechnology

Introduction

The abundance and quality of water bears directly on health, influencing hygiene, the extent of certain infections, and the prevalence and mortality rates of water-borne diseases such as acute diarrheal disease (ADD), typhoid fever, viral hepatitis and dysentery. Over the last thirty years, Cuba has waged an uphill battle to expand water supplies and treatment, but from the early sixties the U.S. embargo posed serious obstacles to this process. During the economic crisis of the nineties, a most critical situation developed in which the general contraction of financing for this sector and a more stringent U.S. embargo have resulted in grave setbacks and renewed outbreaks of disease.

Because of these factors, water resources have deteriorated in three fundamental areas: availability of water, treatment of drinking water, and sanitation systems.

The Water Supply

The island of Cuba has sufficient surface and ground water resources to theoretically supply all its needs. In the western part of the country, most of the water supply systems capture groundwater, while in the central and eastern part of the country, systems are fed primarily by surface water. Water services were progressively extended among both urban and rural settlements from the decade of the sixties forward. In 1960, 65% of city dwellers had ready access to water, but this was true of virtually no rural dwellers. By 1990, these figures had reached 88.6% and 77.8%, respectively. By 1994, 7.8 million people in urban zones had access to drinking water, compared to 2.6 million in 1960, or three times as many. In the rural areas, 19 million had drinking water by 1994, compared to near zero in 1960. Put another way, by 1994, 9,787,000 Cubans had access to drinking water, while 11.8% of the population, or another 1,175,900 did not.

ACCESS TO DRINKING WATER (figures in thousands)								
Year	Population					Population with Drinking Water (%)		
	Total	Urban		Rural		Urban	Rural	Total
		%		%				
1960	6.71	3.95	58.8	2.76	41.2	65.0 ^a	...	38.2
1970	8.57	5.18	60.5	3.38	39.5	71.0 ^a	...	42.9
1980	9.71	6.71	69.0	3.01	31.0	73.6 ^a	67.8	71.9
1990	10.60	7.82	73.8	2.78	26.2	83.6	77.8	82.0
1993	10.92	8.27	75.7	2.65	24.3	94.2	83.0	91.5
1994	10.96	8.16	74.4	2.81	25.6	96.1	69.2	89.2

^aOnly includes household connections.

Note: The information on the rural sector was incorporated into the Statistical System in 1980.

Sources: Population-Institute of Demographics and the Census. State Committee on Statistics. Coverage-National Institute of Water Resources, National Action Program.

Progress in this sector was made despite the U.S. embargo, which had an immediate impact on water resources from the time it was imposed in 1962. Cuba's tradition in water supply and sewerage systems follows the U.S. theoretical and construction model, which separates drainage from sewers, as distinct from the European model.

In 1959, Cuba began installing 300 new aqueducts, following the "autonomous unit" scheme used in Puerto Rico, contracted with IBM. When the embargo was imposed, overnight it became more difficult to obtain piping and even parts for the equipment used by bore pipes for coupling, since Cuba relied (and still does rely) on the National Pipe Thread (NPT) system, with all compatible fittings patented in the USA and manufactured there or under patent license elsewhere. At the time, the U.S. corporation Mueller was the only company supplying Cuba, and after 1962, parts had to be found through third parties, with all the additional costs and delays this implies. In the eighties, the situation became so extreme that the National Institute of Water Resources (INRH) had to wait three years for supplies from Mueller, finally routed through Mexico. At another point in the early 1990s, UNICEF received a license to donate Mueller equipment, a process which took nearly a year, as INRH reports.'

By the decade of the nineties, financial limitations and stiffer embargo restrictions put a stop to further expansion of water supplies, and made for widespread deterioration of installations already in place. The budget for water and sanitation services dropped from \$86 million in 1990 to \$79.6 million in 1992. Investments declined more drastically by 1994, running at only 25-30% of allocations five years earlier. External financing was limited to UNICEF's assistance in rural areas, totaling \$12 million between 1980 and 1992, and smaller grants through the PAHO Environmental Health Program.*

These cutbacks plus the embargo-specific obstacles outlined below resulted in deficient service for one quarter of the population already receiving Water (some 27 million people). This is in addition to the 928,000 who still had precarious or no access to drinking water in 1993—totaling one third of the Cuban population.

DRINKING WATER SUPPLY, 1993 (figures in millions of inhabitants)								
Sector	Total Population		Population with Coverage of Drinking Water %				Without Drinking Water Service	
	Inhabitants	%	Appropriate Service			Deficient Service		Total with Service
			Home Connect.	Public Service	Easy Access			
Urban	8.27	75.7	51.1	10.1	3.0	30.0	94.2	5.8
Rural	2.65	24.3	27.2	23.1	22.7	10.0	83.0	17.0
Total	10.92	100.0	45.3	13.3	7.8	25.1	91.5	8.5

Source: National Institute of Water Resources.

As this chart indicates, supplies are divided into three categories: household connections, public service (usually by tank trucks) and easy access (public taps not more than 300m from a household). From 1993 to 1994, the population receiving tank truck water was reduced by almost half, mainly due to fuel shortages. These households turned to public taps in most cases. Household water connections also continued to deteriorate, reducing the number of families served and the numbers receiving adequate service.³

Technical analyses by INRH reveal that approximately one third of the household connections (about 706,000) were in poor physical condition by 1994. Approximately 800,000 housing units are fitted with Mueller piping and fixtures, and these connections account for the lion's share of those in disrepair. Francisco Rivera of INRH reports that because of the embargo, Mueller machinery to replace fittings is itself out of commission for lack of parts. He states that the last U.S. authorization for Mueller exports to Cuba was granted for a UNICEF donation early in the decade,

but none have been available since then. As a result, repairs have not begun on over 1,500 km of pipes for household connections, 3,000 km of water system piping and 225 km of conduits.'

All three means of providing drinking water are affected by irregular pumping, due to fuel shortages (blackouts) and pumping station breakdowns. 90.0% of the water supply relies on pumping, and the rest on gravity.

When the Cuban revolution arrived in 1959, all water pumping equipment in use in the country was U.S.-manufactured, with the exception of two stations mounted in 1946 with French machinery. Most of this had been purchased from Fairbanks & Morse at the turn of the century; investments by the new government in the sixties brought in Worthington Rump machinery, also from the USA, purchased through intermediaries after 1962 when the embargo was declared, and later through subsidiaries (trade permitted through 1992). Unable to sustain these imports, both because of the embargo and financial limitations, Cuban buyers went to diverse suppliers, none of which, according to Rivera, have been totally satisfactory. Currently, the Russian equipment (which had to undergo major adaptations in the first place) is 'in crisis,' he says, and other units today come from China, Spain and France.⁶

Irregular pumping has led to deficient and unreliable continuity of service: At the beginning of the eighties, service periods averaged 12.3 hours a day, and by 1988, most cities and towns had an average daily water supply of 15.1 hours. However, by 1993, people in half of Cuba's provinces were receiving water for less than 12 hours a day: Havana City (only 8 hours), Villa Clara, Cienfuegos, Camaguey, Las Tunas, Huguin and Granma. Nationally, the average had fallen to 13.1 hours daily.⁷ It is worth noting that the oldest component in the rural systems is the pumping equipment, badly in need of replacement in many areas.

Measurement of water flow and pressure, household metering, and leakage suppression have all suffered setbacks in the nineties, leading to serious and hardly affordable waste. Rivera of the INRH calculates that as much as half the water supply in the country is either wasted or lost to leakage. And INRH official documents say 30% is lost in leaks alone⁸

Cuba has had to make substantial outlays over the years to monitor water supply and usage, amounts considerably inflated by the embargo. Recently, this situation has become more tense, as less money is available. One example is water meters, essential to effectively curtail excesses and waste. Some 300,000 water meters in use in Havana in the 1960s were all U.S.-made. When the embargo was imposed, parts and new meters were impossible to obtain, and over the next 15-20 years, all the instruments were eventually retired to the sidelines. The only cost-effective alternative for Cuba at the time, explains Rivera, was to purchase a stream gauge factory from Japan, to assemble the meters domestically. However, because Havana needed to be re-equipped first (replacing the loss of the 309,000 U.S.-made meters) and on a limited budget, by the time the economically lean nineties rolled around, enough were not yet available to extend the program to the rest of the country. Only Havana, Varadero and government (industrial and office) consumers in Santiago, Pinar del Rio and Matanzas provinces receive metered water. Today, economic difficulties plague repair work in general, while 30% of the Cuban-made meters in Havana lie idle and a higher percentage elsewhere.'

Leak detection and repair has suffered as well: the \$5 million annually allotted in the 1980s for purchases of parts, equipment and accessories for maintenance was substantially reduced at the beginning of this decade. And the embargo has also played a role in declining capabilities to patch the system.

SUPPRESSION OF WATER LEAKS (figures in thousands)					
Year	11988	11990	11991	1992	11993
Leaks Eliminated	1141.4	1114.8	1112.1	1102.0	105.6

Source: **National** Institute of Water Resources.

The embargo has **stalled** or delayed purchases of key equipment for repairs, such as pipe locators, made by the U.S. firm M-Scope. This instrument detects metallic pipes under the street to avoid ripping up long tracts of pavement. Rivera calls this "one of the most difficult pieces of equipment for us to find or buy." Early in the sixties, he says, the U.S. government considered the locator an item "for military use," and denied authorization to Cuba for its purchase. He reports that the Institute has occasionally been able to make purchases through third parties, from Metrotech of Germany and Fuji of Japan—all **with difficulty and** at **considerable** additional cost.

Similar is the fate of the leak detector (geophone), bought from subsidiaries of the U.S. firm Fischer and Porter until the CDA banned such exports to Cuba in **1992**. The price tag was approximately \$200 per unit (each city needs at least one, and Havana requires 25). Later, a French-made substitute did not measure up to standards, and Rivera said it was doubly problematic since it was also too sensitive, and damaged hearing. Seba Electronic of Germany offered Cubans "essentially the same geophone as Fischer" for \$3,000, according to Rivera, and Fuji's prices were also higher." In this case, the embargo had a negative impact on both the quality and quantity of key purchases.

The UNICEF experience illustrates the continuing impact of the embargo on procuring equipment to maintain and improve water supplies: a Nov. 6, 1995 fax from UNICEF's Supply Division in **Copenhagen indicates** that it had managed to obtain prices "with great difficulties" for several pieces of equipment requested for Cuba, noting that it "cannot procure them from USA." Prices finally quoted to UNICEF **appear** significantly higher than expected from the U.S. firms, since the fax also requests a "budget increase or reduction in quantities."

The items include: (50) glass "U tubes for pitometers (for studying water flow and supply), (65) manometers (portable units that measure water pressure), and (1) velocity recorder (still no price available.)"

UNICEF's Resident Program Director in Havana, Luis Zúñiga Zárate, notes that for the agency's program assisting expansion of drinking water services for Cuba's rural population, it has been necessary to purchase polyethylene **pipng** in Italy and other European countries, at considerably higher shipping rates than from the USA. He reports that of a budget of \$600,000, 14% **was thus tied** up in freight charges. "If these were reduced to just 10%," estimates Zúñiga, "and the rates from the United States would come to much less than that, then we could complete 12-15 more aqueducts." In addition, he reports seven to eight-month delays from the time the funds are available until the items are actually received in Cuba.* In the Cuban countryside, some 664,000 people are without ready access to drinking water.

A communication from the UNICEF Director in Cuba makes the following added calculations: In 1993, Cuba paid \$50 million more for maritime and air freight, because it had to **resort** to distant suppliers. This is **enough** to build all the rural aqueducts needed in the entire country, institute a school breakfast program nationwide, provide iron tablets for 170,000 pregnant women and supplement the diets of the 30,000 women every year with high-risk pregnancies.¹⁴

In conclusion: It is our finding that the U.S. embargo, since its imposition in 1962, has constituted an obstacle to making drinking water available to greater numbers of people in Cuba. And, in this

economically difficult decade, the policy has actually contributed to reversing decades of achievement and to creating water shortages.

Safe Drinking Wafer

Guaranteeing clean, safe water is equally as important to health as the water supply itself. However, initial advances in water treatment have been eroded throughout Cuba **during** the last five years, due to inadequate supplies of chemical products and deterioration of installations. The following chart illustrates the sharp decline in the safety of drinking water across the island, especially since 1992, when the CDA went into effect, blocking all subsidiary **trade with Cuba**. **By** 1993, only 69.5% of water supplied to the population was treated; and the continuity of chlorination installation operations had dipped to 51%.

WATER TREATMENT IN CUBA (1990-1993) (figures in millions of cubic meters)			
Year	Water Supplied	Treated Water (%)	Chlorination Continuity (%)
1990	1264.0	85.2	82.2
1991	1374.7	82.5	75.4
1992	1350.0	78.6	71.4
1993	1376.2	69.5	51.0

Source: National Institute of Water Resources.

As of 1994, the worst situations are found in the provinces of Pinar del Rio, Matanzas, Holguin, Granma, Habana, and Camaguey.¹⁵

Water treatment is provided in two major types of installations in Cuba: 49 water treatment plants for the 28% of drinking water from surface sources which requires full treatment-flocculation, sedimentation, rapid descent filtration and final disinfection; and 935 disinfection systems, sufficient to treat the 72% of drinking water that comes from ground sources. The processes used rely on chlorine gas and sodium hypochlorite.¹⁶ The following table illustrates the distribution of these facilities.

TREATMENT SYSTEMS AND DISINFECTION TYPES (1993)						
Province	Drinking Water Treatment Plants		Disinfection Systems		Total	
	Chlorine gas	Hypo Chlorite	Chlorine gas	Hypo Chlorite	Chlorine gas	Hypo Chlorite
Pinar del Río	4	4	14	63	18	67
La Habana	-	4	13	95	13	99
C. de la Habana	1	-	23	20	24	20
Matanzas	-	-	9	84	9	84
Villa Clara	3	-	12	40	15	40
Cienfuegos	3	2	2	21	5	23
Sancti Spiritus	3	3	...	41	3	44
Ciego de Avila	-	1	5	50	5	51
Camaquey	5	1	5	28	10	29
Las Tunas	2	-	2	90	4	90
Holguín	5	-	13	33	18	33
Granma	-	2	5	92	5	94
Stgo. De Cuba	5	-	12	38	17	38
Guantánamo	-	1	11	90	11	91
I. de la Juventud	-	-	2	22	2	22
Cuba	31	18	128	807	159	825

Source: National Institute of Water Resources.

The investments made in water treatment in earlier decades made it possible for the number of chlorination installations to grow from 355 in 1983 to 936 in 1993; and the number of drinking water treatment plants from 30 to 49." Of 1,261 water supply systems in the country, 967 (practically all urban installations) have some form of treatment.

However, this does not tell the whole story. As with water supply systems in Cuba, water treatment has a built-in dependency of several decades on U.S. installations and equipment, now impossible or extremely costly to repair. The water treatment plants, some over 45 years old, are in generally poor condition, due to financial and embargo-specific limitations on purchases of replacement parts and supplies.

Beginning in 1962, the embargo, then in its first year, held up construction on 15 new plants in the country. Equipment for the plants had already been purchased in the USA, some from Honeywell, but not all had been shipped. Much of the contracts went unfulfilled when the embargo closed the door on trade. Plants in Holguin and Trinidad cities were halted, but resumed with arrivals of Canadian equipment. Other plants-in Manicaragua, Cumanayagua, Santiago de Cuba, Cienfuegos, Nuevitas, Guaimaro, San Fernando, Guanés and Jibara-were held up as long as three years, until more purchases arrived through Canada, Czechoslovakia and the Soviet Union (the last two needing major adaptations). In any case, this meant that virtually all the equipment was purchased twice: once from the U.S. manufacturer, and again in another country, the latter racking up steep shipping charges."

Chlorine gas equipment (used both in the water treatment plants and in the disinfection systems) were mainly bought from the U.S. firm Wallace and Tiernan and their subsidiaries abroad. In 1973, Havana's new water treatment plant was purchased from France, with equipment from Wallace's German subsidiary, which at the time sold Cuba some parts for other chlorination units

as well. When the embargo was enforced more strictly in the 1980s (see references to this in chapter on Medical Exports), the cost of Wallace parts from its British subsidiaries began to climb rather sharply, according to Francisco Rivera of the INRH. "In the 1970s, prices rose about 15% annually; but in the eighties, they rose as much as 299% annually. By 1933, we were paying five times the normal price of parts.¹⁹ Since enactment of the CDA in 1992, Cuba has not been able to purchase any parts for Wallace chlorination systems, reports Rivera, who notes that all cities in Cuba over 100,009 people depend on the Wallace equipment, a total of four million people.

"we are now taking parts from one plant for another. All reserve equipment has been used up."²⁰ The result is a very unstable chlorination situation for the last three years: in 1994, Habana (the semi-rural province outside the capital) shut down all 12 of its chlorination plants; and Pinar del Rio province faced the same closures for all of its 18 plants.

Currently Wallace chlorination plants are being slowly re-equipped with French and Spanish credits. This is a very costly process, and even then some Wallace parts just don't have substitutes. Some chlorination equipment (for 29 plants) was purchased through Fischer and Porter subsidiaries in Japan and Spain, also until the CDA stopped sales in 1992. Rivera says this cutoff is having a particularly negative impact on the boarding schools for junior high and high school students, which were built in the 1970s and rely on chlorine gas and hypochlorite equipment from the Fischer subsidiary. All other hypochlorite plants were bought from Wallace and Tiernan.

By 1993, 40% of the chlorination installations were shut down (half of them because of equipment breakdowns, with no parts available.) Another 49% were shut down because of shortages of chemicals.

Cuba requires 3,509 tons of chlorine annually, but by 1994, the country was only producing 1,010.²¹ There are two domestic plants that produce chlorine. One is very old and has a capacity of four tons daily, while the second, constructed with French equipment, was built in 1995, and can produce 10 tons daily. However, the French design uses mercury cell technology, which INRH concedes should have been replaced for environmental reasons with the membrane technology used in modern plants today.

Cuba had an agreement with the USSR to construct a new plant, using this system, at the petrochemical complex in Cienfuegos, which would have produced 50 tons of chlorine daily. However, it was one of the first projects to be scuttled after the disbanding of the Soviet Union. Today, one part of the nafion membrane is produced in Russia, and another in the Ukraine, making more remote hopes of getting the project back on track. DuPont of the United States held the original patent, held now by Italy as well, and by the USSR until production split up. The mercury cell plant in Cuba is still functioning on the Sagua la Grande River. Fishing has been banned there as a result, and the Ministry of Public Health regularly tests workers, who are not permitted to work near the mercury for lengthy periods.

At one time, Cuba also imported chlorine gas from Nicaragua. But when the Sandinistas lost the elections to a new government, the plant was bought out by U.S. interests, and no longer sold to the island. Currently, some chlorine is purchased from Canada and from Mexico, but this is complicated by the CDA's shipping regulations, according to Rivera. "The chlorine shipped from Canada took two months to arrive," he reports. As a result, in 1994 Havana was nearly without chlorine. "There was a time when we had only a one-day margin,"* notes Rivera. The supply is still unstable.

Medicos Sin Fronteras of Spain has made a 1.8 million investment in assisting Cuba's water supply system, with a portion of those funds earmarked for purchases of water treatment chemicals, such as calcium hypochlorite. Armando Jaular, the organization's general coordinator, says that the group's money could go further if this chemical could be purchased from

firms in Georgia, USA, where it can be bought at more competitive prices and for much less freight."

Sanitation and Sewerage

Sanitation has been plagued by many of the same problems as water supply. In 1993, appropriate sewerage service extended to 39% of the population; septic tanks and latrines were used by another 35.2% for a total of 74.2% of the population with some type of sanitation. Approximately 37% of the population did not have adequate sanitation services, or had none at all.²³

SANITATION SERVICES. 1993 (figures in millions of inhabitants)								
Sector	Total Population		% of Population with Sanitation Service					Popula tion without Service %
	Inhabitants	%	Appropriate Service			Inadequate Solutions	Total with Service	
			Sewerage	Tanks and Latrines	Total			
Urban	8.27	75.7	35	31.6	66.6	30.0	96.6	3.4
Rural	2.65	24.3	52	46.8	52.0	20.6	72.0	28.0
Total	10.92	100.0	39	35.2	74.2	27.6	90.6	94.4

Source: National Institute of Water Resources.

The same year, waste treatment installations were described in a "totally critical" state by INRH. By 1996, all five plants were out of commission due to equipment failures, lack of maintenance and operating problems." Due to irregular operation of the plants as early as 1993, only 21.6% of waste water evacuated by urban sewerage systems received treatment, down from 1992 figures.

Stabilization ponds cover a considerable volume of urban, industrial, agricultural, livestock and school wastes. However, less than 16% of these were receiving regular attention in 1996. What's more, the National Epidemiology Department of the Ministry of Public Health reports that, "numerous septic tanks throughout the country are not receiving adequate maintenance. Add this to the fact that the sewerage networks across the island are in a seriously deteriorated state, meaning that the ones used are oversaturated, leading to frequent obstructions and breakage, and causing them to spill into the streets, ditches, superficial waters and soils, and creating the conditions for contaminating drinking water systems."²⁵

Water Supplies, Safe Drinking Water and Health

As we have seen, programs to provide sufficient clean water to the Cuban population have been obstructed by the U.S. embargo, constituting a nearly unsurmountable barrier in the nineties, complicated by general economic limitations which the embargo has only further restricted. As a direct result, hygiene levels in Cuba have seriously degenerated in the last few years, and related diseases are on the rise, in some cases endangering not only wellbeing but also lives.'

The drastic decreases in drinking water treatment and sanitation problems, in combination with the general lack of adequate supply, have caused increases in waterborne diseases since 1996.²⁷

Among the diseases on the rise: typhoid fever, dysenteries and viral hepatitis, which have nearly tripled their rates.

INCIDENCE OF WATERBORNE DISEASES 1989-1993					
Disease	No. of cases				
	1989	1990	1991	1992	1993*
Typhoid Fever	48	59	1100	153	256
Bacillary Dysentery	...	285	209	450	179
Amebic Dysentery	.	356	475	929	1660
Dysenteries (subtotal)	...	641	684	1388	1839
Viral Hepatitis A	2570	5834	19,663	21,160	12,150
ADD"	888,318	1,062,633	1,179,872	1,095,275	1,115,616

*Provisional. "ADD: Acute diarrheal disease (medical consultations)

Source: National Department of Statistics, Ministry of Public Health.

MORBIDITIES FROM WATERBORNE DISEASES 1990-1993 (figures per 100,000 inhabitants)				
Disease	1990	1991	1992	1993'
Typhoid Fever	0.5	0.9	0.5	2.0
Bacillary Dysentery	3.0	2.0	1.0	1.6
Amebic Dysentery	3.0	4.0	9.0	15.2
Dysenteries (subtotal)	6.0	6.0	10.0	16.6
Viral Hepatitis A	50.0	190.0	190.0	110.0
ADD'	100.2	110.3	101.2	102.3

'Provisional. 'ADD: Acute diarrheal disease (medical consultations).

Source: National Department of Statistics. Ministry of Public Health Havana.

Typhoid fever, endemic to Cuba, has been most prevalent where clean drinking water is most problematic. For **example, historically** the town of Costa Rica in Guantánamo Province has shown **high** rates of typhoid fever. This, until the local aqueduct was replaced, and since then only a single case has been reported. In general, notes a report from the Health Tendencies Analysis Unit (UATS) of the Ministry of Public Health, during 1995 the greatest number of outbreaks came in rural communities with poor sanitary conditions and water treatment. That year, there were nine outbreaks altogether, totalling 112 cases, down considerably from 1993 levels, but still over twice **what** they were in 1989. And for the first time in the last five years, children were dying from typhoid fever: two deaths were reported in 1995. (Cuban children receive a typhoid vaccine, but its high level of reactivity limits more intensive use.)"

Viral Hepatitis includes Hepatitis A, B, C, D, E and others. In Cuba, Hepatitis A accounts for 80% of all viral hepatitis: The island has one of the highest rates in Latin America, which continued to rise **sharply** through 1994, with a **slight** dip in 1995, corresponding to both the epidemic cycle and deteriorating sanitary conditions. Suffice to say that in 1989, the country registered 11,167 cases of viral hepatitis (or 106.3 cases per 100,000 inhabitants), which had soared to 17,032 in 1995 (or 153.8 per 100,000).²⁹ A Ministry of Public Health UATS study indicates that various outbreaks of Hepatitis A since 1990 were due to contaminated water supplies. 1996 was expected to be a peak epidemic year.

Dysantaxias: This category includes both bacillary and amebic dysentery, and both have been on the increase since 1989, tripling from 1990 to 1993. (See Chart above.)

Acute Diarrheal Diseases (ADD): By 1995, these diseases occupied second place in the country in the number of doctors' visits; and from 1989 to 1994, the *number* of doctors' visits for ADD increased by 250,090 reaching 1.14 million annually.³⁰ As we *noted* above, 1994 was a critical year for chlorination in the capital of Havana, with 2.5 million inhabitants, a situation which is amply reflected in the epidemic ADD figures for the province that year: 384,622 doctors' visits for ADD were recorded, as compared to 189,153 in 1989, or over 175,000 more cases.³¹

The rising trend, curbed slightly in 1995, is especially worrisome among adults, and in particular those over 65. The INRH explains why this has not affected children to a greater extent: "The contradictory behavior in relation to the marked reduction in *water* quality, is explained by the priority status accorded to child health care programs in general, the level of sanitary care provided by parents to their children, and specifically the boiling of water for small children, even with the shortage of fuel."³²

This same pattern can be seen in the increase of mortality rates for these diarrheas since the beginning of the decade, from 2.7 per 100,000 inhabitants in 1989, to 6.7 per 100,000 inhabitants in 1994. Epidemiologist Dr. Graciela Delgado comments: "These are close to the rates for the 1970s, with the difference being that 20 years ago, the greatest share of these deaths were among infants. Now, 95% are among adults over 65."³³ Dr. Delgado lays the blame for these deaths, and for the rise in ADD in general, on the deterioration of sanitary conditions, and in particular, on the drop in water chlorination and water supplies, **and** deficient sewerage.

Food-transmitted diseases: According to the Health Tendencies Analysis Unit (UATS) of the Ministry of Public Health, outbreaks of illnesses from eating contaminated food or drinking contaminated water have tripled since 1989.³⁴ The same report points to "consumption and utilization of untreated water" as one *of the major* reasons for this alarming trend.

Insufficient water supply alone has been responsible for a dramatic rise in scabiosis and pediculosis (head lice), especially in Cuba's 9,000 elementary and over 500 boarding schools for grades 10-12, where these have reached epidemic proportions. In 1995, 1464 outbreaks of scabiosis were reported (totaling 41,433 cases); and 1,781 outbreaks of head lice (69,268 cases). These diseases, notes the Epidemiology Department, are 'typical expressions of poor hygiene conditions.'³⁵

The situation for boarding school students in the countryside is worse still, according to the same report: "A large percentage of these teenagers can be considered high risk for infectious diseases such as leptospirosis, pediculosis, scabiosis, sexually transmitted diseases, diseases transmitted through the digestive tract and others, due to close contacts in such live-in installations, work-study activities, and the limitations for maintaining institutional and personal hygiene."

Yet more serious is the rise in hospital infections, which public health specialists blame among other factors on "deficient supplies of water in many hospitals and in high-risk services, which leads to a breakdown in hygiene standards."³⁶ In the first nine months of 1995, 51 outbreaks of hospital infections were registered, involving 349 patients, and 60 deaths.

Provinces with Diseases Related to Untreated Water

A further correlation can be noted between the provinces which have had especially severe cutbacks in water chlorination services and the subsequent outbreak of disease.

We visited Pinar del Río (pop. 720,000), and found this to be one of the provinces most seriously affected. While water supplies actually increased slightly from 1989, water treatment plummeted: in 1989, the province received 78.2 million cubic meters of water, of which 91.3% was regularly chlorinated. By 1993, only 44.6% of the province's 80.1 million cubic meters of water was safe to drink. That same year, the province registered 577 cases of amebic dysentery, or 34.7% of all cases on the island. There were also 480 cases of Hepatitis A³⁷ This trend continued in 1994, with outbreaks of Hepatitis A in the city of Pinar del Río; and in 1995, with similar eruptions in rural communities such as Viñales and San Cristobal.³⁸ In 1995, Pinar del Río was again among the provinces with the highest rates of viral hepatitis.

In 1995, dysentery and intestinal parasites in general were a serious problem for the Pepe Portillo Pediatric Hospital in the provincial capital, where Dr. Sara Alvarez told us that they suspect over 50% of the population has parasites of one kind or another. She reported one death in 1995 and one in 1994 at the hospital due to parasites. She says this situation is complicated by the lack of medicines for outpatient **treatment** in general, 'So the cases must be hospitalized, once their situation gets serious.'³⁹

In 1994 and 1995, the province also reported several cases of typhoid fever, associated with unsafe drinking water.

Finally, cases of acute diarrhea1 disease (ADD) rose sharply through 1994, averaging over 5,100 cases per month by that year, with the highest rates in Pinar del Río city. A report prepared for UNICEF by provincial health authorities related this peak directly to the quality of water, and sounded the alarm that in 1994, acute diarrhea1 diseases occupied fourth place as the cause of infant mortality in the province. 'The rates stood at 1.2 deaths per 1,000 live births, attributable to ADD, in comparison with 0.1 to 0.3 per 1,000 live births in the period from 1988-1992.'

The specific areas mentioned-Pinar del Río City, Viñales, and San Cristobal-are the same ones cited in the report as among the most seriously affected by the lack of chemicals for water treatment, and the lack of spare parts and equipment to repair chlorination facilities. In 1994, the province required 130 tons of chlorine, and received only 9.5-a deficit of 120.5 tons.

Ha- Province (the semi-urban and rural province just **outside** the capital city, pop. 670,000) reveals a still more critical situation. Although the water supply appears abundant on paper, a 1995 report from the provincial health and water resources authorities estimated that only 40% of the water pumped was actually reaching the population, because of unrepaired leakage, for the reasons we have outlined above."

Of the 120.9 million cubic meters of water provided in 1989, 76.7% was treated, while by 1993, of 107.1 million cubic meters of water, only 34.6% was safe to drink. This resulted in serious outbreaks of Hepatitis A, with 2,813 cases reported the same year, or 22.1% of the national total. In 1994-95, the province showed viral hepatitis rates well above the national average.⁴²

Just as serious were the rates of acute diarrhea1 disease (ADD), which showed the highest rate of all the provinces in 1993, at over 166,000 cases, and a rate of 160 per 1,000 inhabitants (as compared to 83,000 cases in 1989, for a rate of 129.8) While these figures decreased somewhat by 1995, to 95,000 cases, the rate was still the highest among Cuba's 14 provinces at 145.4.⁴³

In 1993, a serious ADD outbreak was registered in Bauta Municipality, Havana Province, due to the absence of chlorination, and subsequent contamination. A similar outbreak occurred in 1995 in Artemisa Municipality, where some 2,000 people were infected with Shiguella, for exactly the same reasons.

Amebic dysentary cases reported in 1993 were 11; and parasitic infections were the third cause of death in one to four-year-old- rate of 0.7 as compared to 0.5 in 1990.”

In 1994 and 1995, because of poor water quality, two outbreaks of typhoid fever were reported in the same locality of Guanajay, with a total of 23 cases.⁴⁵

We should note here that the sharp rise in cases of scabiosis and head lice mentioned earlier has a particularly high incidence in this province, since between temporary agricultural workers migrating from the city and countryside boarding schools for high school students, nearly 209,090 residents of the province live in dormitories.

In conclusion: We are seeing more waterborne diseases and more deaths from them as a direct result of insufficient water supply and severe cutbacks in water treatment, due to the economic crisis and the particularly negative effects of the U.S. embargo on the water resources available to the Cuban population.

NOTES

- ¹ Interviews with Francisco Rivera, Specialist, National Division of Aqueducts and Sanitation Systems, National Institute of Water Resources, Havana, Oct. 6, 1995, and Dec. 1, 1995.
- ² *Sectoral Analysis in Water Supply and Sanitation in Cuba*, Regional Plan for Investment in the Environment and Health, PAHO/WHO, 1994, p. vii.
- ³ *Programa Nacional de Acción para la Infancia, -Tercer Informe de Seguimiento y Evaluación* June 1995, published by the Government of Cuba in cooperation with UN agencies, p. 66.
- ⁴ *Sectoral Analysis*, p. 89.
- ⁵ Interviews with F. Rivera, Oct. 6 and Dec. 1, 1995.
- ⁶ Ibid.
- ⁷ *Sectoral Analysis*, pp. 92-93.
- ⁸ Ibid., p. 111.
- ⁹ Interviews with F. Rivera, Oct. 6 and Dec. 1, 1995; and Sectoral Analysis, p. 100.
- ¹⁰ Interview with F. Rivera, Oct. 6, 1995.
- ¹¹ Interviews with F. Rivera, Oct. 6 and Dec. 1, 1995.
- ¹² **UNICEF Supply** Division fax. Nov. 8, 1995. from K Nielsen of *Water and Sanitation Group*, to UNICEF-Havana.
- ¹³ Interview with Luis Zúñiga Zárate, UNICEF Resident Program Director, Havana, Dec. 20, 1995.
- ¹⁴ "Nota sobre el embargo a Cuba," Luis Zúñiga Zárate. UNICEF-Cuba, August, 1994, p.2.
- ¹⁵ Programa Nacional de Acción; p. 78.
- ¹⁶ Sectoral Analysis, pp. 85,87
- ¹⁷ Ibid., p. 87.
- ¹⁸ Interviews with F. Rivera, Oct. 6 and Dec. 1, 1995.
- ¹⁹ Ibid.
- ²⁰ Ibid.
- ²¹ *Programa Nacional*, p. 78.
- ²² Interview with Armando Jaular, Coordinador General. Médicos sin Fronteras, April 24, 1996.
- ²³ *Sectoral Analysis*, p. 38.
- ²⁴ Ibid., p. 102.
- ²⁵ *Relación de situaciones ambientales monitoreadas por el MINSAP, Análisis Epidemiológico 1990-95*, Unidad de Análisis de Tendencias en la Salud. (UATS), Ministry of Public Health, Feb. 15, 1996.
- ²⁶ Shortages of soaps and detergents have also been aggravated by the embargo, first because U.S. laws ban direct imports of these bulky shipments, which then must be brought from farther ports at higher prices. Second, because the CDA itself has resulted in cancelations of contracts for soap ingredients, as noted in an earlier chapter.
- ²⁷ *Sectoral Analysis*, p. 115, notes: "Among other things, these increases mirror the deterioration in water quality caused by insufficient disinfection, ruptures and accidents in conduits, limited *maintenance, etc.*"
- ²⁸ 'Fiebre tifoidea," Epidemiology Department, UATS Report Ministry of Public Health, Havana, Feb. 15, 1996.
- ²⁹ Statistics Department, Ministry of Public Health, 1996.
- ³⁰ Ibid.
- ³¹ Statistics Department, Ministry of Public Health, 1996, and UATS Report, Feb. 15, 1996.
- ³² *Sectoral Analysis*, p. 117.
- ³³ Análisis del comportamiento de las EDA," Dr. Graciela Delgado, National Epidemiology Division, Ministry of Public Health, Feb. 15, 1996.
- ³⁴ "Alimentos," UATS Report, March, 1996.
- ³⁵ Relación de situaciones ambientales," Feb. 15, 1996.
- ³⁶ 'Situación higienica de los hospitales," Unidad de Analisis de Tendencias en la Salud (UATS), Ministry of Public Health, March, 1996.

³⁷ *Sectoral Analysis*, pp. 98 and 117.

³⁸ National Epidemiology Division, Ministry of Public Health, Havana, Feb. 15, 1996.

³⁹ Interview with Dr. Sara Alvarez, Chief of ICU. Peps Portillo' Pediatric Hospital, Pinar del Rio, Nov. 28, 1995.

⁴⁰ *Pinar del Rio: Programa Provincial de Acción para la Infancia* June, 1995, pp. 11 and 21.

⁴¹ *Havana: Programa Provincial de Acción para la Infancia*, June 1995, p. 31.

⁴² National Epidemiology Division, Ministry of Public Health, Feb. 15, 1996.

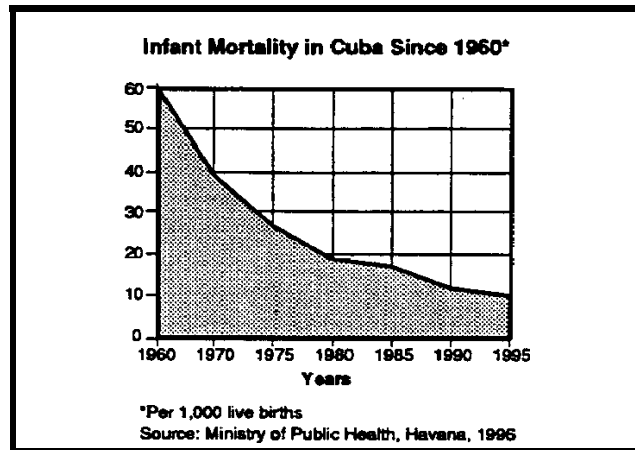
⁴³ Ibid.

⁴⁴ *Havana: Programa Provincial de Acción para la Infancia* June, 1995. p. 13.

⁴⁵ National Epidemiology Division, Ministry of Public Health, Feb. 15. 1996.

Introduction

The Cuban health care model has evolved since the early 1960s with prioritized attention to children as its centerpiece. Budgets, allocation and training of personnel, community-level programs, and above all the two primary health indicators for children reflect this priority: Cuba's infant mortality has declined consistently from an estimated 60-65 per 1,000 live births in 1960, on par with other Latin American nations at the time, to 9.4 deaths per 1,000 live births in 1995, the lowest in Latin America. This, despite the fact that Cuba's per capita GNP is well under the average for the region.*



Reduction in the under-five mortality rate (U5MR) was declared a major challenge at the 1990 World Summit for Children which set the goal of reducing deaths in this group by one third by the year 2000. 1990 UN estimates indicate that, in the 69 countries of the "Third World" where the mortality rate in children under-five is highest (76-297 deaths per 1,000 live births), 59% of all global births and 86% of all deaths occur within this age group, while in 32 industrialized countries the under-5 mortality rate stands at approximately 10. Regionally, current infant mortality rates stand at an average of 36 per 1,000 live births and under-5 mortality at 47.3. In Cuba, the 1995 under-5 mortality rate was 12 in 1995.⁴

INFANT AND UNDER-5 MORTALITY IN LATIN AMERICA (1995) ¹		
COUNTRY	INFANT MORTALITY (< 1 YEAR)	UNDER 5-MORTALITY U5MR
HAI	74	127
BOLIVIA	73	110
GUATEMALA	51	70
BRAZIL	51	61
NICARAGUA	49	68
ECUADOR	48	61
EL SALVADOR	42	56
PERU	41	58
HONDURAS	41	54
DOMINICAN REPUBLIC	38	45
PARAGUAY	28	34
MEXICO	27	32
ARGENTINA	124	27
VENEZUELA	20	24
URUGUAY	19	21
PANAMA ⁴	18	20
COLOMBIA	16	19
COSTA RICA	14	18
CHILE	13	15
CUBA	9	12

¹Per 1,000 live births

Sources UNICEF: *The State of the World's Children*. 1996.

As a result of the Summit, governments agreed to develop and implement National Programs of Action, aimed at translating verbal commitments into strategies and measurable steps towards Summit goals. Cuba's National Program of Action was developed in 1991, as a social policy instrument, carried out through joint efforts by the Ministries of Public Health and Education, and the National Institute of Water Resources and with the support of the UN agency system.⁵

The Program of Action-its progress reviewed in three evaluations since 1991-together with the National Maternal Health Program, National Immunization Program, Family Doctor Program, Day Care and Social Assistance Programs and the sentinel sites strategy for nutritional vigilance, all focus attention and resources on children's health.⁶

In this decade, health authorities responded to the economic plunge by reinforcing priorities, shifting scarce resources from other sectors and adopting new initiatives to shelter children from the crisis and from the impact of the greater inequalities emerging in Cuban society. Thus, there came about the adoption of the "Baby-Friendly Hospital" Program, expansion of maternity homes to hold down low birth weight rates, maintenance of immunization coverage through national efforts and donations, and rationing more food to children than to any other sector. This approach has paid off, by averting the tragedy plummeting economic indicators might otherwise have predicted. Generally, statistics reveal that children's health in Cuba is still protected today. "Despite the severity of the situation and the difficult macroeconomic environment in which social policy must act here," comments UNICEF regional director Dr. Marta Mauràs, "...Cuba continues to advance in absolutely basic aspects of children's welfare."⁷

In fact, a recent report from U.S. pediatricians issued after a visit to Cuba, expressed surprise at "The continued very high health indices among children." Their assessment after completing their fact-finding mission was that We Cuban experience shows that even under conditions of deprivation, careful prioritization of essential goods for children can largely protect their health. Children have not fared so well in other societies which lacked as thorough a commitment to child health during periods of economic crisis."⁸

However, the economic crisis has taken a toll on children's health, and our research leads us to concur with the findings of the United Nations and its agencies operating in Cuba that the U.S. embargo has exacted an extra price. As Luis Zuñiga, resident program director of UNICEF put it: 'For all intents and purposes, the [U.S.] embargo levies a tax on childhood... It's a fact-not just an opinion-that the embargo is directed against children, against women, and against all of the families of Cuba...' ⁹

A 1994 UN Secretary General's report. summarizes UN agencies assessments of the embargo's impact based on their programmatic experience in Cuba:

The U.N. Center for Human Settlements called the U.S. policy a prominent factor in the shifting of priorities in Cuba with 'scarce finances increasingly being diverted to emergency sectors and vital procurement... and... indicators revealing a drastic worsening in the quality of life, impacting directly on the well-being of people, particularly the most vulnerable groups,' including children.

UNICEF cited the embargo as a significant negative influence on "The situation of children" The report goes on to call for 'urgently needed' special efforts, supported by the international community, to protect children, and notes "...particular concern with regards to the availability of essential medical supplies, including scarcities of antibiotics and medicines, micronutrient malnutrition and the high percentage of children between the ages of five months and five years now showing signs of iron-deficiency anemia, as well as other deteriorating food consumption indicators, including a rise in low birth weight babies." UNICEF also spoke of the embargo's role in the deteriorating water supply system, and availability of safe drinking water.

The U.N. Population Fund and the World Food Program also cited embargo-related problems in their areas, all constituting additional pressures on the welfare of Cuban children¹⁰

programs themselves have felt the weight of embargo restrictions, since U.S. legislation requires the Administration to reduce the U.S. contribution to international agencies by a proportion correspondent to the agencies' expenditures in Cuba. Only in 1994, did Congress amend the Foreign Assistance Act to exempt U.S. contributions to UNICEF from this provision.¹¹

In addition, the embargo works to make U.N. cooperation with Cuba more costly and logistically more difficult. (See chapters on Humanitarian Donations and Water Resources.)

The U.S. Embargo and Health Services *for Cuban Children*

Inasmuch as the embargo has been a major factor in the current economic crisis, the prioritization of children's health has required extra effort; but in those areas of health care where the embargo has had a direct impact, no program, or plan of action has been able to completely buffer the impact of the embargo on children.

As an added measure to start babies on a healthy course, since 1991, Cuba has adopted the UNICEF/PAHO-WHO 'Baby Friendly Hospitals' Program to promote breast-feeding. Specific

goals are to 1) achieve exclusive breast-feeding by over 90% of the newborns leaving the hospital end 95% in the year 2000, 2) to achieve 86% exclusive breast-feeding until the fourth month by the year 2090, and 3) to maintain breast-feeding, complemented by other foods, until at least 6 months of age for 60% of babies in 1995 and 75% by the year 2000. 12

The 1995 goal for exclusive breast-feeding on leaving the maternity hospital has been surpassed: 98% of babies go home breast-feeding, with 43 Cuban hospitals to date awarded the international distinction of "Baby Friendly Hospital." Nevertheless, despite some improvement in the prevalence of breast-feeding of babies up to four and six months, the 1995 goals were not met, and partial studies indicate that only 50% of babies continue exclusive breast-feeding through the first four months of life.

A series of plans and actions, including a "baby friendly" community-based movement and education and support program have been initiated to step up implementation.¹³ But continuing exclusive breast-feeding has been hampered by the economic crisis and exacerbated by the blockade. Maternal nutrition is an important aspect of successful breast-feeding and, as we see in other chapters, the nutritional status of the lactating mother is likely to be deficient. Dr. Ana Isabel Valdés, a family doctor who also breast-fed her three children until each was about two years old, told us that many of the young mothers she attends give up well before the fourth month. "Many say they are just exhausted and getting too thin, since they are not eating enough while breast-feeding. Others say their milk dries up, which I think has more to do with psychological factors than physiological ones. I've been breast-feeding for just about all of special period, and I'm certainly too thin, too. In general, we need more support in the community, to help a nursing mother with her problems, so she keeps on breast-feeding and doesn't give up. As the food situation improves, I think these indicators will too. We also have to work to convince people that this is really the best thing for the baby."¹⁴ But educational materials are also feeling the pinch, since resources to develop and distribute them are scarce

Like infant and child mortality, low birth weight rates showed steady declines through the 1980s, reaching 7.3% in 1989. Then, in 1991, the incidence of low birth weight began to steadily rise until 1994 when UNICEF-supported vitamin supplements, a revitalized maternity home network, and increased nutritional support for high-risk pregnant women began to turn the tide.¹⁵

LOW BIRTH WEIGHT IN CUBA

Province	1989	1993	1994	1995 (*)
Pinar del Río	7.0	8.7	9.1	7.9
La Habana	4.5	5.4	5.3	4.9
Ciudad Habana	6.8	9.4	9.4	8.6
Matanzas	7.1	8.4	8.6	7.6
Villa Clara	6.3	7.3	7.5	6.4
Cienfuegos	7.5	7.6	8.3	8.1
Sancti Spiritus	6.3	7.8	7.1	6.0
Ciego de Avila	7.2	8.7	9.8	7.6
Camagüey	7.2	8.7	8.3	6.9
Las Tunas	7.5	9.3	9.8	8.6
Holguin	7.7	9.7	8.9	8.1
Granma	8.5	10.0	9.4	8.1
Stgo. de Cuba	8.2	11.1	10.5	9.8
Guantánamo	8.7	10.4	9.8	9.0
Isla Juventud	6.1	7.4	7.8	6.6
Nationally	7.3	9.0	8.9	7.9

I.; Provisional Source: Ministry of Public Health, Havana

Low birth weight is key since this indicator is associated with infant mortality. Dr. Francisco Valdes Lazo of the National Maternal-Child Division of the Ministry of Public Health told us that a baby born at below 2500 grams is 14 times more likely to die in its first year. He went on to point out that half of the infants who do not reach their first birthday in Cuba die because of the mother's nutrition problems.¹⁶ Our research leaves no doubt that these, in turn are directly related to the U.S. embargo and its restrictions. (See sections on Women's Health and on The Food Supply and Nutrition.)

Neonatology

At every maternity and pediatric hospital we visited, the problem of low birth weight was raised and discussed as an overriding concern of the specialists we interviewed.

Dr. Frank Tobay, Director of the Pediatric Hospital of Central Havana, told us that there is a clear increase in hospitalizations of babies who registered low weight at birth. 'In this hospital, infant mortality is down, but morbidity is up and there are more low birth weight cases. And we are finding infant mortality and low birth weight are definitely associated. The problem is closely related to maternal nutrition during pregnancy. These are high-risk babies. In Cuba, high-risk babies get special attention so the problem is compensated to some extent, yet it is a true and serious concern.'¹⁷

In Pinar del Río, where low birth weight has been consistently higher than the national average for the last 45 years (in 1989, Pinar del Río's low birth weight rate was lower than the national average), the general consensus once more was that the nutritional status of women is the underlying cause for the marked increase. Specialists interviewed during our visit to the Justo Legón Padilla Provincial Maternity Hospital in Pinar del Río also cited low birth weight as a major factor in the increased incidence of disease among infants and the extra pressure on the hospital and the neonatal intensive care unit. Like all of the hospitals of Cuba, this one must cope with increasing demands on declining resources.

