RICHARD I. SMITH
SENIOR VICE PRESIDENT, POLICY AND RESEARCH
PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA

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Chairman Pallone, Ranking Member Deal, and Members of the Subcommittee, thank you for the invitation to participate in today's hearing on prescription drug prices. My name is Richard I. Smith and I am Senior Vice President for Policy and Research of the Pharmaceutical Research and Manufacturers of America (PhRMA).

PhRMA represents the pharmaceutical and biotechnology research sector, which the Congressional Budget Office (CBO) identifies as "one of the most research-intensive industries in the United States."[i] This research investment is yielding extraordinary advances for patients.

As CBO summarizes, "Many examples exist of major therapeutic gains achieved by the industry in recent years…anecdotal and statistical evidence suggests that the rapid increases that have been observed in drug-related R&D spending have been accompanied by major therapeutic gains in available drug treatments."[ii] For instance:

- The Centers for Disease Control and Prevention has identified "new drugs and expanded uses for existing drugs" as contributing to the decline in heart disease and stroke mortality.[iii] Johns Hopkins Medicine professors, writing in the journal *Health Affairs*, report that, while medicines treating cardiovascular disease are not a cure, "Protein enzymes, receptors, or channels identified by the pharmaceutical industry as 'drugable targets' have led to striking, remarkable, and repeated achievement."[iv]

- Academic researchers have associated new medicines with declines in mortality for HIV/AIDS,[v] breast cancer,[vi] and other cancers;[vii] reduced disability rates among elderly persons;[viii] and increased productivity among workers with conditions like rheumatoid arthritis[ix] and depression.[x]

- Many peer-reviewed studies report that medicines help reduce spending on other health care services, principally by helping effectively manage health conditions so that patients can avoid expensive hospitalizations or emergency care.[xi] In addition to these academic studies, a CMS evaluation of a demonstration project recently showed that improving access to medicines for 7 chronic diseases by reducing cost-sharing "reduced gross Medicare spending by 12 percent on average."[xii]

The continuing development of new medicines has a leading role in improving health and health care. For instance, the prevalence of Alzheimer's disease will

increase sharply over the next few decades, imposing large human and economic costs. A report for the Alzheimer's Association projects that new treatments that delay the onset or slow the progression of Alzheimer's by five years could save $100 billion annually in Medicare and Medicaid costs by 2020.[xiii] Likewise, researchers estimate that the number of patients with Parkinson's disease will double by 2030, resulting in an enormous public health challenge.[xiv] The authors of this projection note that the answer "will come from more research and new treatments that protect against Parkinson's, or slow its course."[xv]

Likewise, new drug development's continuing importance to our society is evident in the National Economic Council's (NEC) September 2009 report, *A Strategy for American Innovation: Driving Towards Sustainable Growth and Quality Jobs*. NEC identifies developing "smart anti-cancer therapeutics that kill cancer cells and leave their normal neighbors untouched", "personalized medicine that enables the prescription of the right doses of the right drug for the right person", "nanotechnology that delivers drugs precisely to the desired tissue" and "a universal vaccine for influenza that will protect against all future strains" as among the "Grand Challenges" of the 21st Century for which we must harness science and technology. NEC views meeting the ambitious goals embedded in these Grand Challenges as "improv[ing] our quality of life and establish[ing] the foundation for the industries and jobs of the future."[xvi]

Recent government reports show that prescription drug cost growth has slowed dramatically compared to earlier in the decade—from a high double digit annual growth rate to one in the low to mid-single digits. In fact, government data show that prescription medicine costs have grown more slowly in recent years than the costs of many other health care services. As this slowdown in cost growth has occurred, other reports have claimed that brand drug prices are rapidly increasing. These reports do not reflect the way that the prescription drug market functions and therefore exaggerate prescription drug price trends. Moreover, these reports seem to have no parallel measure of the disproportionately large benefits achieved by the small share of health spending accounted for by medicines.