It is the province's main tertiary care facility of its type, with a broad range of neonatal services and a neonatal intensive care unit. Most of the high-risk cases are referred here: 50% of all births in the province take place in the hospital, and 70% of the low birth weight babies are born there. As a result, the recent period has produced extra burdens on the 242 bed hospital. We saw great overcrowding, including two women to a bed in some wards, coupled with lack of sheets, lighting, cleaning supplies, and other resources which at times limit the full utilization of this facility. This, despite the fact that this hospital is the province's prioritized hospital: "...if there is only one antibiotic in the province, it comes here first," Director Dr. Reinaldo Menéndez told us.¹⁸

The primary causes of infant mortality and morbidity include: the hypertensive states of pregnancy; prematurity, associated mainly with infection and stress, according to some specialists; anemia and other nutritional deficiencies during pregnancy; and neonatal sepsis. Dr. Valdes Lazo of the Maternal Child Division of the Ministry of Health reported sepsis is currently the third cause of infant mortality, nationally, after perinatal problems and congenital malformations.¹⁹ Infant mortality caused by neonatal sepsis in 1995 was 0.9 per 1000 live births, significantly high for a general infant mortality rate of 9.4.²⁰ The Pinar del Río specialists cite this as one of the main causes of infant mortality in their province, due in part to untreated vaginal infections, as well as to greater susceptibility of low birth weight and premature babies to infection.²¹

Despite their priority status, the neonatology services we visited were underequipped and understocked, working with obsolete and insufficient equipment, aggravated by equipment breakdowns. Most of these problems stem from the economic crisis of the recent period, exacerbated by the embargo: purchases of new cardiography fetal monitors, infusion pumps, blood gas analyzers, neonatal respirators, and ultrasound machines, for example, were clearly overdue. We also found severe shortages of accessories and disposable materials ranging from catheters and syringes to gauze, from cotton to paper for sterilisation.²²

However, the case of the U.S. manufactured Preemicare neonatal respirators is a good example of the incidence of the U.S. embargo in this already tense situation for neonatology care, creating excessive stress for the specialists who care for newborn babies with serious problems. 25 donated Preemicare Model 105-4 Neonatal Respirators were distributed throughout the country, 5 of them in the city of Havana. A 'student' who had learned the use of the equipment in the U.S. came to Cuba to train technicians and specialists, since the embargo prohibits not only a Preemicare sale, but also providing such a service. However, electromedicine experts say many of their questions went unanswered. As these respirators now begin to malfunction and the need for spare parts arises, Cuban importers have been hard put to find them, much less at reasonable prices, through third-country intermediaries. Technicians from the National Electromedicine Center told us that three of these units are now out of commission for lack of critical spare parts.³³ of the 25 units originally donated, we located one broken unit at the America Arias Maternity Hospital in Havana, and another in Pinar del Rio.²⁴

In the neonatal intensive care unit of the América Arias Hospital we were told that one of the two Preemicares had been out of commission for six months, its pneumatic diode broken. According to Dr. Mario Lee, chief of neonatology, 35 to 40 babies at the hospital, or one percent of newborns, need mechanical ventilation annually (sometimes for weeks or months at a time). While no baby in need has gone without ~~it~~ other hospital's neonatology units loan equipment if necessary-the situation is a difficult one. Dr. Lee described harrowing moments when two babies need to be ventilated at the same time. The neonatologists on duty rotate manual ventilation, while a free respirator is located at another hospital and then transported, a process that can take hours.³⁵

At the neonatal intensive care unit of the Juan Manuel Marques Pediatric Hospital a critical situation exists since three of their four neonatal cardiomonitors are out of commission for lack of parts.³⁶ These cardiomonitors are manufactured by the Siemens company of Germany, but specialists at the hospital are still concerned about delays in obtaining replacements because of financial limitations and potential snags caused by the embargo. In fact, Siemens USA told us that they have occasionally had to ask for U.S. export licenses when Siemens Germany has requested them to return a 100% German-origin part that is out of stock, for shipment to Cuba. (See chapter on Medical Exports.)

One of the problems with spare parts for some of this more sophisticated neonatology equipment is that Cuba must prioritize its medical equipment and spare part purchases from month to month due to the severe hard currency constraints. By 1996, at least 10 ultrasound machines in the city of Havana were broken and purchases of new blood gas analyzers were urgently needed. These items were on the same list as parts for neonatal cardiomonitors. "When the funds dry up," said Dr. Lee, "your priorities are just on paper."²⁷

In addition to the prenatal testing that is carried out for in-utero detection of congenital malformations,³³ Cuba carries out several neonatal screenings. Thus, for example, the program for early diagnosis and treatment of congenital hypothyroidism in newborns prevents serious illness and mental retardation in those born with this condition (approximately one in every 3000 births in Cuba.) According to Dr. Ricardo Guell, the screening program based on blood extractions from the umbilical cord at birth of more than one million newborns has enabled specialists to

detect and successfully treat 331 cases of congenital hypothyroidism since 1986, when the program began.²⁹

Congenital hypothyroidism can only be diagnosed clinically after three to six months of age when there is already irreversible mental retardation as well as growth retardation. When treatment is initiated earlier, the overall prognosis for normal physical and intellectual development is excellent.³⁰ This program is threatened, however, due to the embargo restrictions limiting purchases by the National Immunoensayo Center, which prepares reagents, plates and entire kits for this testing program. (See section on Diagnostic Testing.)

Equally threatened by the embargo are treatment possibilities for infants born with heart malformations despite the existence of the modern, pediatric cardiac services at the William Soler Hospital in Havana. We describe these problems in the section on Cardiology.

A neonatal screening program to detect hearing impairment using neurophysiological technologies was also routine in at-risk infants such as those who had undergone intensive antibiotic therapy as newborns. The program enabled detection of hearing impairment and deafness at three months, to permit early intervention and enhance these children's possibilities for normal intellectual and social development. This program has essentially been suspended, due to economic difficulties exacerbated by the embargo, including the greatly inflated cost of such items as electrodes and EEG paste when purchased and transported from Europe or Asia.³¹

Cuba's National Immunization Program

During the five-year period prior to 1962, recorded estimates indicate a yearly rate of more than 30,060 cases, 560 deaths and 300 pre-ent paralysis victims, resulting from diseases preventable by vaccination. In fact, these figures are thought to be conservative since so many cases went undetected and untreated prior to 1960.³²

According to Margaret Gilpin, writing *in* the ***Journal of Public Health Policy***, "...in 1360, typhoid fever was endemic, with periodic epidemics of poliomyelitis, diphtheria and tetanus, and high mortality from tuberculosis and the diarrheas. One early measure undertaken was a collaboration agreement with the Pan American Health Organization to eliminate malaria (Cuba was declared free of malaria by the World Health Organization in 1973), followed by the organization of systematic, national vaccination campaigns and programs to control other diseases." ³³

In 1962 the National Immunization Program was established. From 1962 to 1995 more than 230,000,000 doses of nine different vaccines have been applied in the battle against eleven infectious diseases: Polio, Diphtheria, Tetanus, Whooping Cough, Measles, Rubella, Mumps, Meningococcal meningitis, Hepatitis B, Typhoid Fever and Tuberculous meningitis.³⁴ In 1995, Cuba received WHO/PAHO certification for the eradication of polio.

During the past several years, immunization coverage for children and pregnant mothers has been maintained and even increased due to assistance from UNICEF, PAHO-WHO and the Rotary International Club of Mexico, which have guaranteed the supply of these vaccines.³⁵

The following levels of coverage were achieved in 1995

VACCINATION COVERAGE IN CUBA 1995		
VACCINE	AGE or GRADE	COVERAGE
BCG	< 1 year	98.7
HBV	< 1 year	98.1
DPT	< 1 year	100.0
AM	< 1 year	98.5
PSR	1 year	100.0
DPT-R	1 year	99.8
Tetanus-Diphtheria	1 st grade	100.0
HBV	3 rd grade	91.0
Typhoid	5 th grade	90.4
Typhoid	8 th grade	93.8
Tetanus toxin	9 th grade	100.0
HBV	9 th grade	90.3
Typhoid	11 th grade	96.2
Polio	Campaign	96.0

Source: National Epidemiology Division, Ministry of Public Health.

The estimated cost to protect each child under two years of age is USD \$33.00. This does not include the vaccinations of older children. There are approximately 350,000 children under two in Cuba, so this portion of the program costs the country about 11.5 million dollars annually.

Despite the help of U.N agencies' and the Rotary Clubs of Mexico, the Cuban Immunization Program has experienced problems in the recent period. According to Dr. Miguel Angel Galindo, head of the National Vaccination Program, a number of difficulties have impacted the program.³⁶

- The program has been hard hit by the economic situation, exacerbated by the embargo. Oil shortages and power outages have made it difficult to guarantee the necessary refrigeration at the community level as well as transportation for vaccines, especially to distant regions.
- The Rotary Clubs of Mexico donate the polio vaccine, but the rest are produced in Cuba with donations from UNICEF. There have been gaps in production, and problems with raw materials due to changes in suppliers, some of these provoked by the embargo. See sections on Vaccines and Biotechnology and on the Pharmaceutical Industry.)
- The unstable and changing supplies of raw materials for vaccine production have caused changes in vaccine strains which further complicate and delay production, creating gaps at the community level.

Dr. Cristina Vaidivia, National Director for Outpatient Services (Ambulatory Care) told us that the Immunization Program has been quite seriously affected at the community level with deficits for months at a time. In addition, The vaccines now generally are only available in multi-dose form-usually ten doses per vial, as opposed to mono-doses which are easier to administer. Thus, for example, the family doctor, or a group of family doctors, have to organize at least ten babies of approximately the same age for vaccination all at one time. This affects the organization of work at the community level, causes delays in immunization schedules, creates extra work and stress for the primary care health practitioners and for families who are concerned that their babies

receive their vaccines on time.³⁷ Economic constraints dictate this situation, complicated by the embargo, since the cost of production of mono-dose vaccinations is considerably higher.

One of the only vaccines commonly applied in the developed world that is not part of the Cuban program is the Haemophilus influenza B vaccine which prevents haemophilus meningitis. According to Dr. Galindo, this is one of the very few ways that Cuba could further reduce infant mortality. Dr. Galindo estimates a prevalence for Haemophilus meningitis of well over 1000 cases per year, nearly half in infants under one. There are about 40-50 deaths per year in infants under one. This vaccine- was originally patented by Merck, although it now is produced by at least one non-U.S. firm as well. But its expense to Cuba is prohibitive, all the more so since U.S. companies have not expressed a willingness to sell, eliminating the closest market. The cost of one dose of this vaccine on the international market, according to Galindo, is USD \$15.00 and each child needs three doses, bringing the cost of vaccinating the approximately 175,000 babies under one to USD \$7.9 million.⁵⁹

Researchers at the Finlay Institute are currently working on developing a combined meningitis vaccine that would protect against this form of meningitis as well as the meningococcal strains which comprise the Cuban anti-meningitis vaccine currently applied. They are also working on a separate haemophilus vaccine. Both would solve the financial dilemma and be available at a fraction of the cost of imported vaccines. (See section on Vaccines and Biotechnology.) At the pediatric hospitals we visited, specialists confirmed the relatively high incidence of haemophilus meningitis, citing the urgency they feel for the incorporation of a domestically-produced vaccine into the national program.

Because the Cuban Democracy Act directly targets the Biotechnology Industry, including the vaccine development programs being carried out at the Finlay Institute, the development of new vaccines has been threatened, and the embargo has posed specific obstacles to this research and production. (See section on Vaccines and Biotechnology.)

The Health Status of Cuban Children Today

As we saw above, Cuba has managed to maintain good basic indicators in terms of mortality in children, despite the intensity of economic pressures. Among children one to four years of age, principal causes of death were accidents, congenital malformations, and cancer. In the 5 to 14-year-olds, the main causes of death are accidents, accounting for half, followed by cancer, congenital malformations, acute respiratory disease and kidney disease. These indicators have maintained a consistent downward trend for over thirty years now, continuing through the difficult 1990s in spite of the clear, at times alarming, rise in morbidity during the same period.⁹⁹

Dr. Cristina Valdivia told us that 'The family doctor has been key to controlling morbidity. The statistics would be worse for this period if it weren't for the family doctors' presence in the community, in the schools and daycare centers, in work centers. They are able to stay on top of any worsening situation, to catch problems before they can spread, to control infectious outbreaks, detect waterborne diseases early, hospitalize patients at home, organize mini-quarantines, etc.'⁴⁰ While on the one hand children have been spared the harshest repercussions of the economic difficulties, Dr. Valdivia also spoke at length to the authors about the rise in family dysfunction due to stress and tension created by the crisis atmosphere and hardships.⁴¹

Iron deficiency is the most prevalent nutritional problem, and its dominant cause is the inadequate food supply. Since the early 1990s food production and consumption has dropped, and an increase in the frequency of anemia has been observed. It now affects 50% of children 6 to eleven months of age and at least 95% of children 1 to 5 years of age.⁴² Other indicators for the evaluation of nutritional status in children have been discussed both in this chapter and

elsewhere. In general, it is clear that the rise in morbidity also relates to the depleted nutritional status of children, particularly in terms of protein and micronutrient deficiencies, lowering their defenses against disease.

Another important factor in the changing epidemiological picture since 1989 is the general hygiene situation and problems with the water supply. A good share of this deteriorating situation is directly attributable to the U.S. embargo, and the restrictions it has imposed on purchases for Cuba's U.S.-equipped water system and treatment plants. Havana pediatrician, Dr. Roberto Sayas, says that the generally poor hygiene situation -in the city is having some impact on the epidemiological profile at the pediatric hospital where he works and an even greater impact at the primary care level in the community. People keep animals in city apartments for food which creates a real health hazard. Despite laws against this practice, he points out that they are difficult to enforce because of the shortages. There are also problems with garbage collection and scarcity of soap and disinfectants due to the economic crisis. Perhaps most significant, however, are the deficiencies in the water supply. This affects people in their homes but it is also affecting the hospital, Dr. Zayas told us. "We need soap and water to do our work.. often we don't have one or the other, or we have neither." 43

A program against acute diarrheal diseases (ADD) was first instituted in 1962 to combat high mortality rates. 4,147 people died from ADD during that year alone, at a rate of 57.3 deaths per 100,000 inhabitants, representing 8.2% of total deaths in the year. More than 85% of these deaths were in children under one year of age. In 1989, ADD caused a total of 285 deaths, for a rate of 2.7 per 100,600 inhabitants, representing 0.4% of total deaths; 81 or 28.4% were in children under 1 year. This data reflects a mortality reduction of 95.3% in a little less than 30 years. Morbidity from ADD did not descend proportionally, however, and the number of consultations for diarrhea remain relatively high. The 1989 rate was 64.5 per 100,090 for all age groups and 1,274.9 per 109,000 inhabitants for children under 1 year of age. 44

Cuba, like all tropical countries, has a high incidence of ADD cases. These are monitored according to the number of medical consultations, such that one episode of diarrheal illness can generate more than one consultation, especially in children under five years of age. According to a Ministry of Public Health National Epidemiology Division report, the last several years have seen a **slight** rise in total medical consultations for ADD. Consultations in the period 1993-1995 rose to 92.1 per 100,000 inhabitants in relation to the 1989 rate of 84.5. Yet 1994 was considered an epidemic year, particularly in the capital city and in the province of Havana, pushing the national indices up, due primarily to chlorine deficits, along with other hygiene-related problems. Mortality from ADD rose from 2.7 per 100,000 in 1989 to a high of 6.7 in 1994, reminiscent of 1970 rates but with the significant difference being that 95% of these deaths occurred in adults over 66 years as opposed to young children--a reflection both of the vulnerability of this older age group to limitations of the special period and the commitment to the protection of children. 1995 witnessed a slight reduction in ADD consultations, although often serious local outbreaks of water-borne diseases continued to occur, including Shigella diarrheal disease, Hepatitis A, and Typhoid outbreaks. 45

Dr. Valdivia and some of the primary care physicians we interviewed noted that more time was being spent by the family doctor dealing with acute problems like ADD, leaving them less able to develop preventive activities--a recurring contradiction facing health professionals in Cuba today.

Dr. Manuel Santin, National Director of Epidemiology, told us that in addition to the increases in water-borne and diarrheal diseases, there has been a dramatic increase in dermatological problems like head lice and scabies, as well as fungal diseases, because of the general hygiene crisis and the lack of medications for treatment. 46 Intestinal parasites have also presented an increasing problem, particularly in rural areas. When we visited Pinar del

Río, a predominantly rural province, we were told that this is a major health problem of the current period, primarily due to shortages of medicines. At one pediatric hospital we visited, 35% of the tests done at the hospital are positive for helminths (worms). Dr. Jesus Lazo Cabrera, Director of the Pepe Portillo Pediatric Hospital in Pinar del Río explained: We expect that about 50% or more of this province's population have parasites. The only medications available are at the hospital level, and even so there are deficits, so the child has to be in serious condition to receive treatment."⁴⁷

The specialists from this province went on to explain that although parasites are endemic to this mainly rural province, the situation has deteriorated considerably during the special period, with many children playing outside without shoes (perhaps saving their only pair for school), latrine and other hygiene problems.⁴⁸

In a report on school age health, the Ministry of Public Health noted the importance of hygiene and other environmental conditions in the schools and day-care centers and their relationship to prevention programs geared to this sector of the population. "There has been a significant deterioration in the last five years with regards to hygiene, sanitation, lighting, and the water supply in the school environment," the report states. There are 2,224,065 school age children enrolled in 12,041 educational facilities. Most are in poor condition, with poor lighting, furniture and insufficient school supplies.⁴⁹

In 1995 an estimated 3,341 outbreaks of scabies involving at least 950,413 cases, and 2,136 outbreaks of head lice with 117,959 cases were reported by the Ministry of Public Health.⁵⁰ The majority of these occurred in the school age population. The quantities and quality of food for the school lunch programs have also been consistently declining over the past several years. A Ministry of Public Health study indicated that 90% of school age children needed some kind of specialized medical attention during 1995.⁵¹

Accidents constitute the first cause of death in the one to 15 year age group and this mortality rate is rising. In 1995, 30% of preschool mortality and 50% of school age mortality were due to accidents. In addition, accidents are responsible for high morbidity rates in children and adolescents, frequently involving considerable physical and mental sequelae.⁵² Bicycle accidents involving children have risen dramatically since many families depend on the bicycle as their primary form of transportation because fuel shortages have cut public transport. There are no helmets or other protective items available, and it is not uncommon to see parents with one or two children on one bicycle. Because of cooking gas shortages and blackouts, many families keep kerosene and other corrosives in bottles for use in cooking and cleaning, raising the incidence of accidental ingestion of these and other home-made substitutes. Thus, a relatively dramatic rise in corrosive esophagitis has been recorded, according to pediatric surgeons we spoke with at several hospitals visited. Pediatric gastroenterologist, Dr. Odalys Lazo estimates there have been as many as 200 cases a year during the last several years in Havana alone.⁵³

Burns are another rising problem, particularly pavement burns related to bicycle accidents, as well as burns related to the use of kerosene and alcohol for cooking, and burns from hot or boiling water prepared for bathing or inhalations. The overwhelming majority of Cuban households do not have hot running water and vaporizers for inhalations for sick children are non-existent.

Mental Health

In general, treatment for childhood psychiatric illness suffers similar obstacles as other aspects of health care delivery, but particularly in terms of problems with medicines. Caps in the supplies of important anti-psychotic drugs and anti-epileptic medications create special problems for child psychiatrists since substitutes often do not work the way a substitute antibiotic might solve an ear

infection. Thus, Dr. Elsa Gutierrez, Director of a child and adolescent mental health clinic in Havana, explains that 'Substitutions get very complicated in psychiatry. Not only are there problems when you have a good therapeutic protocol for a given patient and have to change it, but also we have problems with gaps in supplies and the need to be repeatedly changing medications. There is no regularity, no stability and this can have a very negative impact on our kinds of patientsn.⁵⁴

We visited a special day care center and kindergarten in Havana, the Circulo Infantil Zún Zún, for mild to moderately mentally retarded children. Many of the children were on some form of medication. One little boy had been doing well, we were told-he was learning and behaved in a sociable way. But when supplies of his medication ran out, he didn't respond well to available substitutes and began having problems and couldn't learn. He stopped participating, in activities, and the problems kept growing. He became aggressive with the other children. Finally, he had to be sent home because teachers couldn't handle him at school without the medication. Dr. Gutierrez commented that 'when you are working with children especially you do not want to start trying out substitutions when you are using something that works. Maybe the substitute is a good drug, but not for a particular patient. Every time you have to change medications under these circumstances it's an aggression against the patient, it's a therapeutic aggression.'⁵⁵

Dr. Gutierrez relates this and other problems to the embargo. In the first place, she says the more modern, better psychiatric medications produced in the U.S. are not available. Or they come in as a donation, but only last for a short amount of time when psychiatric therapy is usually longer term. In addition, she says there have been a lot of changes and adjustments in dosages and forms in which medication can be given and these new forms are often U.S.-patented products either not available or prohibitively expensive from third-country intermediaries. Thus, for example, she cites the drug, Carbamazepine, used in the treatment of epilepsy and some other psychiatric conditions. Generally, treatment is long term, for 3-5 years for example. This medication is available in the U.S. in single dose, time-released tablets but is unavailable in Cuba. "It makes a big difference for a child, having to take just one tablet a day or having to take tablets four or more times a day... For an epileptic child who already has so much to deal with because of his disease to have to take medicine so many times a day is an additional trauma."⁵⁶

Pediatric Hospital Care⁵⁷

Medical equipment is a major problem, for all Cuban hospitals. At the National Medical Supply Company (ENSUME), we were informed that pediatric hospitals are prioritized for replacement and repairs, but that budgets are extremely limited. In addition, we encountered a number of difficulties for which the embargo is to blame.

- Donations of U.S. equipment that depend on U.S.-produced accessories was a problem at several hospitals we visited. Juan Carlos Velazquez of the National Electromedicine Center explained that many companies make their money on the regular supply of accessories and disposable materials specific to the equipment. Without replacement at regular intervals the equipment fails. In Cuba's case the cost of these items is greatly inflated since they must be purchased through intermediaries. At the Pepe Portillo Pediatric Hospital in Pinar del Rio, Director Jesus Lazo showed us an IVAC Corporation (Eli Lilly) IVAC 560 infusion pump, a North American donation that arrived without the infusion set, rendering the equipment dysfunctional. It has been idle for over a year in a 415-bed pediatric teaching hospital with 17 in-patient services including two intensive care units (ICU and a neonatal intensive care service), where no other functioning infusion pump was available. Nearly every hospital we visited spoke about the shortage of infusion pumps, considered critical in surgery for the administration of anesthetics as well as vital to any well-equipped intensive care unit. The problem here involved both old equipment and difficulties acquiring necessary accessories

and spare parts. At the Juan Manuel Marquez Pediatric Hospital in Havana we saw a donated U.S. infusion pump also out of commission for lack of accessory items. Infusion pumps were prioritized for purchase in 1996-97.

- Respirators also posed significant problems. The Pepe Portillo Pediatric Hospital had a Siemens Servo 908, a Babylock, a Preemieare and a Bird respirator-two of these, the Preemiecare and the Bird, are of U.S. origin. All are old, constantly failing and require spare parts that are difficult to get. At the Central Havana Pediatric Hospital, we also found old equipment, including Siemens and Bird respirators, and we were told by specialists in the ICU that they often had difficulties with the equipment. The day we visited this hospital, we were told that a respirator had failed that same morning while ventilating a baby in critical condition.
- X-rays. In addition to problems with obtaining film, mainly for economic reasons, several of the pediatric hospitals we visited had Picker X-Ray machines, parts for which had not been purchased since the U.S. Treasury Department denied a license for their sale, as discussed in the chapter on medical exports. At the Pepe Portillo Hospital in Pinar del Rio we found the Picker equipment broken for lack of spare parts, and specialists at this hospital estimate a 75-80 percent reduction in X-rays done over the past several years. This complicates an already serious cutback in X-ray therapy for budgetary reasons. At the Central Havana Hospital, X-ray department personnel said they were at least two months behind in outpatient x-rays. They were only seeing five cases per day at the time of our visit, down from at least ten times that amount in 1969, with the rest reserved for emergency cases and hospitalized patients, which were also done from 1989.

Medications

The fact that medicines are in such short supply in pediatric services is an indication of the acute drug scarcities in the entire health system. The U.S. embargo sharpens this dilemma in several ways, as we have seen throughout this study, by:

- Shrinking the general resources available for medicine purchases.
- Adding to the purchase price and shipping costs of imported medications.
- Making U.S. firms and subsidiaries leery of offering products to Cuba, or even replying to inquiries.
- Generating licensing red tape that further discourages U.S. pharmaceutical companies from applying for export permission.
- Obligating Cuban importers to purchase U.S.-origin drugs and U.S.-exclusive drugs at significant markups-sometimes so high **that they** are unaffordable-reflecting the risk taken on by trading houses and other intermediaries.
- Keeping U.S.-origin drugs in the pipeline from regularly reaching Cuban patients for at least a decade after they go on the international market.
- Hindering pharmaceutical production in Cuba, and expressly targeting the biotechnology industry for embargo enforcement.

In the nine pediatric hospitals and neonatology units we visited the following drugs were most often mentioned as in critical short supply:

- Flucanazole, an important systemic anti-mycotic, used in the ICUs, for pseudomonas, post-surgically, in immunodepressed patients (cytotoxic chemotherapy and radiation patients, bone marrow transplant patients, etc.), particularly those susceptible to candidiasis. This drug is still under U.S. patent, and therefore not readily available in Cuba.
- Vancomycin, an important antibiotic, especially in patients with antibiotic resistance, gram positive supra-infections, etc. Without substitute, particularly in ICU.
- Third generation antibiotics, in general; cephalosporins: often better, more effective drugs, and/or with specific dosages, are not readily available in Cuba because they are still under U.S. patent.
- Ceftriaxone (Rocephin), an important pediatric medication, especially for meningitis in infants.
- Broncodilators. asthma medication. Lack of this treatment has caused pediatric deaths from asthma to rise.
- Anti-convulsants for epilepsies and other neuropediatric afflictions.
- ACTH, used in West's Syndrome and infant convulsive disease. This drug could keep patients out of ICU. We saw a number of cases of untreated West's Syndrome at several hospitals.
- Cancer medications are always in short supply, particular the combinations needed for typical protocols.
- Dobutamina and dopamina, important in shock, heart failure.
- Growth hormone (somatropin). a treatment for dwarfism.
- Oral analgesics and anti-pyretics. We found no acetaminophen or ibuprofen anywhere. In Pinar del Río, we found acupuncturists on 24-hour duty in emergency rooms to help compensate for the nearly complete absence of these medications. High fevers in children were generally brought down by injection, when available.
- Steroid medications.
- Anesthetics, especially scarce in 1993-94, we were told, and cause for numerous surgery cancellations.
- Eritropoyetina and other medications needed by renal patients (see section on Nephrology);
- Heart medications, including prostin VR (see section on Cardiology).

Disposable materials of all kinds were also in short supply at the pediatric hospitals we visited.

Conclusions

Because children's health is prioritized, general indicators remain good, but scarce resources are further limited by the U.S. embargo, causing holes in the safety net. And so we are seeing a recurrence of dramatic cases like the following:

During a visit to a cancer ward at the Juan Manuel Marques Pediatric Hospital in Havana, specialists informed us they do not have access to the 'Implantofix' or any cell-site-ports for chemotherapy. Dr. Marta Lonjong, head of the National Pediatric Cancer Program told us that as a result, **We** are constantly having to puncture veins, search for new ones, and this is cause for great additional pain and suffering-for the children. If not that we cannot cure our cancer patients-we can and we do-but they are suffering excessively, unnecessarily... and this is a generalized, daily problem." Dr. Lonjong went on to describe the case of a five-year-old girl with Sarcoma who is relapsing. "All her veins are in very bad shape already, but we have to treat her... We had to canalize the jugular vein. She developed a terrible hematoma which almost killed **her**. And she was in excruciating pain. It is hard to describe such suffering. The 'Implantofix' would have prevented all of this."

Implantofix is a U.S. product manufactured by Braun Medical, Inc. of Bethlehem PA. It is restricted for sale to hospitals only, requiring notification of destination and thus effectively eliminating the possibility of Cuban purchases even through third-country intermediaries. Greg Leh, of Braun Medical's International Sales Department, told the authors that the company exports to the Caribbean but confirmed its "for hospital use only" designation. Although Braun is associated with a German company and has an affiliate in France, their cell-site-port is produced in the United States and thus subject to embargo laws. Leh also informed us that the world market leader in such ports is the Swedish firm, Pharmacia, which was bought by the U.S. company Upjohn in August, 1995.⁵³

Mauricio Cassvan Navarrete was 15 months old and hospitalized at the Juan Manuel Marques at the time of our visit. He was suffering from an undetermined encephalopathy which specialists in Cuba have not been able to diagnose. When he decompensates, he goes into respiratory failure, making his condition especially dangerous. Two U.S. medical institutions offered to receive the child and his mother, a physician herself. On two separate occasions, **the** U.S. Interests Section in Havana denied visas for the **boy** and his mother to travel to the U.S. for such fully hosted medical attention. A Canadian visa **was** also refused when treatment was offered there, according to the mother, Canadian authorities citing U.S. visa denials as their reason.

Rosalba Coro Guerra, a 35-day-old baby girl hospitalized in the Pepe Portillo Pediatric Hospital in Pinar del Rio had a serious pseudomonas infection. The staff was desperately looking for Flucanazol. Finally they were able to obtain a small amount from donations but not enough for a full course of treatment. At the time of our visit, the search was still on, with provincial and national level involvement. **We** were told that this is a frequent complication of abdominal surgery. No matter how badly it is needed surgery should not be performed when there is pseudomonas infection present. We left the province without knowing what would happen to this baby.

In the cases of children with leukemia, although the chemotherapy drugs needed for treatment are on the A-1 priority list, and despite the fact that workers in the tourism and civil aeronautics sectors donate hard currency tips and earnings specifically for the purchase of these medications, they are so expensive that problems continue to plague physicians treating these youngsters. In addition, the embargo plays a definite role in keeping these drugs from Cuban children, inasmuch as it hinders their domestic production. The United States is also the world's number one source of new and more effective therapies against leukemia, to which Cuban children of this generation, and at least one more generation to come, have no guarantee of access. (See sections on Oncology and Medical Exports.¹

NOTES

- ¹ "Update – Cuba: On the Road to a family Medicine Nation" by Margaret Gilpin, *Journal of Public Health Policy*, Vol. 12, No. 1, Spring 1991: page 84.
- ² *The State of the World's Children* 1996, published for UNICEF by Oxford University Press, Oxford, UK and New York, 1996: page 80, "Table 1: Basic Indicators"; and *The Politics of Suffering: The Impact of the U.S.: Embargo on the Health of the Cuban People*, by Diane Runts: Report of an American Public Health Association Fact-finding Trip to Cuba June 6-11, 1993.
- ³ "Mortality Rate of Children Under 5 Years (U5MR): Cuba 1970-1993" by Dr. Raúl L. Riverón Corteguera, Poster presentation at the Child Health 2000 2nd Congress and Exposition, Vancouver, British Columbia, Canada, May 30, 1995.
- ⁴ *Third Follow-up and Evaluation Report: World Summit For Children National Program of Action*, Havana, June 1995; page 22.
- ⁵ *World Summit for Children National Program of Action of the Republic of Cuba*, Havana, December 1991.
- ⁶ a) Ibid.; b) "*Programa Nacional de Atención Materno Infantil* 1989", Ministry of Public Health, Havana; c) "*Constitución de la Republica de Cuba*: Editorial Pueblo y Educación, Havana, 1989;
- ⁷ "The National Program of Action Functions in Cuba as a Genuine Instrument of Social Policy", speech delivered by Dr. Marta Maurás Regional Director of UNICEF for Latin America and the Caribbean, at the *Cuban Presentation of the World Summit for Children Second Follow-Up and Evaluation Report on the National Program of Action*. December 1, 1993.
- ⁸ "American Embargo Against Cuba: Effect on Children's Health", by W.T. Whitney, M.D., R. Garfield, DrPH, A Meyers, M.D., draft provided to the authors, 1995.
- ⁹ "Nota Sobre El Embargo a Cuba", by Luis Zúñiga Zárata, UNICEF/Oficina de la Habana, August 1994. NOT FOR PUBLICATION.
- ¹⁰ "Necessity of Ending the Economic, Commercial and Financial Embargo Imposed By the United States of America Against Cuba: Report of the Secretary General," United National General Assembly, forty-ninth session, item 24 of the provisional agenda, September 20, 1994.
- ¹¹ "P.L. 103-236, Foreign Relations Authorization Act: Fiscal Years 1994 and 1995", April 25, 1994; and Letter to Dr. Peter G. Bourne, M.D., American Association for World Health, from George F Ward, Jr., Acting Assistant Secretary of State for International Organization Affairs, United States Department of State, February 12, 1996.
- ¹² *Third Follow-up and Evaluation Report: World Summit For Children National Program of Action*, Havana, June 1995; page 44.
- ¹³ "Balance Anual del MINSAP 1995, Indicaciones Generales del MINSAP Para 1996", Ministry of Public Health. Havana, January 25, 1996.
- ¹⁴ Interview with Dr. Ana Isabel Valdés, Specialist in General Comprehensive Medicine, East Havana, June 4, 1996.
- ¹⁵ "Análisis del Sector Salud en Cuba. Informe de Avance", Ministry of Public Health in collaboration with PAHO/OMS, November 21, 1995, page 8.
- ¹⁶ Interview with Dr. Francisco Valdés Lazo, head of the Division for Maternal Infant Health, Ministry of Public Health, Havana, November 27, 1995.
- ¹⁷ Interview with Dr. Frank Tobay, Director, Central Havana Pediatric Hospital, Havana, November 1, 1995.
- ¹⁸ Interview with Dr. Reinaldo Menéndez, Director, Justo Legón Padilla Provincial Maternity Hospital, Pinar del Rio, November 29, 1995.
- ¹⁹ Interview with Dr. Francisco Valdés Lazo, Maternal Child Division, Ministry of Public Health, Havana, November 27, 1995.
- ²⁰ Balance Anual del MINSAP 1995", Ministry of Public Health, Havana, January 25, 1996.
- ²¹ Interview with Dr. Carlos Brown, 1st Vice Director, Justo Legón Padilla Provincial Maternity Hospital, Pinar del Rio, November 29, 1995.

- ²² Since this was the case at virtually every hospital visited, see the list of institutions in the appendix of this report.
- ²³ Interview with Alexis Cedeño, National Electromedicine **Center**, Havana, December 8, 1995.
- ²⁴ **These** six units were located at the Justo Legón Padilla Maternity Hospital in Pinar del Río (1), the America Arias Maternity Hospital in Havana (2), the Gonzalez Coro, Maternity Hospital in Havana (2) and the Naval General and Pediatric Hospital in Havana (1.) The rest of the units had been distributed to other provinces.
- ²⁵ Interview with .Dr. Mario Lee, Chief of Neonatology, América Arias Maternity Hospital, Havana, July 18, 1996.
- ²⁶ Ibid.
- ²⁷ Ibid.
- ²⁸ See Cardiology chapter, pediatric section.
- ²⁹ "Salvan a 331 Niños Crnbanos del Retraso Mental", Prensa Latina, Havana, April 5, 1995.
- ³⁰ R. E. Behrman, M.D. and R.M. Kliegman, M.D., eds, *Nelson Essentials of Pediatrics*, 2nd Edition, W.B. Saunders Co., Philadelphia, PA, 1994; page 629.
- ³¹ Interview with Dr. Mitchell Valdes Sosa. Director. Cuban Neuroscience Canter. Havana. February 28.1996.
- ³² "Impacto del Programa Nacional de Inmunización de la Republica de Cuba", National Epidemiology Division, Ministry of Public Health, April 1995.
- ³³ "Update -Cuba: On the Road to a Family Medicine Nation" by Margaret Gilpin, *Journal of Public Health Policy*, Vol. 12, No. 1, Spring 1991; page 86.
- ³⁴ "Impacto del Programa Nacional de Inmunización de la República de Cuba", Epidemiology Division, Ministry of Public Health, April 1995.
- ³⁵ **Third Follow-up and Evaluation Report: World Summit For Children National Program of Action**, Havana, June 1995; page 36.
- ³⁶ Interview with Dr. Miguel Angel Galindo, Head of National Vaccination Program, Ministry of Public Health, Havana, November 27,1995.
- ³⁷ **Interview** with Dr. Cristina Valdivia. National Director for outpatient Services, Ministry of Public Health, Havana, January 20, 1996.
- ³⁸ Interview with Dr. Miguel Angel Galindo, Head of the National Vaccination Program, Ministry of Public Health, Havana, November 27, 1995.
- ³⁹ **Third Follow-up and Evaluation Report: World Summit for Children National Plan of Action**, Havana, June 1995, page 20.
- ⁴⁰ Interview with Dr. Cristina Valdivia, National Director for Outpatient Services, Ministry of Public Health, Havana, January 20, 1996.
- ⁴¹ Ibid.
- ⁴² Interview with 'Dr. Francisco Valdés Lazo, Maternal-Child Division, Ministry of Public Health, Havana, November 27,1995.
- ⁴³ Interview with Dr. Roberto Zayas Mojica, Central Havana Pediatric Hospital, November 1, 1995.
- ⁴⁴ **Informe Anual: 1989**, Ministry of Public Health, Havana, page 69; and "Update — Cuba: On the Road to a Family Medicine Nation" by Margaret Gilpin, *Journal of Public Health Policy*, Vol. 12, No. 1, Spring 1991; page 86.
- ⁴⁵ "Análisis del Comportamiento de las EDA", by Dr. Graciela Delgado, National Epidemiology Division, Ministry of Public Health, February 15, 1996.
- ⁴⁶ Interview with Dr. Manuel Santín, National Director of Epidemiology, Ministry of Public Health, December 12,1995.
- ⁴⁷ Interview with Dr.Jesùs Lazo Cabrera. Director of the Pepe Portillo Pediatric Hospital, Pinar del Río, November **28. 1995**.
- ⁴⁸ *ibid*.
- ⁴⁹ "Relación de situaciones ambientales monitoreadas por el MINSAP. Analisis Epidemiologico 1990-1995", Ministry of Public Health, February 15,1996.
- ⁵⁰ 'Balance Anual del MINSAP 1995', Ministry of Public Health, Havana, January 25, 1996.

-
- ⁵¹ "Relación de situaciones ambientales monitoreadas por el MINSAP. Analisis Epidemiologico 1990-1995". Ministry of Public Health, February 15,1996.
- ⁵² "Balance Anual del MINSAP 1995: Ministry of Public Health, Havana, January 25, 1996.
- ⁵³ On-site visits to pediatric hospitals in Havana and Pinar del Rio, 1995.
- ⁵⁴ Interview with Dr. Elsa Gutierrez, Director, Ana Betancourt Child and Adolescent Mental Health Clinic, November 3, 1995.
- ⁵⁵ Ibid
- ⁵⁶ Ibid.
- ⁵⁷ This section is based on on-site visits, at times several to a single institution, and interviews with administration, medical staff and other health-care providers and technicians at the following pediatric hospitals and neonatology units of maternity hospitals: America Arias Maternity Hospital and Neonatal ICU, Havana; Central Havana Pediatric Hospital and National Pediatric Nephrology Center, Havana; Cerro Pediatric Hospital, Havana; Eusebio Hernández Maternity Hospital Neonatal ICU, Havana; Gonzalez Coro Maternity Hospital and Neonatal ICU. Havana; Juan Manuel Marques Pediatric Hospital and Neonatal ICU, Havana; Justo Legón Padilla Maternity Hospital, Pinar del Rio; Pepe Portillo Pediatric Hospital, Pinar del Rio; William Soler Pediatric Cardiocenter, Havana. In addition, the following interviews also provided information for the section: Electromedicina. Interviews with Juan Carlos Velasquez, Director, National Electromedicine Center, Dec. 6,1995 ENSUME, Interview with Alfredo Rivero, Sub-Director for Medical Equipment, National Medical Supply Company (ENSUME), December 22,1995.
- ⁵⁸ Telephone interview with Greg Leh, February 26,1996.

Introduction

For over three decades, the Florida straits have constituted a kind of great divide between family members in Cuba and the United States. Originally separated more by ideology than distance, relatives have seen delicate attempts at reconciliation, simple family business, and mutual comfort over loss of loved ones disrupted over the years by changing government regulations on both sides. It is the scope of this study to examine the impact of the U.S. embargo on the health and welfare of these families-and the ties that, despite-politics, continue to bind.

It is our finding that the U.S. embargo has been and continues to be a serious impediment to maintaining normal relations between family members in the United States and Cuba.

Travel

For much of the last 30 years, the subjective sense of distance between Miami and Havana was something like the old saying, "You can't get there from here." After the 1960s, direct flights were not opened up again until the 1980s. Successive immigration accords between the Cuban and U.S. governments attempted to regulate travel, but were also subject to the sometimes volatile political climate.

U.S. embargo restrictions for travel to the island claim jurisdiction over some one million Cuban-Americans living in the United States. Since the late 1970s and up to 1994, an exemption in the travel ban was made for persons visiting close relatives in Cuba, who were permitted to make the trip under general authorization from the U.S. Treasury Department, provided (after 1989) that they did not spend above the legal limit of \$100 dollars a day on the island.

However, in August, 1994, new presidential restrictions revoked this general permission, and announced that, instead, "travel-related transactions by persons demonstrating a compelling need to travel to Cuba for humanitarian reasons involving extreme hardship...will be considered for a specific license, on a case-by-case basis." The regulations further stated that, "Specific licenses authorizing the transactions...may be issued when extreme hardship is demonstrated in cases involving extreme humanitarian need, to persons and their close relatives, or other persons living in the same household, who are traveling to visit close relatives in Cuba." And finally, they defined close relative as spouse, child, grandchild, parent, grandparent, great grandparent, uncle, aunt, brother, sister, nephew, niece, first cousin, or spouse, widow or widower of any of the foregoing; mother-in-law, father-in-law, daughter-in-law, son-in-law, sister-in-law and brother-in-law.s

This determination of eligibility for travel only under extreme circumstances disturbed normal family relations and visits, making tragedy a prerequisite for travel. Why do I have to wait until my mother is dying before I can visit her in Cuba? questioned Xiomara Levy of the Cuban-American Defense League. "What if I just want to talk to her?"³

Within the legal framework, there was and still is room for broad and even arbitrary interpretation by U.S. government officials of what constitutes 'compelling need', 'extreme hardship' or "extreme humanitarian need." For example, on March 7, 1995, the Treasury Department denied travel authorization to Isabel and Angel G. Muñoz, who had requested permission to visit their mother. The fact that she had cancer, and that supporting documents were presented to this effect, apparently did **not** constitute "extreme humanitarian need." Only when the Cuban-American Defense League wrote to the Treasury Department asking for reconsideration of the case was a travel license granted. On May 3, 1995, Treasury wrote to Xiomara Levy advising her of this change of heart, "as it appears that the applicant's relative is in a final state of cancer."

However, the license arrived too late for Isabel and Angel Muñoz, since their mother died a few days later.

In the Muñoz letter, Treasury also communicated its decision regarding another request for reconsideration: this time the answer was no to Marcelino Rolando Roque Domínguez, whose father of 76 was suffering from a serious heart condition (again, documented in the request), and senile dementia. Such illnesses did not qualify as "extreme humanitarian need."

By the fall of 1995, one year after the new restrictions were imposed, stacks of applications for humanitarian travel licenses were sitting in Washington, beleaguered staff at the Office of Foreign Assets Control (OFAC) insufficient to process them. As a result, thousands of Cuban-Americans were left waiting, during what they considered times of-extreme hardship" for their families. Estimates run as high as 40,000 applications backed up. Meanwhile, denials of license applications sometimes had tragic results. This was so for Maria Dolores Pérez of Hialeah, whose request was turned down in 1995. Her mother died in Cuba within weeks of the U.S. government decision, preventing the two women from seeing each other for the last time.'

After August of 1994, Cuban-Americans who were turned down generated lists of cancellations at Miami and New Jersey travel agencies.⁵

On October 6, 1995, President Clinton announced changes in regulations governing authorization of Cuban-Americans to travel to the island-now permitting travel once a year under a general license for "extreme humanitarian need." In practice, this means that once in a 12-month period, a Cuban-American may visit the island without making an individual application. However, should the person want to go more than once in the same year, a specific license is required. But only in case of family emergency will permission be considered: "Specific licenses...may be issued in cases involving extreme humanitarian need to persons or persons living in the same household, who seek to travel to visit close relatives in Cuba of such persons more than once in a calendar year.*

Five months later, the Clinton administration indefinitely suspended all charter air service between the United States and Cuba, which had been operating for several years. (This was an exemption in the embargo provisions which prohibit direct air service between the two countries.) This ruling effectively rerouted all family travel through third countries. Not only does this make visits more expensive-and grueling, in fact, for the many older travelers on these Sights-but it also makes arrangements more complicated and may delay arrivals for emergencies.

Family Remittances

The U.S. embargo prohibits the transfer of money or property from the United States or a United States person to Cuba or a Cuban national. However, during the Carter administration, on January 9, 1978, the regulations were amended to permit support payments to close relatives in Cuba. These payments could not exceed \$500 in any consecutive three-month period. An additional \$500 one-time payment was allowed to enable a relative to emigrate to the United States.'

With the stated purpose of ensuring compliance with these limitations on family remittances, on November 23, 1988 Treasury's Office of Foreign Assets Control for the first time established licensing procedures for businesses assisting Cuban-Americans in forwarding remittances to Cuba.'

It should be noted that as of 1993, citizens in Cuba were permitted to hold and use U.S. dollars and other hard currency, when regulations obligating them to **convert** these into Cuban pesos were eliminated by the Cuban government. Osvaldo Martinez, Director of Havana's Center for the

Study of the World Economy (CIEM, estimates that when such dollar holdings were legalized, some \$300-500 million dollars were circulating in Cuba.* Since few other sources of such hard currency were open to Cubans at the time, it should be assumed that most of these moneys entered the country as family remittances.

However, aiming to limit "the ability of the Cuban government to accumulate foreign exchange," President Clinton cut off family remittances in August 1994, at the height of Cuba's economic crisis, which was blamed for spilling thousands of rafters into the Florida straits the same month. The only exceptions to this prohibition were payments to facilitate emigration of relatives to the United States, and "case-by-case specific licensing...upon demonstration of extreme hardship...including terminal illness or severe medical emergency."

While the loss of foreign exchange to the Cuban government or Cuban families cannot be calculated accurately-and some remittances continue to flow illegally through third countries and with travelers coming to Cuba-it is clear that this decision had a direct impact on Cuban households which were counting on supportive relatives in the United States to help them meet basic needs at this critical time. A sampling for this study of 50 Havana households which received family remittances during the 1993-94 period revealed that 46 of them listed food, medicines and clothing-in that order-as their main purchases from the funds. Only 22 of these families continued to receive remittances as of March, 1996, 17 of them described these as "irregular."

Gift Parcels

Until 1994, a U.S. person could send a monthly \$200 gift parcel to individual Cubans or Cuban educational, charitable or religious organizations. Since the August 1994 Residential ruling, contents are limited to the following items: food, vitamins, seeds, medicines in dosage form, medical supplies and devices, hospital supplies and equipment, equipment for the handicapped, clothing, personal hygiene items, veterinary medicines and supplies, fishing equipment and supplies, soap-making equipment, end radio equipment only capable of receiving and batteries for the same. Prior to the ruling, any items "normally given as gifts between individuals were permitted." Under new U.S. Commerce Department regulations issued in March 1996, unlimited food may be sent.¹³

However, sending gift parcels to Cuba was significantly complicated with the end of direct charter Sights between Miami and Havana in March, 1996. As a result, rates charged by parcel services increased. (See chapter on Humanitarian Donations.1

In any case, the provisions disrupt normal family **relations** by making it impossible to choose even a birthday gift for a family member in Cuba. The implications are more serious when one considers that these limitations are levied precisely on the items that could help alleviate daily hardships for Cuban families in the precarious nineties, especially in the absence of legal family remittances. The picture is especially dramatic when an urgent need arises for a particular U.S. medication, whose value surpasses the \$200 limit. Thus, for example, family members of a cancer patient cannot legally send a month's supply of U.S. chemotherapy drugs for life-saving therapy.

A general authorization for sending unlimited medicines to family members in Cuba could make a considerable contribution to care, when required. In fact, Rolando Suárez of CABITAS-Cuba suggests that medications sent to seriously ill patients from relatives abroad offer a better option than the riskier and more costly alternative of patients attempting to travel abroad for care.¹⁴

Cubans on the island receive packages of medicines from relatives in Spain and Mexico at reduced rates through the National Red Crosses of those countries. The American Red Cross has offered to send messages and other written communications to Cuba. But even these are delayed by

the fact that there is no direct mail service between the two countries. As a result of the embargo restrictions, companies such as DHL refuse to send anything other than documents to Cuba."

Travel by Cubans to the United States

Cubans wishing to travel to the United States in case of family emergency face a particularly thorny process. Although their predicament is not a direct result of the embargo, the U.S. policy is a complicating factor,- since, even when visas are granted..there are no direct flights to the United states.

Nevertheless, the main problem is obtaining a U.S. visa in the first place, a manifestation of the difficult relations between the two countries over the last three decades The following case histories illustrate the implications for families:

Antonia Herrera Ramírez, 54, lives in Varadero. Matanzas. She explained that she was denied a U.S. visa on November 30, 1995 (despite documentation presented by the Cuban Red Cross), and told to return in one year to apply again. However, as sbe stated in her application, the purpose of her trip was to visit her son Joel Morales Herrera, 22 who lives in Hialeah, FL, and is suffering from leukemia. She requested to travel with another child, and both she and he are candidate donors for a bone marrow transplant. Antonia says she is 'desperate," and that her only hope is that political tensions will ease between the two countries before it is too late for her son.

Olga Quiñones Collado, 46, is a resident of Havana. Her brother, José Toledo Collado of Miami Beach, FL, has been diagnosed with AIDS On January 3, 1995. her first U.S. visa application was met with denial. In June 1995, her brother suffered a severe crisis, and medical certificates in hand, she applied a second time, this time with support from the Cuban Red Cross. She was denied a second time on August 10.1995, on the grounds that she was a possible emigrant. She comments, "Keeping relatives from seeing each other in moments of crisis and illness is simply inhuman."

Guillermo González **Miranda**. 37, is the son of Zoila Mirta Molina Díaz, who lives in Miami and is suffering from metastasized lung cancer. Medical certificates provided to us describe her condition as of November 17, 1995, as "rapidly deteriorating." Guillermo approached U.S. authorities for a visa for the first time in February, 1995, and was told he did not qualify. In November, he made a second visit to the U.S. Interests Section in Havana, and after receiving medical documentation from Miami, returned a third time. He told us that he offered to leave several thousand dollars of deposit at the Section, as 'collateral" that he would return. His visa requests were denied.

Sam González Morejón 70, of Havana wished to travel to Miami to visit her sister Basira González diagnosed with a malignant lymphoma. She applied for a U.S. visa, and presented her sister's medical certificate to U.S. authorities -as well as papers documenting my ownership of property in Cuba, my bank account and so on to **prove** I had no intention of staying in the United States." Her visa was denied, and soon thereafter, her sister passed away.'

These are just a few of the persons interviewed during our research, who did not receive permission to travel to visit close relatives in serious medical condition. (See chapters on Humanitarian Donations and Children's Health for cases of visa denials to Cuban patients for treatment in the USA.1

NOTES

¹ Department of the Treasury, Office of Foreign Assets Control, Cuban Assets Control Regulations: Restrictions on Remittances and Travel "Transactions," August 26, 1994.

² Ibid.

³ Interview with Xiomara Levy, Cuban-American Defense League, June 22, 1996.

⁴ Ibid.

⁵ List of persons denied travel application requests provided by a Miami travel agent, and furnished to the authors by Xiomara Levy, June, 1996.

⁶ "Cuban Assets Control Regulations; News Organizations; Travel Transactions; Intellectual Property," U.S. Department of the Treasury, Oct. 13, 1995.

⁷ U.S. Economic Measures Against Cuba, by Michael Krinsky and David Golove, Aletheia Press, Northampton, MA, 1993, p. 119.

⁸ Krinsky and Golove, p. 121.

⁹ Conference by Osvaldo Martinez, Nov. 1995, CIEM.

¹⁰ "Cuban Assets Control Regulations...", August 26, 1994.

¹¹ Survey conducted by Dr. María Lilian Hamilton, Havana, March 16-30, 1996.

¹² "Overview of the United States Embargo Against Cuba," Memorandum by Michael Krinsky, Feb. 8, 1995, p. 10.

¹³ Memo from M. Krinsky June 13, 1996.

¹⁴ Interview with Dr. Rolando Suárez Cobián, Director, CARITAS-Cuba, May 2, 1996.

¹⁵ Interview with Dr. Héctor Rodríguez Baster, Deputy Secretary General, Cuban Red Cross, Dec. 7, 1995; and conversation with Mary Deffley, International Social Services, American Red Cross, June 13, 1996.

¹⁶ Interviews carried out by Dr. Maria Lilian Hamilton with each individual, February-March, 1996. All documents referred to in the text were examined by our research team.

Common wisdom teaches that in times of crisis you learn who your friends are. From our research into the embargo's impact on health care delivery, we might add that times of crisis reveal enemies as well as friends. The two national health emergencies declared by Cuba in the last 25 years illustrate the noxious effect of the embargo on the ability of the health care system to respond quickly, efficiently and cost-effectively to save lives at critical moments.

Hemorrhagic Dengue Fever

In 1981, a strain of dengue virus as yet unseen in the Caribbean was detected in Cuba, causing potentially fatal hemorrhagic dengue fever.¹ Between May and October, 344,293 cases were reported, and over 116,000 of them were hospitalized in improvised intensive care units at all major hospitals. Severe cases numbered 9,128 among children and 1,097 among adults. A total of 158 people died from the fever: 101 children and 57 adults.²

A national campaign to wipe out the *Aedes aegypti* mosquito, carrier of the fever, was credited with bringing the epidemic under control by October 10, when the last case was reported. Julie Feinsilver notes in *Healing the Masses* that, "The entire population was mobilized to fight the *A. aegypti*," and cleanup drives were organized in virtually every neighborhood, workplace and farm on the island to eliminate breeding places for the mosquito and apply larvicides. Local health activists educated their communities on the symptoms of dengue fever to assure early detection. The Ministry of Public Health took on the care of those stricken with dengue fever, plus the orientation of this broader effort. The Ministry also carried out a program of aerial spraying of insecticides, covering over 240,090 hectares by early July.'

The national mobilization to curb the epidemic received praise from Daniel Joly, then representative of the Pan American Health Organization in Havana.' Feinsilver notes: 'No government in the Third World and few in the developed countries could have achieved as much as rapidly as the Cubans did, because most lack this national capacity to mobilize.'⁶

However, the U.S. embargo made the campaign more costly to Cuba, and delayed its results. During critical weeks when time was of the essence, press reports indicated the U.S. State Department was 'considering' allowing U.S. firms to sell fumigation equipment and insecticides to Cuba on an emergency basis. However, with no decision forthcoming to permit such an exemption to the embargo, the Cuban Public Health Ministry was finally forced to go to faraway manufacturers to buy the items at higher prices and at increased freight costs, losing time and money in the process. Unable to purchase U.S.-made Hudson fumigation equipment (which Cuban importers considered the best), they bought sprayers from Panama, Japan and China. The insecticides (over 500 tons) were also purchased in Panama and Asia. According to the Ministry of Public Health, this resulted in a 29-30% price hike through intermediaries, increased freight costs and delays in arrivals.'

Dr. Rafael Figueredo, in charge of vector control for the National Epidemiology Program of the Ministry of Public Health, told us that such delayed arrivals stemming from the embargo resulted in "postponing national fumigation and eradication of the infected mosquitoes, causing the number of cases to rise, and the number of deaths as well." Once the equipment and insecticides arrived, he states, it took only two months to eliminate the mosquitoes.'

Retrospectively, it is not surprising that the United States did not **authorize the necessary** purchases, even when it was a matter of a national life-threatening emergency on the island: 1981 was the same year that the U.S. Commerce Department overturned more liberal 1969 regulations which would have permitted "certain humanitarian transactions" with Cuba. The 1981 regulations closed the loophole, ending such a policy."

Cuba spent a total of \$26.7 million to quell the epidemic.' Another 500 tons of insecticides have been bought annually since 1981, at a cost of \$15 million, which health authorities estimate would have cost \$5 million less if purchased directly from U.S. manufacturers. In some of these cases, the active ingredient is of U.S. origin, is repackaged by the wholesaler, and sold to Cubans at prices 40-50% over the original list price.¹⁰ It is apparent then that if there have been no further outbreaks of dengue fever in Cuba, it is due exclusively to the efforts of the Cuban health authorities, efforts made more difficult and costly by the U.S. embargo.

More recently, the vector control program in Cuba detected the *Aedes albopictus* mosquito in two neighborhoods near Havana's international airport. This mosquito causes yellow fever, dengue and encephalitis. The breeding areas were eliminated, and hence the danger as well. So far in Cuba, no disease has been traced to this mosquito, which has however caused outbreaks of encephalitis in the United States and elsewhere in the Americas."

Epidemic Neuropathy

As in the case of hemorrhagic dengue fever, Cuba's neuropathy epidemic erupted in a year when the island was feeling the impact of stiffened embargo restrictions. Neuropathy cases were reported throughout Pinar del Rio Province by the beginning of 1992—the same year that the Cuban Democracy Act put more severe limitations on Cuba's import capabilities. By April 1993, the neuropathy outbreak was declared a national health emergency of epidemic proportions. A total of 59,983 cases were reported by June 30, with the disease appearing at a rate of 482.3 per 109,990 inhabitants. The epidemic was brought under control by the fall of the same year, with no loss of life.

A report issued by the WHO/PAHO Department of Humanitarian Affairs at the height of the epidemic described the two forms of neuropathy affecting patients throughout the island: one called optic neuropathy, which led to partial and temporary blindness, including "weight loss, blurred vision, photophobia, and progressive decrease in visual acuity over a period of 1-4 weeks." Patients also noted loss of red-green color vision.¹² By the time the epidemic was in full force, 52% of the cases were reported as optic and another 48% as peripheral. This second type, more prevalent in women, was characterized by pain in the lower limbs and joints, weakness and a burning sensation in the legs, and increased urinary frequency.

As the disease spread across the island from west to east in the first months of 1993, the number of cases rose exponentially. On March 20, a National Task Force was set up, headed by the Ministry of Public Health, Civil Defense and the Academy of Sciences, and similar task forces were created at the provincial and municipal levels. The WHO/PAHO report described the response mounted by these agencies:

. . .massive mobilization of Cuban resources, including a 30% increase in the number of hospital beds, participation of more than 18,000 community-based family physicians, implementation of 60 centers in all provinces for confirmation of diagnosis, staffed by ophthalmologists, neurologists and internists equipped with ophthalmoscopy equipment, tangent screens for visual field testing, Ishihara plates, contrast sensitivity examination, and clinical neurophysiology equipment for measurement of nerve conduction velocities and somatosensory evoked responses.¹³

The same report noted that "an epidemic of the magnitude of the Cuban outbreak has not been previously recorded," and was one of the first to suggest that the causes of the epidemic were to be found in the economic situation facing the country, associated with food shortages:

As a result of economic difficulties and despite the absence of overt malnutrition in the Cuban population, decreased protein intake, food shortages, as well as problems with storage and refrigeration of foodstuffs from electric power blackouts, have occurred during the past few years. Also, energy and calorie expenditures have increased due to widespread use of bicycles as a means of transportation for the adult population [Editor's note: the hardest hit by the epidemic were from 25-64 years of age]. These factors, in addition to excellent response to parenteral treatment with vitamin B-12 and folate, suggest that a nutritional deficit may be an important component in etiology of these syndromes, probably in combination with neurotoxic factors.

These conclusions were later reaffirmed by teams of Cuban scientists, WHO/PAHO-sponsored joint research missions, and visiting specialists from abroad." A third possible causal factor, indicated by the presence of an enterovirus in the spinal fluid of significant numbers of patients, was not discounted.¹⁵

It is our assessment that from the outset, the U.S. embargo was implicated in Cuba's neuropathy epidemic, by contributing to the food and other shortages that were later identified among its principal causes. We have amply discussed the impact of the embargo on nutrition in an earlier section, conclusions shared by various U.S. specialists who participated in research on the 1993 epidemic. Dr. Jean Handy, Associate Director of Clinical Microbiology at the University of North Carolina, visited hospitals in two provinces and noted: Many people may not realize that one of the most direct effects of the U.S. blockade is the shortage of food-by keeping Cuba from trading freely-d the shortage of medicines as well."¹⁶ Dr. Gustavo Román of the National Institutes of Health is also chairman of the World Federation of Neurology Research Group on Neuroepidemiology. He headed a WHO/PAHO mission to Cuba during the epidemic, and wrote on his return: "...in the final analysis, the-outbreak of neuropathy in Cuba may represent the first epidemic of neurological disease whose cause is primarily political. The unforeseen political changes that occurred in eastern Europe since 1990 had major repercussions in the western Caribbean island, and compounded the effects of a to-year-old political decision to maintain an economic embargo on Cuba."

Not only were the causes of the epidemic to be traced in part to the embargo, but U.S. restrictions also negatively affected the Cuban public health system's ability to diagnose and treat the 50,000 neuropathy patients, to carry out national preventive measures, and to effectively investigate the origins of the outbreak.

In 1993 alone, the Cuban government spent some \$100 million to quell the epidemic and prevent further outbreaks." Diagnosis of the neuropathy syndrome was made more costly by virtue of the embargo. For example, research by Cuban importers at the time indicated that prices of reagents used in laboratory diagnostic tests would have been significantly lower, if it had been possible to purchase these items from U.S. suppliers. Cuba paid 134% more for these reagents as a result.

REAGENTS PURCHASED BY MEDICUBA FOR NEUROPATHY DIAGNOSIS				
Product	Unt	Price Paid	Price Quoted by SIGMA, USA	Additional (%) Paid
Agarose (2x500G)	1 KG	\$1,541.90	\$727.35	111
Cacorboxlose (1x1 G)	1G	14.59	6.26	132
Piridoxanine-5 Phosphate (1 xl G)	1G	169.00	67.04	94

Source *Consecuencias Adversas...: Ministry of Public Health, Havana, May, 1993, p.5.*

The eleven treatment protocols for patients diagnosed with either optic or peripheral neuropathy were based on findings that suggested nutritional deficits and imbalances had combined with unidentified toxic substances to produce the syndrome. In particular, patients were found to have lower levels of B-vitamins, which help to ferry toxins out of the body, iron, and vitamin A. A domestically produced vitamin supplement-containing vitamins B1, B2, B6, B12, folic acid, niacin and vitamin A was distributed to patients free of charge. Beginning in May 1993, this same supplement was distributed house-to-house to the entire Cuban population (approximately 10.5 million people), also free of charge.

Production of this supplement was hampered and made more costly by the embargo. First, because the raw materials could not be obtained in the United States at more competitive prices. (It should be noted that no license has ever been issued by the United States government for raw materials used in the Cuban pharmaceutical industry.) And second, because of increased freight costs. Cuba was forced to purchase these raw materials from Europe, and in the interests of time, to ship by air. Thus, both distance and means of shipping added to the bill.

For example, one shipment of 16 components purchased for the vitamin supplements was imported air freight from Europe at a cost of \$287,448.68. MEDICUBA calculated that by not being able to ship from a closer point (the USA), the embargo cost an extra \$181,348.52 for this shipment alone, one of many made during the national emergency.'

The same year that the neuropathy epidemic began spreading across western Cuba, the Cuban Democracy Act singled out Cuba's biotechnology research and production as a special target for embargo restrictions, prohibiting any exports that could assist the industry's development. It should be noted that many neuropathy patients were experimentally treated with interferons and the human transfer factor, both produced at Cuba's biotechnology facilities. And hemorrhagic dengue patients were among the first to benefit from domestic production of interferons, during the 1981 epidemics²⁰

As soon as efforts began to curb the neuropathy, the Cuban government appealed to the international medical community for assistance in investigating the causes of the epidemic. Their initial lack of bibliography on the syndrome (or similar outbreaks) was limited in part by the embargo's negative effects on the flow of scientific literature and information, as noted by Dr. Gustavo Román of the NIH.²¹ (we document this general phenomenon in a later chapter of this study.)

However, the experience of the neuropathy epidemic also illustrates the opportunities for scientific cooperation between U.S. and Cuban medical researchers which are lost because of the embargo. Under the umbrella provided by the World Health Organization and the Pan American Health Organization, specialists from the Centers for Disease Control, National Institutes of Health, Food and Drug Administration and Emory University were provided the rare opportunity for joint investigation with Cuban colleagues during the neuropathy crisis." This experience was described as highly positive, and PAHO Director Dr. Carlyle Guerra de Macedo went so far as to encourage more such collaboration: 1. want to express my expectations concerning the CDC, my hope that this work in common which has begun now will open up new opportunities for cooperation...in the fields of research, study and analysis, and so on, for the progress of health not only in Cuba and the United States, but for the progress of health the world over.²³

The U.S. embargo against Cuba presents barriers to research and patient care in the best of times. In national emergencies, it can mean lives lost or permanently damaged, because of critical time lags and the need to mobilize additional resources. With regard to the neuropathy epidemic in particular, we fully subscribe to the conclusions expressed by Dr. Gustavo Roman in 1994: "Although the U.S. economic embargo may not have been the primary cause of the epidemic in Cuba, it has contributed to its development, complicated its investigation and treatment, and

continues to hamper its prevention²⁴ There is every reason to believe that current U.S. embargo restrictions would reproduce this impact in similar situations of health crisis.

NOTES

¹There was some suggestion at the time by the Cuban Government that the virus had been introduced by the CIA in an attempt at biological warfare against the island.

²Health Education and Popular Participation," in *Healing the Masses*, by Julie Feinsilver, University of California Press, 1993, p. 88.

³Feinsilver, p. 87.

⁴Feinsilver, p. 88.

⁵Feinsilver, p. 88.

⁶*Cansecuencias adversas que tiene para el disfrute de los derechos humanos del pueblo de Cuba el embargo económico de los EEUU*, May 1993, Ministry of Public Health, Havana, pp. 15-16.

⁷Interview with Dr. Rafael Figueredo Gonzales, National Epidemiology Program, Vector Control, Ministry of Public Health, Havana, Jan. 24, 1996.

⁸Krinsky, pp. 116 and 119.

⁹Feinsilver, p. 88; this amount plus 21.3 million in Cuban pesos.

¹⁰Interview with Dr. Figueredo, Jan. 24, 1996.

¹¹Ibid.

¹²Cuba: Neuromyelopathy Epidemic," DHA Situation Report No. 2, Geneva, June 4, 1993, p. 1.

¹³DHA Situation Report, June 4, 1993.

¹⁴Among other reports, see: "Epidemic Optic Neuropathy in Cuba: Clinical Characterization and Risk Factors," by The Cuba Neuropathy Field Investigation Team, *The New England Journal of Medicine*, Nov. 2 1995, pp. 1176-1182, and studies published in *Neuropatía Epidémica en Cuba: 1992-1994*, Centro Nacional de Información de Ciencias Médicas Havana, 1995.

¹⁵See comments by Dr. Carlyle Guerra de Macedo, Director of PAHO, August 10, 1993 in Havana, which appeared in *Neuropatía Epidémica en Cuba. 1992-1994*. Dr. Guerra de Macedo suggests that research should continue on the viral agent, due to the surprising number of cases which were associated with the presence of at least one enterovirus, p. 9.

¹⁶Dr. Jean Handy interviewed by Gail Reed, June, 1993.

¹⁷Article in *Journal of the Neurological Sciences*, No. 127, 1994, pp. 11-28.

¹⁸*The Politics of Suffering: The Impact of the U.S. Embargo on the Health of the Cuban People*, American Public Health Association, 1993, p. 21.

¹⁹Efectos del Bloqueo," report by MEDICUBA, June 4, 1993, p. 1.

²⁰See discussion of dengue epidemic in speech by Cuban President Fidel Castro and First International Workshop on Epidemic Neuropathy in Cuba, in *Neuropatía Epidémica en Cuba: 1992-1994*, p. 239.

²¹See statements by Dr. Gustavo Román in *Neurology*, October 1994, p. 1786.

²²Report on PAHO/WHO Cooperation in the Control, Treatment, Research and Epidemiological Vigilance of Epidemic Neuropathy, presented by Dr. Miguel Marques, PAHO Resident Director in Havana, in *Neuropatía* p.258.

²³Remarks by Dr. Carlyle Guerra de Macedo, Director of PAHO, Havana, Aug. 10, 1993. in *Neuropatía*...

²⁴Article by Gustavo Román, M.D., in *Neurology*, October 1994, p. 1786

Introduction

Since the 1970s, the Cuban health care system has expanded its infrastructure, and now includes 278 hospitals across the island, providing secondary and tertiary care to local populations. Some have also been designated national reference centers in their fields.

HOSPITALS IN CUBA	
TYPE	NUMBER
General	82
Pediatric	26
Maternity (includes Neonatology)	16
OB-GYN	19
Clinical/Surgical	30
Specialized	38
Rural	64
Other	3
TOTAL	278

Source: Ministry of Public Health, Havana, 19%

HOSPITAL OCCUPATIONAL INDEX			
SERVICE	% In 1959	% In 1994	% In 1995
Internal Medicine	84.0	79.3	79.9
Surgery	81.8	72.9	73.7
Pediatrics	67.6	55.5	60.5
Pediatric Surgery	71.4	56.5	61.5
Neonatology	64.9	50.7	48.1
Obstetrics	83.5	78.3	79.2
Gynecology	79.8	74.0	73.3
Psychiatry	88.1	81.5	79.6
Oncology	83.1	75.2	76.0
Adult Therapy*	(1)	71.7	72.8
Children's Therapy*	(1)	50.8	54.8
Average	80.3	72.8	73.2

*included in internal medicine and surgery.

*Both intermediate and intensive care services. Indicators based on actual number of beds available.

Source: Ministry of Public Health, Havana, 19%.

During on-site visits and numerous interviews with directors and specialists on the staffs of hospitals in the cities of Havana and Pinar del Rio, as well as a survey carried out of twelve hospitals in several more distant provinces, it was discovered that the quality of hospital care has been seriously eroded by all manner of shortages, provoked by the current economic crisis and the U.S. embargo. While this analysis falls short of being exhaustive, we provide the following examples to illustrate the conditions of Cuban hospitals today, and the difficulties faced by both patients and staff.

Surgery and Intensive Care

Of all hospital services, surgery and intensive care units we visited were most severely affected by the ravages of the economic crisis. Among the results has been a considerable reduction in the number of surgeries performed since 1999:

SURGERIES PERFORMED 1990-1995						
Province	1990	1991	1992	1993	1994	1995
Pinar del Río	38,217	40,507	33,363	28,294	28,322	28,907
La Habana	18,980	16,381	18,895	15,000	15,697	17,204
Ciudad Habana	369,720	220,547	199,547	161,122	170,634	172,852
Matanzas	138,554	83,968	40,976	31,993	31,637	30,001
Villa Clara	40,003	37,806	35,563	34,461	38,345	38,828
Cienfuegos	18,807	19,076	15,066	13,281	16,644	18,899
Sancti Spiritus	23,431	22,944	22,482	17,883	16,901	18,157
Ciego de Avila	20,373	21,662	18,439	15,192	16,317	18,748
Camagüey	41,706	39,342	40,799	31,143	29,874	35,240
Las Tunas	18,198	40,394	30,346	18,046	17,883	15,995
Holguin	51,510	52,887	61,862	46,851	46,289	61,029
Granma	42,078	39,007	28,332	24,230	29,895	26,397
Santiago de Cuba	33,027	36,892	35,024	26,998	31,881	31,313
Guantanamo	22,948	28,356	20,847	15,879	16,193	18,148
Isla de la Juventud	8,238	7,080	6,565	5,694	5,669	4,829
TOTAL	885,790	706,849	608,106	486,067	512,181	536,547

Source: Ministry of Public Health, Havana, 1996.

The lowest number of operations was reached in 1993, with a reduction of 45.3% in comparison to 1999. A slight increase was registered in most provinces in 1994, but 1995 totals were still only 60.5% of those in 1996.

Our visits and interviews reveal a set of basic problems hospitals have in common that reduce their ability to perform the number of surgeries needed. These difficulties result primarily from limits imposed by the lack of sufficient hard currency budgets and by U.S. embargo restrictions. As a result, surgical services face shortages of most modern anesthetics and related equipment, specialized catheters, third generation antibiotics and other key drugs, sutures, instruments and fabric for surgical greens, air conditioning equipment, and disposable supplies.

Surgery and intensive care are also affected by the lack of sufficient reagents in microbiology and clinical laboratories, drastically reduced purchases of x-ray film, and dearth of spare parts lab and radiology equipment.

In most of the provinces, the situation for surgery is extremely difficult, and for a long time, some of their hospitals could take on only emergency procedures, mainly because of lack of sutures and anesthetics. They have had to resort to alternate methods such as acupuncture, electropuncture, laserpuncture, and moxibustion. However, these can only be used in 15% of surgery cases. (Thyroid surgery and the extraction of molars, for example, have been performed with acupuncture because of lack of anesthetics.¹)

There have been changes in morbidity because of reduced surgeries and subsequent waiting lists. Specialist at the Provincial Hospital in Pinar del Rio explained to us that it was at one time exceptional to find complications of gallstone conditions (such as acute cholecystitis), because surgery for these cases was performed on time. However, we found a 46-year-old male patient who had been waiting for months for surgery since more critical cases were always ahead of his. Finally, his situation also became critical and he had to receive emergency surgery?

The surgeons at the Abel Santamaria Hospital in Pinar del Rio told us they have only been able to take emergency cases, and have, virtually stopped elective procedures, because of lack of resources. They have 16 operating rooms, four of which are completely closed, and in need of repair. They perform nearly half of all surgeries in the province, and from nearly 10,006 operations in 1992, they were down to 8300 in 1994. The Provincial Hospital has reduced surgeries from over 6,060 in 1966 to 3,099 by 1994, and five of their nine operating rooms were closed when we visited, their air conditioning systems waiting for parts.'

Shortages not only mean postponed operations. Because of the lack of resources, specialists now have to invent solutions and use obsolete methods to solve problems. For instance, for lack of catheters they do venous dissections, which are more painful to patients and carry a higher risk of infection. They also manually perform craniotomies for cerebral aneurysm. In general, they say, their operations last longer, requiring more anesthetics-sometimes not the specific one recommended-with greater risk for the patient.'

Key equipment breakdowns stop surgeons from carrying out otherwise normal procedures: at the Abel Santamaria Hospital, their image enhancer has been broken for over a year, making it impossible for them to implant pacemakers. Thus, all their pacemaker patients must be sent to Havana in an ambulance, when one is available, with the risks and stress for the patient that this implies. They have been unable to operate on geriatric hip fractures for the same reason, since the external fixators used in these cases rely on the enhancer to be installed. At the time of our visit, we saw seven patients, each of whom had already waited for over a week for hip fracture

Shortages laid at the doorstep of the U.S. embargo complicate this already serious situation:

The unanimous opinion of specialists we interviewed is that Cuban anesthesiology remains years behind because of direct and indirect consequences of the embargo. They argue that state-of-the-art products in this field are mainly of U.S. origin, and some are only produced by U.S. firms. Therefore, Cuban patients do not have the benefit of the most recently developed and effective drugs and technology, the embargo adding what these physicians term unfair and undue risks for their patients.

One of the most graphic examples is the case of Thalamonal. This anesthetic is bought from Janssen, a Belgian subsidiary of Johnson and Johnson, under license from the U.S. Treasury Department. However, processing the license applications is a lengthy and cumbersome process involving persons and institutions in three countries. It has taken as much as 9 months for the product to arrive in Cuba, from the time the contract was signed. (See chapter on Medical Exports.) Caps in stocks of thalamonal affect the more complex surgeries, in particular, and in some situations, a patient cannot be operated without this anesthetic, since it has substantially fewer side effects than others available to Cuba, which reduce the risk of life-threatening complications ⁶

For example, surgeons at the Abel Santamaria Provincial Hospital in Pinar del Rio report they were forced to use less recommended anesthetics when the supply of thalamonal ran out, including Halotane and Succinylcholine. These anesthetics have more serious side effects, including risks of malignant hyperthermia, which can be fatal. Medicine to treat this hyperthermia (dantrolene) was also unavailable at this hospital.' In other cases, they suspended operations until the

thalamonal was available, seven months later. The delay was one of the reasons they cited for the accumulation of 300 cases on surgical waiting lists between 1994 and 1995.⁹

The Salvador Allende and Joaquín Albarrán Hospitals in Havana as well as the Nephrology and Cardiology Institutes, were among the other institutions which informed us of unstable supplies of thalamonal, with delays of several months at a time. These hospitals substituted with Fentanyl in some cases, but this was not possible for all patients.'

We were informed that Cuban patients do not have the benefit of the use of other modern anesthetics such as Sevoflurane, **which** they described as nearly the ideal anesthetic because of the advantages it presents for patients. It is exclusively produced by Abbott Laboratories in the USA. Another similar anesthetic, Isoflurane, is still under U.S. patent.

Intensive care units as well as recovery and asthma wards in many Cuban hospitals, such as the Salvador Allende and the Joaquín Albarrán, have been using Bird respirators for many years. There are some 800 to 1000 of these respirators in the country; the first m-rived in 1961, as part of the exchange of Bay of Pigs prisoners for medicines and baby food. Later, parts were bought through intermediaries in Holland and Canada, and in 1980-81, Cuba bought second generation Bird equipment in large quantities, through a third country because of the embargo. The necessary training to use the equipment was carried out by an ex-employee of Bird, who came to Cuba to teach the specialists. At another moment, a Cuban engineer went to a third country to receive a course from another person who had just taken it at the Bird factories in the USA (as is standard practice). The director of the National Electromedicine Center in Havana estimates that 40% of the information needed is lost in such a process. And there is virtually no written technical information on the newer Bird equipment."

Bird never sold parts or equipment directly to Cuba. These units regularly need parts such as valves, micro and macro-nebulisers, as well as patient circuits. Without these parts (which the embargo restrictions have made nearly impossible for Cubans to buy, except at much higher prices through third parties, when it is possible to find a supplier) the respirators cannot function. For instance, in the city of Havana, the Salvador Allende Hospital has eight Bird respirators, but only four are in working order; and two are broken at the Calixto Garcia Hospital. At the Joaquín Albarrán Hospital, which has six Bird respirators, only one is in use, because the others lack the necessary patient circuits; and the only two units at the Miguel Enríquez Hospital have been idled for the same reason. More respirators out of service were reported at other hospitals throughout the country.¹¹ This situation has seriously affected intensive care and asthma services and hundreds of patients in a critical condition.

Other respirators used in Cuban hospitals are the Siemens Servo 900-C used in ICUs and the Servo 900-D, used both in intensive care and to administer anesthetics for surgery. For over two years, a number of these ventilators were cut of commission or only partly functional, because of U.S. embargo licensing procedure delays, since the contracts included U.S.-origin components. (See chapter on Medical Exports to Cuba.)¹

Some of these parts were indispensable, such as bacteria filters, step motor, and magnet valves. The bacteria filters, as the name implies, keeps bacteria from circulating in the machine and hence entering the patient's respiratory system. The step motor is the valve that closes when the patient inhales, stopping the gases from flowing back into the lungs; and the magnet valve is the one that closes when the patient exhales.

All patients suffering from respiratory distress, asthma, chronic obstructive pulmonary affections, intoxication, shock, respiratory insufficiency, and conditions causing paralysis of the respiratory muscles, such as Guillain Barre Syndrome, need these respirators. The two-year delay

was mainly felt by patients at hospitals in the provinces of Matanzas, Las Tunas, Santiago de Cuba, Villa Clara, Sancti Spiritus and Granma.

A survey of 12 hospitals in these provinces revealed that an average of 120 patients a year were affected by each Servo 900-C that was waiting for the necessary spare parts. Some examples:

- The Guevara Provincial Hospital in Las Tunas has one Servo 900-C in its Intensive Care Unit, which required bacteria filters, without which the machine could not be used. Until the parts arrived in July 1995, alternative solutions had to be found for over 240 patients, borrowing units from other services and hospitals.
- The Matanzas Provincial Hospital required bacteria filters for its Servo 900-C in the Intensive Care ward. They estimated that approximately 300 patients every year require the use of this machine, so at least 600 patients were affected.
- The Orlando Pantoja Municipal Hospital in Contramaestre, Santiago de Cuba province, required a step motor for its 900-C Servo respirator, as well as bacteria filters. The machine did not fully function for 18 months, affecting approximately 200 patients during this time."
- Also in Santiago de Cuba, the Joaquín Castillo Duany Hospital has two Servo 900-C respirators that required bacteria filters, for which they had to wait two years, affecting approximately 200 patients. Staff said they were able to borrow respirators from other facilities, and in some cases, to use older equipment.
- The Provincial Hospital in Villa Clara had one Servo 900-C not in use because of lack of the magnet valve. As the valve arrived over 26 months from the time the contract was signed, an estimated 300 patients were affected.
- The Camilo Cienfuegos General Hospital in Sancti Spiritus required bacteria filters and a step motor for their Servo 999-C. At least 200 patients were affected during the time the hospital waited for the spare parts.
- Both hospitals in Granma Province, the Carlos Manuel de Céspedes and the Celia Sánchez, have Servo 900-C respirators, and stated that they have not had to stop their service for more than two or three days at a time, until early 1995 when they required bacteria filters, which were delivered to them in July of that year. They estimated that at least 109 patients in each hospital needed these respirators when they were out of service. And they described the extra burden for staff, who had to sometimes hurriedly guarantee alternate methods of ventilation, while another unit could be borrowed."

In 1982-83 Cuba was interested in buying IVAC infusion pumps (IVAC is owned by Eli Lilly of the USA), considered the best for Cuban use, according to anesthetists. At the time, there was no legal way to directly purchase these, under embargo law. Looking for a similar unit, a contract was prepared with IMED of England. But before it could be signed, according to the Resident of the Cuban Anesthesiology Society, the parties discovered that the pump was not available for Cuba, since it was manufactured under patent license from IVAC.

A similar situation occurred when Cuba wanted to buy an intra-aortic counterpulsation pump from Datascope, a U.S. firm. "As they could not sell it to us anesthesiologists, we had to buy it from third parties at a much higher price, but we needed it for our patients," Dr. Sainz asserted. He explained that in general Cuba buys anesthesia equipment from Japan or Europe at increased markups and shipping rates, since they cannot count on getting U.S. licenses for the units or later for replacement parts."

There are a number of U.S. manufacturers that produce advanced accessories for patients under anesthesia, such as catheters to measure cardiac output and venous-lung saturation, catheters for lung flotation to determine intra-arterial oxygen. 'Our patients cannot receive the benefit of these catheters, and we only know of them through donations,' commented Dr. Sainz. He noted that other equipment such as electric perfusion units required for neonatal surgery, and arterial cannules, are bought from Japan or Europe at prices 30% higher than list prices from U.S. manufacturers.¹⁵

Information on developments in anesthesiology is also difficult to come by for Cuban specialists. When the 23rd Latin American Congress of Anesthesiology was held in Havana in 1995, all the U.S. suppliers in the field which **participate** regularly in such events (Abbott, Puritan Bennet, Arrow, etc.) stated that because of embargo restrictions, they could not take the risk of coming to Cuba. Ohmeda, a company formed by Ohio Medical of the USA and British Oxygen, decided not even to send its British representatives, on advice from counsel (even though this would have been legal). Ohmeda's stand remained empty 'as a monument to the embargo,' says Dr. Sainz, who also noted that "Cuban anesthetists were prevented from seeing the latest technological advances in respirators...".

Back-to-back with this event, the 18th General Assembly of the Latin American Conference of Anesthesiology Associations (CLASA) met in Havana, with 19 Latin American countries in attendance as well as the Resident of the World Anesthesiology Association. In a unanimous resolution, they made specific reference to the damaging effects of the embargo on their medical field and patient care in Cuba, and called for an end to the policy."

Physical Rehabilitation for orthopedic surgery patients has been hindered by the U.S. embargo, specifically by licenses for equipment parts denied to the Enraf Nonius Company in 1991.(see chapter on Medical Imports). At the Frank País Orthopedic Hospital in Havana, specialists in the physical therapy department explained that ultrathermy equipment from Enraf Nonius has been out of service for the last four years, since it has been impossible to buy replacement intensity controls. At least 450 patients have been unable to use this equipment, according to hospital staff. ¹⁶

Radiology

Over the last 20 years, the Cuban health system has made major investments to equip the country's hospitals and specialized institutes with x-ray units, CAT scans, ultrasounds, image enhancers and even MRIs in selected cases. However, at the end of 1995, out of a total of 10 hospitals with CAT scans, five reported their units were not functioning (4 in Havana and 1 in Santiago de Cuba) for lack of tubes or other components.¹⁹

In this case, the price of European technology is generally higher than that of U.S. production, and so the U.S. embargo has a direct incidence in the quantities of parts and accessories importers can buy on a limited budget. For instance, a CAT scan tube was quoted by Siemens Germany at USD \$40,000. A major U.S. producer of the same-specification tube lists prices in their catalogue at \$16,000 to \$33,000.²⁰ That means that with the same funds, Cuba would be able to buy six to 10 tubes from the U.S. manufacturer, instead of only five in Europe.

One of the hospitals waiting for a new tube was the Salvador Allende which we visited on October 26 and 31, 1995. For more than one year they had been using their CAT scan with a borrowed and **deficient main** tube that allowed them to do only cranial scans. Before, they used to scan an average of 70 cases daily, but by the time of our visit, only 15-20 patients were being examined. Approximately 80% of their cases are referrals from other hospitals, including those in Pinar del Rio and Matanzas provinces.²¹

The two general hospitals we visited in Pinar del Rio, were also affected by this situation. The Abel Santamaria sends only emergency cases to Havana-at a time when their Emergency Room is receiving an increasing number of head injuries. due to bicycle accidents, which have risen in the **country with the fuel shortages.**²²

Sometimes the difficulties are not only with the availability of hard currency, or the prices quoted, but also with delivery delays. Such is the case of a Brucker (Germany) MRI that was not in service at the Hermanos Ameijeiras Hospital in Havana for more than a year before our visit, because it required helium gas to function. There are serious difficulties bringing this helium from Europe, as it has to be imported in refrigerated tanks. Because the helium shipment did not reach Cuba in time, the equipment broke down, and experts estimated it would cost \$250,000 just to repair it.²³

This is another case where the embargo has played a role: helium was imported from Mexico, until March, 1993, when Union Carbide Mexicana S.A, a subsidiary of Union Carbide Corp in Connecticut, advised the Cuban importer that they could no longer sell to Cuba due to the ban on subsidiary trade declared by the Cuban Democracy Act (CDA) of 1992.'

Between 1975 and 1978 Cuba bought 101 Picker X-ray machines from Picker International, Inc. of Canada, a subsidiary of the Cleveland, Ohio Company of the same name. In 1994 Cuba attempted to purchase spare parts for dozens of these machines. The spare parts, with a value of CAN\$705.30 had a U.S. content equivalent to 27% of the total, or CAN\$193.10, and required a U.S. export license. During a period of eight months, Picker International tried in vain to obtain the license, but finally on December 24 advised the Cuban importer, MEDICUBA, that all applications and appeals had been turned down by Washington. (See Medical Exports for details of this case.)²⁵

Of the original 101 machines, there were only 12 functioning as of May, 1996, and none of them with the original tubes. They have been kept working primarily with parts from other companies, except those with no substitutes. Most of the machines are located in small rural hospitals and polyclinics, such as:

- Camarote Rural Hospital, Guaimaro, Camaguey;
- Mártires de Manati Rural Hospital, Las Tunas;
- Romérico Oro, Polyclinic, Puerto Padre, Las Tunas;
- Maternity Hospital, Matanzas;
- General Municipal Hospital, Santa Cruz del Sur, Camaguey; and
- Tamara Bunke Maternity Hospital, Santiago de Cuba.

These X-ray units are mainly used for simpler procedures, such as chest x-rays and diagnosing bone fractures, making immediate medical attention possible in the same locality where the patient lives. The denial of the U.S. export license for the Picker parts has meant that hundreds of persons-including pregnant women, children and older people-have had to be taken long distances with fractured limbs and in pain to the nearest city hospital x-ray facility before they can be treated. Delays in therapy have run up to 24 hours, according to staff at the Romérico Oro Polyclinic in Puerto Padre, Las Tunas. The Picker case has further discouraged Cuban importers from looking to U.S. firms when they make substantial investments in equipment, fearing that replacement parts will later be impossible to obtain."

And the Picker machines have been placed permanently out of commission at a time when they are most needed: the total number of X-ray studies in Cuban hospitals has been reduced, in some cases because the units are awaiting repairs, and in others because the film itself is in scarce supply. The provincial hospital of Pinar del Rio now has only one fourth the film they were using in the 1980s, and of an inferior quality. During 1994-95, chiefs of services were assigned a daily quota of x-rays for their patients: only the most serious cases were x-rayed. The Abel Santamaría hospital, which at the time of our November, 1995, visit had the only functioning adult emergency room for Pinar del Rio's population of 720,000, was only using film when it was absolutely indispensable, and then only on the authorization of the Chief of Radiology. Before 1991, they did about 100 studies a day for outpatients and 60 for inpatients; now they do 15 daily in all.²⁷

Ultraound is a non-invasive diagnostic technique which gives immediate results, at no discomfort or risk for patients. However, ultrasound equipment, once widely used in Cuba, is now in a general state of disrepair. In Pinar del Rio province there are only four ultrasound units working, three of them for the Maternal-Child Program, leaving only one to cover the rest of the needs for the entire province.' In Havana's **Albarrán** Hospital, the ultrasound is out of order, presenting a critical problem for this facility and the municipality it serves.

As noted by engineers at the National Electromedicine Center, the United States is the hemisphere's number one supplier of refurbished medical equipment, an attractive and feasible alternative for most buyers in Latin America. Some equipment is on sale for one third to one quarter of the price of a new unit. But this is not an option for Cuba, since the embargo disrupts normal sales practice in such dealings, requiring the buyer to make an on-site inspection of the equipment before signing a **contract**. Alexis Cedeiio, vice director of Electromedicine, says that millions of dollars could be saved if Cubans had access to the U.S. refurbished medical equipment market, making it possible to alleviate the current critical situation faced by hospitals.

Microbiology Laboratories and Clinical Analysis

The economic crisis has severely cut into hospital labwork: microbiology and clinical laboratories have had to reduce the number of their tests by 25-40% since 1969. The range of **testing** is also more limited: at the Abel Santamaria Hospital in Pinar del Rio, lack of particular reagents have cut **back their battery of tests from 68 to 32 by 1995.**²⁹

At the Joaquin **Albarrán** in Havana, the clinical laboratory is doing 5,000-8,000 fewer tests each month than in 1991; and microbiology workups have been reduced from 10,000 to 4,000 monthly. Here, they informed us that they once received reagents from U.S. subsidiaries, but not since the CDA was passed in 1992. This, they say, puts a dent in both supplies and quality.³⁰

The direct implications of the restrictions imposed by the embargo are very clearly shown in the case of Pharmacia, a Swedish company that until its 1995 merger with Upjohn, sold Cuba not only a wide range of reagents, but also specialized laboratory and pharmaceutical production equipment." When the company pulled **up stakes in Havana** in November of the same year, it created real havoc for laboratory testing. Havana's Hermanos Ameijeiras Hospital offers a prime example.

This hospital had purchased three integrators for chromatography, which are attached to other equipment to program them for the type of results that are to be read out for any given tests. Of the Three integrators, two are broken and the hospital has not been able to obtain spare parts. If the third integrator breaks down, this will idle the following units which rely on it:

- . HPLC (High performance Liquid chromatography). 2 units, also from Pharmacia, were used to determine the levels of medications in the blood (for example, levels of anti-epileptic drugs,

barbiturates, cardiotonics, etc.), in order to prevent intoxication or drug interaction.= (The Institute of Nephmlogy also has an HPLC from Pharmacia-LEB. which is broken, and they likewise have no way to obtain parts since the merger.”

- Electrophoresis unit. Used to study serum blood protein levels. This is for routine analyses for hepatitis. cirrhosis; and hematology, nephrology and immunology; and to classify hematological tumors. This unit is not from Pharmacia, but could not function without the integrator.

The Ameijeiras also bought fraction collectors from Pharmacia, used to purify substances such as proteins, carbohydrates, lipids, DNA, RNA, etc. These two units are broken. with no spare parts in sight. This means that the hospital currently cannot purify any substances for the uses mentioned above.”

The Institute of Nephmlogy has two pieces of equipment from Pharmacia, also broken: the Tachophor used to study elimination of toxins from urine, and an isoelectric focusing unit.

Pharmacia was for several years the main supplier of chemical reagents to purify substances such antibodies, used in the preparation of clinical analyses. Their sudden merger with Upjohn affected the work of the specialized medical institutes as well as hospitals while new suppliers were found. It also has to be taken into consideration that there is some Pharmacia LKB equipment that require their own reagents, that cannot be substituted by those of another producer.

Blood Banks were also affected as they used these chemical reagents to produce the antisera and other reagents to maintain a healthy blood supply. Pharmacia reagents such as Ficoll 400 and Ficoll Paque are used in the separation of lymphocytes and are required by all the centers that do transplants like the ‘Ameijeiras’ Hospital, the Institute of Nephrology, etc. In endocrinology, they are used to isolate purified proteins and thus determine hormone levels; in hematology for bone marrow work, and also for cellular immunology (oncology, gastroenterology, etc.)

Medications of U.S. Origin

Since the early nineties, distribution of medications has been even more strictly controlled in Cuba, with chronic patients and drugs for hospital use only given priority. Thus, more people turn to hospitals when they cannot find the medicine they need in their local pharmacy. This, however, puts more pressure on hospital stocks, minimal as these are.

This situation has prompted secondary and tertiary care institutions across the island to hold weekly and even daily sessions to review medications on hand: At the Abel Santamaria in Pinar del Rio, the director told us that the ‘antibiotics committee’ meets daily, to look at patient needs for these critical medications.³⁵

The U.S. embargo restricts the sale to Cubans of medications developed and produced in the United States, by U.S. subsidiaries, and those which have ingredients or packaging (such as bronchial inhalers) which incorporate U.S. elements. Some of these have no substitutes, or are not available in the same form or dosage from any other manufacturer. of particular concern to the physicians in Cuba are the new, and more effective medications-those still under U.S. patent-for which there are no generic equivalents available from producers in other countries. Thus, the brand name drugs are almost impossible to obtain: they are more expensive by definition, through third parties and even more so for Cuban importers, and finally, not readily for sale to Cuba, except through the licensing process that has put off U.S. manufacturers up to now. (See chapter on Medical Exports to Cuba.) This includes third generation antibiotics, drugs for cardiac and high blood pressure patients, chemotherapy agents, antimycotics, analgesics, anti-inflammatory

drugs, psychotherapeutics, and steroids, among others. Some of the U.S. medications that Cuban specialists say would be key for their patients are the following:

- Aprotinin (Trasylol), Miles Laboratories. Antifibrinolytic. Used to reduce preoperative blood loss/need for transfusion in select coronary patients.
- Captopril, Bristol-Myers Squibb. Treatment of left ventricular dysfunction following myocardial infarction.
- Enalapril Maleate, Merck. Treatment of asymptomatic left ventricular dysfunction
- Doputrex (Dobutamina 259). For the treatment of coronaries. (At the Pinar del Rio Hospitals, because of the scarcity of this type of drug, difficulties with transportation of the patients and other problems related to the treatment of cardiac patients, they have created a pre-coronary watch ward for patients that have had chest pains even though they have a normal electrocardiogram.
- Amantadine Hydrochloride, Dupont. For influenza A virus infection.
- Ceftriaxone Sodium, Roche. Antibiotic used in intensive care units, also in treatment of meningitis in pediatric patients.
- Vancomycin, Eli Lilly and Co. Wide spectrum antibiotic. In general, the newest generations of cephalosporines, quinolones and penicillins are not available or received only through donations.
- Cisplatin, Bristol-Myers Squibb. Used for ovarian cancer.
- Fluconazole, Pfizer. This is an important systemic antimycotic, used in pseudomonas infections, and for immunodepressed patients.
- Megestrol Acetate (Megace), Bristol-Myers Squibb. Progesterone derivative for treatment of anorexia or unexplained weight loss in patients with AIDS.
- Methotrexate, Lederle. Key cancer medication, used in numerous protocols.
- Warfarin sodium, DuPont. Important anti-coagulant. (This product's domestic production in Cuba has also been hindered by the embargo. See chapter on Medical Exports.)

Hospital Nutrition and Hygiene

Although dietary needs of patients are prioritized, they are not exempt from shortfalls in food production and imports over the last five years. (See section on the Food Supply and Nutrition for detailed discussion.) Thus, 40% less powdered milk was available to patients in 1994 than in 1991; over 43% less beef, fish, and chicken; and nearly 30% less eggs; in addition to serious shortages of cooking oil." The quality of patients' nutrition suffered as a result, calories and proteins seriously reduced.