As a trade association, PhRMA maintains a strict antitrust compliance policy. The antitrust laws prohibit us from obtaining or discussing our members' proprietary information about the prices or discounts each individual company negotiates independently with its customers or the ways in which each company determines the prices or discounts it will offer. Therefore, I do not have information concerning any individual company's pricing or discounting policies or practices. My testimony addresses overall trends based on aggregate, market-wide data and government reported information.

Prescription Drug Cost Trends Have Slowed Dramatically

Short term cyclical changes in prices (up or down) do not reflect underlying trends in drug spending. The most recent available National Health Expenditures (NHE) Account data, issued by CMS, covers 2007 and reports that drugs were about 10 percent of national health spending. The report's findings about drug costs are summed up in its title--"National Health Spending in 2007: Slower Drug Spending Contributes to Lowest Rate of Overall Growth Since 1998." In 2007, prescription drug cost growth was 4.9 percent (the lowest rate since 1963), compared to 6.1 percent for health care overall.[xvii] This rate is far lower than growth experienced in the last decade; for example, prescription drug cost growth was 13.3 percent in 1997 and 14.0 percent in 2002. The slowdown in drug spending was not a one-year aberration. From 2003-2007, the average annual growth rate was half of the rate for 1998-2002.[xviii]

CMS's NHE data also point to prescription medicines playing a smaller role in overall health care cost growth. In 2002, prescription medicines accounted for about 18 percent of the growth in National Health Expenditures. In 2007, prescription medicines accounted for 8 percent of growth in NHE. Other services accounted for the remaining 92 percent of cost growth. In 2009, CMS's Office of the Actuary reduced its 2008-2017 cumulative projection for prescription drug spending by $515 billion, or 14 percent. This compares to a decline of 3 percent for all health care except prescription medicines.[xix]

IMS Health provides another measure of drug cost trends. Like CMS, it reports that cost trends are far lower today than a few years ago. For instance, between 1997 and 2003, IMS reports drug cost grew at a simple average rate of 14.9 percent per year.[xx] In the following five years, this dropped to 5.4 percent. For 2009 alone, IMS projects total prescription drug cost growth of 4.5 to 5.5 percent—the mid-point of this range would be the third lowest growth rate reported by IMS since 1995, and over 5 percentage points lower than the average growth rate since 1995.

IMS has reported growth rates below five percent only twice in the last forty-five years: -- 2007 (3.8 percent growth) and 2008 (1.3 percent growth).[xxi] Despite growth below 5 percent only twice since 1964, IMS now projects growth below 5 percent for each of the next five years. IMS's most up-to-date forecast states that "market growth is expected to remain at historically low levels," averaging 3.5 percent per year from 2009 through 2013.[xxii] This is about 11 percentage points lower than the growth rate reported by IMS for the 1997-2003 period.

CBO has found that Medicare Part D is costing far less than previously projected, principally because of "the competition that's occurring in the private market" among plans.[xxiii] Medicare Part D plans have achieved significant cost savings for beneficiaries and taxpayers by negotiating greater-than-expected discounts from prescription drug manufacturers. CBO's 2009 estimate for total Medicare

Part D spending over 10 years (FY 2007-2016) has dropped $520 billion, or 43 percent, compared with CBO's 2006 estimate for the same period.[xxiv] Part D plan bids for 2010 were up just 4.7 percent from the previous year, and are actually 4.3 percent lower than bids in 2006.[xxv]

CBO also confirms that the rate of growth for prescription drugs in recent years has been historically low. In an October 2009 paper, it reported that "From 2004 to 2007, drug expenditures grew by an average of just 3.2 percent per year, slightly less than the rate of growth in overall health care spending."[xxvi]

There are many reasons for this lower growth rate, including but not limited to the emergence of powerful, aggressive purchasers who bring many tools to bear in negotiating for lower drug costs. Using multi-tier formularies (which spread over the past decade from a small share of the market to nearly the entire market), prior authorization and step therapy, these purchasers have been able to drive a very high level of generic use and relatively low level of brand drug use.[xxvii] Moreover, they have driven virtually all brand use to their preferred tier where they typically receive the biggest discount from drug manufacturers.[xxviii] Many drugs have come off patent. These molecules developed by innovator companies continue to be widely used by patients and continue to achieve important health benefits at a low cost to the patient with little to no return to the innovator company.[xxix] And fewer new drugs have been approved in recent

years, notwithstanding innovator companies' intensive effort and large scale investment in drug discovery.