By 1996, modest increases in food production plus donations (primarily from the European Community) to hospitals and social institutions had made discreet improvements in this situation. Micronutrients such as vitamin A were still a problem. During the last three years, more outbreaks have been registered of intrahospital infections, generalized sepsis, phlebitis and infections in surgical wounds. At the national level, during 1995, 2.4% of the patients in non-

surgical wards had intrahospital infections; 4.1% of the surgery cases, and 10.1% of the cases in Intensive Care units for adults.

Some of the main factors associated with this problem identified by the Ministry of Public Health were insufficient water supplies in many hospitals, including those in high-risk areas. (The incidence of the embargo in water supply and treatment is discussed in the section on Water Resources.¹ Additional problems include shortages of disinfectants, alcohol and cleaning agents; broken autoclaves for sterilization; deficits of disposable supplies for procedures such as taking blood samples; and shortages of antibiotics to fight infection.

It is important to take into consideration that all these supplies have to be brought to Cuba from Europe or Asia, because its natural market, the United States, does not provide a viable and dependable alternative, due to the embargo. For this reason, freight rates are 30% higher on the average, and shippers often charge additional "risk taxes" for docking in a Cuban port, since under the CDA that vessel is taken out of circulation for entrance into U.S. ports for the next six months. And the embargo has even delayed shipments of ingredients for basics like soap: this was the case of tanks of tallow stranded on the wharf in Argentina, because a tanker could not be found willing to make the trip to Cuba. This single snag held up soap production for months in the critical 1992-93 period.³⁷

Medical Personnel

Physicians, specialists and medical staff in general, feel that the impact of the economic crisis aggravated by the embargo restrictions has been very damaging to the quality of medical services in Cuba. They told us they are working under conditions not seen in Cuba for some time: they were used to relying on a broad therapeutic arsenal of drugs and procedures. Today, as they stated, "We live in the agony of not knowing what resources there will be each day to fight disease, to keep our patients healthy."³⁸ Not having the wherewithal to cure the curable, prevent the preventable or ease pain is a constant in the lives of Cuban professionals today.

Stress is everywhere in the health care delivery system, as only extra effort, dedication and intelligence seem to make a dent in otherwise insurmountable barriers. And, as one doctor said: "We have to give exaggerated attention to our patients, sometimes doing the heroic and even the seemingly ridiculous to help them. And this is how we are managing-that is what keeps the indicators from plunging. We have the minds, the education, the thinking of medical and scientific personnel at the level of the first world, using the tools of Third World medicine..."

We found Cuban specialists to be highly trained and motivated, yet frustrated at not being able to do the job they know they are capable of. At a meeting with the director and heads of departments in one hospital, a physician told us "We only have a stethoscope and a scalpel. The rest is heart, mind and sheer will."⁴⁰

The U.S. embargo undoubtedly adds to frustration-not only by its direct incidence on material resources, but also because Cuban health professionals like the ones we interviewed see it as increasing the odds against their patients. At an interview with the administration and staff of another hospital, they voiced indignation at the 35-year U.S. embargo. Wow can you explain that a country like the United States that is so powerful, and has done so much for humanity, enforces this policy against Cuba, doing damage to so many people?"

Medical students, graduates and specialists noted that just keeping up in the medical field has become a major hurdle in this period. We discuss the embargo's impact on their access to scientific information and education in a later chapter.

At a personal level, the situation in the country hits hard on medical professionals. While their salaries continue to be in the higher government brackets, they are no longer sufficient for their needs, and certainly not comparable to the incomes of those persons that have access to hard currency or who are self-employed. Some doctors have left the country, in search of a better standard of living and professional opportunities. Most stay on the job, "out of a humanitarian commitment. At this point there is no other reward. The human factor is key; right now, it is the decisive factor."⁴²

NOTES

- ¹ Interview with Dr. Raúl Obrerón. Director, Abel Santamaria Hospital, Pinar del Rio, November 28, 1995; and with Dr. Humberto Sainz, Havana, November 24, 1995.
- ² **I**nterview with Dr. Luis A Sarmiento. Director, Provincial Hospital, Pinar del Rio, November 28, 1995.
- ³ Ibid.
- ⁴ Ibid.
- ⁵ Interview with Dr. H. Sainz, November 24, 1995.
- ⁶ Interview with Dr. Alberto Martínez Sardiñas, member of the National Anesthesiology Group of the Ministry of Public Health, and head of Anesthesiology at the Institute of Nephrology, Oct. 20, 1995.
- ⁷ Interview with Dr. R. Obrerón, November 28, 1995.
- ⁸ Interview with Dr. L. Sarmiento, November 28, 1995.
- ⁹ Interview with Dr. Rodolfo Pérez Felpeto, Subdirector, Salvador Allende Hospital, October 26, 1995; and with Dr. Luis Teareaux, head of Pharmacy, Joaquín Albarrán Hospital, Oct. 17, 1995.
- ¹⁰ Interview with Alexis Cedeño vice-director, National Electromedicine Center, Havana, December 8, 1995.
- ¹¹ National Electromedicine Center, Memo from Respirator Department, Oct. 26, 1995.
- ¹² Telephone survey by Dr. María Lilian Hamilton, May-March, 1996, with the directors and/or staff of these hospitals.
- ¹³ ENSUME report, January 9, 1996 and Dr. Hamilton telephone interviews.
- ¹⁴ Ibid.
- ¹⁵ Ibid.
- ¹⁶ Ibid.
- ¹⁷ Interview with Dr. José Santos, Institute of Cardiology and Secretary of the National Group of Anesthesiology, November 10, 1995.
- ¹⁸ Interview with Enrique Pereira, Head of Electromedicine, Frank País Orthopedic Hospital, Feb. 13, 1996.
- ¹⁹ Interview with A Cedeño, December 8, 1995.
- ²⁰ Interview with Paul Moore, Varian X-Ray Tube Products, Salt Lake City, Utah, DATE.
- ²¹ Interview with Dr. R. Peres Felpeto, October 26 and 31, 1995.
- ²² Interview with Dr. R. Obrerón, November 28, 1995.
- ²³ Interview with Dr. Orlando Valls, Chief of Radiology, "Hermanos Ameijeiras" Hospital, Havana, December 15, 1995.
- ²⁴ Documents provided to the authors by the Ministry of Foreign Trade.
- ²⁵ Interview with Juan Suárez Deputy Director, National Center for Electromedicine, December 8, 1996; and with Ing. Rivero, deputy director for Medical Equipment, ENSUME. December 22, 1995.
- ²⁶ Interview with Orlando Romero. General Manager of MEDICUBA Oct. 23, 1995.
- ²⁷ Interviews at the "Abel Santamaria" Hospital and the Provincial Hospital of Pinar del Rio, November 28, 1995.
- ²⁸ Interview with Dr. R. Obrerón, November 28, 1995.
- ²⁹ Ibid, and interview with Dr. Mario Sanchez, head of the Clinical Laboratory, and others, "Abel Santamaria" Hospital, Pinar del Rio, November 28, 1995.
- ³⁰ Interviews with Dr. Nancy Cabrera, head of the Microbiology Laboratory, and Dr. Maribel López Bancells, head of the Clinical Analysis Laboratory, 'Joaquín Albarrán" Hospital, Havana, October 17, 1995.
- ³¹ Meeting with Nancy Blanco. Sub director of MEDICUBA for medications and Raw Materials, ~~September~~ **September** 7, 1995.
- ³² Interviews at the "Hermanos Ameijeiras" hospital in Havana, with Dr. Celso Cruz Rodríguez, head of Laboratories, Dr. Jorge Suardiáz Paredes, head of Medical Equipment at the Laboratories, and Dr. Wilfredo Tones, Chief of the National Laboratory Group of the Ministry of Public Health,

Havana, June 5,1996.

³³ Ibid.

³⁴ Ibid.

³⁵ Interview with Dr. R. Obreron, November 28,1995.

³⁶ European Community report.

³⁷ Documents facilitated to the authors by the Ministry of Foreign Trade.

³⁸ Interviews with staff at the "Abel Santamaria" Hospital, Pinar del Rio, Nov. 28,1995.

³⁹ Interviews with staff at the "Pepe Portillo" Pediatric Hospital, Pinar del Rio, Nov. 26,1995s; and the National Oncology and Radiology Institute, Oct. 16,1995, and April 3,1996.

⁴⁰ Interviews with staff at the Provincial Hospital of Pinar del Rio, Nov. 28 and 29, 1995, 'Salvador Allende" Hospital, Havana, Oct. 26, 1995; and "Joaquin Albarrán" Hospital, Havana, Oct. 17, 1995.

⁴¹ Interviews with staff at the "Abel Santamaria" Hospital, Nov. 28,1995.

⁴² Interview with Dr. Manuel Garcia, Director of the González Core" Maternity Hospital, Havana, Nov. 2,1995

CHAPTER SIX

PREVENTION, DIAGNOSIS AND TREATMENT OF DISEASE

Cancer is the second cause of death in Cuba (as it is in the United States), after cardiovascular disease. The incidence as well as mortality rates are expected to climb over the next years, reflecting, among other factors, the longer life expectancy of the population (many cancers are more common in older people). Prevention, early detection and treatment thus are becoming more of a priority within the general health care system, according to Dr. Rolando Camacho, Director of the National Oncology and Radiology Institute.

The Institute is the national reference center for research and treatment of adult cancer, and oversees national preventive programs, such as the National Program for Early Detection of Breast Cancer.

The Havana center includes a 450-bed hospital with 128 attending physicians staffing full surgical, oncological medicine and radiation therapy services. Pediatric as well as adult patients receive treatment at the Institute. In 1994, 6,186 patients were hospitalized; and a total of 60,682 patients were seen on an outpatient basis.¹

After visiting diagnostic and treatment facilities, adult and pediatric wards, and pursuing detailed interviews with specialists, we have concluded that the U.S. embargo has significant direct and indirect impact on the quality of patient care and indeed the chances for survival of Cuba's cancer victims. It has also placed an additional burden on the health care system, medical personnel, and on the families of cancer patients.

Cancer Incidence and Mortality

Every year, between 20,000 and 25,000 new cases of cancer are diagnosed in Cuba: men are at greater risk with 222.6 cases per 106,060 inhabitants, while women account for 194.1 cases per 100,000 inhabitants. Incidence of cancer, for both sexes, show lung cancer to be the most prevalent, followed in order by skin cancers, prostate, breast and colon cancers. Mortality rates are highest for lung cancer, followed by prostate, colon, breast and stomach cancers. As mentioned earlier, both incidence and mortality rates are on the rise.²

FIRST FIVE CANCER SITES AMONG WOMEN, 1991.			
Site	Cases	Per 100,000 Women	Worldwide Rate Per 100,000 Women
Breast	2,096	39.41	36.88
Skin	1,340	25.20	21.90
Cervix	1,166	21.93	20.17
Lung	959	18.03	15.67
Colon	754	14.18	11.91

Source: National Oncology and Radiology Institute, Havana.

FIRST FIVE CANCER SITES AMONG MEN, 1991			
Site	Cases	Per 100,000 Men	Worldwide Rate Per 100,000 Men
Lung	2,597	48.30	43.13
Prostate	1,747	32.50	25.60
Skin	1,710	31.80	28.73
Colon	626	11.60	9.90
Larynx	530	9.86	9.29

Source: National Oncology and Radiology Institute, Havana.

LEADING CANCERS CAUSING DEATH IN CUBA, 1994					
Site	Deaths: Women	Per 100,000 Women	Site	Deaths: Men	Per 100,000 Men
Breast	990	18.61	Lung	2253	41.10
Lung	811	15.25	Prostate	1611	29.38
Colon	670	12.60	Colon	509	9.28
Uterus	529	9.94	Stomach	405	7.39
Cervix	332	6.24	Larynx	381	6.95

Source: National Oncology and Radiology Institute, National Cancer Registry, Havana, 1996

Prevention, Early Detection and Diagnosis

Since 1960, Cuba has developed nationwide programs for prevention and early detection of pediatric cancers and those of the lung, cervix, breast, and mouth. An anti-smoking campaign has had considerable success in this tobacco-producing country, showing fewer smokers (36% of people over 17 by 1990), and less consumption (down to 4.4 cigarettes daily by 1993).³ These education and early detection programs are carried out in communities throughout the island, with the support of the media, local organizations, and the family doctor program. Dr. Camacho notes that they are particularly costly, and have been seriously affected by the economic crisis, aggravated by the U.S. embargo, primarily because scarce funds must be saved for curative procedures and treatments.

One striking example of a direct effect of the U.S. embargo is the unavailability of Kodak mini-R film for the national mammography program, which would permit women to be exposed to considerably fewer doses of radiation than film available to Cuba from non-U.S. sources. Experts say that they have had to buy less sensitive film from these non-US suppliers, because the price of Kodak mini-R through intermediaries was completely out of range.⁴ As noted above, breast cancer is the number one cause of death by cancer in Cuban women. (For a more detailed discussion of embargo-related difficulties with the national mammography program, see discussion of women's health in chapter on selected aspects of health and welfare).

Diagnosis is directly and indirectly impacted by the embargo: A case in point involves the only platelet aggregometer in Havana, a unit for specialized blood workups and coagulation studies. Three hundred and sixty patients a month require these analyses (from the Institute and referred from other hospitals). However, while the equipment is Italian (Omniscrite Series D-6991, the metallic tape used to inscribe the test results is of U.S. origin, and Cuba has not been able to buy it from any source. For lack of the tape, the use of the Omniscrite is limited to reading only **half the** information from each patient's tests.⁶

Dr. Lorenzo Anasagasti, Vice-Director for Medical Equipment at the Institute, also reports delays in arrivals of spare parts for other equipment, when a U.S. partnership is involved. This is true, for example, of the blood chemistry equipment from Ciba-Corning, which requires six to eight months to receive spare parts through third parties.

The diagnosis and followup on patients with intra-ocular tumors has been frustrated by the inability to purchase parts for the Institute's U.S.-origin ophthalmological ultrasound equipment. In 1985, 10 Cooper-Vision Model System IV ultrasound units were purchased through Mexico. Cooper-Vision is a U.S. company, located in Redding, California, and according to Cuban specialists no comparable equipment was available at the time.⁶ Since the original purchase, however, it has been impossible to buy parts for this equipment, even through third parties, according to Cuba's National Medical Supply Company (EMSUMEI).⁷ In the case of the Oncology Institute, their ultrasound has been broken for the last two years, leaving some 1200 patients without the benefit of this important diagnostic tool, which permits, among other things, earlier

detection and more precise location of tumors. In a few cases, according to hospital records, patients were able to be referred to other institutions with working ultrasounds, **but** for the vast majority of patients, physicians had to rely strictly on methods of clinical diagnosis.⁸

These direct effects of the embargo are complicated by economic limitations, in which the embargo has played a role. For example, the Institute's endoscopy equipment (used for diagnosis of digestive tract cancers) was purchased in the 1970s from Japan, a decade in which trade between the two countries increased significantly with Japan's importation of Cuban nickel. However, when the United States refused to buy any Japanese product that contained the island's nickel, Cuban trade with Japan hence credits-slumped, and such financial constraints limited future purchases, among them replacement parts for the Institute's endoscopy equipment.

Broader economic factors, exacerbated by the embargo, have limited purchases of key equipment. The Institute has no CAT scan, which specialists consider vital to diagnosing the extension of tumors and determining whether they are operable. Dr. Anasagasti notes that of the 3,000 candidates for surgery they receive annually, 2,000 require CAT scans. And, he says, one half the patients who receive radiation therapy also require CAT scans. The Institute is only able to refer 10-12 patients monthly to other hospitals with CAT scans, since there are so few units (ten in the country as a whole, nine of which are in working order). There is no MRI (magnetic resonance imaging), which could in some cases substitute CAT scan studies.

The Institute has only one x-ray machine (specialists estimate their needs at ten, including three portables).⁹

Radiation Therapy and Surgery

Quality and cost of equipment are at issue in this sensitive area of cancer therapy. Dr. Anasagasti is of the opinion that U.S. firms have the best quality cobalt radiation therapy equipment and accelerators. 'The fact that we do not receive bids from them means that other companies offer us a quality inferior to U.S. manufacturers at a higher price,' he says.¹⁰ This, he states, has made replacing old equipment an expansive proposition, given current economic limitations. The result is that there is one cobalt therapy unit working in the hospital, which is in use from 6:00 a. m. to 1:00 a.m. the next day, with technicians rotating on round-the-clock duty, should it break down. Maintenance is done on weekends. This causes untold hardship for the patients (who often must come from far away at difficult hours) and for staff (who are under additional stress). The equipment itself suffers: Dr. Anasagasti calculates that in the last three years, this unit has in fact used up eight years of its normal 12-year lifespan.

The hospital is also under an extra burden: Because of transportation problems created by the lack of fuel and spare parts, patients who could receive radiation on an outpatient basis are often hospitalized. And their treatment is often delayed, which can affect prognosis: At the time of the visit to the radiation therapy service, there were 25 patients on a waiting list for treatment; and the wait was averaging 20 days per patient. (The period of treatment itself averages six weeks).¹¹

Optimally, states Dr. Anasagasti, the Institute should have two cobalt therapy units and one accelerator, this last piece of equipment representing a significant improvement in therapeutic alternatives, since radiation is directed at a smaller area, potentially affecting less healthy tissue. Neither does the Institute have a simulator for planning surgery, and specialists must use x-ray and clinical means to estimate the extent of tumors, among other factors.

In surgery, the Institute faces serious problems with the anesthesia units: Of four 20-year-old Swedish units, three are working *without* their automatic alarms, causing extra stress for personnel and added danger to patients. Four of five respiratory ventilators for post-operative and

intensive care are in use (the one that is broken is from the U.S. manufacturer Merck, with no possibility for repair).

Dr. Anasagasti and importers at MEDICUBA agreed that the fundamental problem in the surgical service of the Institute has been lack of hard currency to replace equipment, a situation exacerbated by the U.S. economic embargo.

Chemotherapy: Application and Research

Chemotherapy drugs are among the most costly for the Cuban health system. Nineteen of these are included on the Basic List of Medicines prioritized for 1995/96, but because of financial limitations, aggravated by the embargo, all of these are continually in short supply. Cuban purchasers and cancer experts estimate that this situation would be considerably alleviated if Cuba could purchase chemotherapy medicines from the U.S. market, since the United States is the world's number one producer of these cancer-fighting drugs—and at competitive prices, not to mention considerably reduced freight costs from purchasing close to home instead of from European suppliers. The embargo has also directly affected Cuba's attempts to produce chemotherapy products domestically, which would mean even greater savings and, therefore, significantly improved product availability. (See below).

Chemotherapy drugs must often be used in tandem, in specific protocols to be effective against particular cancers. The reduction of therapeutic options produced by scarcities thus has a direct impact on the chances of disease-free survival among patients. Dr. Maria del Carmen Barroso, in charge of medicines at the Oncology Institute, describes what she calls "the morning agony" of reviewing the stock and variety of chemotherapy drugs available each day for each patient.

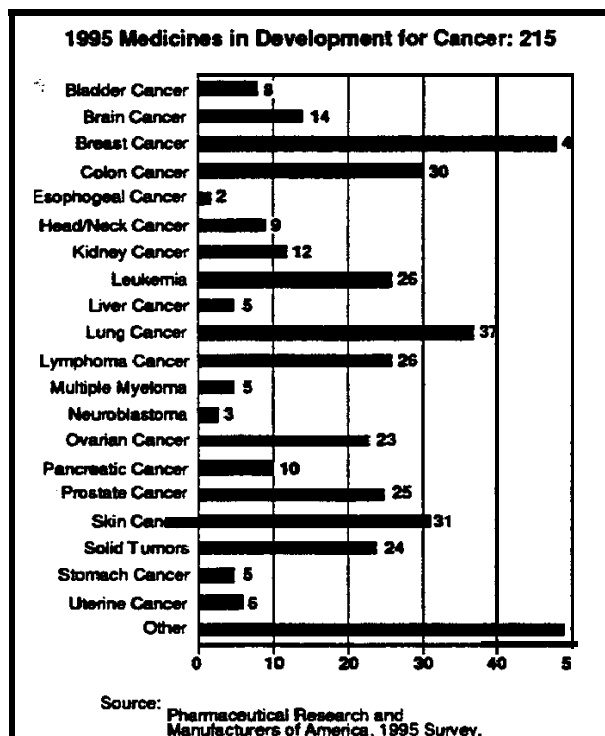
She cites the example of treatment of breast cancer patients, noting that this requires 5-fluorouracil and cyclophosphamide in combination with either methotrexate or Adriamycin (doxorubicin HCl). These combinations are not always available. On the day of our interview, she described the following problems in this regard: "Right now, we don't have either 5-fluorouracil, methotrexate or Adriamycin. This is terrible psychologically for the patients and their families." All the more so, she says, because chemotherapy must be started within a certain period of time after surgery—in the case of breast cancer, within two to three weeks. Otherwise the disease-free survival prognosis becomes dimmer. In general, she noted, "within the last two weeks, we have not been able to accept a single new patient for chemotherapy" because of drug shortages. Ten breast cancer patients were on the waiting list, but the real need was greater, she said, because all other hospitals had been advised to hold up referrals.¹²

The situation is especially tragic with children, virtually all of whom require chemotherapy, according to Dr. Barroso. She cites the case of an eight-year-old girl operated on for non-Hodgkin's lymphoma, who needed high doses of methotrexate in her treatment protocol. With this drug, she would have had a 90% chance of total remission. But because the amount needed for her case was not available and doctors **were** forced to substitute another chemotherapy medication, the chance of remission was uncertain.¹³

Ironically, Cuba's ability to produce methotrexate was stalled by the embargo in 1993, when the United States refused to issue an export license to the German subsidiary of Pfizer, Heinrich Mack Nachf, for sale of the raw materials for methotrexate to Cuba. (See chapters on Medical Exports and the Pharmaceutical Industry.) This held up trial production runs for this key chemotherapy agent. Pull-scale manufacture has been delayed as a result and also by another embargo-specific obstacle: difficulties in purchasing key equipment.

Domestic production of this and other chemotherapy drugs has been stalled for some time because Cuba has not been able to purchase a freeze dryer (lyophilizer), Model LYOFLEX-16, from the

British firm Edwards. According to Marlene Porto, Director of Cuba's Center for Medication Research and Development (CIDEM), this unit is needed to dehydrate injectable chemotherapy powders to assure the long-term stability of the product. However, she says that because the unit in question is produced in the United States, We have not been able to even obtain a price quotation." other freeze dryers are on the market, says Porte, but they do not meet Cuba's quality control standards. As a result of this direct incidence of the embargo, Cuba has not been able to produce such chemotherapy drugs as cisplatin, actinomycin D, vincristine sulfate (used against childhood leukemia), vinblastine sulfate and bleomycin sulfate, in addition to a number of other vital medications (see chapter on the Pharmaceutical Industry).



The shortage of chemotherapy drugs not only restricts therapeutic options but it also stops application of certain treatment protocols which would guarantee maximum disease-free survival rates. According to Dr. Camacho, limited supplies also result in decision-making that is a 'nightmare' for cancer specialists, trained as they are to make efforts against all odds to save their patients. Dr. Camacho states that scarcities of chemotherapy medications force doctors to reserve these life-saving drugs only for cases where the chances of recovery are especially promising "In 80% of the cases where we should be using chemotherapy for palliative reasons, we cannot." 14

Currently, then, the U.S. embargo negatively impacts the availability of finished chemotherapy medications as well as raw materials to produce these drugs domestically in Cuba. Over the longer term, it may also prove to have a negative effect on the availability of new and more effective cancer-fighting medications. The United States **has the** world's number **one** research and development capability for these drugs. **From** 1970 through May of 1992, U.S. firms led the world in marketing major global drugs for fighting cancer: Five of 16 new medications which were approved worldwide during those 22 years were developed in the United States, more than in any other single country. 15

In its fifth survey of New Medicines in Development for Cancer, the Pharmaceutical Research and Manufacturers of America reports that an unprecedented 215 new medications were in Phase I-III FDA testing in 1995, with 211 of these patented by U.S. manufacturers. None of the 211 new medications will be available to Cuban doctors for at least a decade, since law prevents their generic production by non-U.S. firms for the period protected by patent; and only under exceptional licenses granted by the U.S. Treasury Department could they otherwise be sold to Cuba.¹⁶ Of the 211, 171 or 66% are medicines that target the five main types of cancer found in Cuba: lung, skin, prostate, **breast** and colon.¹⁷

According to the same survey, another 26 drugs are being studied for the treatment of leukemia, a disease that primarily strikes children and young people. If the embargo remains in place, **none** of the children diagnosed with leukemia in Cuba today will have access to these new and more effective life-savers. Indeed, more cases can be expected like that of Oncaspar (pegaspargase), a drug patented by Enzon of the United States and already approved by the FDA for patients allergic to L-Spar (L-asparaginase). Each of these drugs has been found to produce longer remission when added to treatment protocols for acute lymphoblastic leukemia (ALL), but L-Spar has an allergy rate of 40% for first-time use, and 79% for relapsed ALL. This **type** of leukemia, which strikes at the rate of three per 166,669 youngsters under 15 in the United States,¹⁸ is fatal in two to three months, if left untreated. Oncaspar is less traumatic to a child suffering from ALL, since it requires one to two injections, instead of six to 12 of L-Spar, to induce remission.¹⁹

However, the effect of the embargo on cancer medicine research and development is not limited to preventing U.S. advances from reaching Cuban patients: The Cuban Democracy Act (CDA) of 1992 takes specific aim at Cuba's biotechnology capabilities, with the purpose of withholding from Cuban scientists any imports which could contribute to research or manufacture in the field. At the same time, biotechnology is one of the greatest hopes for treating cancer, according to Gerald J. Mossinghoff, President of the Pharmaceutical Research and Manufacturers of America: "Biotechnology has given a special boost to cancer research, and advances appear to be accelerating."²⁰

His words might refer to several areas of research which have become hallmarks of **Cuban** biotechnology: recombinant **interferons** for use against cancer, AIDS and various viral agents. Specifically, Cuba's Heberon Alfa N and Alfa R recombinant interferon injections have been used successfully to treat hairy-cell leukemia, chronic myelogenous leukemia, low and medium-grade non-Hodgkins lymphomas, and some carcinomas and sarcomas, including Kaposi's sarcoma (associated with AIDS). And Cuba has developed at least one monoclonal antibody, or "magic bullet," for carrying cancer-fighting drugs directly to malignant tissue.²¹ (See chapter on Vaccines and Biotechnology).

Dr. Camacho also suggests that the U.S. embargo deprives Cuban specialists in oncology of joint research opportunities with colleagues in the United States. And he contends that Cubans have never been able to obtain fellowships offered through the U.S. National Cancer Institute, which he characterized as one of the world's most significant supporters of cancer study and research.²²

Additional Medications

As with chemotherapy medications, Dr. Barroso explains that cancer patients cannot count on "a stable arsenal" of hormones, antiemetics (which prevent nausea during chemotherapy treatment), analgesics, or antibiotics. While this situation is due primarily to the scarcity of hard currency, this is one more arena in which the embargo constitutes an aggravating factor. (It is useful here to recall that Cuban importers of medicines and medical equipment have had to pay \$6.7 million in

excess shipping costs from faraway markets over the last three years alone, when compared to the cost of shipping from the United States.)

At a minimum, gaps in availability of these medications increase patient suffering and prolong hospital stays and in extreme cases can be life-threatening.' The problem of antiemetics is particularly dramatic in the pediatric ward. At the time of our visit there, the hospital was into its 22nd day without metoprolol HCl. This drug is used in combination with others such as betamethasone for children receiving chemotherapy. Without them, states Dr. Barroso, the child will vomit an average of 28 to 50 times a day. There were 35 children in chemotherapy at the time of our visit, and none of them had the benefit of combination treatment.²³

Analgesic scarcities create another series of problems: Since many times first and second-tier analgesics are unavailable (such as acetaminophen, ibuprofen and other non-steroid anti-inflammatory drugs), specialists must resort sooner to stronger pain-killers such as codeine and morphine, fully aware that these are contra-indicated at lower pain levels but unable to offer their patients an alternative. These are controlled substances, and their sale is restricted internationally. What's more, by applying them earlier on, the patient builds up a resistance to their effectiveness and needs greater doses to control pain later.

Finally, in the case of hormones, some situations become life-threatening. This is the case of thyroid hormones. Patients with thyroid cancer require two to three times the usual therapeutic dosage and can die if they do not receive it. Often this hormone is in short supply. "The first two weeks, the patient comes looking for the medicine; after that, his family comes, since he is just too weak," comments Dr. Camacho.²⁴ At the time of our visit to the Institute, an x-ray technician at the hospital itself had been bed-ridden for two weeks for lack of thyroid hormone to treat his cancer.

NOTES

- 1 Anuario Estadístico. Instituto Nacional de Oncología y Radiología, 1994, pp. 2 and 7.
- 2 Anuario Estadístico, Instituto Nacional de Oncología y Radiología, 1994, pp. 17-18.
- 3 Hygiene and Epidemiology Dept., Ministry of Public Health, Havana
- 4 Interview with Professor Orlando Valls, Resident of the National Radiology Society and Head of the Radiology Department, Hospital Hermanos Ameijeiras, Havana, December 15, 1995.
- 5 Interview with Dr. Lorenzo Anasagasti, Vice-Director for *Medical* Equipment, National Oncology and Radiology Institute, Havana, October 16, 1995.
- 6 Interview with Alexis Cedeño, Vice-Director. National Electromedicine Center, Havana, December 8, 1995.
- 7 Interview with Rivero. Vice Director for Medical Equipment of the National Medical Supply Company (EMSUME). December 22, 1995.
- 8 National Oncology and Radiology Institute fax December 19, 1995.
- 9 Interview with Dr. Lorenzo Anasagasti, Oct. 16, 1995.
- 10 Interview with Dr. Lorenzo Anasagasti. Oct. 16, 1995.
- 11 Visit to radiation therapy service, National Oncology and Radiology Institute, Havana, Oct. 16, 1996.
- 12 Interview with Dr. Maria del Carmen Barroso, National Oncology and Radiology Institute, October 16, 1995.
- 13 Dr. Barroso estimates that remission rates of 60% achieved in Cuba for non-Hodgkin's lymphomas may return to the 1960s rates of only 26% if the availability of chemotherapy agents continues to be seriously affected. Remarks to authors on April 3, 1996.
- 14 Interview with Dr. Rolando Camacho, Director, National Oncology and Radiology Institute. Havana, October 16, 1995.
- 15 Therapeutic Class Profiles by Area of Origin of 265 Major Global Drugs," *Price Regulation and Pharmaceutical Research*, by Heinz Redwood, Oldwicks Press, Suffolk, England, 1993, p. 77.
- 16 While these might be obtained through third-country wholesalers. the price tag would certainly be much higher than if directly exported to Cuba, and perhaps unbearably so. To the high cost of patented chemotherapy drugs, one must add 'surcharges' for the intermediary, which include the usual profit margin plus a percentage for the risk that the sale to Cuba represents.
- 17 '1995 Survey: Over 200 Medicines in Testing for Cancer-The Number Two Killer of Americans,' published by PhrMa, Pharmaceutical Research and Manufacturers of America, May 12, 1995.
- 18 **Richard** E. Behrman, M.D. and **Robert M.** Kliegman, M.D. *Nelson's Essentials Of Pediatrics*, Second Edition, W. B. Saunders Company, 1994, pp. 556-557.
- 19 Interviews recorded by Dr. Anthony Kirkpatrick with Dr. Abraham Abuchowski. Enzon Corporation; Dr. Joan Hertzberg, Pediatric Clinical Research Group; and Dr. Steve Sallan, Dana Farber Cancer Institute, March 15, 1995.
- 20 PhRMA, "1995 Survey...".
- 21 Center for Genetic Engineering and Biotechnology, Heberfarma. Catalogue, 1993-94, pp. 3-16.
- 22 Interview with Dr. Rolando Camacho, Oct. 16, 1995.
- 23 Interview with Dr. Barroso and visit to the pediatric ward, October 16, 1995, National Institute of Oncology and Radiology, Havana, Cuba.
- 24 Interview with Dr. Camacho, Oct. 16, 1995.

Introduction

Heart disease is the number one cause of death in Cuba, with ischemic cardiopathies accounting for over half of these fatalities each year. Mortality rates have generally been rising for both sexes since the beginning of the decade: In 1989, there were 189.3 deaths per 100,000 inhabitants, with 210 for men and 168 for women. In 1995, however, figures had reached 199.8 for both sexes, with 216.1 for men and 183.2 for women. Some 22,966 Cubans died in 1995 from heart disease.²

Cerebrovascular disease, accounting for over 7,000 deaths in Cuba every year, is the third case of death and shows a rising mortality rate since 1989.

High blood pressure affects about one quarter of the Cuban population, or some 2.6 million people, one third of them receiving regular primary attention through the community family doctor program. It is estimated that, in 112,000 of these cases, hypertension has been clinically controlled. In fact, deaths attributable to high blood pressure have decreased over the last two decades to 8.2 per 100,000 inhabitants in 1995.

Over the years, the Cuban medical system has developed broad strategies of prevention and therapy for heart disease, including the use of implantable pacemakers and defibrillators, surgical transplants, and research on new drugs for treatment.

The Cardiology Institute in Havana includes research facilities, plus an 84-bed hospital for surgical and other therapies for heart patients. While all general hospitals in Cuba afford attention to victims of heart disease, the Institute bears a major responsibility in the field, which has become a bigger burden with the economic crisis of the nineties, as some other facilities are not able to maintain all their services. For example, normally the Institute would implant about half of the pacemakers installed annually, but this proportion is now greater, since other hospitals are having difficulties in guaranteeing conditions for this procedure. In 1995, the Institute implanted 597 pacemakers of some 800 total.³

However, the Institute has itself been affected by the adversities and shortages of the last several years. As a result, while through 1990 an average of 466 major operations were performed there annually, this figure has been gradually decreasing, with 1995 surgeries numbering only 174. As of December 31 1995, there was a waiting list of 297 patients, a delay which specialists estimate exposed them to a 19% greater risk of death.⁴

During visits to the Institute and other hospitals, and based on extensive interviews with specialists, we have found that the U.S. embargo constitutes a significant impediment to optimum patient care and research, which at times has presented a clear threat to human life.

Cuban patients needing pacemakers or implantable defibrillators were placed in particular danger. Pacemaker implantation is a regular procedure in Cuba, performed on the basis of physician recommendation and patient consent alone, since, like other surgeries, it is gratis. Thus, pacemakers were imported on the basis that each patient who needed one would get one. Until 1993, these purchases were made from Siemens-Elema of Sweden and Telectronics Pacing Systems of Australia. However, within a period of six months, sales from both were art off as production was transferred to plants and ownership in the United States, thus falling under the jurisdiction of the U.S. embargo.

In the case of Siemens-Elema, its Pacemaker Division was sold to St. Jude Medical of Minnesota. Telectronics pacemakers were being produced in the TPLC, Inc. plant in Hialeah, Florida, where corporate executives decided not to pursue sales to Cuba, for fear of offending the Cuban-American community, following recommendations of legal counsel to this effect.⁵

As MEDICUBA searched for new suppliers in Europe, a potentially dangerous situation was developing for cardiac patients on the pacemaker waiting list. Finding a new source was an especially complex process, since not only did the quality of the pacemakers have to measure up, but once a new manufacturer is identified, its own line of accessory equipment must be purchased to program the pacemakers, making it more expensive, complicating expedient delivery, and introducing a period of technical training for personnel.

Cardiology Institute specialists report that the situation was overcome with no time to spare and that no fatalities were registered. However, this situation illustrates how vulnerable these life-saving procedures are to unpredictable and sudden consequences of the U.S. embargo.

It should be noted that the urgency of finding another supplier and the delays and uncertainties accompanying application for a U.S. export license discouraged Cuban importers from following such a route. Importers reported that for budgetary reasons pacemaker purchases are made ten times a year, which would have meant filing a separate license application for each one, with patients waiting for the outcome of U.S. Commerce Department decisions and dependent on the U.S. government's consistent good will. We just couldn't take that risk," commented Rolando Días of MEDICUBA.⁷

Even so, a U.S. export license only permits Cuba to buy from a U.S. supplier: It does not offer Cuban patients any recourse should the equipment purchased be defective. This is not as hypothetical as it sounds: Telectronics, according to an *ECRI Alerts* bulletin issued in June of 1995, was prohibited by the FDA from further distribution of certain pacemaker models and electrodes until they satisfied federal production guidelines. -(The problem concerns an electrode that could pierce the patient's heart.) A Security Alert" from Cuba's Ministry of Public Health, distributed to hospital directors throughout the country, noted that in May of the same year the Ministry's Center for Medical Equipment Control had warned of the sudden failure of a Telectronics pacemaker in a Cuban patient, 'endangering the life of the patient.'" The alert noted: -At that time, **our** investigation indicated that the pacemaker had malfunctioned, which in our judgment corroborates the FDA decision.... But it should be noted that the prohibition on marketing this equipment only applies to new sales, and thus (Cuban hospitals) should take precautions with pacemakers already in stock or those which have already been implanted."⁸

No additional problems had been reported with Telectronics devices in Cuba through January 19, 1996, according to Dr. Francisco Dorticós of the Cardiology Institute. However, in the not unremarkable event that **such** a failure should have occurred, or should occur, and presuming that a Cuban patient or his/her family were to be awarded damages from a U.S. court, these damages would by virtue of the embargo be held in a blocked account in the United States, cut of reach of either family or patient and consequently not **constituting any type** of compensation whatsoever.⁹

The move of Telectronics production to Florida led Cuban importers to eventually seek alternate suppliers for **implanted** defibrillators of the same brand, although these were still being manufactured in Australia. Six to eight of these defibrillators are needed in Cuba each year, and because they are very costly, they are purchased on a case-by-case basis. Locating, signing and ensuring delivery on new contracts, including the purchase of the necessary programmers and the visit of a technician to Cuba to teach specialists the workings of the new line of devices, is again a costly and time-consuming venture, thrust on MEDICUBA as it seeks to ensure 'embargo-proof' supplies.

At the end of 1995, while the switchover was still in progress, there were two 21-year-old Cuban patients with malignant ventricular arrhythmia waiting for these defibrillators: a young man with a Telectronics defibrillator implanted, nearing its expiration date; and a young woman, with no defibrillator **as** yet, and whose unstable condition dictates hospitalization until she can receive

one. Nineteen other patients have Teletronics defibrillators which will reach their expiration date in 1996. 10

Cuban heart specialists faced a tragic situation in 1988-89, when a male patient, who had suffered a heart attack and was reported with malignant ventricular arrhythmia, required an implantable defibrillator to survive. According to Dr. Dorticós, when the U.S. firm CPI was approached to purchase the device (over which U.S. manufacturers had a virtual monopoly at the time), they expressed a willingness to make the sale, but it was vetoed by the U.S. Government. Two months later, the patient died. (Ibid.) **We** have attempted to verify this data with the U.S. Commerce Department, but as of June, 1996, no reply has been forthcoming.¹¹

Cuban physicians report their frustration at not being able to make available to their patients other items manufactured in the USA, which would significantly improve the quality of their care. In this regard, they made specific reference to heart muscle stimulators and other units from Medtronic, whose technology they consider one of the best in the world. In other cases, the equipment has been purchased through third parties, at a significant sacrifice of additional funds. This is the case of a unit for extracorporeal circulation, used in open heart surgery and produced by the U.S. firm Sams. Dr. Humberto Sainz of the Cardiology institute reports that they paid three times the usual price of the equipment-both a higher price and higher shipping fees-since the U.S. embargo prevented them from buying directly through normal channels.¹²

U.S.-manufactured medications for heart patients and especially new U.S. medications are for the most part inaccessible to Cuban physicians. They listed the following drugs as essential, but for at least 8-10 years after the FDA approval date unavailable to Cuba by virtue of the embargo:

Chemical Name	Use	Trade Name	Firm	FDA Approved
Dobutamina	Shock	Dobutrex	Eli Lilly	1978
C a p t o p r i l	Left ventricle dysfunction; hypertension.	Capoten	Squibb	1981
Enalapril maleate	Asymptomatic left ventricle dysfunction; hypertension	Vasotec	Merck	1985
Amrinone lactate	Shock	Inocor	Winthrop	1994

Source: Interviews at the Cardiology Institute, Havana and Statistical Report, Offices of Drug Evaluation ^{FD}A Washington, DC, 1993.

It is significant that the embargo prevents the world's number one source for new drugs against heart disease-U.S. manufacturers-from making their **products** readily available to Cuban patients. From 1970 through May of 1992, U.S. laboratories accounted for 17 of 47 new major global drugs discovered for heart disease and 7 of 14 of the new medications for blood-related conditions more than any other country in the world. And their leadership continues today.¹³

Finally, the U.S. embargo has obstructed Cuban research into new biotech products for heart patients, such as the recombinant streptokinase developed at the Center for Genetic Engineering and Biotechnology (CIGB). Like natural streptokinase, this product is used to dissolve blood clots during heart attacks, to prevent cerebral embolisms, and for treatment of deep venous thrombosis, among other conditions. The Cuban-produced version, available at considerable savings (imports

run at \$150 per dose), makes this drug a candidate as a major contributor to **reducing** deaths from heart attack. In a 1992 study, Cuban recombinant streptokinase cut fatalities in half, and the Ministry of Public Health goal is to reduce heart disease mortality rates overall by 29% by the year 2000. The drug is now available in all Cuban hospitals, and being considered to stock neighborhood polyclinics, which would bring it to the primary care level and closer to patients important, since early administration is key to the medication's performance.¹⁴ (See chapter on Vaccines and Biotechnology.)

In addition to these obstacles and to the incidence of the embargo in the general economic limitations **facing** the field of cardiology **in Cuba today**, **physicians** interviewed said without exception that they believed their right to pursue scientific advances **in their field** has been significantly hindered by the embargo, since its restrictive travel and communications regulations prevent a normal and **natural exchange with U.S. colleagues.** **They referred to the** need for international organizations to step in on their behalf on many occasions to ensure a U.S. visa. And Dr. Hernández Cañero, Director of the Cardiology Institute and President of the Cuban **Cardiology Society, was one** of five Cuban cardiologists denied a U.S. visa in 1966 to attend a World Cardiology Congress in Washington.¹⁵ Dr. Hernández also described visits by U.S. cardiologists canceled because of the U.S. embargo's travel ban. In particular, he made reference to a scientific exchange program initiated during relaxed restrictions under President Carter, which was subsequently canceled under **Resident** Reagan, when prohibition on travel was reinstated.¹⁶

Pediatric Cardiology

Pediatric cardiology and the treatment of congenital heart malformations were given greater priority in Cuba, beginning in 1986, with the opening of the Pediatric Cardiocenter at the "William Soler" Pediatric Hospital in Havana, the hub of a three-hospital network to give special attention to these patients, whenever possible from infancy.

In Cuba, between six and eight of every 1,000 live births bring with them a form of congenital cardiovascular malformation, which is about the international average. The main types are **ventricular** septal defect, patent ductus arteriosus, Fallot's tetralogy, transposition of great arteries, and atrial septal defect. Among the acquired cardiopathies, the most important in these young patients is rheumatoid cardiopathy. Several of these conditions require surgery, and others may benefit from surgery.¹⁷

The 80-bed Cardiocenter serves children up to age 18 (sometimes to age 20) if the case requires significant follow-up and performs all cardiovascular surgery for Cuban children under five years.

Outpatient visits at the Center averaged about 6,000 a year through 1992, but they dipped by some 1,000 thereafter, reflecting both difficulties at the Center and problems in transporting patients from the **provinces.**¹⁸

PEDIATRIC CARDIOCENTER OUTPATIENT VISITS									
YEAR	1987	1988	1989	1990	1991	1992	1993	1994	1995
VISITS	6,543	17,329	5,642	6,961	7,206	5,678	14,695	4,274	4,715

Source: *William Soler Pediatric Cardiocenter, Havana 1996.*

In nine years, through December, 1995, surgeons at the Center carried out 3,666 procedures on these high-risk children, with an 85% survival rate. (Nearly 2,000 of these operations required

extracorporeal circulation.) This represented between 50 and 85% of all pediatric cardiovascular operations in the country.¹⁹

PEDIATRIC CARDIOCENTER SURVIVAL RATES FOR SURGERY									
YEAR	1987	1988	1989	1990	1991	1992	1993	1994	1995
RATE	84.2	86.7	85.9	83.3	86.1	82.0	80.2	84.4	88.5

Source: William Soler Pediatric Cardiocenter, Havana 1996.

In all, 3,289 children have been operated on, some more than once, including 240 foreign patients from 30 countries. In addition, some 2,910 cardiac catheterizations have been performed, 410 of these interventional, as well as 46,900 EKGs and 3,042 ergometry examinations.²⁰

The Center once averaged 500 surgical procedures annually, but by 1993, it was down to 250; in 1994, 275; and in 1995, 315. They accumulated a waiting list for the first time between 1993 and 1994, with 87 cases pending, most of them needing complex surgeries which required resources unavailable at the time. This waiting list was eliminated in 1995, but 1993 began with serious repair problems in the electric system, which created a new waiting list in January, totaling 30 cases and growing, since the breakdowns specifically affected operating rooms.²¹

Pediatric cardiology, despite its priority status, has been seriously impacted by limitations in patient care imposed by the U.S. embargo.

In addition to the U.S. medicines unavailable to the general population of heart patients, the virtual ban on sales to Cuba is now threatening the lives of Cuban infants suffering from heart malformations.

Specifically, drugs such as Prostin VR (from Upjohn) have been removed from neonatology for infants with cyanotic heart disease, including Fallot's tetralogy, pulmonary atresias, etc. These babies die before surgery if the Prostin is not administered in time; There is no substitute. Purchases were difficult but possible through trading companies throughout most of 1995, although specialists report several deaths related to the lack of this drug. However, the Cardiocenter was faced with a sudden cutoff in supplies in 1995, after Upjohn declared the medication for hospital use only and therefore unobtainable without the name of the hospital for which it was destined. Since this is a U.S. product destined for Cuba, the name of the hospital itself would block normal sale. On January 18, 1996, the Cardiocenter used its last vial of Prostin for a 14-day-old baby requiring surgery. At the time MEDICUBA and staff at the Cardiocenter were still trying to find a way to buy the drug to prevent the otherwise inevitable: Unless more Prostin was acquired, and rapidly, the next child in this condition would die.²²

In general, specialists at the Pediatric Cardiocenter concurred that children in their care do not have the benefit of the full range of therapeutic options because of the obstacles the embargo presents to purchases of U.S. medications. And this opinion extends to U.S. equipment, which they contend accounts for 80% of modern technology in pediatric heart surgery today.

An example is the stent produced by Cordiss Corporation for Johnson and Johnson. This tubular device is used to prop open damaged blood vessels, preventing deterioration that might, otherwise lead to the need for a heart transplant. Press reports indicate that the February, 1996, acquisition of Cordiss by Johnson and Johnson gives the company "about one third of the worldwide market for heart intervention products," and mentions the stent as a top-ranking money-maker.²³ Cuban cardiologists say they have never had access to the stent. The same is true for a number of

specialized catheters for angioplasty and the umbrella device produced by U.S. companies, which would help to avoid the risks and trauma of more complex surgeries.²⁴

In this highly specialized field of medicine, devices are often needed for a handful of patients, or even just one. When MEDICUBA is faced with the prospect of identifying quality equipment at a reasonable price, which must be delivered immediately, the embargo presents a particular challenge. MEDICUBA's Rolando Díaz says this was the case of a neonatal pacemaker purchased in 1992. On March 14 that year, baby boy Julio Gómez received an external pacemaker at the Cardiocenter, as surgeons waited to insert an implanted pacemaker, which had to be found on the international market. Dr. Ramón Casanova, Director of the Cardiocenter, appealed to MEDICUBA to find such a device as swiftly as possible. Díaz himself purchased the Medtronic (USA) device in Peru, through intermediaries, but even so it did not arrive in Cuba until August 2, and then at a cost inflated well above the market price, since intermediaries added their own markup. Such delays, and even longer ones, are not uncommon. If this device could have been purchased in the USA, argues Díaz "it would have been a matter of a phone call and a trip to the Havana airport the next day, not to mention the savings for other medical needs."²⁵

Finally, the Pediatric Cardiocenter specialists refer to difficulties maintaining dialog and exchange with U.S. colleagues, for the same reasons as those discussed by physicians at the Cardiology Institute. Among the visas denied: that of Dr. Ramón Casanova, Director of the Cardiocenter, for the 1989 Congress on Pediatric Cardiology in the United States.²⁶

NOTES

- 1 *Balance anual* del MINSAP, 1995, p. 100; and 'Enfermedades no transmisibles, análisis epidemiológico', Unidad de Análisis de Tendencias en la Salud (UATS), March, 1996.
- 2 There was a slight decline in 1995 over 1994 rates of 209.7, but the general tendency is increasing.
- 3 Interview with Dr. Francisco Dorticós Chief of Pacemaker Service, Cardiology Institute, Havana, Jan. 19,1996.
- 4 Interview with Dr. Alberto Hernández Cañero, Director of the Cardiology Institute and President of the Cuban Society of Cardiology and the National Cardiology Group, Oct. 27, 1995, and information provided from his office on Jan. 22, 1996.
- 6 Telephone interview by Stephen Kimmerling with William Nealon, TPLC legal counsel, Oct. 27,1995, and follow-up fax 'from Mr. Nealon; and fax from Siemens-Elema, dated June 29,1994.
- 6 Interviews with Dr. Roberto Zayas, Pacemaker specialist, Cardiology Institute, Oct. 39,1995; Dr. Francisco Dorticós, Nov. 14,1995; and Rolando Díaz, Deputy Manager of MEDICUBA for Medical Equipment, Sept. 6,1995.
- 7 Interview with R. Díaz, Sept. 6,1995.
- 8 "Alerta de Seguridad: Problemas con marcapasos y electrodos de la firma Teletronics Pacing Systems", November, 1995, issued by the Center for Medical Equipment Control, Ministry of Public Health, Havana.
- 9 Consultation with Michael Krinsky, of Rabinowitz, Boudin, Standard, Krinsky and Lieberman, P.C., New York, March 24, 1996.
- 10 Interviews with Dr. Hernández Cañero, Oct. 27, 1995, Dr. R. Zayas, Oct. 30, 1995, and Dr. F. Dorticós, Nov. 14,1995.
- 11 Communications to the U.S. Commerce Dept. made by Wallie Mason, attorney.
- 12 Interview with Dr. Humberto Sainz. Chief of Anesthesiology and ICU and the Cardiology Institute, and President of the Cuban Anesthesiology Society, Nov. 24,1995.
- 13 *Price Regulation and Pharmaceutical Research*, Heinz Redwood, Oldwicks Press, Suffolk, England, 1993, p. 77.
- 14 Interview with Dr. Orlando Rucabado, Chief o Coronary ICU at the Cardiology Institute, June 5, 1996.
- 15 Interview with Dr. Hernández Cañero and other specialists at the Institute. As mentioned elsewhere in this study, U.S. immigration policy, and whether or not to grant visas to Cuban physicians in particular, does not in fact fall under the U.S. embargo. However, the authors believe that the climate and economic pressures generated by U.S. policy ultimately influence such decisions.
- 16 Ibid, Oct. 27,1995.
- 17 Interview with Dr. Herminia Palenzuela, William Soler Pediatric Cardiocenter, July 12, 1996.
- 18 Interview with Dr. H. Palenzuela, Jan. 16,1996.
- 19 Ibid.
- 20 Ibid.
- 21 Interviews with Dr. H. Palenzuela, Dr. Eugenio Selman and Dr. Felipe Cárdenas, Cardiovascular Surgeons, Nov. 23, 1995, and Dr. H. Palenzuela, Jan. 16, 1996.
- 22 Interview with Dr. F. Cárdenas, Jan. 18,1996; end telex to MRDICUBA from Spain, notifying the hospital use only" clause for Prostins, dates July 6, 1995.
- 23 Reuters dispatch by Richard Jacobson, April 16,1996, datelined New York.
- 24 Interview with Dr. B. Reyes Vega, Pediatric Cardiocenter, Oct. 26, 1995.
- 25 Interview with R Díaz Sept. 6,1995, and documents from MEDICUBA on Contract 26969 of 1992 for Medtronic DDD Bipolar Neonatal Pacemaker, Model 940,24 grams. He paid over \$4,000 for the device; other quotes were as high as \$5,599.
- 26 Interview with Drs. Palenzuela and Reyes Vega, Oct. 26, 1995.

Introduction

From 1996 when the first HIV-positive cases were identified in Cuba, until January of 1998, the cumulative number of persons testing seropositive was 1,208, including 440 AIDS patients, 292 of whom have died. The average incubation time from HIV infection to full-blown AIDS is 11 years, and the average survival time from the onset of AIDS is 18 months.¹

The National AIDS Prevention and Management Commission was founded in 1983 by the Public Health Ministry, which the same year set up an epidemiological surveillance system and prohibited importation of hemoderivatives, which were from that point produced in Cuban laboratories. In 1985, \$2 million was invested by the governmental public health system to develop the National AIDS Prevention and Control Program, and in particular to furnish the first 750,000 ELISA-system diagnostic kits and related equipment for the provincial blood banks and 42 diagnostic centers in the country.

By late 1986, screenings included all blood donations; persons returned from service in Africa (every six months); and workers in tourism, the merchant marine, fishing and airlines industries (once-a-year). Later, testing would be extended to pregnant women in their first trimester, hospitalized patients, prisoners and patients suffering from sexually-transmitted diseases. In 1987, Cuban laboratories began producing their own diagnostic kits; and a year later, a domestically-designed kit was introduced, using SUMA technology.² According to the Ministry of Public **Health**, the Cuban AIDS strategy was based on four main programs:

- Serological screenings of large population groups.
- Epidemiological study of each HIV-positive case, with an attempt to identify partners at-risk.
- Hospitalization of seropositive patients in 13 sanatoriums, to offer specialized care, education and follow-up, and to reduce the dissemination of HIV in the Cuban population.
- Development of an effective policy in health education and promotion concerning AIDS.³

Perhaps the most controversial of these programs has been the sanatorial care for HIV-positive patients, which originally obligated seropositive Cubans to live the rest of their lives in these institutions. Organized like small communities, the sanatoriums are made up of apartment complexes and small houses, plus infirmary, offices, and other patient facilities.

In 1993, the sanatorium policy underwent changes. Until then, patients were permitted daily visits but only allowed to return to their families and communities on the weekends. That year, an outpatient program was begun. Under this variant—after an initial six months in the provincial sanatorium for extended diagnosis and treatment recommendations, psychological counseling and education—patients are evaluated by an interdisciplinary team to determine their eligibility for the ambulatory program, based on their “understanding of their condition and commitment to safe sex.” If they are approved and choose to do so, they return to their homes and receive regular care from the local family doctor, in addition to periodic visits to specialists. By the end of 1995, 192 patients, or one fourth of the 780 HIV patients who have not developed full-blown AIDS, were enrolled in this ambulatory care program.⁴

Since 1993, sero-positive persons in Havana and other provinces have been incorporated into other aspects of the National AIDS Program, through the AIDS Prevention Group at the Havana Sanatorium and AIDS prevention work at the National Center for Health Education—whose participation includes educational efforts in the high schools and other institutions, and counseling of newly-diagnosed HIV patients and their families.

The Pedro Kouri Institute for Tropical Medicine is the national reference center for clinical management of HIV-AIDS and provides hospitalization for AIDS cases when necessary and for those whose AIDS-related illness requires more complex services than those offered by sanatorium infirmaries.

Other Cuban institutions directly related to the prevention, education, diagnosis, treatment and research concerning AIDS are the National Reference Laboratory for HIV, the National Immunoassay Center, the National Blood Bank System, and the Center for Genetic Engineering and Biotechnology.

CUBA AIDS STATISTICS		
(FROM JANUARY 1, 1986 TO JANUARY 30, 1988)		
	Number	%
TOTAL HIV POSITIVE	1,200	
Men	847	70.6
Women	353	29.4
Gay or Bisexual (male)	520	43.3 of total 1,200 61.4 of men
WHERE HIV ACQUIRED		
Cuba	982	81.8
The Americas	35	2.9
Africa	167	13.9
Europe	10	0.8
Unknown	6	0.5
Total	1,200	
MODE OF TRANSMISSION		
	Number	%
Heterosexual	520	43.3
Gay or Bisexual	604	50.3
Blood Recipients	9	0.8
Hemophiliacs	2	0.2
Occupational Exposure	1	0.1
Perinatal	4	0.3
Under Study	60	5.0
AIDS CASES		
Total AIDS Cases	440	
Death from AIDS	292	
Deaths from other causes	25	

Source: Epidemiology Department, *Havana AIDS Sanatorium, 1996*

HIV-Positive Cases by Region and Sex*						
Province	Female		Male		Total	
	Cases	Rate	Cases	Rate	Cases	Rate
Pinar del Río	38	10.02	74	18.63	112	14.42
La Habana	10	2.81	33	9.16	43	6.00
City of Havana	134	11.84	379	36.97	513	23.81
Matanzas	9	2.68	24	7.02	33	4.87
Villa Clara	51	11.54	120	26.69	171	19.18
Cienfuegos	15	7.54	24	11.63	39	9.62
Sancti Spiritus	25	10.65	56	23.15	81	17.00
Ciego de Avila	10	4.98	13	6.25	23	5.62
Camaquëy	7	1.70	26	6.19	33	3.97
Las Tunas	7	2.58	19	6.63	26	4.66
Holguin	10	1.83	17	3.02	27	2.43
Granma	12	2.73	19	4.24	31	3.49
Santiago de Cuba	9	1.62	25	4.51	34	3.06
Guantánamo	13	4.71	15	5.39	28	5.05
Isla de la Juventud	3	7.40	3	7.08	6	7.24
National	353	6.15	847	14.88	1,200	10.52

*Annual rate per 1,000,000 inhabitants.

Source: Epidemiology Department, Havana AIDS Sanatorium, 1996

HIV, AIDS and the U.S. Embargo

On the basis of on-site visits to the **Havana** AIDS Sanatorium and the Pedro Kourí Institute of Tropical Medicine, interviews with specialists and patients, bibliographic materials, and statistical data, it can be concluded that prevention, diagnosis, treatment and research involving HIV-AIDS have been negatively impacted by the U.S. embargo: Specifically, by restrictions on exports from U.S. companies and their foreign subsidiaries; limitations on exports of U.S.-composition or patented items; prohibitions on exports that would contribute to Cuba's biotechnology research and industry; end travel restrictions leading to reduced access to scientific information and fewer opportunities for scientific exchange. The families of AIDS patients have also been negatively affected by limitations on travel (see chapter on Family Relations and Humanitarian Emergencies).

During the economic crisis of the nineties, educational efforts in prevent HIV-AIDS have been considerably impaired, a situation exacerbated by the embargo's contribution to the general contraction of the economy. **Manuel** Hernández heads national educational efforts around AIDS at the National Center for Health Education in Havana. As early as 1994, he noted the impact of the economic crunch on what he described as an otherwise prioritized program: "We need more printed materials. We need funds for AIDS hotlines, key for these kids who desperately want their privacy protected. And we need more condoms. This year's purchases will cover only **40%** of our needs. So what good are TV spots if you don't have the condoms to back them up? 6

By 1995, the condom situation he described had not improved: Of the 120-125 million needed for optimum coverage (or 69 million at a minimum), MEDICUBA had funds available for only 16.6 million, with another seven million in donations.⁶ While some of these purchases were made in China, Dr. Miguel **Sosa**, President of the Cuban Society for Family Education, reports that his nongovernmental organization is also aware of emergency purchases of U.S.-origin condoms

made through third parties in India that "cost 200% over the average wholesale price" due to mark-ups plus higher shipping fees.⁷

AIDS testing, diagnosis (involving a battery of confirmatory tests) and protection of the blood supply have been threatened by the U.S. embargo, to the extent that mergers of European suppliers with U.S. companies have suddenly cut off parts and equipment, supplies of reagents, and plastic modules for this lab work, and over the long run promise to make this process significantly more expensive (see chapter on Diagnostic Testing and Protection of the Blood Supply for details). In addition, the Pharmacia-Upjohn merger negatively affected supplies of reagents **such** as Ficoll-400 and Ficoll Paque, both used in laboratory blood work to follow the progress of the disease in patients: In particular, the laboratories faced sudden shortages of this reagent until substitutes could be located, purchased and shipped, making it impossible to carry out Cd4, Cd8, Cd22, Cd33 and Cd25 tests for specific T-lymphocytes. other Pharmacia reagents regularly used in the AIDS program, with similar gaps in availability, included Sephadex Deae, Sepherosa 4B Lentil Lectin and CNBR Sepharosa 4B ACT.⁸

According to Dr. Pérez, key equipment for diagnosis and follow-up has also been impossible to purchase at various times, attributable to embargo restrictions. He sites as an example flow cytometers from the U.S. firm Coulter. This equipment is used to measure T lymphocytes. Dr. Pérez reports that he personally attempted to purchase a unit during a medical convention in the Netherlands in 1992 but was told by the Coulter representative that embargo restrictions prevented his company from selling to Cuba.⁹

Maintaining healthy life styles and the most effective treatment for HIV-positive and AIDS patients is an area that is and has been especially vulnerable to the embargo: first, due to economic limitations aggravated **by** the embargo; and second, resulting from embargo-specific regulations.

In the first category, we find the general conditions of sanatorial care, nutrition, and the requisites of the outpatient program since 1993. At the sanatoriums, patients receive a diet rich in calories (5000 kcal daily) and proteins, free of charge; and it is estimated that each resident costs the health system some \$15,000 a year.¹⁰ The nutritional situation outside the institutions, exacerbated by the embargo (see chapter on Nutrition), is so difficult that it has been cited by residents as one reason they have not opted to rejoin their families through the out-patient program.¹¹

Medications for. HIV/AIDS Patients

Limiting Cuban AIDS patients' access to medicines is the most critical result of the U.S. embargo that we observed. Because of embargo restrictions, Cuba does not have ready access to any FDA-approved medications manufactured by U.S. firms and which have been patented in the last 17 years; nor will they have access to those U.S. products now in development until a decade after they have been introduced on the market. Dr. Pares noted: **We** will have to wait years until these patents are no longer exclusive and other companies in other countries can manufacture these products. The problem is that our patients don't have the time to wait. So, to prolong their lives and provide them a better quality of life, we must purchase U.S. medications through intermediaries at much steeper prices. If it were not for the embargo, with the same budget I could buy larger quantities of the drugs needed by my patients."¹²

It is not surprising that U.S. manufacturers are an important source of AIDS medications for Cuba: This is true everywhere. A recent study reveals that for 22 years (between 1970 and May of 1992) the United States was the world's number one source for new immunology drugs: In fact, over two thirds of the new medications introduced in the field (10.5 of 15) were developed by U.S. companies.* By 1995, the number of U.S.-developed and FDA-approved medications for AIDS and AIDS-related conditions was up to 30.¹⁴

Dr. Peres offered the following examples, corroborated by MEDICUBA and cross-referenced with FDA approval dates, of AIDS medications which are not freely available to Cuba:

- Azithromycin (Zithromax) by Pfizer, FDA approved Nov. 1, 1991): This drug is used against toxoplasmosis (a parasitic infection which can affect muscle tissue, heart, liver, brain and the central nervous system; in AIDS, tumors may form within the brain). Autopsy studies through 1993 showed that 24.3% of Cuban AIDS patients suffered from toxoplasmosis at the time of death.¹⁵
- Fluconazole ("Diflucan" by Pfizer, FDA approved Jan. 29, 1990): This drug has no specific substitute for use in treatment of cryptococcosis (produced by a fungus which attacks the central nervous system and can cause meningitis and death). Autopsies performed through 1993 revealed that 11.7% of Cuban AIDS patients suffered from cryptococcosis at the time of death.¹⁶ In the cases of both these Pfizer medications, Dr. Peres personally approached the Pfizer representative at a Montreal medical meeting and was told that the company could not sell to Cuba because of embargo restrictions. Since then, MEDICUBA has only sporadically been able to purchase fluconazole, because prices quoted by intermediaries have been out of range; and never have they been able to afford azithromycin. Both have come into Cuba in small amounts in donations, according to Dr. Pérez.¹⁷
- Ganciclovir (Cytovene) by Syntex and Roche Bioscience; FDA approved June 23, 1989): This drug is used against cytomegalovirus, which can produce suprarenal insufficiency, and coreoretinitis, which destroys the retina and leaves scar tissue, causing loss of vision. Autopsy studies through 1993 showed 39.6% of AIDS patients suffered from CMV disseminated at the time of their deaths.¹⁸ This medication is currently unavailable to Cuba because of high price quotations through intermediaries. Small amounts have come through donation.¹⁹
- Antiretroviral products, including zidovudine (AZT) ("Retrovir," Burroughs-Wellcome; FDA approved March 19, 1987); didanosine (ddI) (Videx) Bristol Myers Squibb; FDA approved Oct. 9, 1991); and zalcitabine (ddC) (Hivid) Roche; FDA approved June 19, 1992). When these products first appeared on the market, they were not freely available to Cuban importers due to embargo restrictions. Since then, AZT has been purchased at what Dr. Peres describes as well above market prices, and ddC and ddI have only been received through donations.²⁶

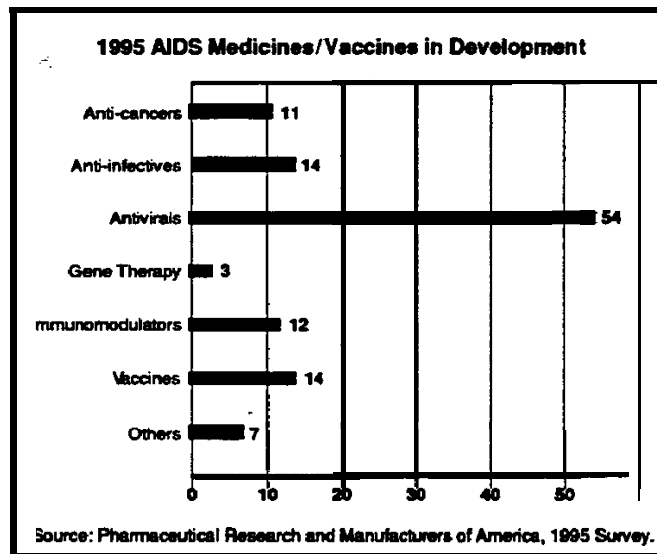
The case of AZT is illustrative: Approved by the FDA in early 1987, it took several months for Cuban importers to locate suppliers willing to sell even small amounts to Cuba, at a cost which Dr. Pérez calls 'astronomical.' He states that the embargo was directly responsible for at least six-month delays in AZT treatment for a total of 176 HIV patients in Cuba.²¹ (At the time, AZT was the only approved medication, heralded for slowing the progress of the virus.) Federico Ramos, 42, has been a patient at the Havana AIDS sanatorium for nearly a decade and was one of those waiting for the drug's arrival: "I remember the months of agony: knowing there was a drug that could help us, but that we couldn't get because of the embargo."²² Ramos says HIV and AIDS patients have seen gaps in AZT supplies over the years, and they are aware that the drug is purchased through wholesalers in Europe.

AZT studies in Cuba have shown that AZT diminishes the time before onset of AIDS and also lengthens survival time after an AIDS-defining diagnosis.²³

The outlook is even more bleak for medications in development in the United States, to which Cuban patients will not have ready access for a period of 17 years following patent. The *1995 Survey on AIDS medications in the pipeline*, published by the Pharmaceutical Research and Manufacturers of America, indicates that 110 medicines have begun the FDA approval process-

only three of them by manufacturers outside the United States, and thus outside embargo restrictions (two of the three are jointly patented with U.S. firms).

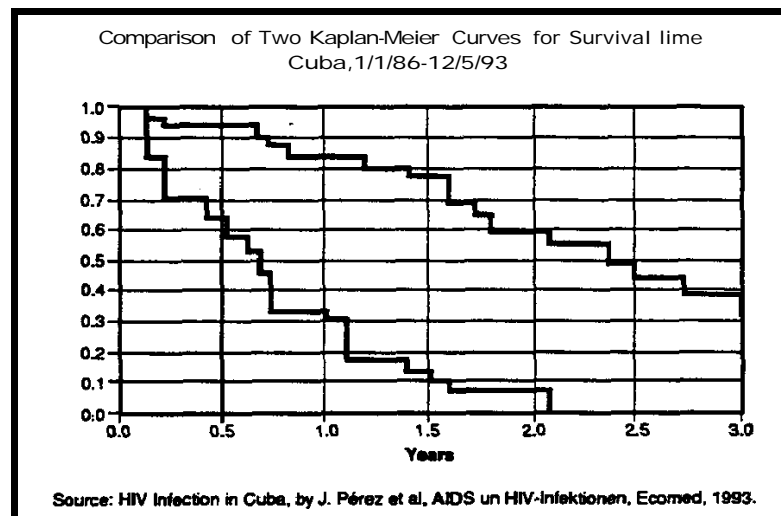
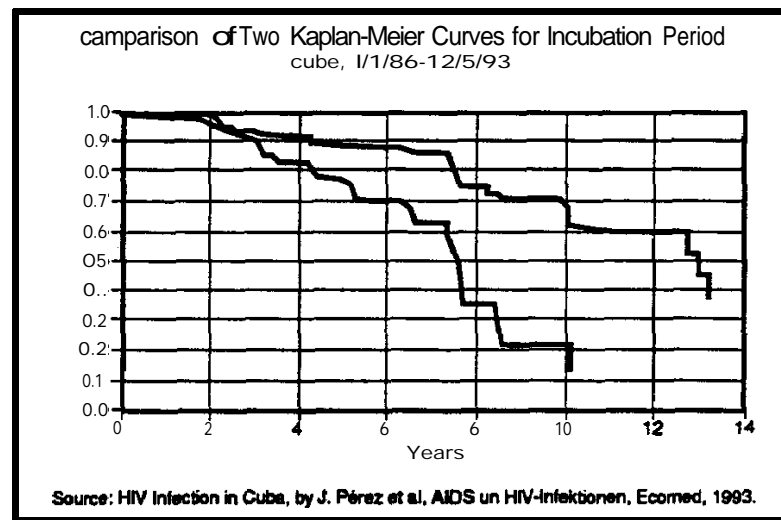
Dr. Peres says that Cuban specialists are particularly interested in the protease inhibitors, a new class of AIDS drugs which are being developed by at least four U.S. pharmaceutical corporations, part of the \$15 billion U.S. companies will spend on AIDS research this year.



Source: *Pharmaceutical Research and Manufacturers of America, 1995 Survey*

As disturbing as Cuban *patients'* inaccessibility to U.S.-manufactured drugs is the embargo's provision aimed at the Cuban pharmaceutical industry's capabilities for domestically producing key AIDS-fighting medications such as interferons. (See chapter on Vaccines and Biotechnology Research, Development and Production). Dr. Pérez notes that studies carried out in Cuba indicate the beneficial effects of interferon, both in prolonging the incubation period for seropositive patients and the survival time for AIDS patients-

The following Kaplan-Meier curves illustrate the results: Approximately half of the HIV patients treated with interferon showed a greater delay-of 5.5 to 6 additional years- in the onset of AIDS; and interferon showed similar effects on survival time.



Source: HIV Infection in Cuba, by J. Pérez et al AIDS un HIV-Infektionen. Ecomed, 1993.)

Approximately 70% of all Cuban AIDS patients receive interferons as part of their treatment.²⁴ Production has already been negatively effected by the U.S. embargo's export prohibitions as a result of the Pharmacia-Upjohn merger, which impacted virtually all biotechnology production facilities in Cuba. This is also true for the Human Transfer Factor, a Cuban biotech product also used against HIV/AIDS.

At the same time, however, scientists estimate that research on the AIDS vaccine being developed in Cuba-one of 18 worldwide, 14 of which are U.S. products would be further ahead today if it were not for the embargo. Nevertheless, the vaccine is due to begin trials in human beings in September, 1996.

Cuban scientists contend that research and development as well as exploration of treatment alternatives have been seriously impacted by the U.S. embargo, which has reduced their access to scientific information and professional exchange. Examples cited include:

For five consecutive years (from 1989 to 1993), the U.S. State Department gave no answer on visa applications from Dr. José Joanes, proposed by the World Health Organization (WHO) to attend an epidemiology course on AIDS at the Centers for Disease Control in Atlanta, in conjunction with Emory University.

U.S. scientists were unable to attend a series of scientific workshops sponsored by the Pedro Kourí Institute for Tropical Medicine and the National AIDS Prevention and Control Program in Havana, due to tightened travel restrictions issued under the embargo in August, 1994. The courses included 'Infection by HIV,' "Treatment and Diagnosis of Parasitic Diseases" and others.²⁵

NOTES

- 1 Documentation Center; National AIDS Program, Havana AIDS Sanatorium, January 30, 1996.
- 2 Interview with Dr. Jorge Pérez, Vice Director of the Pedro Kourí Institute for Tropical Medicine, and Director of the Havana AIDS Sanatorium, Nov. 3, 1995; and "HIV Infection in Cuba," by Dr. Jorge Pérez et al, *AIDS an HIV-Infektionen, Diagnostik, Klinik, Behandlung*, Ecomed, 1988, p. 2.
- 3 "National AIDS Prevention and Control Program," Ministry of Public Health, Division of Epidemiology, 1992.
- 4 Interview with Dr. J. Pérez. Nov. 3, 1995; and "AIDS, Sexuality and the New Man (sic), by Gail Reed. in Cuba update, May, 1994, pp. 21-22.
- 5 Manuel Hernández interviewed by Gail Reed for "AIDS, Sexuality and the New Man (sic)," *Cuba Update, May, 1994, p. 22.*
- 6 Interview with Orlando Romero, Director, MEDICUBA, June 21, 1996, and Dr. Miguel Sosa, President, Cuban Society for Family Education, SOCUDEF, Nov. 27, 1995.
- 7 Interview with Dr. Miguel Sosa, Nov. 27, 1995.
- 8 Interviews with Dr. J. Pérez, Nov. 3, 1995 and May 21, 1996.
- 9 Interview with Dr. J. Pérez Nov. 3, 1995. A similar experience was also reported by Rolando Díaz of MEDICUBA, who stated to the authors on November 23, 1995 that his firm has not been able to purchase these units directly from Coulter. The only exception in the purchase of U.S.-manufactured flow cytometers has been registered on February 25, 1994, when Ortho Diagnostics Systems Ltd., a British subsidiary of Johnson and Johnson, received a U.S. Treasury license to sell one modular unit to the Cuban importer Servicex. with the provision that the Pan American Health Organization, (International) Red Cross or "other appropriate internationally recognized multilateral relief or non-profit organization" furnish a confirming affidavit that "the exported item is for use for the purposes for which it was intended and only for the use and benefit of the Cuban people, mailed to Treasury no later than June 30, 1994."
- 10 "AIDS, Public Health, and Human Rights in Cuba," by Nancy Scheper-Hughes, *The Lancet*, Vol. 342, October 16, 1993, p. 966.
- 11 Interviews with AIDS patients, May 23, 1996, Havana AIDS Sanatorium; Gail Reed's interviews with five AIDS patients at the sanatorium for "AIDS, Sexuality and the New Man(sic)"; and "AIDS, Public Health, and Human Rights in Cuba," by Nancy Scheper-Hughes, *The Lancet* Vol. 342, October 16, 1993, p. 967.
- 12 Interview with Dr. Jorge Pérez February 2, 1996.
- 13 Therapeutic Class *Profiles by Area of Origin of 265 'Major Global Drugs',* in Price Regulation and Pharmaceutical Research: The Limits of Co-Existence*, by Heinz Redwood, Oldwicks Press, Suffolk, GB, 1993, p. 77. The author cites as sources for this information Pharmaprojects 1992, Marshall Sittig 1988, and the author's historical database.
- 14 "Approved Medicines for AIDS and Related Conditions." in *1995 Survey: AIDS Research Promising--110 Medicines in Development*, by the Pharmaceutical Research and Manufacturers of America, received December 19, 1995.
- 15 "HIV Infection in Cuba," J. Pérez et al, 1993, p. 6.
- 16 "HIV Infection in Cuba," J. Pérez et al, p. 6.
- 17 Interview with Nancy Blanco, Sub Director for Medications of MEDICUBA, Nov. 24, 1995; Interviews with Dr. J. Pérez Nov. 3, 1995 and May 21, 1996; and *Statistical Report, Offices of Drug Evaluation*, U.S. Dept. of Health and Human Services, Public Health Service, Food and Drug Administration, Washington, D.C., 1993, Appendix 3, NMEs Approved During 1950-1993.
- 18 "HIV Infection in Cuba;" J. Pérez et al, p. 6.
- 19 Blanco, *Statistical Report*, and J. Pérez interviews.
- 20 Ibid.
- 21 Interview with Dr. J. Pérez May 21, 1996.
- 22 Interview with AIDS patient Federico Ramos, Havana AIDS Sanatorium, May 23, 1996.
- 23 "HIV Infection in Cuba," by J. Pérez et al, p. 7.

24 Interview with Dr. J. Pérez May 21, 1996.

25 Interview with Dr. J. Pérez Nov. 3, 1995. As we have noted in other sections of this study, while the prerogative of granting visas to Cuban researchers and physicians belongs to the U.S. State Department, and does not fall within embargo legislation, we have found that visa denials are consistent with the climate concerning Cuba created by the embargo policy.

introduction

Renal failure occurs when the kidneys cannot maintain normal biochemical balance. In acute renal failure, the nephrons are injured, often reversibly; in the chronic form, the nephrons are progressively destroyed. Chronic renal failure must be thought of as a total body disease, with clinical and laboratory findings relating to nearly every organ system and, if not reversed, leading to end-stage renal failure and death. End-stage renal disease (ESRD) is diagnosed when renal function is no longer sufficient to sustain life. Thus, early recognition and management of kidney failure are critical.

Clinical findings in patients with chronic renal failure include progressive anemia in almost all cases, hypertension and other cardiovascular manifestations, central nervous system disturbances, skeletal affectations, and chronic biochemical **and** mineral imbalances. Children also demonstrate serious growth retardation, and both pediatric and adult patients tend to be more susceptible to infections and more apt to handle them poorly because of their generally debilitated **State.**

Adults and particularly children with renal insufficiency have special dietary needs including increased calorie and protein intake and certain vitamin and mineral requirements. In addition, since children have diminished growth rates and progressive retardation of bone development, therapy with growth hormones is often indicated.

The principal treatment for end-stage renal disease (ESRD) is kidney transplant. Thorough evaluation and preparation for dialysis and transplantation should be begun before the threat of end-stage renal failure becomes immediate. Dialysis is effective for sustaining patients awaiting kidney transplant or for whom transplant is not possible.

The indications for dialysis are determined clinically and on the basis of laboratory findings. Early dialysis can simplify management and reduce fatalities from kidney failure. Methods include peritoneal dialysis, hemodialysis, and modifications of hemodialysis such as hemoperfusion. The choice of peritoneal dialysis or hemodialysis depends on availability as well as therapeutic indicators. Peritoneal dialysis is generally preferred in children because of the relative ease of vascular access, performance, and the generally better results.

The development of continuous ambulatory peritoneal dialysis (CAPD) and continuous cycling peritoneal dialysis (CCPD) have become the methods of choice for children awaiting transplant, since they are both well-tolerated and effective. There are clear advantages to the use of ambulatory dialysis for adults as well.³

Profile of Kidney Disease and Treatment in Cuba

The incidence of chronic renal failure in Cuba (including end-stage renal disease) is 255 per million inhabitants. Each year, approximately 80 per million inhabitants (or 840 persons) are added to the group of patients with end-stage renal disease, and this rate is rising. These patients must receive dialysis to survive, while they await possible transplant.²

In Cuba, 160200 kidney transplants are performed each year with a survival rate of approximately 55%. Estimates are that 400-450 transplants are actually needed, with the principal obstacle identified as organ availability.³

Drs. Raúl Herrera and Santiago Valdés Martín, directors of the Institute of Nephrology and the National Reference Center for Pediatric Nephrology, argue that Cuba's economic crisis of the last

five years, aggravated by the tightening of the U.S. embargo during the same period, has meant serious problems for the treatment of patients suffering from kidney disorders, and especially those requiring dialysis or transplant. They contend that because of the complex organization and considerable finances needed to support universal, comprehensive care in this field, nephrology is particularly vulnerable to economic constraints.

In January 1995, 694 patients with end-stage renal disease were enrolled in the dialysis-transplant program, receiving regular dialysis. However, not all were receiving the optimum number of dialysis sessions indicated for adequate treatment, due to the shortage of dialysis units in the country. During 1995, 447 patients died of renal failure and another 847 were newly incorporated into the dialysis program with the limitations previously mentioned. Thus, by the end of the year, 1,034 patients with end-stage renal disease were eligible for regular dialysis: 712 of these were enrolled in the dialysis program as of Dec. 31 1995, though again, not all receiving the optimum number of treatments. Enrollment figures fluctuate over the months due to death, transplants, drops-outs from the program, and, in a minority of cases, recuperation of renal function.⁴

Specialists at the Nephrology Institute explain that at this point the incorporation of new patients into the program means that all patients necessarily receive fewer hours of dialysis because equipment is limited. Dr. Herrera stated the problem: 'We simply do not have sufficient functioning dialysis equipment to guarantee the **required frequency** of treatment for all patients who reach end-stage renal disease.'⁵

With purchases and donations in early 1996, the country had 124 functioning dialysis units by May. Specialists calculate that 300 are needed to adequately attend to all patients requiring this life-prolonging treatment during the next year.⁶ Dr. Charles Magrans, a specialist from the National Nephrology Institute, explained that each dialysis machine currently accommodates approximately five patients, with the equipment functioning day and night. A number of these units are donated and cannot necessarily be adapted to suit each patient's needs, since factors such as state of health and weight determine which equipment and which type of dialysis can be used.

On the basis of our visits to the dialysis service of the Nephrology Institute and interviews with specialists and medical importers, we concur that Cuba's economic crisis has indeed severely affected the availability and options of treatment for nephrology patients requiring dialysis. Thus, for example, while peritoneal dialysis is preferred for diabetics, the elderly and young children, only intermittent peritoneal dialysis, considered rudimentary by specialists, is minimally available in Cuba today. This is true, essentially because the peritoneal methods are significantly more costly than hemodialysis and rely more on expensive disposable accessories.⁷

In addition, our interviews and observations in both adult and pediatric care units convince us the U.S. embargo has compounded such difficulties, which at times have become life-threatening.

Dialysis Treatment and the U.S. Embargo

The problems in procuring dialysis equipment offer an eloquent example of the range of embargo-related obstacles which impact patient treatment-and indeed survival-in one of the most sensitive areas of Cuban health care. It should be noted that mortality rates for end-stage renal disease have been rising in Cuba in the last few years.

First, the embargo effectively closes to Cuba its nearest, most technologically developed and often most competitively priced market for dialysis equipment, accessories and maintenance. Historically, Cuban importers have had negative results in dealing with major U.S. suppliers in the field. Baxter Healthcare Corporation, a U.S. company, is a leader in dialysis equipment and

accessories sales in Latin America and has cited compliance with the embargo for its consistent policy to refuse to sell to Cuba or allow its affiliates abroad to do so. Michele Lockwood of Baxter's International Sales Department told the authors that the company does not sell to Cuba and does not wish to pursue licensing procedures- she stated that it is official company policy not to sell to any country which the U.S. embargoes.⁸

Drake-Whillock, a U.S. based firm, has also been approached by Cuban importers through intermediaries abroad. However, MEDICUBA's Rolando Díaz reports that the company "has not even been able to send equipment to Cuba for testing because of the embargo."⁹

Vitalmex Interamericana, S.A., a Mexican distributor for the U.S. dialysis manufacturer Cobe, notified MEDICUBA importers in July, 1995, that it could not furnish prices requested for 20 Cobe dialysis units, asserting that since Vitalmex is "associated with" a U.S. firm, it was "not authorized to sell equipment or supplies to your -try." Cobe representative Ellen Cohig told our researchers that "we have a policy and that is that we comply with U.S. law. So, we cannot sell to Cuba." ¹⁰ And, according to Rolando Díaz of MEDICUBA importers, other U.S. firms have also refused to quote prices to the Cuban company. (See chapter on Medical Exports to Cuba.)

Such reluctance even extended to bids requested for these units by the Pan American Health Organization (PAHO) in 1995. In September, PAHO approached three U.S. manufacturers, among others, on Cuba's behalf, asking for price quotations on 18 renal dialysis units. A report furnished to the authors by PAHO indicates that two of the companies contacted-Cobe and Guiball (of Sterling, VA)-did not initially **want** to quote for Cuba because they could not ship there." The same report notes that they eventually sent quotes, only after they were informed that PAHO would be responsible for obtaining US authorizations and arranging for the shipping..¹¹

However, these quotes were received well after the October 5 deadline PAHO established-provoking a first followup inquiry from Cuba-d even too late to be included among the bids faxed to PAHO-Havana on November 10. With year-end deadlines closing in, and the urgent need for this equipment, MEDICUBA made its purchase in late October from a European supplier, which Rolando Díaz said "offered excellent prices and a safer source of accessories and spare parts, as well, under the circumstances."¹² This situation is still problematic, however, since quality considerations narrow the range of possible suppliers, according to Díaz of MEDICUBA, who shares the opinion of experts such as Juan Carlos Velásquez, Director of the National Electromedicine Center in Havana, and of leading Cuban nephrologists, including Drs. Herrera and Valdés Martín that in this field, United States' manufacturers have the longest track record of dependability. ¹³

Refurbished dialysis equipment, where the United States is not only the logical source but also the hemispheric leader in sales, is a more reasonably priced alternative heavily used by other Caribbean and Latin American countries, but closed to Cuba due to the embargo. Juan Carlos Velasquez explains that such buys can cut prices by as much as two thirds to three fourths and consequently multiply the number of units procured by three or even four. However, in addition to problems of licensing, he explains that on-site inspection of the used equipment is crucial to sound purchases, and Cuban importers and technical experts are not freely permitted to travel to the United States for this or any other purpose. (At least two visas have been denied to Electromedicine engineers in the last five years.)¹⁴

Even when third parties donate U.S.-manufactured equipment to Cuba, its upkeep is made impossible by the embargo. Such was the case of 59 Cobe dialysis units donated to Cuba's nephrology services by a European organization. According to Juan Carlos Velasquez, only 29 of these machines could be placed in working order, because the necessary parts could not be obtained to repair the remaining 30.¹⁵ (It should be noted that these donations are not the only Cobe units in

the country, and others have been placed out of commission for the same reason. And spare parts are also unavailable for a number *of* Drake-Whillock units received as donations.)

Dr. Magrans estimates that the "loss" of the 30 donated machines mentioned above means approximately 150 patients will **not** receive complete dialysis in 1996. Extrapolating further: Since Cuban importers had no access to the nearby U.S. market for refurbished equipment, where they could have purchased at least 54 units for the cost of the 18 new ones they bought in Europe, another 180 patients are losing out on full dialysis. Thus, a total of 339 Cuban **patients have access only to partial dialysis treatment at best, as a direct result of the embargo.**¹⁶ **These are people suffering from terminal renal failure, whose only real hope for survival is a kidney transplant-but less-than-optimum dialysis keeps them in such a weakened state that they may never be eligible for surgery.** In short, if it were not for the U.S. embargo, they would have a better chance for life.

More problems occur with the systems, parts and accessories needed for an effective dialysis program. For example, water used in dialysis should be treated by a process known as reverse osmosis. Pediatric nephrologist Dr. Noemí Levy explains that in Cuba this cannot be done for lack of appropriate technology. Instead, an obsolete process is used to treat Cuba's naturally hard water by softening it, which does not produce the same desired results as reverse osmosis, considered fundamental in nephrology today.¹⁷ Dr. Valdés Martín asserts that Cuba has not been able to invest in this technology primarily for economic reasons, including the fact that this already expensive equipment would cost significantly more with U.S. firms out of the bidding.¹⁸ Without these water treatment plants in place, patients do not receive optimum dialysis.¹⁹

Cuba faces other problems-both of a general economic nature and embargo-specific-when it comes to maintaining sufficient stocks of dialysis accessories, including carbon cartridges, blood collection bags and specialized catheters. In this field, the issue of limited access to quality products once again arises, since Cuban specialists consider U.S. manufacturers the best in many of these lines.

According to MEDICUBA, U.S. producers "virtually monopolize" the market of quality items for renal use. They pose as examples visceral catheters made by the Cordis Corporation, for which MEDICUBA receives "rather high" price quotations through third parties.²⁰

Blood collection bags provide another example: Once again, Baster Healthcare Corporation is one of the few competitive producers of this product and an undisputed market leader in this hemisphere. Dr. Jose Manuel Bayesteros He-, Director of the National Hematology Institute, referred to an incident in 1994, when an urgent need arose for these blood collection bags. He explained that the Institute is responsible for guaranteeing supplies for the whole country, and due to this emergency, Mexican wholesalers were asked to attempt a purchase from Baster, which they did. However, according to Dr. Bayesteros, they were told it was **company** policy not to sell any product destined for Cuba. (In fact, when our team visited the Central Havana Pediatric Hospital, we saw a Baster bag. The bag carried on it a warning that it was not for use in Cuba.) Since the U.S. market represents the closest and fastest route in such emergencies, a closed door can present a serious hazard to health.²¹

This example illustrates the time/expense dilemma that Cuban importers often face when they are forced to turn to faraway markets: Not only are these more costly, but unless still more funds are put into air freight, distance can also delay getting products to patients. Cuba's latest purchases of blood collection bags have been made in Japan, from companies such as JMS, which quoted a price of \$2.30 for each double bag and \$3.05 for triples, including air freight.²²

Several companies in Europe and the Americas have also refused to sell equipment and accessories for dialysis to Cuba, citing the embargo, according to documentation provided by MEDICUBA. These include Hospital of Germany, which said in a March 15, 1994, memo that it

could not supply dialysis and plasmapheresis equipment or supplies for this reason. MEDICUBA reports Medix of Argentina was 'denied a license' for sale of parts for units to clean dialysis equipment, and Miramed of Italy reportedly refused sale to Cuba on the grounds that it did not have permission from the U.S. government to export disposable dialysis accessories to Cuba.²³

Kidney Transplants and the Embargo

It is our finding that the embargo has negatively impacted the capabilities of nephrology specialists in Cuba to carry out necessary and successful kidney transplants. Before any transplant, a series of tests are required to determine compatibility between the donated organ and the receiving patient. Dr. Hector Rojas, head of the Nephrology Institute's Immunology Department, stated during our on-site visit that since the economic crisis his unit is experiencing shortages of antiserum used for these tests, known as HLA (histocompatibility lymphocyte antigen) Typage. "Sometimes we cannot do the typage, which is standard procedure throughout the rest of the world, and essential for a good match," he explained.

Quality of products in this delicate field can make the difference to a transplant patient, contends Dr. Rojas. "Good testing translates into a better match and a longer life," he states. The specialists in his department concur that the best reagents and supplies they have seen for such testing are produced in the USA, by companies such as by One-Lambda, which manufactures Lympho-Kwik Kits. Dr. Rojas described what he considers the advantages of these Kits: "For example, if the Lympho-Kwik Kit has 70 specificities, the European one only carries 20 to 30. In addition, for an HLA-DR Typage, we must extract 20 ml of blood using the obsolete method (nylon fiber). The Kit only requires 2 or 3 mls of blood. For an already weak patient with anemia, typical of our kidney patients, this difference is important, not to mention the superior speed and exactitude provided by the Kit." ²⁴

In conversations with Mehnas Shamsai and Nadim Elawar of One Lambda's International Sales Department, they confirmed that their company does not sell to Cuba: "We are a manufacturer and we sell only through distributors and we do not have a Cuban distributor," said Elawar.²⁵

The sudden cutoff of reagents and other chemicals bought from Phamacia of Sweden until its merger with Upjohn last year is another potentially critical problem for the Institute's Immunology Department. For example, Ficoll-400 and Ficoll Paque are fundamental for isolating lymphocytes, a necessary part of the procedures for organ compatibility testing. With the merger of Pharmacia and the U.S. company, specialists say they are facing a gap of weeks to months in supplies of these vital reagents, while substitutes are sought, tested, contracted and delivered.²⁶

Further shortages or frank absences of important elements for managing kidney patients awaiting transplant include difficulties stemming from the economic crisis exacerbated by embargo-related price increases paid for absolutely essential purchases as described above. Thus, key medications like eritropoyetin, Vitamin D3 and cyclosporine immunosuppressors, plus special supplementary nutrients commonly used in nephrology services, are not available in adequate quantities, contributing to the less than ideal health status of these patients, as they prepare for transplant. As we have seen, physicians emphasize that deterioration of patients' health threatens their ability to undergo the complicated surgery and their prognosis for survival once operated on.

Eritropoyetin alone-which reduces the need for transfusions and fights anemia in hemodialysis- costs the Cuban healthcare system \$5,000-\$6,000 per patient per year.²⁷ Curiously, the Cuban Institute for Genetic Engineering and Biotechnology (CIGB) is expected to begin producing

recombinant eritropoyetin this year-the industry which is specially targeted by the Cuban Democracy Act for strictest enforcement of embargo export prohibitions.²⁶

Cyclosporines, the first drugs known to prevent organ rejection, are considerably more costly for Cuba to import and are currently only guaranteed to pediatric patients and adults who have shown highly reactive immunology responses. Once again, the Cuban biotech industry could provide a solution to this dilemma, with a domestically produced monoclonal antibody known as "ior t-3." The antibody has shown promising results in preventing organ rejection and has been used so far in Cuba, Uruguay, Chile, Argentina, Russia and India.²⁹ However, a final twist is offered by the embargo once more: Production of "ior t-3" depends on the Biopilot unit at the Center for Molecular Immunology, sold to Cuba by Pharmacia of Sweden before its 1995 merger with Upjohn. One Biopilot (at the Beterá Laboratories) has already been crippled by lack of parts and the monoclonal antibodies could be the next-to go.

In general, Cuba does not have ready access to any U.S. medications for renal disease patented since 1979, and kidney patients alive today will most likely never receive the benefits of U.S. drugs in the research pipeline. The leadership of U.S. pharmaceutical firms in the field of immunology, for one, is well established: From 1970 to 1992, U.S. manufacturers developed 10.5 of 15 new medications acting on the immune system.³⁶

Pediatric Nephrology

In addition to dialysis services in many pediatric hospitals in Cuba, substantial investments were made in the 1980s to establish and equip three major pediatric nephrology centers, distributed geographically across the Island in Havana, Santa Clara and Santiago de Cuba. Dr. Valdés Martin, Director of the National Reference Center for Pediatric Nephrology; Dr. Frank Tobay, Director of the Central Havana Pediatric Hospital where this center is located; and other specialists we interviewed all spoke to the fact that pediatric nephrology is a medical specialty requiring expensive, sophisticated medical technology and supplies, as well as specific laboratory equipment and reagents.³¹

"This has always been a costly service in general," observed Dr. Valdés Martin. "In addition, great advances have been made in the field, particularly during the last decade or so, and especially in **pediatric** nephrology, with improved dialysis methods for small children. **We've** had trouble keeping **abreast of these developments**, directly due to the U.S. blockade and due to economic constraints, also very much associated with the blockade. Our problems not only have to do with the acquisition of technology and other products, but also with our inability to access information on new developments in the field. The most important source of medical information is the U.S., where we have the greatest **difficulty** both in obtaining information and sharing experiences with our colleagues." ³²

In Cuba, the incidence of chronic renal disease is seven per million inhabitants under eighteen years of age. Thus, every year approximately 20 to 30 youngsters are treated for end-stage renal disease with dialysis and transplant when possible. About 30% of Cuban children with chronic renal failure die. In 1993, 360 per 1006 patients in treatment died due to kidney failure. There are currently 21 pediatric patients receiving dialysis, their cases **prioritized** within the national nephrology system.³³

In Cuba, standard hemodialysis is the primary type of dialysis available for children. However, it is not possible to use this method in children weighing less than 10-12 kilograms which, because of the growth retardation common in these patients, may include children up to approximately five years old. Cuba depends on the necessarily limited **use** of manual **intermittent** peritoneal dialysis in the smaller children. After about six months, however, this method must be discontinued for

medical reasons (peritonitis) and the children continued with hemodialysis **if their size and general condition permit**. The problem here relates principally to the difficulty in accessing small blood vessels in the littlest children for hemodialysis.³⁴

Although the Cuban specialists are well aware of the superiority of continuous cycling peritoneal dialysis (CCPD) for small children and in fact for all pediatric patients with renal failure (it can keep these youngsters alive for years instead of months and is certainly less traumatic) they cannot provide it and encounter serious obstacles to bringing their nephrology services up to date in this respect.