Reports on Prices (1) Misunderstand How Public Policy and the Market Are Structured to Promote Continued Innovation and Savings and (2) Exaggerate Price Trends

Some reports attempt to isolate price trends just for brand drugs. This approach is inconsistent with how public policy and the market operate. Our system is designed to:

(1) fund the next generation of medical advances through innovator drugs that have a limited time on the market[1] before nearly all of their use is converted to generic substitutes, while

(2) achieve cost savings through high use of generics that do not support research contributing to medical advances.

As noted above, powerful payers use numerous tools to drive generic use as high as possible, while negotiating aggressively for rebates on brand drugs. Today, nearly three out of every four prescriptions used by patients is dispensed

[1] Peer-reviewed research reports that only 3 out of 10 marketed drugs earn sufficient revenue to achieve a positive return on their research and development investment. J. DiMasi and H. Grabowski, "The Cost of Biopharmaceutical R&D: Is Biotech Different?," *Managerial and Decision Economics*, 2007. More recent analysis reports that this has dropped to 2 out of 10 marketed drugs earning sufficient revenue to achieve a positive return. J. Vernon et al., "Drug Development Costs when Financial Risk is Measured Using the Fama-French Three Factor Model," Unpublished Working Paper, 2008;

as a generic.[xxx] And CRS reports "[l]arge pharmacy benefit managers (PBMs)[2], such as Advance PCS (75 million covered individuals), Medco Health Solutions (65 million) and Express Scripts (57 million) have significant market power and an established track record in negotiating prescription drug discounts for large populations."[xxxi]

We do not believe that all of the cost containment tools used by purchasers always yield the best possible outcomes, [3] and are encouraged that some forward-looking employers and insurers are experimenting with alternative, quality-based approaches that make better use of medicines, including both brands and generics, to improve patient outcomes and control overall health costs.[xxxii] Nonetheless, this market-based system has led to drug costs that as a whole are growing more slowly than health costs overall, and it has allowed consumers to use drugs that were once innovator molecules as generics in large volume for many years.

Analyses that seek to isolate price trends for brand drugs do not recognize these features of our market system, thereby reaching conclusions that conflict with these government-reported data and appear to be skewed toward finding higher prices. For instance:

[2] In 2009, the top five PBMs purchased 62 percent of all prescriptions sold.

[3] For example, there is extensive evidence that improved patient adherence to prescribed therapies can improve health and reduce overall costs, and that high cost sharing and barriers to access may have adverse consequences. For example, see D.T. Lau and D.P. Nau, "Oral Antihyperglycemic Medication Nonadherence and Subsequent Hospitalization Among Individuals with Type 2 Diabetes." *Diabetes Care*, September 2004; D.Goldman et al, "Pharmacy Benefits and the Use of Drugs by the Chronically Ill." *JAMA*, May 2004; D. Goldman et al, "Prescription Drug Cost-Sharing: Associations with Medication and Medical Utilization and Spending and Health." *JAMA*, July 2007.

- Analyses that track prices over time typically fail to adjust for the price drop that occurs when a brand medicine goes off patent and patients convert to using the drug's generic form. For instance, eight of the drugs included in the top 25 brands tracked by the AARP report are now sold as generics.[xxxiii] These drugs appear to be counted in that report's brand price calculation as though patients continue to use the same volume of these drugs as they did in 2006, even though brand drugs typically lose nearly all of their sales after going generic[xxxiv]—specifically because of the policy and market factors discussed above. This has the effect of overstating consumers' actual cost for these therapies.