CCPD systems are extremely costly, requiring repeated purchases of products, accessories and expensive disposable materials. Dr. Valdés Martín estimates that the cost in most countries can reach as much as \$25,000 to \$30,000 annually per patient (for dialysis alone, not including other basic costs of management).³⁵ (Note: One hemodialysis machine, which can accommodate approximately five patients, costs Cuba between \$12,000 and \$25,000 on the average.)

Dr. Digna Espinosa, one of the Cuban pediatric nephrologists we spoke with, referred to the additional disadvantages suffered by their patients due not only to the unavailability of CCPD systems but also continuous ambulatory peritoneal dialysis (CAPD), which permits at-home dialysis overnight, thus greatly reducing disruption to the child's normal activities, allowing the child to attend school, remain socially integrated, etc. The methods available to Cuban children can be 10-12 hour ordeals three times a week, requiring hospitalization.³⁶

Again, the issue of Baxter's dominance of the Latin American market was raised. Top-of-the-line pediatric dialysis technology is produced by Baster at competitive prices, according to the Cuban specialists, and Baxter is certainly one of the firms in which they have greatest confidence. However, the prospect of paying higher prices to far-away firms only makes the CCPD and CAPD more elusive for pediatric nephrology services in Cuba.

According to Drs. Valdés Martín, Espinosa and Noemi Levy, head of Havana's pediatric dialysis service, such modern pediatric dialysis technology would permit longer-term maintenance of small children with renal insufficiency, prolong their lives and reduce complications, increase the possibility for successful transplants, and significantly enhance quality of life for these children.³⁷

In the final analysis, there is little hope for the very small Cuban patient with end-stage renal disease and, in fact, the small child with kidney failure who quickly progresses to a chronic condition and then end-stage disease may not survive, for lack of modern peritoneal dialysis technology. In Cuba, some five to six of these children under the age of five are diagnosed annually with chronic renal insufficiency.

NOTES

¹Richard E. Behrman, M.D. and **Robert M. Kliegman**, eds., *Nelson Essentials of Pediatrics*, W.B. Saunders Company, Philadelphia, 1994; C.Henry **Kempe**, et al., eds., *Current Pediatric Diagnosis and Treatment*, Appleton & Lange, 1987.

²Analisis de la Morbimortalidad por Enfermedad Renal", Analisis *Epidemiológico*. Ministry of Public Health, Havana, 1995; and interview with Dr. Raul Herrera, Director, Nephrology Institute, Havana, October 19, 1995.

³Interview with Dr. R. Herrera, Oct. 19, 1995; and Maria del Pilar Vilá Director of the Statistics Department, Nephrology Institute, May 5, 1996.

⁴Interview with Dr. R. Herrera, Oct. 19, 1995, and interviews with Dr. Charles Magrans, specialist at the Nephrology Institute, and M. Vilá Director of its Statistics Department, May 5, 1996. Dialysis figures do not include intensive care dialysis, transplant patients, acute cases, nor other sporadic needs for emergency dialysis treatment.

⁵Interview with Dr. R. Herrera, October 20, 1995.

⁶Interview with Dr. C. Magrans, May 5, 1996.; and "Analisis de la Morbimortalidad por Enfermedad Renal", Epidemiology Department, Ministry of Public Health, March, 1996.

⁷Interview with Dr. C. Magrans, May 3, 1996.

⁸Interview with Michele Lockwood of Baxter Healthcare Corp., conducted by Wallie Mason, DATES.

⁹Interview with Rolando Díaz Vice Director of MEDICUBA for Medical Equipment, Nov. 23, 1995.

¹⁰Interview with Ellen Cohig, Cobe International Department, Lakewood, Colorado, May 15, 1996.

¹¹The third U.S. company-An-Med of Ft. Lauderdale, FL-was "going to ship out of their (overseas) office to avoid the problem (Ed. note: presumably after receiving U.S. authorization to sell.)," according to PAHO. This report was attached to a letter from PAHO Deputy Director A. D. Brandling-Bennett, M.D., to Mr. Richard L. Wittenberg, President of the American Association for World Health, dated February 20, 1996.

¹²Interview with Rolando Díaz Sub-Director of MEDICUBA for Medical Equipment, Havana, September 6, 1995.

¹³Interviews with: Alexis Cadeño, Vice-Director of the National Center for Electromedicine, Havana, December 8, 1995; Dr. R. Herrera, Havana, Oct. 19, 1995; and Dr. Santiago Valdés Martin, Director of the National Pediatric Nephrology Program, December 20, 1995.

¹⁴Interview with Juan Carlos Velasquez., Director of the National Center for Electromedicine, Havana, January 4, 1996; and Ministry of Public Health list of U.S. visas denied to public health personnel.

¹⁵Interview with J.C. Velázquez, Jan. 4, 1996.

¹⁶Interviews with Dr. C. Magrans. Oct. 19, 1995 and May 3, 1996.

¹⁷Interview with Dr. Noemí Levy, Chief of Dialysis Services, Havana Pediatric Nephrology Center, Central Havana Pediatric Hospital, November 1, 1995.

¹⁸Interview with Dr. S. Valdés Martin, Dec. 29, 1995.

¹⁹In 1996, several units of reverse osmosis were received as donations.

²⁰Interview with Rolando Díaz, Havana, September 6, 1995. He reported that MEDICUBA had been quoted a price of \$36.00 per package of No. 7F, 100 cm. renal catheters, with 2-sided hole in the month of September.

²¹Interview with Dr. Jose Manuel Bayesteros, Herrera. Oct. 26, 1995.

²²Interview with Rolando Díaz MEDICUBA, Sep. 6, 1995.

²³MEDICUBA reports, September 15, 1995.

²⁴Interview with Dr. Hector Rojas, Immunology Department, Nephrology Institute, Havana, November 24, 1995.

²⁵Interview with Mehnas Shamsai, One Lambda, Inc., Feb. 26, 1996 and Nadim Elawar, April 4, 1996.

²⁶Interview with Dr. H. Rojas. Nov. 24, 1995.

²⁷Interviews with Dr. R. Herrera, Oct. 20, 1995 and Dr. S. Valdés Martin, Dec. 20, 1995.

²⁸Comments to the authors by Dr. Manuel Limonta, CIGB Director, June 12, 1996.

²⁹Subrayan eficacia de anticuerpo monoclonal cubano”, by Lidia Senaris, *Prensa Latina News Service*, April 26, 1995, quoting from Dr. Dario Moreno Vega of the Nephrology Institute’s Transplant Program.

³⁰Therapeutic Class Profiles by Area of Origin of 265 Major Global Drugs”. Price Regulation and *Pharmaceutical Research*, by Heinz Redwood, Oldwicks Press, Suffolk, England, 1993, p. 77.

³¹Interviews with specialists at Central Havana Pediatric Hospital, December 20, 1995.

³²Interview with Dr. S. Valdés Martin, Dec. 20, 1995.

³³Interviews with Dr. S. Valdés Martin and Dr. Digna Espinosa, National Reference Center for Pediatric Nephrology, Central Havana Pediatric Hospital, May 8, 1995.

³⁴Ibid.

³⁵Interview with Dr. S. Valdés Martin, Havana, May 8, 1995.

³⁶Interview with Dr. Digna Espinosa, Havana, May 8, 1996.

³⁷Interviews with Dr. S. Valdés Martin, Dr. D. Espinosa and Dr. N. Levy, November 1, 1995, December 20, 1995, and May 8, 1996.

introduction

Diabetes mellitus is a common disorder affecting approximately 200,000 in Cuba (18.9 per 1,000 inhabitants). Diabetes is classified as Type I or Insulin-dependent Diabetes Mellitus (IDDM), requiring insulin for survival; or type II Non-Insulin-dependent Diabetes Mellitus (NIDDM), the more prevalent form, which generally should not require insulin. Some 50,000 diabetics in Cuba, or about one quarter, are insulin-dependent.

The complications of diabetes account for a substantial percentage of all new cases of end-stage renal failure and about half of all lower extremity amputations. In addition, diabetes is a leading cause of blindness. Other conditions treated within this specialty include malfunctioning of the thyroid and adrenal glands, hypoglycemia, growth retardation, and hormonal difficulties affecting human reproduction.

The Endocrinology Institute, located in Havana, monitors these and related problems for the national health care system. The Institute functions as a World Health Organization (WHO) collaborative center for human reproduction and international center for comprehensive attention to diabetics. As most national centers of this kind in Cuba, the Institute also dispenses hospital and outpatient services.

On the basis of an on-site visit to the Institute, and interviews with specialists there and at MEDICUBA importers, the National Pharmaceutical Supply Company (ENSUFARMA), the Hermanos Ameijeiras Hospital, Baterá Laboratories, and the "Pando Ferrer" Ophthalmological Hospital, the team found that, especially during the last few years, the U.S. embargo has had a particularly damaging impact on the diagnosis and treatment of diseases of the endocrine system.

The U.S. Embargo and Diabetes

Early diagnosis of diabetes, once an active nationwide program in Cuba, has been hampered by an unstable supply of reagents for laboratory testing, a situation which results from the general economic crisis complicated by the embargo and from embargo-specific obstacles. Since 1990, laboratories at the Endocrinology Institute have had to reduce testing for all conditions: In 1995, 96,177 analyses were performed, down from 149,000 in 1991.¹

The 1992, denial of U.S. government licenses to Sweden's Fluka Chemical (regular suppliers) and the more recent merger of Sweden's Pharmacia with the U.S. firm Upjohn have led to serious problems for diagnostic and follow-up lab work at the Institute, due to gaps in restocking key reagents. According to Dr. Oscar Díaz, Deputy Director for Research, his laboratories were relying on such Pharmacia products as Ficoll-400, Ficoll Paque and Sephadex Deae, but these reagents have not been readily available after the August, 1995 merger and subsequent ban on sales to Cuba.² As we have noted elsewhere, not only was regular purchase of these items immediately affected, but over the longer run the procurement of the same reagents is becoming more expensive through third party trading companies: For Sephadex DEAE alone, the price of 500g shot up \$250 after Pharmacia shut down its Havana sales.³ In addition, key Pharmacia equipment used in the Institute's research—such as peristaltic pumps, fraction collectors and spectrophotometers—was now without spare parts.

Maintaining the health of diabetics largely depends on careful adherence to special dietary requirements. However, here too the embargo has aggravated the general economic situation, which in turn has led to dangerous imbalances for these patients. The recommended diet is between 25 and 39% lipid (fat) with a polyunsaturated to saturated fat ratio of at least 1:1 and with a low cholesterol content; 50% to 69% carbohydrate; and 19% to 29% protein. However, Dr. Díaz notes

that in 1963, the consumption levels for fats and proteins were actually too low, while those of carbohydrates reached an unhealthy 80%.⁴ (See chapter on the Food Supply and **Nutrition** for a more extensive discussion of the embargo's impact on diet.) It was during the same period that, a slight increase was registered in the mortality rates from diabetic coma as well as hypoglycemia, a situation which specialists also blamed on the unstable supplies of dextrose, due to production difficulties in the pharmaceutical industry—these also related in part to the U.S. embargo. (See chapter on the Pharmaceutical industry, for difficulties with equipment and cutoffs in supplies of such items as seals for sera, dextrose and other liquids.)

Most dramatically, when the CDA became law in 1962, Cuba was faced with the sudden and urgent need to find another supplier for over 50,000 vials of insulin a month, spending considerably more in the **Process**. Until that time, MEDICUBA—unable to buy insulin directly from U.S. manufacturers—purchased it from the Eli Lilly subsidiary in Canada. As we have seen, while the CDA ostensibly provided for licensing of direct and subsidiary sales of medications to Cuba, it has effectively cut such exports, as pharmaceutical firms are discouraged from seeking licenses. And in fact, Keven Krambeer of Lilly's International Corporate Affairs department in the USA specifically stated his (mistaken) understanding that further restrictions imposed by the CDA forbid even subsidiary sales to Cuba.⁵ And MEDICUBA reports that Lilly subsidiaries in other countries, notably Spain have also refused to sell insulin to the Cuban importers based on the same reasoning.⁶ Dr. Díaz of the Institute notes: "Lilly could provide us with insulin at more competitive prices, and at significantly less freight costs." ⁷

This embargo-inflicted inflation is particularly serious given Cuba's current hard currency constraints. Thus, although insulin is on the Absolute Priority (P-1) list of medications, achieving a constant supply has been touch-and-go; according to ENSUFAHMA. At one point, there was enough insulin in the country for just one month.⁸ Currently, MEDICUBA purchases insulin from Novo in Denmark. The annual price tag to cover national needs is \$3,785,800 (600,000 vials of 100U Intermediate Insulin (Lente) and 460,000 vials of 40U Regular Insulin), with air freight running at over 885,000, or enough for two months' supply of SIMPLE. ⁹ At this rate, it is not possible to purchase all that is needed.

Donations of insulin and disposable syringes (ironically, from Lilly itself) have helped to close the gap at critical moments, but Dr. Díaz reports that assimilating these has created still other problems: "We have been trying to use the 100U doses of Intermediate Insulin, which are more convenient for patients who are instructed to inject themselves. However, the donations often come in 20,40 or 60U doses, thus complicating the process for the patients." ¹⁰

Home blood glucose monitoring, employing a variety of different techniques, is the method of choice for monitoring diabetic control. Optimum diabetes management relies on home measurements at various times throughout the day. This kind of consistent testing is near impossible for diabetics to maintain in Cuba, due to economic factors, exacerbated by the embargo. Not only do they not have access, to the test strips convenient for testing glucose, but alternative methods require constant availability of reagents for home use, electricity, and cooking gas, none of which can be fully counted on. So diabetics turn to labs at their local polyclinics or nearby hospitals, a much more cumbersome ordeal, and where they are also certain to encounter problems with electricity and reagents, making consistent monitoring of their condition all the more difficult to achieve.

Lack of adequate management can introduce complications, and even put the diabetic's life at risk. Most chronic complications fall into three categories: 1) microvascular disease, which is diabetes-specific, and involves small blood vessels, particularly of the eye and kidney; 2) macrovascular disease, involving the large blood vessels, and clinically expressed as coronary, cerebral and/or peripheral vascular disease; 3) diabetic neuropathy, which can affect motor, sensory, cranial, and autonomic nerves. Diabetics are also particularly susceptible to foot and leg

ulcers, as well as other skin lesions. A substantial proportion of these patients go on to develop one or more of these complications.

Cuba has a critical absence of laser equipment for photocoagulation, which is used to treat diabetic and other retinopathies, thus keeping these patients from going blind. Dr. Díaz states that about one quarter of Cuban diabetics suffer from some degree of retinopathy, although not all of them require laser treatment. However, for those that do, laser therapy is literally a sight saver. A number of these units were purchased in the eighties in Germany and have required expensive parts from time to time, with purchasing capabilities further limited in the nineties, as we have seen. Thus, a number of these units lie idle, one of them in the Endocrinology Institute. A new German one was purchased for the "Pando Ferrer" Ophthalmological Hospital in 1995 but arrived in unusable condition: They were still awaiting a replacement as of June 25, 1996.¹¹ This is a case where the possibility of purchases directly from the USA could have saved both time and money, and the need to ship through a third country eliminated.

If patients with severe diabetic retinopathies do not receive laser therapy, at a specific **point** in the progressive condition some may become candidates for surgery. If these patients are not treated, they will go blind. The "Pando Ferrer" Ophthalmological Hospital reports that thousands of their patients could have made use of this equipment, and several hundred have lost their sight over the **last** two years as a result of its absence, including patients suffering from diabetic retinopathies.
12

The U.S. Embargo and Other Hormonal Conditions

Thyroid gland dysfunction causes some of the most common endocrine disorders, including hyperthyroidism (thyrotoxicosis) due to excess thyroid hormone, hypothyroidism (myxedema) which is a hormone deficiency condition, and autoimmune thyroid disease (for example, Graves disease). A variety of tests must be employed in the management of thyroid disease to determine thyroid status, and these must be interpreted in an integrated fashion in conjunction with the patient's clinical presentation.

Hypothyroidism is 'a condition highly vulnerable to economic consequences, and in this case to the vicissitudes imposed by the U.S. embargo. Timely deliveries to patients of some five million tablets of hormones (levothyroxine sodium with liothyronine sodium) produced at the Reynaldo Gutierrez Pharmaceutical Plant in Havana has been placed in serious jeopardy by the U.S. embargo. Specifically, as noted in the chapter on the Pharmaceutical Industry, because Cuban importers have been unable to replace parts to repair broken Pharmacia equipment (High Performance Liquid Chromatography unit, or HPLC), the working units are over-utilized. This causes delays in products reaching the pharmacies. Without HPLC quality control approval, the tablets cannot be released for sale. According to Haydee Cela, chief of quality control at the plant, she has had to wait for as much as one month for samples to be tested by the working HPLC at another center. The result at year's end is not only backlogged production but supplies that are lagging significantly further behind demand, a problem already experienced because of the general economic difficulties.¹³

At the Endocrinology Institute, Dr. Diaz explained that when patients cannot take this hormone as prescribed, 'they fall into depression, somnolence and in the most serious of cases, can fall into thyroid coma.'
14

During the recent years of economic hardship, hormones such as somatotropin for growth retardation therapy-used in some kinds of dwarfism and for treating children and adolescents suffering from renal failure- have been difficult to guarantee for the 700-800 Cuban patients who need them. This is true not only because of the elevated cost of such a drug, in which Cuban

importers once invested some one million dollars annually. Somatropin was last purchased in 1994 with contracts filled in the first quarter of 1995.¹⁵ Efforts to buy this medication have been further complicated in the short run by the need to identify a new supplier at competitive prices, since earlier purchases were from Pharmacia, which, as has been noted, left Havana after the Upjohn merger in 1995.

For a discussion of the obstacles posed by the U.S. embargo for availability of oral contraceptives and for treatment of diabetic women during pregnancy, see the chapter on Women's Health.

NOTES

- 1¹ Interview with Dr. Oscar Diaz Diaz, Deputy Director for Research, Endocrinology Institute, October 19, 1995.
- 2² Visits to the laboratories. and interview with Dr. O. Diaz, Jan. 22, 1996.
- 3³ Documentation from MEDICUBA, provided to the authors June 20, 1996.
- 4⁴ Interview with Dr. O. Díaz, Oct. 19, 1995.
- 5⁵ Interview with Keven Krambeer, International Corporate Affairs for Latin America, Eli Lilly, March 28, 1996.
- 6⁶ Interview with Diana Guzman. Medications Department, MRDICURA, Sept. 7, 1995.
- 7⁷ Approached by our researchers, Eli Lilly of the USA would not give wholesale pricing information for direct sales to comparable Caribbean markets. Report from Stephen Kimmerling, Nov. 13, 1995.
- 8⁸ Interview with Leonel Zúñiga Director, ENSUFARMA, Feb. 7, 1996.
- 9⁹ Information provided by MEDICUBA, which notes that the price of Intermediate Insulin (Lente) 100U is \$4.83 per vial and of Regular Insulin 40U is 1.93 per vial; air freight runs \$5.65 per kg., for approximately 15,080 kgs. While MEDICURA imports at these prices, diabetics are charged \$1.25 pesos for the 100U Intermediate insulin, or about six cents.
- 10¹⁰ Interview with Dr. O. Díaz, Oct. 19, 1995.
- 11¹¹ Interview with Dr. Maritza Miquel, Deputy Director of the "Pando Ferrer" Ophthalmological Hospital, June 25, 1996.
- 12¹² Interview with Dr. M. Miquel, June 25, 1996.
- 13¹³ Interview with Haydee Cela, Deputy Director for Quality Control, Reynaldo Gutierrez Pharmaceutical Plant, July 4, 1996.
- 14¹⁴ Interview with Dr. O. Diaz, Oct. 19, 1996.
- 15¹⁵ Interview with L. Zúñiga, Feb. 7, 1996.

Ophthalmology care in Cuba is centered at the Pando Ferrer Hospital in Havana and in ophthalmology departments at major hospitals throughout Cuba. Visits to these health care facilities and interviews with physicians, pharmaceutical production experts and executives of the National Blind Association have led to the conclusion that the economic crisis and fortified U.S. embargo during the last few years have put serious strain on this medical specialty, optometry services, and the ability to provide adequate assistance to the blind and visually impaired.

Diagnosis of eye disorders has been hindered by the inability to repair key equipment, in some cases due to the general hard currency shortage and in others more specifically to the embargo. Ophthalmologic ultrasound units are used to diagnose internal pathologies of the eye, when the external area is opaque—in cases where an intra-ocular tumor is suspected; or in accidents where there has been substantial bleeding in the eye, and it is necessary to determine the presence of non-metallic fragments. In 1995, Cuban importers purchased ten Model System IV ultrasound units manufactured by Cooper Vision of Bedford, CA. The equipment was bought through intermediaries in a Latin American country, and engineers at the National Electromedicine Center note that there was “no comparable equipment available at the time.”¹

These ultrasounds were distributed to the Pando Ferrer, Salvador Allende, Oncology, and Hermanos Ameijeiras Hospitals in Havana; the Sotomayor Lora General Hospital in Santiago de Cuba Province; and one hospital each in Sta Clara and Holguin Provinces. Over the years, repairs have required purchase of various components. Yet, not even intermediaries approached were willing to sell these parts to Cuba, citing the U.S. embargo, according to the National Electromedicine Center.²

As a consequence, during the last three-years, none of these units has been in operation. At the Oncology and Radiology Institute, specialists report that they have not been able to make use of this key equipment for at least 1200 patients, and thousands more throughout Cuba have also gone without benefit of this diagnostic tool.² Dr. Maritza Miquel, Vice Director of the Pando Ferrer Hospital reported that, despite the fact that her facility had sent out word to other hospitals not to refer cases for ultrasound testing, they continued to receive patients who expected such service.

In April, 1996, the Pando Ferrer Hospital finally received a new ultrasound unit, made by another manufacturer and donated by a group of ophthalmologists. Since this equipment was also of U.S.-origin, engineers from a third country had to come to Cuba to train technicians on its use and management.⁴ Meanwhile, all Cooper Vision units—including the one at the ophthalmologic hospital—lie idle, since export of parts at a fraction of the cost of new ultrasound equipment is stalled by virtue of the embargo, subject to the embargo “chill factor”.

A similar history concerns attempts by MEDICUBA to obtain quotations for purchase of a simple autorefractometer (used to measure vision) from Carl Zeiss Jena GmbH (Germany) in 1995. Zeiss Jena answered inquiries by fax, dated June 2, 1995, explaining that “according to the embargo, an autorefractometer cannot be ordered for MEDICUBA.”

The embargo has also affected acquisition of diagnostic and surgical equipment for ophthalmological services by adding to the price, shipping distance, and time, since these cannot be purchased or repaired in the United States. This is the case of laser photocoagulators, required in treatment of a number of retinopathies, including diabetic retinopathy (see chapter on Endocrinology). If not diagnosed and treated within a specific time period—first with laser therapy, and at another point with surgery—a number of these conditions can lead to blindness.

The argon laser photocoagulators used in Cuba were bought in East Germany during the eighties and after several years suffered breakdowns of various kinds. These include the units at the Pando Ferrer Hospital and the Endocrinology Institute. This equipment, according to Cuban importers, is quite expensive, especially in the European market, and thus particularly difficult to

replace in Cuba's current economic situation—at least in the numbers required. Finally, in 1995, one new unit was acquired for the Pando Ferrer Hospital from a European supplier. However, it arrived in Cuba in June, 1996, in poor condition, and over a month later a substitute had not arrived.⁵ The only other laser available at the hospital is not *of* the same technology and is painful for patients. Even with the new photocoagulator, the hospital will not be able to assimilate all the patients that require it.

As a result of the disrepair of the laser photocoagulators, delays in purchase and delivery of a new one, and related problems of surgical supplies, specialists say it is too late for many of these retinopathy patients, and over 200 people will have suffered a substantial loss of eyesight and even blindness.⁶

Intra-ocular lenses have to be brought all the way from Sweden at higher prices, since U.S. manufacturers are not in the bidding. This is the crystalline lens implanted during cataract surgery. For six months in 1995-96, some 1,000 patients were on the waiting list for these lenses. Only 800 lenses could be purchased at the time, and the waiting list is growing again.⁷

Because of general economic limitations—which have affected all aspects of surgery, from disposable supplies to air conditioning and anesthesias—operations carried out at the Pando Ferrer Hospital in 1995 totaled 7,939 as compared to 15,725 in 1989, or just about half.⁸

Medications are in serious shortage for ophthalmologic patients, some as a direct result of the embargo's negative impact on domestic pharmaceutical production. Eye drops produced in Cuba include atropine and homatropine for dilating the pupil; kanamycin and chloramphenicol antibiotics; and timolol and pilocarpine for use in glaucoma. Amado González Landa, President of the National Blind Association, made particular reference to timolol, of which he said there is "never enough."⁹ The Julio Trigo Pharmaceutical Plant in Havana also turns out prednisone and other steroids, intended for direct injection into the eye.

The prices of these medications when imported are inflated by the embargo, as we have demonstrated in the chapter on Medical Exports. Their domestic production is subject to obstacles posed by the U.S. policy: less efficient and reliable quality control (by virtue of the inability to repair a computerized particle counter); delays in releasing these products to pharmacies (due to backups in testing samples, caused by inability to repair U.S.-origin equipment), and other embargo-related factors described in the chapter on the Pharmaceutical Industry.

The nefarious impact of the *embargo* on prevention, diagnosis and treatment of optic neuropathy patients during the 1993-94 epidemic is documented in the chapter on National Health Emergencies. In addition to the incidence of the embargo in the reduced nutritional levels that were a major factor in the national outbreak, Cubans paid an additional 134% for diagnostic reagents from Europe and, for a single shipment of vitamins from Europe, paid nearly \$200,000 more than it would have paid for these items if imported from the United States.

Finally, international cooperation and humanitarian donations have also felt the brunt of the U.S. embargo in this field. Amado González of the National Blind Association notes that donations of medicines, Braille paper and typewriters, canes, and other aids for his organization have been held up in European ports—in Norway, for example—waiting for Cuban ships to pick up the cargo, after no other vessel could be found to *bring* it to Cuba, due to the CDA shipping restrictions imposed by Washington in 1932 (see chapter on Medical Exports).¹⁰ González relates that it has also been very difficult for this organization of some 26,666 members to purchase Braille typewriters, since the patent belongs to a U.S. firm.¹¹

In the case of Project Orbis, the flying ophthalmological surgery unit which has provided service to some 60 countries, a U.S. license to travel to Cuba was denied to the Orbis physicians in February

of 1991. The purpose of the trip was to carry out joint operations with Cuban physicians on board and at the Pando Ferrer Hospital. It took significant lobbying efforts to finally get a license for the trip four months later. Some 70 patients waited for surgery as a result, for procedures which included cornea transplants, etc.¹²

NOTES

¹ Interview with Alexis Cedeño, Vice Director of the National Electromedicine Center, Havana, Dec. 8,1995.

² Ibid. and interview with Dr. Maritza Miquel, Vice Director, Pando Ferrer Ophthalmological Hospital, June 25,1996.

³ Interviews at the Oncology and Radiology Institute, Oct. 16,1995.

⁴ Interview with Dr. M. Miguel, June 25,1996.

⁵ Interview with Dr. M. Miquel, June 25,1996.

⁶ Ibid.

⁷ Ibid.

⁸ Ibid.

⁹ Interview with Amado González Landa. Resident of the National Blind Association, Havana, Jan. 10,1996.

¹⁰ Ibid.

¹¹ Ibid.

¹² "Eye to Eye with Orbis" by Meic Haines in Cuba Update, the Center for Cuban Studies, New York, Nov. 1991, p. 10.

The U.S. embargo **stipulates** that no medical equipment or medications authorized for sale or donation to Cuba be "re-exported." These restrictions essentially target the growing Cuban "health tourism" industry, which attracts foreign patients who pay for medical care in Cuba and thus constitute a source of hard currency. The U.S. Commerce Department has requested exporters to indicate if items are intended for Cuban or foreign patients.¹

This embargo provision has a direct impact on health care delivery to the Cuban population, since all net earnings from health tourism, and the treatment of foreigners in general, are plowed back into the Public Health system, constituting an important source of hard currency for much-needed purchases of medical equipment, medicines and supplies. Thus, this regulation penalizes Cuban patients for the country's medical assistance to foreign patients.

Also penalized by the provision are the foreign patients themselves who seek treatment in Cuba. These include those who come to Cuba specifically for this purpose, the so-called health tourists, as well as foreigners working in Cuba on a temporary basis who rely on Cuban health services, such as members of the diplomatic and international NGO communities, journalists, and business executives.

Servimed, the Cuban health tourism agency, reported that 3,540 patients from 70 countries had received treatment through Servimed in 1995, some 59 of these from the United States. **Servimed's** Sonia Baéz told us that they receive eight to ten inquiries a month from people in the United States about possibilities for medical attention in Cuba. Olga Ceballos Alvarez of the Public Relations and Promotion Department reported that the majority of foreign patients receive treatment for retinitis pigmentosa at the Camilo Cienfuegos Hospital, for vitiligo and psoriasis at the Center for Placental Histotherapy, and for neurological disorders such as Parkinson's disease at the International Center for Neurological Restoration. She points out that these figures do not represent all the foreigners coming to Cuba for medical treatment, since many do not use **Servimed** but make **direct** arrangements with specialized institutes, hospitals and health programs.²

Direct arrangements of this kind are frequently made with the Camilo Cienfuegos Hospital, which is the International Retinitis Pigmentosa Center located in Havana. Retinitis pigmentosa is a debilitating, progressive, hereditary disease which affects approximately one in every 5,000 people, reducing night vision first and eventually leading to blindness. The actual cause is, in fact, unknown, although specialists suggest that as many as one in 80 people could have a genetic predisposition to the disorder. Successful treatment for retinitis pigmentosa is credited to Cuban scientist and ophthalmologist Dr. Orfilio Peláez, who has won international recognition for his work in the field, including the "Vision" Prize from the Retinitis Pigmentosa International Foundation in Los Angeles in 1994.

Since 1987, over 7,999 patients have received Dr. Peláez treatment. These include 3,917 foreign patients from 38 countries and some 5,939 Cubans. In over 90% of cases, the therapy has halted progress of the disease and has led to recovered vision in approximately 58%. All of the Cuban patients and about 100 foreign patients have been treated free of charge.³

The retinitis program in Cuba is an example of a medical option available to non-Cuban citizens as well as to Cubans; it is directly impacted by the U.S. embargo, which poses obstacles to purchases of U.S. medical products for treatment and has stepped up economic pressure on the health care delivery system as a whole. In some cases, such as the Prostins, exclusive to Upjohn, their "for hospital purchase only" designation effectively keeps out of Cuban hospitals this medication of choice in this case for inducing labor. Such unavailability affects all pregnant women on the island, Cuban and foreign alike.

There are two special categories of foreign patients treated in Cuba: The first are those seen free of charge, the majority of whom are children. For example, the Cuban Program for Medical Attention to the Chernobyl Victims has provided diagnostic services and treatment for 13,414 children and 422 adults from regions of the Ukraine, Byelorussia and Russia affected by radioactive contamination from the April 1936 nuclear accident. Dr. Raciél Llanes, coordinator of the program, says 3% of the children who come to the Center at Tarara, to the east of the City of Havana, suffer from oncological and hematological diseases, such as malignant tumors and leukemia; 17% have serious kidney, cardiovascular or neurological problems. These patients require the services of specialized institutes and hospitals in Havana. Another 60% receive outpatient care by specialists at the center; and the remaining 29% come mainly for a complete medical check up, with no obvious pathologies.⁴

Since the Chernobyl Victims program began in 1990, over 70 surgical interventions, 18 complex heart operations, six bone marrow transplants and two kidney transplants have been performed in Cuban hospitals, in addition to other specialized procedures, including surgical and chemotherapy treatment for cancer and intensive dermatological therapies. Valentina Mijailenko, a Russian mother whose son was seriously affected by the accident, said: Many of us have come to Cuba as a last resort, after we have been told that there is little hope for our children. Yet, in this country, the doctors have been amazing...and our children get better."⁵

On the basis of experience gained with the Chernobyl cases, Cuba has treated a number of radiation victims, such as children from a Brazilian catastrophe: Discarded radioactive medical equipment was illegally abandoned in a garbage dump, where youngsters played. Over 100 children were exposed to the Cesium-137 radioactive waste, and several died before the rest were brought to Cuba.

The William Soler Pediatric Cardiocenter has operated on 240 foreign children, free of charge, until two years ago. In 1994 and 1995 approximately 12 and no more than 15 children have been charged for their medical treatment. The 10 Chernobyl children operated on in this center also received free care.⁵ At the National Hematology Institute in Havana, a number of foreign patients have been treated, principally children from Latin America and Africa. Since 1990, 295 Chernobyl children and 50 children from the Brazilian disaster have been treated at the Institute.⁷

Thus the embargo's impact on health care delivery also affects children from other countries seeking treatment in Cuba-treatment they often could not afford elsewhere. By increasing the cost of these programs, the embargo essentially "punishes" Cuba for making a humanitarian gesture.

A second special category of foreign patients are U.S. patients, whom the embargo prevents from travel to Cuba to receive medical treatment. Thus, U.S. citizens afflicted with certain conditions cannot take advantage of Cuban medical advances. As a result, 78 people (four of them children) have had to come to Cuba in defiance of U.S. law in order to receive treatment for retinitis pigmentosa, a treatment **without** which they would have gone blind. In this case, the U.S. embargo on Cuba forced people from the United States to choose between U.S. law and their health.

In addition, U.S. citizens who are in Cuba under U.S. license are restricted to spending a maximum of \$100 a day in the country (hotel, food, **etc**). Should **such** an individual fall sick and require medical treatment, including hospitalization, for example, they would be unable to stay under the dollar limit and would, therefore, become liable for penalties that apply.

When two-year-old Becky Kirsch came to Cuba with her parents on a legal tip in 1993, she became seriously ill and was hospitalized for two weeks. The hospital, a health tourism facility, treated Becky and lodged her parents during the full two weeks. Because payment for these services could have caused this family legal complications and fines upon return to the U.S., the Cuban hospital

waived the bill. The following year, this family attempted to organize urgently needed medical donations for a Cuban child with cancer, describing endless obstacles to their effort⁸

NOTES

1 Communication from Iris Medical to the U.S. Department of Commerce, January 11, 1994.

2 Interview with Olga Ceballos Alvarez, Public Relations and Promotion Department, **Servimed**, Cubanacán S.A., Havana, February 22, 1996,

3 interview with specialists from the Retinitis Center, Camilo Cienfuegos Hospital, Havana, June 21, 1996.

4 'Niños de Chernobyl en la Isla de la Última Esperanza' by Lidia Senaris, Prensa Latina, Havana, February 3, 1995.

5 Ibid.

6 Interview with Dr. Herminia Palenzuela, William Soler Pediatric Cardiocenter, July 12, 1996.

7 Interview with Dr. José Manuel Bayesteros Santovenia, Director of the Hematology Institute, Havana, **October 26, 1995**.

8 Correspondence to Dr. Michele Frank from David and Mia Kirsch, January 12, 1995.

CHAPTER SEVEN

CONTINUING MEDICAL EDUCATION & EXCHANGE OF SCIENTIFIC INFORMATION

Lack of Access to the U.S. Medical & Scientific Community

Cuba's universal health care delivery system and its concentration in various fields of research has grown over the last 15 years, involving over 57,900 physicians by 1995, as compared to a mere 3,000 in the early 1960s. In addition Cuba now has some 9,000 dentists. In the 1995-96 academic year, 15,600 medical students were enrolled throughout the island. Residency training is currently offered in 53 specialties, and scientific societies are active in 50 fields of medicine.

Access to the United States medical and scientific community for Cuban health professionals is vital for two reasons. First, the United States generates more medical and scientific information than any other country in the world, largely derived from its status as world leader in medical education and research endeavors.

The vast majority of the world's clinical and research publications are published in the United States: Many of the most important professional journals, magazines, textbooks, and significant medical and scientific reports are now available on-line. In addition, all the major indices of recent articles, whether in print or as computer data bases, come out of the United States, along with bibliographic information from virtually all international sources. Access to this body of literature is considered fundamental for the continuing education and updating of researchers, physicians and other health care professionals in Cuba and elsewhere.

Moreover, Cuban medical education was modeled on the U.S. medical education model and to this day maintains close theoretical and scientific identification with this heritage. Dr. Juan José Ceballos, Director of the National Center for Continuing Medical Education (CENAPEM), referred to this phenomenon and its relevance: 'Our school of medicine is similar to the U.S. medical education system because it is an excellent one. This was the case before 1959, and it is the case now. Although we have worked to develop a different kind of health care delivery model, we never veered away from U.S. precepts for the teaching of medical sciences. Our residency system is the same, for example; U.S. textbooks are commonly used in our classes. We borrowed some experience in fields such as epidemiology and prevention from the former socialist countries, but we never looked to them for our fundamental approach.'¹

During visits to the Victoria de Girón Medical School campus in Havana, research and library facilities, specialized medical institutes, and teaching hospitals, the team found a dearth of scientific information, textbooks and on-line services. And references to this paucity of literature constituted a universal lament by professionals in over one hundred of our interviews.

The team found that the U.S. embargo has constituted a serious and sometimes impenetrable barrier for the free flow of ideas and scientific information to Cuban medical researchers and clinicians and for exchange with their colleagues in the United States. Undoubtedly, the economic limitations of the last five years, coupled with the stiffer restrictions posed by the CDA of 1992, have made the embargo a still more formidable obstacle to acquiring knowledge of U.S. and worldwide medical advances whose ultimate beneficiaries would be Cuban patients as well as medical professionals.

The U.S. Embargo Restricts the Flow of Medical Information

Until 1988, the U.S. embargo banned export to Cuba of books, journals and other informational materials originating in the United States. For the first time that year, an amendment to the Foreign Trade Act (introduced by Rep. Howard Berman, Democrat of California) exempted such materials, enabling U.S. entities or persons to export them to Cuba or Cuban nationals and to receive payment free of blocking. The amendment also authorized importation into the United

States of Cuban informational materials, expanding on the 1974 liberalization of this permission.⁹ Under the original language, electronic materials (such as news wire feeds and computer information) could not be exported.

In 1994, Congress adopted the **Free** Trade in Ideas Act, removing these remaining limitations for Cuba and all other countries. The legislation stipulates that the President can no longer regulate or prohibit "The importation from any country, or the exportation to any country, whether commercial or otherwise, regardless of format or medium of transmission, of any information or informational materials, *including but not limited* to publications, films, posters, phonograph records, photographs, microfilms, microfiche, tapes, compact discs, CD ROMs, artworks and news wire feeds." Thus, U.S. persons as a matter of statutory right may send any information or informational materials to Cuba or Cuban nationals, including technical information if it is not restricted for national security (as distinct from foreign policy) reasons.³

Despite that legislation, the free flow of information and scientific exchange are limited by embargo regulations which, in practical terms, restrict the application of the Free Trade in Ideas Act. These include the following restrictions:

- The elimination of all banking relations between the United States and Cuba, making it impossible for Cuban nationals to "put their check in the mail" for subscriptions and other literature. The embargo also prohibits third-country banks from maintaining United States dollar-denominated accounts for Cuba or Cuban nationals (from which payments might be made to U.S. publishers, etc.) and the use of U.S. currency or U.S. dollar-denominated accounts in transactions between third-country nationals and Cuban nationals⁴
- The virtual ban on export to Cuba of computer hardware, limiting options to support software programs, Internet connections and on-line services.
- The elimination of direct mail service between Cuba and the United States and, until 1994, serious obstacles to telephone and telex communications. Thus, all journals and other literature must pass through at least one other country en route from the United States to Cuba, with consequent delays and higher postage.
- Shipping restrictions: No maritime shipping is permitted between the United States and Cuba under the embargo, with the exception of specially licensed humanitarian goods. In addition, until 1975, foreign aid was withheld to any country which permitted its ships to dock in Cuba, and a blacklist was kept of such vessels. This provision was eliminated by the State Department in 1975, and Congress ended the blacklist in 1977. However, barriers to shipping went up once more with the Cuban Democracy of 1992, which forbids access to U.S. ports for a period of six months to any ship which has docked in Cuba. Thus, bulk shipments of textbooks, for example, most often must come to Cuba by more expensive air routes.
- Restrictions that constitute a travel ban for all but a handful of U.S. citizens wishing to go to Cuba. These center on prohibiting U.S. nationals from paying for travel-related services in Cuba, including meals, hotels and airline tickets on Cuban carriers. The ban was lifted during the Carter presidency, from 1977 to 1982, but reinstated during the Reagan years. One exception to the restrictions has always been U.S. visitors to Cuba who are fully hosted by the Cuban government: in that case, however, they are prevented by law from spending any money in Cuba.
- Limitations on research travel to Cuba. From time to time during the embargo's tenure, a small loophole in the travel ban has been opened for certain U.S. professional researchers, provided they fall within U.S. government guidelines (which themselves have undergone periodic changes) and provided they do not spend more than \$100 a day on the island. In any

case, these persons are not automatically allowed to travel to Cuba but must apply for an individual license from the U.S. Treasury Department.

- In 1994, under general amendments issued to "limit the ability of the Cuban government to accumulate foreign exchange," the eligibility criteria for such licenses were further narrowed, allowing persons to apply "only if they are full-time professionals who travel to do research in their professional areas, their research is specifically related to Cuba and will constitute a full work schedule 'in Cuba, and there is a substantial likelihood of public dissemination of the product of their research.'" ⁵
- Limitations on travel to Cuba for medical conferences. Until October, 1995, U.S. professionals wishing to travel to Cuba to attend conferences in their field might only be eligible to do so if the agenda of the meeting was directly related to Cuban **developments in the** field. (In other words, they might apply for a travel license to attend a meeting of the Cuban Pediatrics Society, but not for one of the International Society of Pediatrics held in Cuba.) In practical terms, this meant that parallel "national" programs had to be designed for U.S. participants in international medical conferences and conventions in Cuba. In 1995, Resident Clinton amended this restriction, allowing a professional to apply for a travel license to attend an international meeting in Cuba, provided that the person had an established interest in the subject of the meeting and that it was "organized by an international institution or association that regularly sponsors meetings or conferences in other countries." ⁶ As with all licensed travel, there is a \$100-a-day limit on expenditures.
- Prohibition on providing a service in Cuba. Interpretation of this regulation has historically meant a ban on providing lectures on professional topics for Cuban colleagues, even if the U.S. person was in Cuba by virtue of a U.S. Treasury Department license. In October of 1995, President Clinton opened the envelope just slightly by authorizing consideration of licenses on a case-by-case basis for individuals to teach at Cuban academic institutions, if the applicant is "regularly employed in a teaching capacity at a college or university located in the United States and provided the activities are related to a college or university academic program." In other words, a license might be issued for a medical school professor, regularly employed as such in the United States, to offer a series of lectures at a Cuban medical school. But lectures by a medical researcher or clinician not employed in a teaching capacity in the United States, or lectures at a hospital or research center, would not be permitted.⁷
- Restrictions on Cuban professionals' travel to the United States. Aside from the difficulties of obtaining a U.S. visa, the embargo prohibits Cuban nationals from making payments to any U.S. entity once in the United States, or from receiving or spending a travel stipend provided by a sponsoring U.S. organization. This has created a cumbersome and even embarrassing situation for Cuban professionals and their hosts, and an often prohibitively costly one for the latter, since the only type of travel permitted is fully hosted by a U.S. institution, in which no transfer of money to the Cuban national takes place. In October of 1995, President Clinton amended these provisions to make eligible for licensing "transactions related to the sponsorship of a Cuban scholar to teach or engage in other scholarly activity at a college or university located in the United States." However, no change is made in the case of a Cuban medical doctor or other medical specialist wishing to attend a conference, meeting or course in the United States.
- Elimination of direct air travel between the United States and Cuba. For decades after the embargo was imposed, no direct air service existed between the two countries. U.S. government provisions opened up the possibility of charter flights from Miami in the 1980s. However, these have been running only off-and-on since then, largely subject to the ups and downs of U.S.-Cuba relations. In the August, 1994, presidential amendments the travel regulations, persons going to Cuba who were fully hosted by the Cuban government were

prohibited from traveling on board these direct charter flights; end Treasury Department officials began inspecting passenger lists and individual documents on each flight to Cuba, interviewing and in some cases searching passengers before they boarded. In March, 1996 all direct charter service was cut off, by order of President Clinton.

Medical Education

There are currently 28 medical schools and four dental schools in Cuba, plus numerous facilities for health technicians. The School of Public Health, closed a decade ago, is also about to be reorganized and reopened. Through the 1980s, medical students were sold a basic set of textbooks at subsidized prices—a set of some 20 texts would add up to about 200 pesos, or \$200 at the official exchange rate. Specialized texts were readily available at university bookstores, also at subsidized prices. So the average graduate ended up with 40-50 textbooks on their home bookshelf for ready reference.

However, due to the economic contraction of the nineties, fewer funds went for textbook purchases. Students are now loaned deteriorating and out-of-date texts, which must nevertheless be returned at the end of the year for the next class; and there are currently not even enough of these to go around, with students doubling up on a single book.

This situation was complicated with the decision of the Spanish firm Editorial Interamericana, S.A to stop sales to Cuba after the company became a subsidiary of the U.S. publisher McGraw Hill in 1990. McGraw Hill then advised Interamericana that because of its new U.S. association, its personnel could not attend an international book fair in Havana, nor could it make any future sales to Cuba. This is another case where embargo legislation has constituted a chill factor, discouraging companies from exporting to Cuba for fear of prosecution, since in actual fact such sales of medical texts were exempted from U.S. sanctions by virtue of the Berman Amendment of 1988, later ratified with the Free Trade in Ideas Act of 1994. Furthermore, U.S. law permits employees of third-country subsidiaries to travel to Cuba under Treasury Department regulations.⁸

However, the result was devastating: In oncology alone, from the quantities of 73 titles needed, only 19 titles were available by 1992.⁹

Enlisting a U.S. publisher as a new supplier would be ideal under normal circumstances, since prices and shipping costs would suggest the wisdom of such a move, not to mention quality of texts and speed of delivery. But this is no easy task under the embargo: First, it is reasonable to assume that other publishers might balk, as did McGraw Hill; second, if a supplier were found, the operation would have to be carried out in cash, because of banking restrictions outlined above, a logistical problem to say the least; and finally, getting the textbooks to Cuba could present both a formidable challenge and expense, since shipments would necessarily have to be routed through a third country. So, while the Free Trade in Ideas Act is on the books, it has yet to offer a practical option for Cuban textbook importers.

Dr. Ceballos went on to say that some textbooks are being bought in Latin America, but often those available are translations of U.S. texts, which put them about five years behind the latest English language edition. Thus, they prefer to buy English language textbooks—yet these are usually of U.S. origin and consequently more expensive through a third country.¹⁰

Teaching aids, microscopes, laboratory equipment, computers and photocopiers—all are scarce at Cuban **medical** schools, many in need of repair, primarily due to shortages of hard currency. As with many other products, access to the close and natural U.S. market could provide some relief were it not for the embargo. Instead, most of these items are bought in Europe or Japan at much

greater cost. "Calling this a simple problem of economic constraints isn't accurate," asserts Dr. Mayda Arza, Professor of Medicine and staff of the Medical Education Division of the Ministry of Public Health. "If I need to buy bulk supplies-paper, equipment, what have you-if I can buy them next door, it's not the same as going to The other side of town." She informed us that virtually all the paper for the medical schools is now being imported from China.¹¹

Maintenance presents further problems, compounded when U.S. parts are involved. Dr. Ceballos reported that several spectrophotometers in the medical school labs are in need of repair. These were originally bought from the British company Perkins-Elmer. Replacement parts, however, contain U.S. components, available (if at all) through third parties at inflated prices. "Everything would be so much simpler, more expedient, less expensive if we had access to the U.S. market," asserted Dr. Ceballos. " He recalled the ferries from Florida, which once brought goods on a day's notice. "But now," he mused, "it's as if the two countries were worlds apart." ¹²

Scientific Information, Literature and Research

As a result of the scarcity of textbooks, medical students rely ever more on classroom lectures for fundamentals and, in turn, on the ability of their professors to keep abreast of current medical developments, according to Dr. Arza.¹³ However, professors and residents alike are having greater difficulties accessing medical literature, whether in the form of books, journals or on-line services.

One factor is economic: The numbers of subscriptions have been cut, even to key national institutes, because the funds are not there. Thus, the National Oncology and Radiology Institute had 43 subscriptions to foreign medical journals in 1988, but only nine by 1992.¹⁴ However, as we have seen in other chapters (such as the Pharmaceutical Industry), subscriptions to vital U.S. publications can run as much as 50-100% more through European distributors, which-because of embargo banking and mail regulations-are the only way to guarantee consistent arrival, albeit delayed.

Library acquisitions are currently relying on limited purchases and donations from colleagues abroad, or from Cuban physicians returning from trips. However, embargo obstacles come into play when the donations are from U.S. doctors or institutions: Dr. Ceballos and Dr. Jeramias Hernández Ojito, Director of the National Center for Medical Sciences Information, reported delays of several months in the arrival of such publications. They assert that even World Health Organization and Pan American Health Organization journals mailed from the United States have arrived as much as one year later.¹⁵

As a result, we found that the library of Havana's medical sciences campus is poorly stocked, with holdings severely depleted over the past five years. Our research indicates that medical textbooks are in stock up to 1991, although many are in deteriorating condition, and journals are in stock only until 1990-91 as well. We observed recent donations on the shelves: five current textbooks (*Gray's Anatomy*, 1994; *Ganong's Physiology*, 1994; another physiology text, 1995; a biochemistry text, 1996; and an immunology text, 1996). U.S. journals donated were limited to four 1995 issues of the *American Journal of Genetics*.¹⁶

Hospital libraries are also woefully lacking in literature. Most have little or no journals or magazines beyond 1991. And, although the Ministry of Public Health central library in Havana is a little better off, librarians there consider their material quite outdated.

Even the most basic bibliographic references are difficult, if not impossible, to obtain from the United States. The Dutch distributor SWETS indicated to Cuban research libraries that it could not

sell them the U.S.-published listing of new titles in the sciences, Current Contents. since a request by the publisher for information on the customer had revealed end-use was for Cuba.¹⁷

Receiving medical literature from the United States which is furnished on computer disk or CD-ROM is almost impossible, according to medical education authorities and research institutes in Havana. They cite the case of the *Sciences* Citation Index, which several Cuban institutions attempted to purchase (for \$17,000) from the Institute for Scientific Information (ISI) in Philadelphia, PA, through SWETS. However, ISI informed SWETS that such a publication-a one-of-a-kind listing of abstracts and bibliographic references-is not available to Cuba on **CD-ROM** because of the U.S. embargo. (See chapter on Vaccines and Biotechnology for further details.) Although, as we have seen, current U.S. embargo regulations would in fact permit such an export to Cuba, this appears to be yet another case where confusion and temerity lead to refusal. In fact, in the course of this study, we were confronted by a similar negative: DHL offices in Washington, D.C., informed us that they could not send a computer disc of medical information to writers in Cuba, due to embargo prohibitions. Instead, we had to mail hard copy, at a significantly higher cost.

Computer access for bibliographic consultations is a necessary but not very effective tool for Cuban medical **personnel**, first because of the limited **number** of computers functioning on the island, most of those older models. (It should be noted that U.S.-made computers, even for medical use, cannot generally be donated or sold to Cuba; this fact significantly hampers plans to extend computer networks such as Infomed beyond the hospitals it now serves to local polyclinics in the near future.)¹⁸

Medical science institutions have access to Medline-and with Internet capabilities in Cuba, this will be more extensive. However, when the article needed is by a U.S. **author**, and a request is made for a hard copy reprint, Dr. Arza reports that only 20-40% of these reprints actually end up in Cuba, with arrival three to four months later. 'I don't know where the snag is,' she reports. "But the lack of normal mail services certainly must have a hearing since we don't have this same **difficulty** with other countries."¹⁹

Sometimes this situation brings with it peculiar twists and added frustrations: Dr. Maria Antonieta Bobes, a neurobiologist at the Cuban Neuroscience Center, published an article in the U.S. journal *Biological Psychiatry*, but when she attempted to obtain a number of reprints, she found there was no way she could pay for them, with no financial mechanisms between the two countries.²⁰ Hers is not the only example of this phenomenon: Several Cuban scientists interviewed had published in U.S. journals and encounter similar obstacles to obtaining copies of the journal itself, as well as reprints for their personal use.

Even greater difficulties are encountered by physicians in the provinces. We visited a number of facilities in Pinar del Rio, where we were told that access to scientific information is practically nil. Although *Infomed* provides linkage to the central library in Havana, the system is rudimentary, plagued with problems ranging from old technology to equipment failures and lack of paper for printing out literature if and when they can access it from Havana. At the "Abel Santamaria" Provincial Hospital in Pinar del Río, we met with a number of specialists and administrative staff, who without exception decried the absence of current medical information, reporting that they have no reliable, systematic way to assure delivery.²¹

Cuban clinicians state that this problem is seriously hampering their efforts to keep abreast of developments in their field and provide continuity for upcoming generations of physicians. For example, Dr. Ceballos reports that a team of top pediatric specialists organized to write a new basic text for Cuban medical schools is hampered by problems in accessing sufficient up-to-date information from any source. As a result, the textbook project has been put on the shelf.

Most clinicians and researchers report that, in the absence of systematic consultation with the literature in their field, they attempt to make maximum use of scientific interchange whenever possible—through conventions and conferences, visits from foreign colleagues to Cuba, and visits of Cubans abroad. However, as we have seen, all these activities are complicated by the embargo when they concern visits to and from the United States—closing the door to Cuban medical science.

Exchange, Study and Participation in Events in the USA

The U.S. travel ban and the complex eligibility requirements for U.S. professionals wishing to apply for licensed travel impedes any natural flow of clinicians or medical researchers to the island. Add to this the fact that travel plans are difficult to pin down, since license requests sometimes take as much as two months for the U.S. Treasury Department to act on. In addition, the prospect of infringing on U.S. law by even an inadvertent violation of the regulations, with penalties up to \$50,990, does not provide a climate which encourages scientific visits to the island.

The result is that, while interest may exist, travel by U.S. medical specialists to Cuba is limited:

- Dr. Mitchell Valdés Sosa, Director of the Cuban Neuroscience Center, told us that on numerous occasions U.S. scientists scheduled to come to conferences or events have canceled at the last minute, expressing either fear or confusion as to the legality of their trip. He particularly spoke about the difficulties his center has had inviting specialists to teach courses or seminars to young scientists. (Under U.S. law, this could be interpreted as a violation of the ban on providing a service to Cuba, as outlined in the beginning of this chapter.)²²
- Dr. Jorge Perez, Director of the Havana AIDS Sanatorium, likewise reported that U.S. participation at several important AIDS events held in Cuba has been well below the actual interest expressed, due to legal concerns.²³
- Project Orbis, a non-governmental, non-profit organization of ophthalmologists, which operates internationally out of an aircraft serving as a hospital and university faculty, had difficulty coming to Cuba although it had visited more than 60 countries, performing operations and providing seminars and courses for local physicians. After an initial denial of a U.S. Treasury Department license in 1991, Project Orbis finally was able to go to Cuba on the condition that it spend only moneys raised through offices outside the USA.
- Due to decades of difficulties in communications between the two countries, it is virtually impossible for any Cuban institution or organization to effectively advertise in the United States to promote attendance at national and international professional meetings held in Cuba. (Note that complex regulations govern attendance at such conferences, so without specific orientation, it cannot be assumed that physicians would simply sign up.)
- There are also examples of U.S. institutions and individuals which have invited Cuban medical specialists and researchers to the United States to participate in an event, course, seminar or meeting—with all expenses paid, as U.S. embargo legislation stipulates. However, it has been the experience of Cuban medical professionals that these invitations by no means assure a U.S. visa. In fact, their visa applications are quite often left without a response, denied or granted late. (See also chapter on Vaccines and Biotechnology.) Dr. Jorge Peres informed us that the AIDS Sanatorium sought visas in 1999, 1990, 1991, 1992 and 1993 for a Cuban scientist, sponsored by WHO, to attend an Emory University course in Atlanta, in conjunction with the CDC. These visa applications were backed by prominent scientific figures in the U.S., but were never approved.

- The Center for Genetic Engineering and Biotechnology maintains a list of its scientists who have been denied visas to attend international congresses, courses and other events in the U.S. (See chapter on Vaccines and Biotechnology.)
- Dr. Charles Magrans of the national Nephrology Institute said a number of physicians from the Institute received invitations to a Latin-American Nephrology Congress in Puerto Rico. However, they were not permitted to attend, since the hosts did not include an "all expenses paid" clause in their letter. In this case, even with the funds in hand, the specialists were prevented from attending due to embargo restrictions on the transfer of cash between Cuban and U.S. nationals.
- The Director of the Institute of Hematology, Dr. Jod Manuel Bayesteros Santovenia, related that in 1993, Dr. Gisela Martínez was invited by the Albert Einstein College of Medicine in NY for three months. Despite efforts by the College, the visa was denied that year. In 1994, a visa was finally granted, but the Treasury Department prohibited payment of her stipend. Dr. Santovenia, who is also President of the National Society of Hematology, told of his own experience in 1994, when he requested a U.S. visa to attend the Annual Meeting of Blood Banks in San Diego, CA. He states he received the visa when the four-day event was into its third day.²⁴
- Dr. Hernández Cañero, Director of the National Cardiology Institute, told us that in his experience his medical staff have only received U.S. visas when they are invited through an international organization like WHO or PAHO, and then not always. He reported that they periodically receive invitations from the American Heart Association for events for which the admission or registration fees are waived, but again unless all expenses are covered by the hosts, the Cubans are barred from attendance by the U.S. embargo. Dr. Hernández and several specialists from the Institute were denied visas to the 1986 World Cardiology Congress held in Washington D.C. and have repeatedly been denied visas to a variety of events since.²⁵ Dr. Eduardo Rivas, a rehabilitation specialist from the same Cardiology Institute, was able to obtain a visa to attend a 1995 meeting of the American Heart Association: His trip and all expenses were covered by the Interamerican Heart Foundation.²⁶
- However, even under the sponsorship of an international organization or a prestigious U.S. medical institution, travel by Cuban specialists is not always possible, because visas are denied. Thus, in 1992, Dr. Cristina Mateo de Acosta and Dr. Ana María Vázquez were invited for training by the Sloan Kettering Memorial Cancer Center of NY and the Molecular Biology Institute at UCLA, both under the auspices of a PAHO program. However, on April 8 Dr. Miguel Márquez, PAHO representative in Cuba, received a note from PAHO in Washington advising him that "lamentably, the position of the U.S. government has not changed, and continues the same after many years. Thus, we do not see the possibility of carrying out such a training program."²⁷

Long-term study for Cubans in the United States is one of the most difficult travel options. According to Dr. Rolando Camacho, Director of the National Oncology Institute, the U.S. National Cancer Institute is the world's major financial backer or provider of scholarships for study in the field. Cubans, however, are not ordinarily eligible for these scholarships, due to the embargo.²³

Dr. Arza says this situation is true in almost all cases. She notes, however, that with the political conditions inherent in the CDA of 1992, which refer to people-to-people contacts, invitations have come to Cubans stipulating that a scholarship is available, but only for a particular medical student, leaving the Cuban medical schools with no say in the matter. "This is clearly politics," she remarks, "since such a personal invitation is natural when it comes to a well-known figure in medicine or science, but when it carries a name tag for a medical student, this is something else again."²⁹

Finally, the U.S. embargo, visa limitations and related financial restrictions reduce the effectiveness of Cuban scientists' international participation and even leadership. At the National Endocrinology Institute in Havana, the Sub-Director for Research, Dr. Oscar Díaz Díaz reported that, although his institute is a WHO-designated Center for Comprehensive Attention to Diabetics, the only way specialists have been able to participate in U.S.-based events is if WHO itself steps in, never in direct relation to the host institution. Even so, he relates, there are cases of visa denials.³⁰

Six members of the Cuban Nephrology Institute are members of the International Nephrology Society, which has its headquarters in the United States. To pay dues, they have had to find someone traveling to the USA and willing to pass along the funds, since there are no banking relations between the two countries.³¹

Cubans elected to posts in regional institutions based in the United States or meeting in the USA face serious problems with maintaining an active role. A case in point: denial of a U.S. visa to former Minister of Health, Dr. Julio Teja, who was thus prevented from attending the 120th Assembly of the American Public Health Association (APHA), of which he was then Vice Resident, a post to which he was re-elected at the same meeting.=

Information on U.S. Medical Equipment and Drugs

Finally, the information barriers presented by the embargo keep technical information from reaching Cuba- information essential to the functioning of medical equipment and to the proper use of medications.

For example, the "Hermanos Ameijeiras" Hospital in Havana acquired a linear accelerator from Siemens of Germany for the treatment of cancer patients. (This hospital is a regional reference center designated by PAHO.) However, from 1991 to 1993, the United States consistently denied permission to Cuban specialist Carlos **Sandín** to receive special training on the operation and maintenance of this unit in California.³³

When equipment donations are received in Cuba, these units may come without the necessary operation and maintenance guides, and when this is a case of U.S. items, this is particularly problematic, postponing use. This was the case of some 25 U.S.-manufactured Preemicare Model 105-IV neonatal respirators donated to Cuba through a third country. Since Cuban technicians had no manuals, nor could they readily travel to the United States for training on the equipment, a student who had learned to use the units in the United States came to Cuba expressly to train technicians in their operation. But many of the Cubans' more complex questions were left unanswered, and National Electromedicine Center engineers contend "there were too many gaps." ³⁴

Cuba also purchased nearly 1,000 U.S.-produced Bird respirators through intermediaries. The operational training for this equipment was done by an ex-employee of Bird who came to Cuba. At another point a Cuban engineer went to a third country to receive a course from a person who in turn had been trained (as is standard practice) at the Bird factories in the United States. Alexis Cedeño of the National Electromedicine Center estimates that about 40% of the information needed was lost in this process.³⁵

This situation is complicated by the fact that U.S. pharmaceutical and medical supply firms have not been able to regularly participate in trade fairs and delegations to Cuba, and thus Cuban technicians and physicians are not familiar with their products. For example, the Ohmeda corporation, which sells respirators and related equipment, was invited to an annual trade fair in Havana, **but on** advice of counsel decided not to participate, due to fears of reprisals under the U.S.

embargo. Donna Boehme, in-house counsel, told us that she had specifically advised against taking an action with regard to Cuba which might incur any risk of U.S. government reaction. 'Ohmeda plays by the rules,' she said.³⁶

Conclusions

By virtue of the U.S. embargo, Cuban physicians and researchers are decidedly kept outside the loop when it comes to scientific information generated in the United States. And the policy erects an insurmountable barrier to systematic scientific exchange with U.S. colleagues and study and training opportunities helpful to Cuban specialists end ultimately to the patients in their care.

NOTES

- 1 Interview with Dr. Juan José Ceballos, Director of the Center for Continuing Medical Education, CENAPEM, Havana, January 24,1996
- 2 Michael Krinsky and David Golove, United States **Economic** Measures Against Cuba Aletheia Press, Northampton MA, 1993.
- 3 'Overview of the United States Embargo Against Cuba,' memorandum from Michael Krinsky, of Rabinowitz, Boudin, Standard, Krinsky and Lieberman, P.C., New York, Feb. 8, 1995, pp. 3-4.
- 4 Krinsky and Golove, pp. 86-91.
- 5 'Cuban Assets Control Regulations; Restrictions on Remittances and Travel Transactions,' Office of Foreign Assets Control, Dept. of the Treasury, August 30,1994.
- 6 "Cuban Assets Control Regulations; News Organizations; Travel Transactions; Intellectual Property Office of Foreign Assets Control, Dept. of the Treasury, Oct. 13,1995.
- 7 Ibid.
- 8 Krinsky and Golove, p. 102.
- 9 Interview with Ramón Díaz Vallina, Vice Minister for Economics, Ministry of Public Health, Havana, March 14,1996.
- 10 Interview with Dr. J. Ceballos, Havana, January 24,1995.
- 11 Interview with Dr. Mayda Arza. Professor of Medicine and staff of the Medical Education Division, Ministry of Public Health, Havana, July 10, 1996.
- 12 Interview with Dr. J. Ceballos, Jan. 24, 1996.
- 13 Interview with Dr. M. Arza, July 10,1996.
- 14 "Consecuencias adversas del bloqueo...," Ministry of Public Health, Havana May, 1993, p. 12.
- 15 Interviews with Dr. J. Ceballos and Dr. Jeremías Hernández Ojito, Director of the National Center for Medical Sciences Information, Havana, January 24, 1996.
- 16 Visit to the library at the "Victoria de Girón" Higher Institute of Basic Sciences, where medical students spend their first two years, on July 10,1996.
- 17 Interview with Gilberto Sotolongo, Finlay Institute, Havana, Nov. 17, 1996
- 18 The U.S. organization Pastors for Peace, which regularly defies the embargo with donations to Cuban institutions, attempted to bring several hundred computers **to Cuba** for **Infomed early in** 1996. These were confiscated by U.S. Customs officials on the basis that the donation of the equipment was prohibited under U.S. embargo law. After several months of civil disobedience, the computers were finally released to the Methodist Church in the USA, **but** had not been authorized to for export to Cuba by July, 1996.
- 19 Interview with Dr. M. Arza, July 10,1996.
- 20 Interview with Dr. Maria Antonieta Bobes, Director of the Cognitive Neurosciences Department, Cuban Neuroscience Center, Havana, February 28, 1996.
- 21 Visit to the "Abel Santamaria" Provincial Hospital, Pinar del Rio, November 28, 1995.
- 22 Interview with Dr. Mitchell Valdés Sosa. Director, Cuban Neuroscience Center, Havana, February 28,1996.
- 23 Interview with Dr. Jorge Perez. Havana, November 3,1995.
- 24 Interview with Dr. Jose Manuel Bayesteros Santovenia, Havana, October 26, 1995.
- 25 Interview with Dr. Hernández Cañero, Havana, October 27,1995
- 26 Interview with Dr. Eduardo Rivas, Cardiology Institute, Havana, November 22,1995.
- 27 'Consecuencias adversas...,' p. 13.
- 28 Interview with Dr. Rolando Camacho, Havana, DATE
- 29 Interview with Dr. M. Arza, July 10,1996.
- 30 Interview with Dr. Oscar Díaz Díaz, Sub Director for Research, National Endocrinology Institute, Havana, October 19,1995.
- 31 Interview with Dr. Charles Magrans, Nephrology Institute, Havana, October 19,1995
- 32 "Consecuencias adversas...," p. 13.
- 33 Ibid.

34 Interview with Alexis Cedeño, National Electromedicine Center, Havana, December 8, 1995.

35 Ibid.

36 Interview by Wallie Mason with Donna Boehme. DATE.

CHAPTER EIGHT

HUMANITARIAN DONATIONS & INTERNATIONAL COOPERATION

Donations from within the United States, from parties in third countries, and from international organizations are each affected by the U.S. embargo as they make their way to recipients in Cuba, whether **the** beneficiaries are the Cuban government, non-governmental or religious organizations, or individuals.

Donations to Cuba from U.S. Nationals: The Law

Current U.S. law applies to and regulates various categories of humanitarian donations made directly from U.S. nationals to Cuba. These include the following

- **Food:** The Cuban Democracy Act (CDA) of 1992 **authorizes** the donation of food to non-governmental organizations in Cuba **but** not to the Cuban government. A license must be obtained to ship the foodstuffs to Cuba, whether by sea or **air**. (**Under** no circumstances does the law permit sale of food to Cuba.)
- **Medicines:** The CDA establishes the right to donate medicines” **to** non-governmental organizations. However, that right is conditioned upon showing that there is a reasonable likelihood that the medicine will not be used for torture or other human rights abuses; that there is not a reasonable likelihood that the item to be exported will be re-exported by Cuba (interpreted to include treatment of third-country patients in Cuba); and that the item will not be used in the production of any biotechnology product. An export license is required from the U.S. Commerce Department for medicines, even under new regulations issued in March, 1996 (see below),’ as well as a separate shipping license. Most recently, Commerce has insisted that the non-governmental organizations (**NGO**) rather than individual Cuban hospitals or clinics be designated as the “ultimate consignee,” apparently to avoid any implication that the United States has **recognized** the “**non-governmental**” status of such health care facilities.
- **Medical supplies, instruments and equipment:** For donation to either an **NGO** or the Cuban government, the CDA **affirms** licensing and other requirements for medicines, **but** also conditions the right to donate on the President’s ability to determine that “the United States Government is able to verify, by on-site inspections and other means, that the exported item is **to** be used for the purposes for which it was intended and only for the use and benefit of the Cuban people.” In practice, however, applications for licenses authorizing donations of these items have been treated **the** same as medicines, when donated to non-governmental organizations. We have no knowledge of any attempts to donate medical equipment or supplies directly to the Cuban government. Shipping, as well as Commerce Department export licenses, are required for medical supplies, instruments and equipment.
- **“Humanitarian” Goods:** Whether to license such donations was a matter of U.S. Commerce Department discretion, until revised Commerce Department Export Administration Regulations were issued on March 25, 1996, doing away with the licensing requirement for qualifying donor organizations and a specific list of commodities. The revised regulations provide that, without any government **authorization**, organizations with “experience in maintaining a verifiable system of distribution that ensures delivery **to** the intended beneficiaries” may export donations to meet “basic human needs.”

Eligible organizations are defined as those with an ‘established record of involvement in **donative** programs and experience in maintaining and verifying a system of distribution **to** ensure delivery of commodities and software to the intended beneficiaries.’ The new regulations require these organizations to maintain a permanent staff **in** the recipient country to monitor receipt and distribution; conduct periodic spot-checks by members of the exporter’s **staff**; or utilize the services of a charitable organization that has a monitoring system in place.

The March 1996 regulations list the items that may be donated to meet basic human needs:

Health equipment for the handicapped, vitamins, water resources equipment, food, agricultural materials and machinery suited to small-scale farming operations, fertilizers, fishing equipment and supplies suited to small-scale fishing operations.

Food: insecticides, pesticides, seeds, small-scale irrigation equipment, veterinary medicines and supplies.

Clothes and Household Goods: bedding, clothes, cooking utensils, fabric, personal hygiene items, soap-making equipment, weaving and sewing equipment.

Shelter: building materials, hand tools.

Educations: books, individual school supplies, school furniture, special education supplies and equipment for the handicapped.

Basic equipment and supplies necessary to operate and administer the donative program: audio-visual aids for training, generators, office supplies and equipment.²

It is unclear whether any humanitarian licenses had been granted for goods outside the category of food and medicines before March, 1996, since the Commerce Department does not itemize such licenses. Authorized recipients may include any Cuban national. A shipping license is still required for carriers, under the "humanitarian goods" category.

- Gift Parcels: the embargo makes an exception for the limited donation of gift parcels, under certain circumstances. Specifically, a U.S. national may send one gift parcel per month to each qualified recipient in Cuba, a category which includes individuals and "religious, charitable and educational" organizations. 'Contents of the gift parcel must have a retail value of no more than \$200, and as of August, 1994 are limited to the following items: food, vitamins, seeds, medicines (in dosage form), medical supplies and devices, hospital supplies and equipment, equipment for the handicapped, clothing, personal hygiene items, veterinary medicines and supplies, fishing equipment and supplies, soap-making equipment, and radio equipment (capable of receiving only) and batteries for the same.³ Since the revised Commerce Department regulations were issued in March, 1996, food is exempt from these restrictions: Hence, gift parcels of food may be sent as frequently as desired and without any limitation as to value.' (See section on Family Relations and Humanitarian Emergencies for restrictions on family remittances.)

Donations to Cuba from U.S. Nationals: The Record

On February 8, 1996, President Clinton's advisor on Cuba at the time, Richard Nuccio, told the European press that, while the United States government was not directly involved in Cuba, the American people were the world's largest contributors of humanitarian aid, with \$120 million over the past two years channeled through non-governmental organizations.⁵ And since the passage of the CDA in 1992, several legislators have testified that the United States is 'doing everything we can to help the people of Cuba [by permitting humanitarian donations],' while continuing to prohibit sale of food and other "humanitarian goods," and restricting sales of medicines⁶

However, we find that donations are no effective substitute for purchases and certainly do not "make up for" the damaging effect of the CDA on the availability of food and medicines to the Cuban population. In particular, the CDA's provisions ending subsidiary trade and penalizing

third-country ships carrying goods to Cuba-in addition to embargo restrictions on direct U.S. sales-have reduced the flow of food and medicines from U.S. sources and have cut Cuba's purchasing power for these and other products:

- The CDA's penalty provisions on shipping have forced Cubans to pay more for freight and hence less on actual purchases of imports. This has made it even more expensive to import products from Europe and Asia, where Cuba currently buys the majority of its medications and foodstuffs. (See chapter on Medical Exports above.)
- The \$120 million in non-governmental U.S. donations, or \$60 million annually, do not "replace" Cuban imports from U.S. subsidiaries, which had climbed to \$533 million by 1990 before the CDA cut off such trade. That year, well into Cuba's economic emergency after the Soviet collapse, three-fourths of Cuban imports from these U.S. subsidiaries were food and medicines.'

The \$120 million figure quoted by Nuccio for U.S. NGO donations to Cuba between January, 1994, and January, 1996, has itself been placed in doubt: A letter from Iain S. Baird, Deputy Assistant Secretary of Commerce, notes that there were 82 individual validated licenses approved for shipments to Cuba (covering foods, medicines and medical supplies) between October 23, 1992 (the date the CDA went into effect) and May 3, 1995, with their total value listed at \$62,882,513. However, the letter notes: "...the records do not distinguish between sales of a commercial nature and donations." and in fact, include both. Four more licenses were issued for the same period for "humanitarian goods" donations, valued at \$1.2 million. In all cases, Baird says, "it is important to note that the dollar amounts listed above represent the dollar amount for applications processed by the U.S. Bureau (of Export Administration). The Bureau does not know if the amounts approved for export were actually shipped and therefore has no record of the dollar amount of such goods entering Cuba." ⁸

Thus, to reach the \$120 million Nuccio calculates in donations for 1994-1996, one would have to presume the following: that all of the \$64 million approved from October, 1992, to May, 1995, was in fact donated in 1994-95; that another 956 million in licenses were approved between *May, 1995* and January, 1996 (more in one year than in the previous 2 1/2 years); that all of the exports to Cuba were donations, none sales (while the U.S. Commerce Department insists it keeps no separate records); and that all goods approved were actually shipped (a conclusion Commerce specifically warns against making).

On this last point: There are several known instances where the items were not shipped. In February of 1995, the U.S. humanitarian organization *Children Now!* received a license to export to Cuba a donation of \$3 million in medications. However, these were later found to be in poor condition and were never shipped.'

Making a fair estimate of the volume and dollar value of donations is nearly impossible, given the sparse and contradictory data available from U.S. government agencies,¹⁰ and the random way that shipment values are determined by donors. While NGOs often receive goods free-of-charge or at wholesale prices, they may use either retail or wholesale prices when calculating the value of their donations for license application.

By any count, we conclude that the volume of donations is insufficient to substitute for purchases which could be made by Cuban importers from U.S. subsidiaries-let alone direct purchases from U.S. manufacturers. In addition, while donations may indeed be free-of-charge, they present a series of problems for Cuban recipients:

- The products donated are determined by availability as much as need. Although the Ministry of Public Health maintains a list of prioritized medications, it must often decide which items to

accept based primarily on what is offered, not on what is most needed. Thus, domestic transportation, inspection facilities, warehouses and staff time are occupied with these shipments, which only in part recognize the needs of recipients. Enrique Comendeiro, responsible for international donations for the Ministry of Public Health, states that while this process is moving closer to matching offers with necessities, the very essence of donations means that this approximation is limited.”

- In the case of medicines, pharmaceutical companies only list certain products as available for donations abroad: most often these are drugs which are coming close to their expiration date and for which there is consequently no domestic market. This situation puts an extra burden on donating organizations. They must find the fastest and thus usually the most expensive way to transport these medications. More money goes into shipping and less is available to purchase the medicines themselves. And a major burden is suddenly thrust upon the health care delivery system in Cuba, faced with the urgency of unloading this shipment, whisking it through importation, customs and health inspection procedures and arranging immediate transportation to as many as 14 provinces, and from there to hospitals and clinics. Our research team was witness to several such operations in 1996-1996.
- Relying on donated medications also **means that specialists** are unable to use the treatment of their choice: They must give the medication available at the time. For chronic patients, this problem is worse. They **may** receive one medication one month and be required to adapt to a completely different medication the next month, with different dosages, side effects, and effectiveness. This is particularly harmful for patients suffering from conditions such as hypertension, asthma, psychiatric problems and diabetes.
- In the case of medical equipment, when of U.S. origin it is often impossible for Cuba to maintain or repair, or to buy disposable accessories. This was the case of the 59 donated Cobe dialysis units, for which distributors were unwilling to sell replacement parts because of the U.S. embargo, putting 30 of the units out of commission, affecting 150 patients who are not receiving **adequate** dialysis. If direct and unhampered purchases could be made, these units could be functioning for these **patients** today. (See section on Nephrology and chapter on Medical Exports.).

The Experience of Donors and Recipients

Once in Cuba, medicines and medical supplies are distributed to health care facilities agreed upon with donors, and patients receive them free.”

Cuban NGOs and NGOs in the United States, Canada and Europe are essentially satisfied with the distribution procedures in Cuba, in which, according to Cuban regulations, donors have the right to witness distribution and verify end-use results.¹⁹ Accusations appearing in the Florida **press** that donations are customarily re-exported by the Cuban government for profit (whether exported directly or sold to ailing tourists) do not represent the opinion of the U.S. Commerce Department, whose latest report on donations to Cuba states that “re-exports were insignificant” of goods licensed for donation in 1994-1995, “the vast majority of items [being] foodstuffs, medicines and consolidated shipments of gift parcels.”⁴

The research team found that the U.S. embargo, while authorizing certain donations to Cuba in the letter of the law, presents obstacles for those attempting to carry out assistance programs.

With regard to medical donations from U.S. organizations: The licensing requirements, complicated by legal fees, additional overhead and red tape serve to delay arrivals of shipments to recipients in Cuba. Rolando Suárez, Director of the Catholic Church’s CARITAS-Cuba, notes that

licensing procedures delayed donations from six to eight months, until Catholic Relief Services in the United States was able to **obtain** a two-year license. "This delay cost lives," he states.¹⁵

There is also the factor of double licensing: The carrier (whether by air or by sea) is required to obtain an additional shipping license for donated goods destined for Cuba. While it is the general policy of the U.S. Treasury Department to issue such licenses once Commerce has approved export, application constitutes extra red taps for donors and shipping companies. Cuba's National Blind Association (ANCI) states that its members have been unable to receive several donations from counterpart organizations in the United States because they have not been able to find a shipper, even though presumably such donations of equipment for the blind, including wheel chairs, walking sticks and Braille aids, have been eligible for shipping licenses.'

Shipping is further complicated **by** recent U.S. restrictions which cut off charter air routes from the United States to Cuba as of March, 1996. (See President Bill Clinton's executive order of February 26, 1996.) Without direct flights, sending donations from the United States to Cuba not only requires making arrangements through three countries, but also becomes **more** expensive and presents further delays in reaching recipients. Dr. Noemí Gorrín, in charge of medical cooperation for the Cuban Council of Churches, reports up to three-month delays in donations shipped to Cuba from the United States through Canada." Rolando Suárez, Director of CARITAS-Cuba told us: "The shipment of medicines has become more complicated since flights were suspended. Our last shipment (from Catholic Relief Services), \$25 million in cephalosporins for Intensive Care Units, cost us \$30,696 to bring through Canada."¹⁸ With that money, he says another donation of medicines could have been put together. And Eddy Levy, Resident of Jewish Solidarity of Miami, reported in May of 1996 that his group had gathered 82 packages of food and medicines, but had found no cost-effective way of sending them to Cuba. He notes that with the direct routes eliminated, charters are flying smaller planes to intermediate points and have less space, increasing delays and air freight costs as a result."

Restrictions on travel to and from Cuba have generated another set of obstacles for donations. Some organizations have reported difficulty in obtaining travel licenses in time for their representatives to accompany a shipment and verify its end-use.²⁰ The Cuban churches report delays in U.S. travel licenses issued to representatives of sister denominations and churches in the United States, who propose delegations to Cuba to explore areas for humanitarian donations and religious cooperation.²¹

Project Orbis, which sends a plane equipped with a full ophthalmological surgical service to some 60 countries, was denied a travel license for a trip to Cuba planned for February of 1991. The purpose of the visit was to operate on dozens of Cuban patients, in cooperation with Cuban ophthalmological surgeons, and to exchange professional experience in the field. The travel license was denied, presumably because the U.S. specialists on board were **providing a service to** Cuba. After significant lobbying, a second application was approved for **a** trip in June, 1991, thus delaying for four months operations performed on board on nearly 50 patients and 20 more surgeries carried **out** by joint Orbis-Cuban teams at the Pando Ferrer Ophthalmological Hospital in Havana. Patients received cornea transplants, laser therapy, and were treated for glaucoma, among other afflictions.²²

The U.S. embargo and refusal to issue U.S. visas to Cubans needing medical treatment in the United States has frustrated attempts by U.S. medical institutions and specialists to donate their services to help prolong or save the lives of Cuban patients. Dr. Noemi Gorrín of the Cuban Council of Churches cites the case of the daughter of the Chief of Psychology at Havana's Ameijeiras Brothers Hospital, who was finally sent to Britain for heart surgery because she was denied a U.S. visa, despite the fact that her operation was fully financed by hospitals and professional staff in Boston.=

In cases of extreme emergency, U.S. citizens have consciously or unconsciously violated the embargo, end-running licensing procedures to get medications to Cuban patients with the urgency required. In January, 1994, nine-year-old Hernán Pérez was operated on at the Havana Hematology Institute to remove a malignant tumor (non-Hodgkin's lymphoma) from his abdomen. The right combination of chemotherapy drugs was unavailable in Cuba during the critical weeks following his surgery, and his family appealed to friends in the USA for assistance. Hernán Pérez, Sr. described to us his trip to the Havana airport to receive an "anonymous" package in February, containing several thousand dollars worth of the necessary medications, among them methotrex from Lederle Laboratories. "My son has a fine prognosis today," said Pérez, "but if my friends had waited for a (U.S.) government license to ship these drugs, they may well have arrived too late."²⁴

In Miami, a privately-funded Hotline has been set up to encourage reporting such embargo violations. The move was praised by the Treasury Department's Director of OFAC, Richard Newcomb, who told a Miami conference on Cuba in May, 1996 that the Hotline had resulted in a Treasury Department investigation into suspected "illegal shipments" to Cubans of \$40,000 in medications.²⁵

Gift packages, primarily from Cuban-Americans, constitute by far the greatest share of donations to Cuba.²⁶ However, getting these packages to their recipients is a complex, costly and time-consuming process, especially now without direct flights, as we noted earlier. Companies located primarily in Miami and New Jersey charge for this service. One ad in the **Miami Herald** on April 18, 1996 offered a "Mother's Day Special" of \$12 a pound for **new** clothing destined for Havana and \$10 a pound for food and medicine for both Havana and interior provinces.²⁷ At the same time, the American Red Cross has no service similar to the one offered by the Spanish Society of the Red Cross, which allows Cuban émigrés to send gift parcels to families on the island for discounted rates. (Reference: Interview with Dr. Hector Rodriguez Baster, Deputy Secretary General, Cuban Red Cross, December 7, 1995.)

Other forms of aid beyond humanitarian donations are limited by the embargo, including development assistance, which by definition permits greater participation of Cuban partners as actors rather than simply recipients. This **raises** issues beyond the competence of this study concerning the philosophical objectives of international aid. One aspect is worth noting, however: Certain assistance eligible for licensing under the CDA requires that U.S. and Cuban NGOs prioritize the political aims of their relations as they decide on cooperation projects." While it is too soon to assess the effects of explicitly politicizing assistance, it is reasonable to assume that it may skew the results of aid towards political ends, which becomes the yardstick for benefiting the Cuban population. It may be useful to study whether tying assistance to political objectives does not tend to discourage NGOs, and in particular Private Voluntary Organizations, from taking on Cuba as a partner country.²⁹

The perception that any form of donation to Cuba will be interpreted in a negative political light by the U.S. government and certain Cuban-American constituencies is currently a deterrent to donations for some organizations and even some pharmaceutical companies.³⁰ Limitations imposed by the U.S. embargo on additional forms of cooperation, such as technology transfer and the application of appropriate technology; travel by scientists and medical experts; access to scientific and medical information; and joint research projects are discussed in other chapters of this study.

Donations And Cooperation From Third Countries

Significant donations reach Cuba from Canada, Europe and Latin America. In fact, the European Union, bilateral government assistance and NGO aid from these countries constitute most of the \$20 million in annual contributions to the health sector.³¹

One major problem these donors face is shipping: In its restrictions imposed on shippers, the CDA makes no explicit exemption for shippers of humanitarian donations from third countries. While legal experts consulted believe that granting U.S. licenses for such carriers would be consistent with current U.S. policy, NGOs refer to experiences which suggest that shippers, who have generally decided not to ship to Cuba to avoid reprisals under the CDA, are either ignorant of or unwilling to test this hypothetical exception.³²

This has been the experience of several organizations on the receiving end in Cuba, including the National Blind Association (ANCI), the Cuban Red Cross, and the Cuban Council of Churches. ANCI notes that shipments from the National Blind Association of Norway and other European donors have had to wait for Cuban ships to pick them up in Norwegian ports because freight companies there insist they cannot take goods to Cuba under the CDA. ANCI notes that this has meant medications needed by the blind in Cuba have arrived so near to their expiration data as to be useless.³³

Particularly striking is an example cited to us concerning disaster relief for flood victims, homeless after Tropical Storm Gordon hit the eastern provinces of Guantánamo and Holguín in November, 1994. The Cuban Red Cross issued a draft appeal to the International Federation of the Red Cross (IFRC), which was approved and urgently distributed to Red Cross and Red Crescent Societies, governments, and the European Union. The EU agreed to fulfill the entire request for assistance, nearly \$500,000. The IFRC then selected a delegate to handle procurement and shipment of the relief aid, working out of Central America. By January, 1995, the funds were in hand. The Red Cross decided to purchase fibercement roofing materials for housing repair in Cuba itself, and so an attempt was made to transfer funds directly to the Cuban Red Cross for this purpose. The moneys were initially sent to Bonn, where they were routed to Costa Rica in U.S. dollars. However, the embargo prohibits U.S. dollars from being transferred to Cuba through international banking transactions. After several attempts to re-route funds failed, they were finally returned to Europe and channeled to Cuba from Geneva in Swiss francs. This process took over two months.

However, the complications continued: Unable to purchase other materials from the United States for export to Cuba, the Red Cross delegate bought fumigation equipment, insecticides, electrical wiring and several more items in Mexico. However, delivery was not made until April and May because of difficulties in finding a shipping company willing to carry these goods to Cuba. Thus, relief assistance to 11,967 disaster victims in Guantánamo and Holguín provinces-including 2,510 families whose homes were demolished- was delayed from January to May." And victims received food, housing repair materials and equipment to control mosquitoes and other vectors ***six months after the floods.***'

Armando Jaular, General Coordinator of Spain's Médicos Sin Fronteras (Doctors Without Borders). reports that his organization has so far invested \$1.8million in programs to enhance water supply and purification in Cuba. However, he blames the embargo for reducing 'the effectiveness of every dollar spent by the organization to assist Cuba,' to the extent that they cannot purchase from the closer and more competitive U.S. market. He cites the example of calcium hypochlorite, used to make water safe for drinking, which he says Medicos Sin Fronteras would

buy in the state of Georgia, USA, at considerably lower prices than it pays now from suppliers in Britain.=

Because of the restrictions on sending U.S. dollars to Cuba, banking difficulties have also been reported by groups such as ANSOC (Cuba's National Deaf Association). According to its President, Blas Eduardo Mora Maestre, the General Secretariat of the World Federation of the Deaf, headquartered in Finland, forwarded a donation from the Italian Deaf Association to the Regional Deaf Association in Colombia to buy a fax machine and a personal computer for ANSOC, to be used at the Pan-American Meeting of the Deaf in September, 1996. However, he reports that when the funds reached City Bank, they were frozen on the grounds that they were destined for Cuba. Mora Maestre states that the Deaf Association had not been able to unblock these funds as of May, 1996.³⁷

Donations And Cooperation From International Agencies

The U.S. embargo presents the same dilemmas to international agencies providing assistance to Cuba as it does to third parties in other countries. The United Nations system maintains a strong presence in Cuba, and its cooperation programs in health amount to some \$3 million annually, channeled through PAHO/WHO, the UN Development Program, UNICEF, the World Food Program and the UN Family Planning Program.

When it comes to Cuba, several of these and other international agencies state that they have difficulty purchasing products for donations or cooperation from U.S. manufacturers or their subsidiaries. For example, UNICEF (which also receives considerable supplementary funds from NGOs and National Committees for UNICEF in European countries and Canada) has had to purchase raw materials for children's iron supplements and pregnant women's vitamins from European producers at higher prices. In a more recent example, the UNICEF office in Havana was notified by its Copenhagen purchasers on November 8, 1995, that they had encountered serious difficulties in finding measuring equipment vital to the recuperation of water and sanitation systems in Cuba because "we can not procure them from USA and had to find other sources."³⁹

The price of shipping from Europe has also affected agencies such as the World Food Program (WFP), UN Development Program and UNICEF. The WFP has had to bring fertilizers, irrigation equipment and other resources from Canada and Europe, paying additional shipping.⁴⁰ In the case of UNICEF, projects for rural and peri-urban sanitation have been hampered, since polyethylene piping (both high and low density) has had to come from Europe instead of U.S. suppliers. The total budgeted for these purposes was US \$600,000 but of that amount 14% was tied up in shipping. UNICEF-Cuba notes that if that sum were reduced to 19% (still much higher than it would have cost to ship directly from the USA), 12 to 15 more aqueducts could have been completed. An additional factor here, they state, is shipping delays: the Havana UNICEF office reports it takes seven to eight months from the time moneys are available to portside arrival of products.

And finally, international agencies to which the United States belongs are subject to a cut in the United States Government's contribution, by law, determined by the share of their budget that is spent in Cuba. The Foreign Relations Authorization Act of 1961 provided that "any voluntary United States contribution to an international organization must be reduced by the proportionate United States share of such organization's activities carried out in specified countries (including Cuba). The purpose of the provision is to insure that no United States funds are used to conduct activities in cooperation with these states."⁴¹ Until the passage of the Foreign Relations Authorization Act for Fiscal 1994-95, it is our understanding that this provision reduced funds available for all United Nations programs in Cuba: UNDP, UNESCO, WFP, the UN Population Program, the UN Drug Control Program, FAO, WHO, PAHO, UNIDO, the office of the UN High Commissioner on Refugees, the International Atomic Energy Agency and UNICEF. In the Act of 1994-1995, only UNICEF and the International Atomic Energy Agency were restored to full U.S.

funding, effective with the amendments on April 30, 1994.” It seems that for some time the United States government contradicted its humanitarian aid policy when it came to its own contributions to international organizations.

NOTES

¹ Attorney Michael Erinsky notes that these regulations have been issued to apply to donations to a number of countries, and in all cases except Cuba they permit donations without license of 'hospital supplies and equipment, laboratory supplies and equipment, medical supplies and devices, medicine-processing equipment and medicines," memo from Erinsky, entitled 'Revised Commerce Department Export Administration Regulations," June 13, 1996.

² Ibid.

³ See Memorandum from Michael Krinsky, of Rabinowitz, Boudin, Standard, Krinsky and Lieberman, P.C., Attorneys at Law, dated February 8, 1995, and presented to a meeting of non-governmental organizations hosted by the American Friends Service Committee, Philadelphia, PA, February 23, 1995.

⁴ Memo from Michael Erinsky, June 13, 1996.

⁵ Reuters dispatch by Jeremy Lovell, Brussels, Belgium, Feb. 8, 1996.

⁶ Congressional Record, September 21, 1995, H9386-9389, testimony of Rep. Dan Burton (R.-Ind.) and others.

⁷ *New Opportunities for U.S.-Cuban Trade*, by Donna Rich Eaplowits and Michael Kaplowits of the Cuban Studies Program, Johns Hopkins University, 1992, pp. 11 and 13.

⁸ Letter from Iain S. Baird to Richard Newcomb, Director of the Office of Foreign Assets Control, Department of the Treasury, May 19, 1995. in response to an inquiry by Rep. Charles Rangel (D.-NY).

⁹ Conversations with Dr. Paul McCleary, then Resident of *Children Now!*, February and March, 1995.

¹⁰ Repeated attempts to gain further information on licenses for this study through the Freedom of Information Act were unfruitful. See May, 1995 correspondence between Peter Kornbluh of the National Security Archives and Wallie Mason, describing results of FOIA inquiries; and letter from Richard Newcomb of OFAC to Rep. Charles Rangel, received June 14, 1995, *noting that the* information provided to OFAC from the Bureau of Export Administration is "only summary information due to certain rules it is under pertaining to the release of information."

¹¹ Interview with Enrique Comendeiro, Advisor to the Minister of Public Health, and responsible for health sector international cooperation programs, Sept. 8, 1995.

¹² Policy of Cuban government on donations, as explained by Enrique Comendeiro, Advisor to the Minister of Health, interviewed Sept. 8, 1995.

¹³ Interviews with the following persons: Armando Jaular, General Coordinator, Medicos Sin Fronteras (Spain), April 24, 1996; Dr. Noemi Gorrin, Cooperation Program, Cuban Council of Churches, Jan. 25, 1996; Rolando Suárez, Director, CARITAS-Cuba, May 2, 1996; Claude Moncorge, General Secretary, Médecins du Monde (France), Jan. 26, 1996; Rev. Raúl Suárez Director, Centro Memorial Dr. Martin Luther King, Jr., Havana, Jan. 19, 1996; Dr. Hector Rodriguez Baster, Deputy Secretary General, Cuban Red Cross, Havana, Dec. 7, 1995; Amado **González** Landa, President, National Association of the Blind, Havana, Jan. 10, 1996; Ida Hilda Escalona del Toro, Cuban Association of the Disabled, Havana, Jan. 23, 1996; Blas Eduardo Mora Maestre, National Association of the Deaf and Hearing Impaired, Havana, Jan. 29, 1996, and written materials from OXFAM-America, United Church of Canada, National Council of the Churches of Christ in the USA.

¹⁴ U.S. Department of Commerce Export Administration Annual Report, 1994-1995 on Foreign Policy Export Controls. p. III-19.

¹⁵ Interview with Rolando Suárez, CARITAS-Cuba, May 2, 1996.

¹⁶ Communication from Amado Gonzalez Landa, President, ANCI, January 10, 1996.

¹⁷ Interview with Dr. Noemi Gorrin Cuban Council of Churches, January 25, 1996.

¹⁸ Interview with Rolando Suárez, CARITAS-Cuba, May 2, 1996.

¹⁹ Interview with Eddy Levy, May 9, 1996.