    - For example, a statin on AARP's list has been available as a generic since 2006 and by 2009 less than 1 percent of sales were for the brand form of the medicine. Approaches that treat generic use at generic prices as if they are brand use at brand prices do not reflect consumers' experience, since they calculate price growth (1) as if the volume of the brand drug used today is the same as it was in 2006, even though 99 percent of the use is now generic and (2) as if consumers are paying brand price for this drug, even though they are paying generic price. When we use an approach based on what

consumers actually purchase to look at average price growth for this medicine, we find that between 2006 and 2009 the average price per prescription (including purchases of both brand and generic) declined by 58 percent.

- The federal government's publicly available data on medical inflation is the best, most current measure of price trends for medical costs. These government data show that prescription drug prices grew by 2.3 percent per year on average for the last three years – more slowly than prices for medical care overall and for most other medical services tracked by CPI. [xxxv]

    - Government's CPI data on prescription medicines includes a market basket of brands and generics that reflects what consumers actually buy. These same government CPI data show prescription drug prices grew 2.7 percent during the 12 months ending September 2009, which is half of the 5.4 percent reported by AARP for its own sample of drugs.[xxxvi] One analyst has written of AARP's report, "Comparing list prices for a single product category to a computed, non-list price index for a broad basket of goods (CPI-U) is mathematically illogical. After all, the CPI-U for prescription drugs increased at a rate less than half the rate of list prices."[xxxvii]

- Many reports rely on data that exclude off-invoice discounts and rebates, and so do not take into account rebates paid by brand manufacturers that lower drug costs. This is akin to analyzing sticker prices, when the actual price paid is often much lower, due to negotiations between purchasers and manufacturers.[4] Reports based on this type of data do not reflect these additional savings to purchasers. To illustrate, if Thrifty Car Rental bought a fleet of cars from Ford motor, it would negotiate a purchase price below the sticker price. An analyst wouldn't determine the cost of the deal by going to the local Ford dealer, writing down the sticker price, and multiplying it by the number of cars purchased. As discussed above and as referenced in the CRS report, the same type of negotiation that would occur between Hertz and Ford occurs when a major health plan or PBM, typically buying on behalf of millions or tens of millions of people, agrees to put a drug on their formulary.

[4] According to the Medicare Trustees, under Part D, "Many brand-name prescription drugs carry substantial rebates, often as much as 20-30 percent." In 2008, Medicare actuaries estimated savings through discounts, rebates, and utilization management techniques in Part D were 29 percent—almost double the 15 percent originally projected in the 2005 Medicare Trustees Report for the first year of the program. (2009 Annual Report of the Boards of Trustees of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds, p. 162; and 2005 Annual Report of the Board of Trustees of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds, p. 144; and Testimony of Kerry Weems, CMS Acting Administrator before the House Oversight and Government Reform Committee, July 24, 2008. Medicare actuaries in OACT conduct all analyses in Medicare Trustees Reports.)

The Pharmaceutical Research Sector is Facing Significant Challenges as It Works to Develop the Next Generation of Medicines

The implicit message of reports on brand prices, such as AARP's, seems to be that the pharmaceutical research sector stands in a uniquely favorable position. In fact, the sector currently is characterized by slow growth, rapid substitution of generics for brand medicines, and the exceptional challenges inherent in discovering new medicines that safely and effectively treat disease. One source projects that 18 best selling brand medicines accounting for $90 billion of U.S. sales will go off patent over the next 4 years[xxxviii]—meaning that these drugs will become widely available and used at generic prices, as our system uses its various tools to rapidly substitute generics for virtually all use of the innovator drug. In this context, the sector has been forced to cut jobs—58,000 through October of this year as reported by *Forbes*,[xxxix] on the heels of significant cuts in 2007 and 2008.

Notwithstanding these challenges, there is much reason for optimism that valuable new medicines will continue to improve medical care into the future as they have in recent decades. This is evident in the opportunities being created by advances in scientific understanding, a pipeline of drug candidates targeting many conditions that do not currently have adequate treatments, and companies' on going efforts to reengineer the drug discovery process. The Grand Challenges identified by the National Economic Council and involving advances

in medicines can be realized. Investment in pursuing these objectives is accounted for by the share of health spending going to brand medicines is repaid to society in longer, healthier, more productive lives.[xl]

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