- ²⁰ See information from the U.S.-Cuba Medical Project, 1995 and 1996; end interview with Dr. Noemí Gorrín, Cuban Council of Churches, January 25, 1996.
- ²¹ Interviews with Dr. Noemi Gorrín, Cuban Council of Churches, January 25, 1996; and Rev. Raúl Suárez, pastor, Ebenezer Baptist Church of Marianao, Havana, January 19, 1996.
- ²² "Fraternidad Científica," *Granma*, April 13, 1991, and "Eye to Eye with Orbis" by Meic Haines in Cuba *Update*, published by the Center for Cuban Studies, New York, Nov., 1991, p. 10.
- ²³ Interview with Dr. Noemí Gorrín, Cuban Council of Churches, Jan. 25, 1996.) (See also sections on Family Relations and Humanitarian Emergencies.
- ²⁴ Interview with Hernán Pérez, Sr., Havana, Feb. 26, 1996 and invoices from medications provided.
- ²⁵ Comments by Richard Newcomb to the Helms-Burton Conference, sponsored by the American Conference Corporation, Miami, FL, May 10, 1996.
- ²⁶ See Commerce Department Bureau of Export Administration reports.
- ²⁷ See April 18 advertisement for VIAJES A CUBA ALMACEN EL ESPAÑOL, 1359 SW 1 Street, Miami. -FL.
- ²⁸ See Cuban Democracy Act of 1992, as published *in full in United States Economic Measures Against Cuba*, by Michael Krinsky and David Golove, Aletheia Press, 1993, pp. 147-155.
- ²⁹ There has already been some objection expressed by U.S. NGQs to politicizing their assistance, as per the CDA See document issued by OXFAM and the American Friends Service *Committee* on the bases of cooperation with Cuban NGOs, and discussions of the Interaction Working Group on Cuba over the past two years, especially talks with U.S. government representatives on August 8, 1995.
- ³⁰ See pharmaceutical company survey in the chapter on Medical Exports.
- ³¹ Analisis del Sector Salud en Cuba: *Informe de Avance, Ministry* of Public Health in cooperation with WHO/PAHO, Nov. 21, 1995, Havana, p. 15.
- ³² **The** Cuban Assets Control Regulations, published by the U.S. Treasury Department, indicate that the CDA licenses may be sought for vessels carrying food to NGCs or individuals in Cuba; or to medicines, medical equipment; or telecommunications supplies authorized by the U.S. Commerce Department. The fact that these exports would have to be authorized by Commerce suggests that in the letter of the law, this exception only applies to exports from the United States. However, consulted on this point, Attorney Michael Krinsky stated that it would be consistent with current U.S. policy, nevertheless, for the Treasury Dept to use its authority to license vessels carrying humanitarian donations from third countries to Cuba as well. At the same time, he stated that this authorization would require sufficient interest to analyze and interpret the potential legality of such an operation, an application procedure, and strict adherence to regulations limiting the ship's cargo to the *donation* itself. Interview with Michael Krinsky, June 19, 1996.
- ³³ Communications from Amado González Landa, President, ANCI, January 10, 1996.
- ³⁴ "Daños en diversas provincias por lluvias y vientos," *Gmmma*, Nov. 15, 1994; and data provided to the authors by the Cuban Red Cross.
- ³⁵ Interview with Dr. Hector Rodriguez Baster, Deputy Secretary General, Cuban Red Cross, December 7, 1996.
- ³⁶ Interview with Armando Jaular, General Coordinator of Spain's Médicos Sin Fronteras, April 24, 1996.) (Also see section on Water Resources.1
- ³⁷ Interview with Blas Eduardo Mora Maestre, President, National Deaf Association, January 20, 1996.
- 38** *Analisis del Sector Salud...*, p. 14.
- ³⁹ Information from Luis Zúñiga, Resident Program Director, and Osvaldo Montero, Projects Director, UNICEF-Havana. Fax from UNICEF Supply Division, Copenhagen, Denmark, November 8, 1995, sent to Osvaldo Montero.
- ⁴⁰ Interviews with UN representatives in Cuba, November 15, 1995.
- ⁴¹ HR Conf. Eep. 103-482, Foreign Relations Authorization Act of 1961, Section 431.
- ⁴² Letter and accompanying documentation from George F. **Ward**, Jr., Acting Assistant Secretary of State for International Organization Affairs, to Dr. Peter Bourne, February 12, 1996.

CHAPTER NINE

INTERNATIONAL LAW & THE EMBARGO

The Principle of Extraterritoriality

Since its enactment in 1992 the CDA has provoked an outpouring of **protests** from various nations around the world, as well as official denouncements by international and regional bodies such as the United Nations and the Organization of American States. The objections of many major U.S. trading partners have been made known through various demarches which criticize the extraterritorial aspects of the CDA, particularly those which place prohibitions of third-country ships from entering the U.S. within a six-month period of having docked in Cuba. These provisions, which seek to coerce and control the trade practices of other nations by penalizing them for continuing to do business with Cuba, are an affront to the sovereign right of each nation to determine its own foreign commerce practices. On October 7, 1992, one day after Congress passed the CDA, the European Community made a formal demarche to the U.S. government, warning that the law would be met with strong **opposition** and **disapproval**. The EC stated:

The European Community and its member states are seriously concerned about the reinforcement by the U.S. Congress of the trade embargo against Cuba. Furthermore, the Act's proposed sanctions for vessels that enter a port in Cuba would be in conflict with longstanding rules on comity and international law, and adversely affect international **shipping** as well as the European Community's trade with the United States. . . . Although the EC is fully supportive of a peaceful transition to democracy in Cuba, it cannot accept that the U.S. unilaterally determines and restricts EC economic and commercial relations with any foreign nation which has not been collectively determined by the United Nations Security Council as a threat to peace or order in the world of nations.'

The Canadian government **made** similar complaints, stating that the extraterritorial aspects of the CDA are an affront to the sovereignty of Canada and other nations which have the right to determine their own policies with regard to Cuba.

When the CDA's extraterritorial provisions went into effect in 1992, it signaled a reversal of the United States' earlier-stated **policy** that it would not seek to penalize third-country trade relations with Cuba. In fact, the inclusion of the third-country penalties once again in the embargo against Cuba specifically contradicted actions taken by the U.S. in 1975 when the government acknowledged the impropriety of such provisions and removed them from earlier laws setting forth the terms of the embargo against Cuba.

In 1962, the Organization of American States adopted stringent resolutions mandating that all member states cut diplomatic ties with Cuba. The OAS also imposed a collective embargo against Cuba at that time. In 1962, the terms of the U.S. embargo against Cuba, the strongest of any of the nations in the hemisphere, included sanctions against other nations which continued to deal with Cuba, similar to those found in the CDA today which prohibit the entry into the U.S. of vessels having visited Cuba.

By 1975, a change in sentiment had taken place within the OAS as various member states asserted their right to determine their own policies with Cuba, and some reestablished relations with the island nation. On July 29, 1975, the OAS adopted a resolution rescinding its mandatory embargo on Cuba. Based on the principle of nonintervention, a fundamental cornerstone of the OAS which is mentioned throughout the organization's Charter, the regional body called on each member state to freely determine its own policies with regard to trade and other relations with Cuba.*

In direct response to the 1975 OAS resolution, the U.S. modified its policies, removing those provisions of U.S. law which sought to penalize or control third countries' relations with Cuba. In a September 1975 official State Department Bulletin, the U.S. announced:

In keeping with the action by the OAS, the United States is modifying the aspects of our Cuban denial policy which affect other countries. Effective today, August 21, 1975, it will be U.S. policy to grant licenses permitting transactions between U.S. Subsidiaries and Cuba for trade in foreign-made goods when those subsidiaries are operating in countries where local law or policy favors trade with Cuba.... In order to conform farther with the OAS action, we are taking appropriate steps so that effective immediately countries which allow their ships or aircraft to carry goods to and from Cuba are not penalized by loss of U.S. bilateral assistance. We are initiating steps to modify regulations which deny bunkering in the United States to third-country ships engaged in the Cuba Trade.³

Echoing this recognition of the inappropriateness of third-country penalties, then Assistant Secretary for Inter-American Affairs, William Rogers, testified before the U.S. Congress as to why the "third-country constraints" were being lifted:

As a logical and practical corollary to the termination of mandatory OAS sanctions, the U.S. government, on August 21 announced modifications of those aspects of our Cuban denial policy which affect other countries.... This was basically a measure to remove a recurrent source of friction between the United States and friendly countries both in this hemisphere and overseas which, for reasons of their own, have engaged in or never ceased to trade with Cuba.'

In 1992 the CDA restored the third-country constraint provisions which had been specifically denounced by the U.S. government in 1975 as unacceptable to other nations and incompatible with the 1975 OAS resolution affirming the right of each member state to freely determine its own policies toward Cuba. The current U.S.-imposed embargo which punishes those who trade with Cuba patently violates the OAS resolution and runs counter to the OAS Charter, which upholds nonintervention as one of the fundamental principles upon which the organization is founded.

In addition to the individual protests of foreign trading partners prompted by the CDA's passage, the law has also brought about formal denouncements from the United Nations. In four consecutive sessions of the United Nations General Assembly, that body has passed resolutions condemning the U.S. embargo against Cuba and calling on the United States to rescind those aspects of its law which are violative of international law principles as well as of the U.N. Charter. In its most recent resolution (passed on November 15, 1995) entitled 'Necessity of ending the economic, commercial and financial embargo imposed by the United States of America against Cuba,' the U.N. General Assembly held, inter alia:

Beaffrming, among other principles, the sovereign equality of States, non-intervention and non-interference in their internal affairs and freedom of international trade and navigation, which are also enshrined in many international legal instruments . . .

Concerned about the continued promulgation and application by Member States of laws and regulations whose extraterritorial effects affect the sovereignty of other States and the legitimate interests of

entities or persons under their jurisdiction, as well as the freedom of trade and navigation...

Concerned that, since the adoption of its resolutions 47/19, 48/16 and 49/95 further measures of that nature aimed at strengthening and extending the economic, commercial and financial embargo against Cuba continue to be promulgated and applied, and concerned also about the adverse effects of such measures on the Cuban people and on Cuban nationals living in other countries...

[The U.N. General Assembly] reiterates its call to all States to refrain from promulgating and applying laws and measures of the kind referred to in the preamble to the present resolution in conformity with their obligations under the Charter of the United Nations and international law which, inter alia, reaffirm the freedom of trade and navigation...*

Notwithstanding repeated U.N. resolutions calling for the rescinding of practices against Cuba and against nations that trade with Cuba which violate international law, the U.S. has steadfastly maintained and even reinforced its policies.

Human Rights Violations Precipitated by the US. Embargo on Sales of Medicines to Cuba

While the extraterritorial aspects of the CDA have outraged the international community and provoked much opposition, the primary focus of this report is the human **suffering** precipitated by the restrictions on sales of medicines to Cuba. The CDA's provisions, which serve to cut off Cuba's international supply of medicines and medical equipment, violate the acceptable parameters established by customary international law for trade embargoes as well as human rights guarantees enshrined in international human rights agreements to which the U.S. is bound.

Most notably, the CDA violates U.S. obligations as a member of the Organization of American States. In addition to running counter to the terms of the 1975 OAS resolution mentioned above, the restrictions on medicines also serve to violate U.S. duties arising under the OAS Charter and those articulated in the American Declaration of the Rights and Duties of Man (the American Declaration), a key document within the inter-American system that sets forth fundamental human rights obligations of all OAS member states, including the U.S.'

The American Declaration and the OAS Charter are "sources of international obligation for member states of the Organization of American States."⁸ These documents envision a regional, inter-American human rights system protecting all peoples in the Americas from rights violations by their own or another American government. As such, the American Declaration codifies rights and duties which survive border crossings. Both the American Declaration and the American Convention on Human Rights articulate fundamental human rights guarantees which their drafters envisioned as being respected systemwide. Just as the European system of human rights on which it is modeled establishes regional community-wide rights and **obligations, so** does the inter-American system suggest the extraterritoriality of American states' human rights obligations.

With regard to human rights obligations created by instruments such as the American Declaration, the American Convention, and the OAS Charter, it should be noted that the Restatement (Third) of the Foreign Relations Law of the U.S. recognizes their binding nature, stating:

Like multilateral agreements generally, an international human rights agreement creates rights and obligations between each party and every other party. Most multilateral agreements, however, are essentially networks of bilateral agreements, creating obligations between each pair of parties as regards their particular interests *inter se*, e.g., as to trade or communication between them.... Human rights agreements, however, are more genuinely multilateral. The obligations run to all parties equally and do not ordinarily engage the interest of one state more than another; unless otherwise provided, all states parties have the same remedies for violations.*

In asserting the importance of the "international protection of the rights of man," the American Declaration asserts that regional, intergovernmental cooperation is required to protect the 'essential rights' protected by that document. Echoing language in the American Declaration, the OAS Charter also proclaims "the consolidation of this continent [i.e., the Americas] into a system based on respect for the essential rights of man."¹⁰

In examining the specific dictates of the American Declaration which are of relevance in determining the compatibility of the CDA with U.S. human rights obligations, the following should be noted:

Art. I provides: "Every human being has the right to life, liberty and the security of his person."

Art. VII provides: "All women, during pregnancy and the nursing period, and all children have the right to special protection, care and aid."

Most notably, Art. XI provides: "Every person has the right to the preservation of his health through sanitary and social measure relating to food, clothing, housing and medical care, to the extent permitted by public and community resources."

These articles impose an affirmative duty on the government of each state to ensure these protections to its citizens and residents. Likewise, the Declaration and OAS Charter require that each state must refrain from taking actions which would hinder or prevent other **states** from carrying out these obligations. As is discussed elsewhere in this report, the U.S. restrictions on the sales of medicines to Cuba directly impact the ability of the Cuban population to preserve its health through adequate and proper medical care."

The Humanitarian Exception of All Embargoes

The use of economic embargoes as a political sanction is not new. However, over the course of time, various limitations have come to be recognized by the international community as to what is the proper scope of a permissible embargo. In short, international practice has come to include an exception for medicines, medical supplies and certain basic foodstuffs in any embargo in order to prevent unnecessary suffering among civilian populations.

Humanitarian exceptions permitting the free flow of medicines and food were features of multilateral embargoes imposed against North Korea, Vietnam, South Africa, Chile, El Salvador, the Soviet Union and Haiti. In the recent U.N.-supported embargoes against Iraq and the territories of the former Yugoslavia, the U.N. upheld the principle that food and medicines must be allowed through in order to serve the basic needs of the civilian population. In the case of Iraq, a special Sanctions Committee was established within the U.N. to ensure that shipments of food and

medicines were permitted to get through to Iraqi civilians. In explaining the rationale for allowing these exceptions to the embargo, U.N. Security Council officials stated that it is internationally "unacceptable to cause wide-spread suffering among civilians through impeding the shipment of food and medicines" in order to punish a country's leaders."

In addition to the U.N. General Assembly resolutions denouncing the U.S. embargo against Cuba for its extraterritorial aspects, the United Nations Commission on Human Rights has decried the embargo for its direct impact on the human rights of Cuban citizens who are harmed by its restrictions of food and medicine shipments. In Resolution 1994/47 entitled "Human Rights and Unilateral Coercive Economic Measures," the U.N. Commission on Human Rights particularly singled out the practice of large developed nations such as the U.S. in singling out smaller, less developed nations for unilateral embargoes. The U.N. Commission stated that such unilateral coercive measures against developing countries are in "clear contradiction of international law" **and** that "such unilateral coercive economic measures create obstacles to trade relations among States, adversely affect the socio-humanitarian activities of developing countries, and hinder the full realization of human rights by the people subject to those measures."

It should be noted that the purposeful impeding of food and medicines to civilians in time of war is expressly prohibited under customary international law and is codified in the Geneva Conventions. If international law requires a humanitarian exception for food and medicine even in times of war, then certainly the U.S. cannot take actions to achieve the same result in times of peace. Through the CDA, the U.S. creates a de facto blockade of Cuba which prevents the country's civilian population from obtaining adequate medicines, medical supplies and foodstuffs.

The Geneva Convention,* to which some 165 countries, including the United States, are parties, requires "free passage" of all medical supplies intended for civilians." This duty is placed on states even in times of war. Surely the recognition of the fundamental human right to medicines must be applied with equal diligence and vigor in the arena of international relations and trade sanctions. As is demonstrated elsewhere in this report, the U.S. restrictions on sales by U.S. companies and their subsidiaries of medicines to Cuba and the penalties against third countries who continue to trade with Cuba (including through the sale of medicines) serve to severely restrict the flow of medicines to Cuba's civilian population.

Lastly, it should be noted that the 1962 multilateral embargo against Cuba, mandated by the OAS at the height of tensions with that nation, allowed for the sale of medicines to Cuba, noting that such a "humanitarian exception" is mandated by international law and practice. Indeed, the OAS's Inter-American Commission on Human Rights, in a February, 1995, letter to the United States with regard to its embargo on the sale of medicines to Cuba, stated

[The Inter-American Commission on Human Rights] requests that the United States of America faithfully observe the traditional exemption from an embargo under customary international law, of medicine, medical supplies and basic food items, for humanitarian reasons.

The Commission further stated:

[I]t is aware that the Cuban Democracy Act contains such exemptions; however, the Inter-American Commission Human Rights has been informed that the bureaucratic and other requirements which have to be met in relation to those exemptions [i.e. on-site verification] render them virtually unattainable. Accordingly, the Inter-American Commission on Human Rights requests that the United States of America put in place mechanisms

to ensure that the necessary steps are taken for exemption from the trade embargo in respect of medicine, medical supplies and basic food items, capable of effective and speedy implementation.”

As it has ignored the resolutions of the U.N. General Assembly and the U.N. Commission on Human Rights calling for an end to the embargo against Cuba, so also has the U.S. ignored the pleas of the Organization of American States. The U.S. embargo on medicines remains in place unabated.

NOTES

¹ European Community Press Release (Oct. 8, 1995), *reprinted in* Michael Krinsky *et al.*, United States Economic Measures Against Cuba: Proceedings in the United Nations and International Law Issues 194 (1993).

² See Final Act, Sixteenth Meeting of Consultation of Ministers of Foreign Affairs, Serving as Organ of Consultation in Application of the Inter-American Treaty of Reciprocal Assistance, July 29, 1975, OEA/Ser.FfiI.Doc.9/75, Rev. 2 (1975).

³ Dep't St. Bull., Sept. 15, 1975, at 494, *reprinted in Krinsky et al., supra note 94*, at 214.

⁴ *U.S. Trade Embargo of Cuba: Hearings Before the Subcomm. on Int'l Trade & Corn. & Int'l Organizations of House Comm. on Int'l Rel., 94th Cong.*, 1st Sess. 366 (1975), *quoted in Krinsky et al., supra note 94*, at 216.

⁵ These numbers refer to the three previous resolutions passed by the U.N. General Assembly calling for the elimination of policies against Cuba which violate these principles.

⁶ **G.A. Res.**, U.N. GAOR, U.N. Doc. A/RES/50/10 (1995).

⁷ The Declaration can be found in its entirety in Basic Documents Pertaining to Human Rights in the Inter-American System, General Secretariat of the Organization of American States, OEA/ser.L./V./II.82 (1992).

⁸ Case 10.573, Inter-Am. C.H.R. 31, OEA/ser. I/RJ, doc. -rev. (1993).

⁹ Restatement (Third) of the Foreign Relations Law of the United States, § 701 cmt. 3. (emphasis added).

¹⁰ Charter of the Organization of American States, May 2, 1948, U.S.T. 2, Doc. 2394, T.I.A.S. no. 2361(1948); U.S.T. 21, Doc. 607, T.I.A.S. no. 6947 (as *amended* 1970) (at introductory text). See also art. 29 of the Charter which reaffirms a hemispheric approach to human rights ("The Member States, inspired by the principles of inter-American solidarity and co-operation, pledge themselves to a united effort to ensure social justice in the Hemisphere and dynamic and balanced economic development for their peoples.").

¹¹ A petition charging that the CDA violates U.S. obligations under the American Declaration and OAS Charter is currently pending before the OAS Inter-American Commission on Human Rights. A copy of the petition can be obtained from the Center for Constitutional Rights, 666 Broadway, Seventh Floor, New York, New York 10012.

¹² *United Nations Eases Rules on Food and Fuel for Iraqis, N.Y. Times, Mar. 23, 1991.*

¹³ Geneva Convention, No. IV, Aug. 12, 1949. Int'l Comm. of the Red Cross.

¹⁴ Convention Relative to the Protection of Civilian Persons in Time of War. Geneva Convention, No. IV, art. XXIII.

¹⁵ A copy of the letter notifying the petitioners in the action of the sending of this letter to the U.S. Department of State is included in the appendix at XXX.¹⁶

THE APPENDICES

Appendix A

American Association of World Health Delegation to Cuba- October 4-11, 1996

ALFRED **W. BRANN, M.D.**, is Professor of Pediatrics, Emory University School of Medicine, specializing in neonatal and perinatal medicine and in child neurology. As the current Director of the World Health Organization (WHO) Collaborating Center in Perinatal Health and Health Services Research in Maternal and Child Health, he evaluates the quality of perinatal/neonatal care and performance of the health systems that deliver that care. Dr. Brann has also worked with the Carter Center of Emory University, the Task Force of Child Survival, Project Hope, and the World Bank. He has consulted in Central and South America, Asia, Eastern Europe, India, Bangladesh and Pakistan.

PETER G. BOURNE **M.D.**, is currently Chairman of the Board of the American Association for World Health. He is also Professor and chair of the Department of Psychiatry at St George's Medical School in Grenada. He was an advisor to former President Jimmy Carter on health issues and served as Assistant Secretary General of the United Nations from 1979-1981. He has authored over 100 articles and several books on international health and political issues. He has traveled on numerous occasions to Cuba on behalf of the White House, the United Nations, and as a professional researcher.

C. **WILLIAM KECK, M.D.**, M.P.H., is currently Director, Akron Public Health Department, and Director, Division of Community Health Sciences, Northeastern Ohio University's College of Medicine. He has served in these positions since 1976. He was Field Professor of Community Medicine, University of Kentucky College of Medicine from 1972 through 1975. After earning his medical degree, Dr. Keck served as a Peace Corps physician for three years. He has served as Resident of the following organizations: Summit County Medical Society, American Public Health Association, Association of Ohio Health Commissioners, and the Ohio Public Health Association.

THOMAS **M. HERKERING, M.D.**, is Professor of Medicine at the Medical College of Virginia in Richmond, Virginia. He directs the Richmond AIDS Consortium, an NIH-funded clinical research program on HIV/AIDS, and heads the Child Survival Program for Guatemala, recently funded by USAID. He is an author on 57 publications in peer-reviewed journals, 60 abstracts at national/international meetings, and 10 book chapters dealing with the subjects of mycology, HIV/AIDS and international health. He has assessed health programs and health status in Russia, the Baltic states, Poland, Ethiopia, Kenya, Uganda, Zambia, Angola, Sierra Leone, the Gambia, Senegal, Bolivia, Guatemala, India, Sri Lanka, and Cuba.

KAREN OLNESS, M.D., is Professor of Pediatrics, Family Medicine, and International Health at Case Western Reserve University. She is also Director, International Child Health at Rainbow Babies and Children's Hospital, where she coordinates international child health training for pediatric residents. She has served on the faculties of George Washington University, University of Minnesota, and Case Western University. For the past nine years, she has directed research on pediatric AIDS in Uganda and a faculty development project in Laos. In 1995, she was a WHO consultant, working to develop a Community and Social Pediatrics curriculum for Laos.

Appendix B

Researchers and Authors of the Full Study

MICHELE FRANK, M.D., is Health Editor of Cuba Update, the journal of the Center for Cuban Studies and is pursuing a residency in child psychiatry.

GAIL REED is a journalist and development consultant, who has written for the U.S. press on Cuban economic policy and social conditions for the last ten years. She is currently associated with the World Policy Institute, New York. She has also conducted research in Cuba for UNICEF, the Christian Children's Fund, and For Children, evaluating potential NGO cooperation in the Cuban social sector. Before making Havana her professional base, Ms. Reed served on the executive staff at Church World Service, New York. She is a graduate of the Columbia School of Journalism.

The American Association for World Health wishes to thank Wallie Mason and Stephen Kimmerling for their research on the legal aspects of the embargo, licensing procedures, patent law and international human rights agreements.

ELISABETH A. SQUEGLIA, J.D., is a practicing attorney specializing in government affairs, health care and insurance, serving as a partner in the law firm of Bricker & Eckler in Columbus, Ohio. In addition to serving on the Board of Directors of the American Association for World Health, Ms. Squeglia is a member of the Health Cam **Forum** of the American Bar Association, the National Health Lawyers Association, and the American Academy of Hospital Attorneys. Formerly, she served as the Chief of Staff and Assistant to the Minority Leader of the Ohio Senate.

ROBERT J. WHITE, M.D., PH.D., is currently Professor of Neurosurgery at Case Western Reserve University School of Medicine and Director of the Division of Neurosurgery and the Brain Research Laboratory at the MetroHealth Medical Center. He is a consultant to the Burdenko Institute of Neurosurgery in Moscow, the Polenov Neurological Institute in Saint Petersburg, Russia, and the Ukrainian Research Institute in Kiev. He has served as Editor or on the Editorial Board of several journals and has authored almost seven hundred publications on clinical neurosurgery, brain research, medical ethics, and health care delivery.

ROBIN WILLIAMS, M.D., is the Medical Officer of Health for the Regional Municipality of Niagara, Ontario, Canada.

RICHARD L. WITTENBERG has served as President and CEO of the American Association for World Health since 1991. In that position he has successfully directed world health initiatives promoting public health education and community involvement in the areas of oral health, early immunization, violence prevention, HIV/AIDS, tobacco, healthy cities/communities, and cardiovascular disease. Before assuming leadership of AAWH, Mr. Wittenberg served as the Chief of Public Affairs for the Ohio Department of Health. Formerly, as a member of the Ohio legislature, Mr. Wittenberg took a strong leadership role in health care legislation.

Appendix C

VISITS TO PATIENT CARE FACILITIES

Cardiocentro "William Soler"
("William Soler" Pediatric Cardiology Center)
Havana

Centro Nacional de Genética Médica
(National Center for Medical Genetics)
Havana

Centro de Referencia Nacional de Nefrología **Pediátrica**
(National Reference Center for Pediatric Nephrology)
Central Havana Pediatric Hospital
Havana

Centro de Rehabilitación de Niños Asmáticos "Celia Sánchez Manduley"
("Celia Sánchez Manduley" Rehabilitation Center for Asthmatic Children)
Havana

Centro de Retinosis Pigmentaria
(Retinosis Pigmentosa Center)
Havana

Clínica del Adolescente "Ana Betancourt"
("Ana Betancourt" Child and Adolescent Mental Health Clinic)
Havana

Family Physician and Nurse Offices (3)
Habana del Este Municipality
Havana

Hospital Clínico-Quirúrgico "Manuel Albarrán"
("Manuel Albarrán" General Hospital)
Havana

Hospital Clínico-Quirúrgico "Salvador Allende"
("Salvador Allende" General Hospital)
Havana

Hospital Docente Pediátrico del Cerro
(Cerro Pediatric Teaching Hospital)
Havana

Hospital Maternidad Docente Gineco-Obstétrico "Eusebio Hernández"
("Eusebio Hernández" Maternity Teaching Hospital)
Havana

Hospital Materno-Infantil "América Arias"
(América Arias Maternity Hospital)
Havana

Hospital Oftalmológico "Pando Ferrer"
("Pando Ferrer" Ophthalmology Hospital)
Havana

Hospital Ortopédico "Frank País"
("Frank País" Orthopedic Hospital)
Havana

Hospital Pediátrico de Centro Habana
(Central Havana Pediatric Hospital)
Havana

Hospital Pediátrico "Juan Manuel Márquez"
("Juan Manuel Márquez" Pediatric Hospital)
Havana

Hospital Pediátrico "Pepe Portillo"
("Pepe Portillo" Pediatric Hospital)
Pinar del Río

Hospital Provincial "Abel Santamaria"
("Abel Santamaria" Provincial Hospital)
Pinar del Río

Hospital Provincial Gineco-Obstétrico "Justo Legón Padilla"
("Justo Legón Padilla" Provincial Maternity Hospital)
Pinar del Río

Hospital Provincial Docente Clínico-Quirúrgico de Pinar del Río
(Pinar del Río Provincial Teaching Hospital)
Pinar del Río

Hospital Psiquiátrico "27 de Noviembre"
("27 de Noviembre" Psychiatric Hospital)
Arroyo Naranjo

Instituto de Cardiología
(Cardiology Institute)
Havana

Instituto de Endocrinología
(Endocrinology Institute)
Havana

Instituto de Hematología
(Hematology Institute)
Havana

APPENDICES

Instituto Nacional de Oncología y Radiología
(National Cancer Institute)
Havana

Instituto de Nefrología
(Nephrology Institute)
Havana

Instituto de Medicina Tropical "Pedro Kourí"
(Pedro Kourí Institute for Tropical Medicine)
Havana

Sanatorio "Los Cocos"
(Los Cocos AIDS Sanatorium)
Havana

VISITS TO INSTITUTIONS

Agencia de Medio Ambiente
(Environmental Agency)
Ministry of Science, Technology and the Environment
Havana

Centro de Ingeniería Genética y Biotecnología
(Genetic Engineering and Biotechnology Center)
Havana

Centro de Inmunoensayo
(Immunoassay Center)
Havana

Centro de Investigación y Desarrollo de Medicamentos (CIDEM)
(Research and Development Center for Medications)
Havana

Centro Nacional de Electromedicina
(National Center for Electromedicine)
Havana

Centro Nacional de Información de Ciencias Médicas
(National Center for Medical Sciences Information)
Havana

Centm Nacional de Perfeccionamiento Médico (CENAPEM)
National Center for Continuing Medical Education
Havana

Centm de Neurociencias de Cuba
(Cuban Neurosciences Center)
Havana

Dirección Provincial de Salud
(Provincial Health Headquarters)
Pinar del Río

Empresa Nacional de Suministros Farmacéuticas (ENSUFARMA)
(National Pharmaceutical Supply Company)
Havana

Empresa de Suministros Médicos (EMSUME)
(Medical Supply Company)
Havana

Instituto de Biotecnología de las Plantas
(Plant Biotechnology Institute)
University of Las Villas
Villa Clara Province

Instituto Finlay
(Finlay Institute)
Havana

Instituto de Nutrición
(Nutrition Institute)
Havana

Instituto de Recursos Hidráulicos
(Water Resources Institute)
Havana

Instituto Superior de Ciencias Básicas "Victoria de Girón"
(Higher Institute for Basic Sciences, Havana Medical School)
Havana

MEDICUBA Import-Export Firm
Havana

Ministerio de Comercio Exterior
(Ministry of Foreign Trade)
Havana

Ministerio de la Industria Alimenticia
(Ministry of the Food Industry)
Havana

Ministerio de Relaciones Exteriores
(Ministry of Foreign Relations)
Havana

Planta Farmacéutica "Reynaldo Gutierrez"
(Reynaldo Gutierrez Pharmaceutical Plant)
Havana

APPENDICES

VISITS TO NON-GOVERNMENTAL AND INTERNATIONAL ORGANIZATIONS

Asociación Cubana de Limitados Físico-Motores
(Cuban Association of the Physically Disabled)
Havana

Asociación Nacional de Ciegos
(National Association of the Blind)
Havana

Asociación Nacional de Sordos de Cuba
(Cuban National Association of the Deaf)
Havana

CARITAS Cuba
Havana

Centro Memorial "Dr. Martin Luther King, Jr."
("Dr. Martin Luther King, Jr." Memorial Center)
Marianao Ebeneser Baptist Church
Havana

Consejo Nacional de Iglesias
(National Council of Churches)
Havana

Consejo Nacional de Sociedades Científicas
(National Council of Scientific Societies)
Havana

Cruz Roja de Cuba
(Cuban Red Cross)
Havana

Pan American Health Organization (PAHO)
Havana

Sociedad Cubana de Anestesiología
(Cuban Society of Anesthesiology)
Havana

Sociedad Cubana de Cardiología
(Cuban Society of Cardiology)
Havana

Sociedad Cubana de Pediatría
(Cuban Society of Pediatrics)
Havana

Sociedad Cubana de Educación Familiar (SOCUDEF)
(Cuban Society for Family Education)
Havana

United Nations Development Program (UNDP)
Havana

United Nations Children's Fund (UNICEF)
Havana

PROFESSIONALS INTERVIEWED

Dr. Zamira Acosta
Chief of Clinical Analysis Department
"Frank País" Orthopedic Hospital
Havana

Dr. Sonia Aguila
Chief of Perinatology
"Eusebio Hernández" Maternity Hospital
Havana

Dr. Raúl Alonso
Chief of Radiology
Pinar del Rio Provincial Teaching Hospital
Pinar del Rio

Dr. Rodrigo Alvarez Cambras
Resident, Cuban Society of Orthopedics and Traumatology
Director, "Frank País" Orthopedic Hospital
Havana

Dr. Sara Alvarez
Chief, Intensive Care (ICU)
"Pepe Portillo" Pediatric Hospital
Pinar del Rio

Dr. Lorenzo Anasagasti
Vice-Director for Technical Equipment
National Cancer Institute
Havana

Daniel Aponte
Director of Electromedicine
Granma Province

Dr. Mayda Arza
Professor of Medicine
Staff, Medical Education Division, Ministry of Public Health
Havana

Sonia Baez
Post-graduate Studies Program
SERVIMED
Havana

APPENDICES

Mabel Balbín
International Department
Ministry of the Food Industry
Havana

Dr. Mayra Barbón Peña
Vice-Director
"27 de Noviembre" Psychiatric Hospital
Arroyo Naranjo

Dr. Maria del Carmen Barroso
Director for Medicines
National Oncology Institute
Havana

Dr. Jose Manuel Bayesteros Santovenia
Director
Hematology Institute
Havana

Dr. Armando Bello
Psychiatrist
"Hermanos Ameijeiras" Hospital
Havana

Dr. Oscar Beltrán
Director, Beterá Laboratories and Provincial Blood Bank
Havana

Mary Lou B'Hamel
Policy Department
Ministry of Foreign Trade
Havana

Iraida Blanco
Chief of Nursing
"Justo Legón Padilla" Provincial Maternity Hospital
Pinar del Rio

Nancy Blanco
Vice-Director for Medications and Raw Materials
MEDICUBA
Havana

Dr. Maria Antonieta Bobes
Cognitive Neuroscience Dept.
Cuban Neuroscience Center, Havana

Dr. Carlos Brown
First Vice-Director
"Justo Legón Padilla" Provincial Maternity Hospital
Pinar del Rio

Dr. Maria Luisa Buch
Director, National Program for Early Detection of Breast Cancer
Havana

Dr. Evelio Cabezas
Chief of National Obstetrics and Gynecology Program
Ministry of Public Health, Havana

Dr. Nancy Cabrera
Chief of Microbiology Laboratories
"Joaquín Albarrán" General Hospital
Havana

Dr. Pastor Cabrera
Director
Cerro Pediatric Teaching Hospital
Havana

Dr. Rolando Camacho Rodríguez
Director
National Cancer Institute, Havana

Walkiria Cao
Director, International Relations
Hematology Institute
Havana

Dr. Felipe Cárdenas
Surgeon
"William Soler" Pediatric Cardiology Center
Havana

Dr. Juan J. Ceballos Arrieta
Director
National Center for Continuing Medical Education (CENAPEM)
Havana

Alexis Cedeño
Sub-Director
National Center for Electromedicine
Havana

Haydee Cela
Deputy Director for Quality Control
Reynaldo Gutierrez Pharmaceutical Plant
Havana

Enrique Comendiro Hernández
Chief Advisor to the Minister of Public Health
Havana

APPENDICES

Dr. Celso Cruz Rodriguez
Chief of Clinical Laboratories
Hermanos Ameijeiras Hospital
Havana

Dr. Luis Delgado Méndez
Director, National Dental Program
Ministry of Public Health
Havana

Dr. Mirta Díaz
Technical Vice-Director and Clinical Laboratory Specialist
"Justo Legón Padilla" Provincial Maternity Hospital
Pinar del Rio

Dr. Oscar Díaz Díaz
Vice-Director for Research
Endocrinology Institute
Havana

Rafael Díaz Valdés
Specialist
Dept. of Oxygen Therapy
National Center for Electromedicine
Havana

Ramón Díaz Vallina
Vice-Minister for Economics
Ministry of Public Health
Havana

Rolando Díaz
Vice-Director for Medical Equipment
MEDICUBA
Havana

Dr. Francisco Dorticós
Chief of Pacemaker Department
Cardiology Institute
Havana

Ida Hilda Escalona del Toro
President. Cuban Association of the Physically Disabled
Havana

Dr. Digna Espinosa
Pediatric Nephrology Center
Havana

Dr. Noris Estrada
Pediatric Anesthesiologist
Central Havana Pediatric Hospital
Havana

Dr. Lino Farley
Chief of Intensive Care
Pinar del Rio Provincial Teaching Hospital
Pinar del Rio

Dr. Ubaldo Farnot Cardoso
Resident, Society for Obstetrics and Gynecology
Professor, "América Arias" Maternity Hospital
Havana

Dr. José L. Fernández Yero
Director, Immunoassay Center
President, TECNOSUMA
Havana

Raso Fernández
Public Relations
National Cancer Institute
Havana

Dr. Rafael Figueredo González
Chief, Vectors Department
Epidemiology
Ministry of Public Health
Havana

Dr. Gilberto Fleites
Surgeon
National Oncology Institute
Havana

Noelio Flores
Laboratory Specialist
Center for Research and Development of Medications
Havana

Dr. José de la Fuente
Research Director
Genetic Engineering and Biotechnology Center
Havana

Rosa Fuentes
General Manager
Pharmaceutical Raw Materials Division
MEDICUBA
Havana

Dr. Miguel Angel Galindo
Chief, National Immunization Program
Ministry of Public Health
Havana

APPENDICES

Dr. Jorge Mario Garcia Fernández
Director of Information
Environmental Agency
Ministry of Science, Technology and the Environment
Havana

Dr. Manuel Garcia Domínguez
Director
"González Coro" Maternity Hospital
Havana

Dr. Alberto González Ruiz
Deputy Director fo International Medical Care
"Frank País" Orthopedic Hospital
Havana

Amado González Lamda
President, National Association of the Blind
Havana

Dr. Noemi Gorrín
Medical Director
National Council of Churches
Havana

Dr. Margarita Graupera
National Cancer Registry
National Oncology Institute
Havana

Dr. Manuel Grillo
Department of Food Hygiene
Nutrition Institute
Havana

Dr. Elsa Gutierrez
Director, Adolescent and Child Mental Health Clinic
Professor of Child and Adolescent Psychiatry
Havana

Diana Guzman
General Manager, Medications
MEDICUBA
Havana

Dr. Luis Heredero
Director, National Center for Medical Genetics
Havana

Dr. Enrique Hernández
Secretary
National Asthma Commission
Havana

Dr. Jeremías Hernández Ojito
Director, National Center for Medical Sciences Information
Havana

Dr. Alberto Hernández Cañero
President, Cuban Society of Cardiology
Director, Cardiology Institute
Havana

Dr. René Hernández Valdéz
Provincial Health Staff
Pinar del Río Province

Iván Herrera
Sub-Director of Research
Genetic Engineering and Biotechnology Center
Havana

Dr. Manuel Herrera
Neurology Dept.
Pepe Portillo Pediatric Hospital
Pinar del Río Province

Dr. Raúl Herrera
Director
Nephrology Institute
Havana

Dr. Raquel Huerta
Chief, Microbiology Laboratory
Pepe Portillo Pediatric Hospital
Pinar del Río Province

Armando Jaular
General Coordinator
Médicos Sin Fronteras (Doctors Without Borders)
Spain

Dr. Elio Jiménez
Research Director
Institute for Plant Biotechnology
University of Las Villas
Villa Clara Province

Dr. Santa Jiménez
Specialist
Nutrition Institute
Havana

APPENDICES

Prof. José Jordán
President, National Council of Scientific Societies
Professor of Pediatrics, Havana

Dr. Angela Justiz
Technical Director
'Juan Manuel Márquez' Pediatric Hospital
Havana

Dr. José Lagomasino
Proteins Department
Beterá Laboratories
Havana

Dr. Jesús Lazo Cabrera
Director
'Pepe Portillo' Pediatric Hospital
Pinar del Río

Dr. Mario Lee
Chief of Neonatology
América Arias Maternity Hospital
Havana

Dr. Noemí Levy
Chief of Dialysis Services
Central Havana Pediatric Hospital
Havana

Juan Carlos Leyva Oliva
Director of Imports
Finlay Institute
Havana

Dr. Manuel Limonta
Director
National Center for Genetic Engineering and Biotechnology
Havana

Dr. Marta Lonjón
Chief of the National Pediatric Oncology Program
Havana

Dr. Maribel López Bancells
Chief of Clinical Laboratories
'Manuel Albarrán' General Hospital
Havana

Dr. Orlando Lorenzo Alvarez
Director
'Manuel Albarrán' General Hospital
Havana

Dr. Maria Victoria Luna
Chief, Sanitary Controls
Nutrition Institute
Havana

Sara Llanes
Specialist in Reagents
National Pharmaceutical Supply Company
Havana

Susana Llovet
Cuban F&d cross
Havana

Dr. Otto Machado
National Maternal-Infant Cam Program
Ministry of Public Health
Havana

Dr. Charles Magrans
Nephrologist
Nephmlogy Institute
Havana

Dr. Pedro Marrero
Chief of Neuropediatrics
"Juan Manuel Márquez" Pediatric Hospital
Havana

Dr. Rosa Marrero
Chief of Clinical Laboratories
"Juan Manuel Márquez Pediatric Hospital"
Havana

Dr. Albert0 Martinez Sardiñas
Chief of Anesthesiology
Nephmlogy Institute
Havana

Dr. Eric Martinez
Director
"Juan Manuel Márquez" Pediatric Hospital
Havana

Dr. Isabel Martinez
Vice-Director for Internal Medicine
"27 de Noviembre" Psychiatric Hospital
Arroyo Naranjo

Dr. Reynaldo Menéndez
Director
"Justo Legón Padilla" Provincial Maternity Hospital
Pinar del Rio

APPENDICES

Dr. Maritsa Miguel
Deputy Director
Pando Ferrer Ophthalmologic Hospital
Havana

Dr. Luis Mitjans
Vice-Director for Internal Medicine
Pinar del Rio Provincial Teaching Hospital
Pinar del Rio

Osvaldo Montero
Projects Director
UNICEF
Havana

Nicolás Montoto
International Relations
Ministry of Public Health
Havana

Blas Eduardo Mora Maestre
President
Cuban National Association of the Deaf
Havana

Dr. Miriam Musa
Chief of Radiology
"Abel Santamaria" General Hospital
Pinar del Rio

Dr. F. Navaroli
Chief of Laboratories
Endocrinology Institute
Havana

Dr. Claude Moncorge
General Secretary
Medicins du Monde (Doctors of the World)
France

Marta Nodarse Hernández
Chief of Production for Cooking Oils
Ministry of the Food Industry
Havana

Dr. Raúl Obrerón Llano and heads of departments
Director
"Abel Santamaria" Provincial Hospital
Pinar del Rio

Dr. José Oliva
Director, Prenatal Genetics Program
'González Coro' Maternity Hospital

Havana

Miguel Ortiz
Director of Electromedicine
Las Tunas Province

Dr. Enrique Otero
Production Director
"Frank País" Orthopedic Complex
Havana

Mercedes Oviedo
International Relations
MEDICUBA
Havana

Dr. Herminia Palenzuela López
Chief of Clinical Cardiology
"William Soler" Pediatric Cardiology Center
Havana

Dr. Irene Pastrán
Vice-Director, Chief of Training, Chief of Intensive Care
"Abel Santamaria" Provincial Hospital
Pinar del Rio

Enrique Pereira
Chief of Electromedicine
"Frank País" Orthopedic Hospital
Havana

Dr. Jorge Pérez
Director, Havana AIDS Sanatorium
Vice-Director, "Pedro Kourí" Institute for Tropical Medicine
Havana

Dr. Julián Pérez Peña
Coordinator, National Ad-Hoc Commission for Medications
Ministry of Public Health
Havana

Dr. Rodolfo Pérez Felpeto and heads of departments
Vice-Director
"Salvador Allende" General Hospital
Havana

Dr. Daisy Pina
Chief of Microbiology Laboratories
"Frank País" Orthopedic Hospital
Havana

APPENDICES

Dr. Alfredo Portero Urquiza
President, Cuban Society of Pediatric Surgery
Vice-Director, "Juan Manuel Márquez" Pediatric Hospital
Havana

Marlene Porto
Director
Research and Development Center for Medications
Havana

Dr. Claribel Presno Labrador
President, Cuban Society of Family Medicine
Havana

Dr. Jorge Quintana
Chief, Cytogenetics Laboratory
González Coro Maternity Hospital
Havana

Dr. D. Reyes Vega
Chief of Inpatient Services
William Soler" Pediatric Cardiology Center
Havana

Dr. Jose Reyes Díaz
Professor of Medicine
Pharmacology Consultant to the Minister of Public Health
Havana

Catherine Ribas Hermelo
Director of International Relations
Finlay Institute
Havana

Francisco Rivera
Specialist
National Department of Aqueducts
Institute of Water Resources
Havana

Dr. Héctor Rodríguez Baster
Deputy Secretary General
Cuban Red Cross
Havana

Dr. Fidel Rodríguez Calla
Deputy Secretary
National Asthma Commission
Havana

Dr. Nestor Armando Rodríguez Rodríguez
Chief of Intensive Care
"Manuel Albarrán" General Hospital
Havana

Dr. Rubén Rodríguez Gavaldá
Head of Pediatric Section, National Asthma Commission
Havana

Dr. Daniel Rodríguez Milord
Director
Health Tendencies Analysis Unit (WATS)
Ministry of Public Health
Havana

Teresa Rodríguez
Chief of Nursing
Pinar del Río Provincial Teaching Hospital
Pinar del Río

Dr. Héctor Rojas Alvarez
Dept. of Immunology
Nephrology Institute
Havana

Orlando Romero Mérida
Director-General Manager
MEDICUBA
Havana

Alberto Rosabal
Deputy Director for Social Attention to Patients
Havana AIDS Sanatorium
Havana

Dr. M. Rucabado
Chief, Coronary Intensive Care
Cardiology Institute
Havana

Dr. Rosaura Ruíz Fernández
Dept. of Radiology
"Manuel Albarrán" General Hospital
Havana

Dr. Humberto Saínz Cabrera
President, Cuban Society for Anesthesiology
Chief of Anesthesiology and Intensive Care, National Cardiology Institute
Havana

Dr. Aldo L. Sánchez
Technical Vice-Director
Pinar del Río Provincial Teaching Hospital
Pinar del Río

APPENDICES

Dr. Mario Sánchez
Chief of Clinical Laboratories
“Abel Santamaria” General Hospital
Pinar del Río

Maritza Sánchez
Health Commission
CAFUTAS-Cuba

Miguel San Martín
Director of Electromedicine
Santiago de Cuba Province.

Dr. Antonio Sandino
Vice-Director for Surgery
Pinar del Río Provincial Teaching Hospital
Pinar del Río

Dr. María Cecilia Santana
Provincial Health Director
Pinar del Río Province

Dr. Manuel Santin
National Director of Epidemiology
Ministry of Public Health
Havana

Dr. José Santos Gracia
Anesthesiologist
Cardiology Institute
Havana

Dr. Luis Alberta Sarmiento López and heads of departments
Director
Pinar del Río Provincial Teaching Hospital, Pinar del Río

Dr. Arquímedes Sedeño Argilagos
Director, National Council of Scientific Societies
Havana

Dr. Eugenio Selman
Surgeon
“William Soler” Pediatric Cardiology Center
Havana

Dr. Carmen Serrano
Epidemiologist
Ministry of Public Health
Havana

APPENDICES

Dr. Francisco Valdes Lazo
National Maternal-Infant Care Program
Ministry of Public Health
Havana

Dr. Mitchell Valdés Sosa
Director
Cuban Neurosciences Center
Havana

Dr. Ana Isabel Valdez
Specialist, General Comprehensive Medicine
Havana

Dr. Santiago Valdez Martín
Director, National Reference Center for Pediatric Nephrology
Havana

Dr. Crisitina Valdivia
National Director of Ambulatory Services
Ministry of Public Health
Havana

Dr. Orlando Valls Pérez
President, Cuban Society of Radiology
Chief of Radiology, "Hermanos Ameijeiras" Hospital
Havana

Juan Carlos Velasquez
Director
National Center for Electromedicine
Havana

Dr. Alejandro Velazco
"Eusebio Hernández" Maternity Hospital
Havana

Dr. Venancio Vera
Director
América Arias Maternity Hospital
Havana

Maria del Pilar Vilá
Statistics Department
Nephrology Institute
Havana

Dr. Roberto Zayas Mojica
Pediatric Intensive Care Unit
Central Havana Pediatric Hospital
Havana

Dr. Gladys Sirién
Chief of Pathology
"Abel Santmaría" Provincial Hospital
Pinar del Río

Dr. Aldo Sixto
Vice-Director for Training
Pinar del Río Provincial Teaching Hospital
Pinar del Río

Dr. Miguel Sosa
President
Cuban Society for Family Education (SOCUDED)
Havana

Gilberto Sotolongo
Director of Scientific Information
Finlay Institute
Havana

Juan Suárez
Vice-Director
National Center for Electromedicine
Havana

Rev. Raúl Suárez
Pastor, Marianao Ebenezer Baptist Church
Director, "Dr. Martin Luther King, Jr." Memorial Center
Havana

Rolando Suárez
Director
CARITAS, Cuba
Havana

Dr. Luis Teareaux
Chief of Pharmacology
"Manuel Albarrán" General Hospital
Havana

Dr. Frank Tobey
Director
Central Havana Pediatric Hospital
Havana

Abel Torres
Specialist, North America
Ministry of Foreign Trade
Havana

Dr. Wilfredo Torres
Chief of the National Laboratory Group
Ministry of Public Health
Havana

Dr. Arecea Zenéa
Medical Director
“Celia Sánchez Manduley” Rehabilitation Center for Asthmatic Children
Havana

Leonel Zúñiga
Director
National Pharmaceutical Supply Company (ENSUFARMA)
Havana

Luis Zúñiga Zárata
Resident Program Director
UNICEF
Havana

NOTE: Numerous patients and family members were also interviewed, as indicated in chapter footnotes.