Which Principles, Doctor?

The early crystallization of clinical research ethics in the Netherlands, 1947-1955

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The image on the front cover is a segment of the painting *Roadmap* by the young Dutch artist Fransje Pansters. The painting conveys the journey of finding one's way and establishing meaningful boundaries, while taken-for-granted categorizations disappear. When she is asked whether *Roadmap*, with its portrayal of human legs attached to a mouse's romp, also reflects upon the ontological relationship between humans and animals, Pansters answers: “It is in the eye of the beholder which images come floating to the surface of *Roadmap*. It could be that the human mouse is the theme you see as central to the painting, but that is only ever your individual point of view”. For more work of Fransje Pansters, visit: www.fransjepansters.com.

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· Preface ·

On 1 February 2012 I attended the symposium 'Wishes and Boundaries in the Practice of Medicine' of the Dutch Centre for Ethics and Health. I was already working on this thesis project and interested in the ideas and opinions regarding the ethics of permissible medical interventions of some of the leading authorities on health and medicine in the Netherlands. Representatives of the Dutch *Health Council*, the Dutch *Council for Public Health Care*, the Dutch *Council of Health Insurances*, the *Royal Dutch Medical Association* and the Dutch *Patients Consumers Federation* were present, as well as specialists in the field of vascular medicine, plastic surgery, psychiatry and medical ethics. The topic of discussion was how far medical practitioners should go in meeting the ever-growing desires of patients. Do doctors have any paternalistic responsibilities towards their patients or should the individual patient be treated as a royal costumer who is free to do with his or her body whatever (s)he finds desirable?

Up until that symposium I had been investigating for my thesis how medico-ethical principles have historically come to crystallize. To do so, I had been mapping the historical relationship between the internationally promulgated 1947 Nuremberg Code and the locally formulated Dutch *Guidelines for Tests upon Human Beings* of 1955, whilst trying to understand *how* such principles had come to be formulated and to what extent two documents separated in time and space can be evaluated as two members of the same family tree. This was inspired by a summer and autumn's worth of wild reading into a wide range of books and articles on the history of clinical research ethics. During this exercise I had come to notice that historians of medical ethics seem to be modestly obsessed with the epistemological status of medico-ethical documents, or rather, with the principles contained in these documents and their applicability to contexts other than the ones in which they had first been formulated.

During the 'Wishes and Boundaries' symposium however, I discovered something that is probably very basic to physicians, but surprisingly novel to someone who had read only works on medical ethics written by ethicists and historians: medical doctors are not interested in principles. Each of the specialists speaking at the symposium repeated the very same message: the responsible physician has to decide on a case-by-case basis whether or not the particular wishes of the individual patient transgress some fundamental ethical boundaries. What these boundaries precisely are, is something that cannot be decided *a priori* – it all depends upon the specific medical problem that has to be dealt with and upon the specific patient who is asking. In theory, that did not really help me. If no absolute principles can be determined, then why has a myriad of medico-ethical Declarations and Codes been promulgated in the past 60 years to do precisely that: establishing principles? And in addition, on what grounds does the medical practitioner separate right from wrong in these individual cases if there is no yardstick to measure them by?

But in this context, there was one talk I found particularly illuminating. One of the plastic surgeons present had filled his entire presentation with photos of men and women that he had operated on for cosmetic reasons: penis and breast enlargements, fat and skin reductions, etc. When asked by a member of the audience whether he sometimes felt he should stop one of his patients from having another breast enlargement, he responded: “No, I let the patient decide. My duty is to inform them carefully about their options and about the risks and benefits of the operation. I require them to demonstrate that their decision has been well thought-through, but I am not their father. If they want a DD cup, that's their decision.” After a moment of pause, he added however: “Of course there are always exceptions. There are some cases in which I obviously would not operate. If patients for example request a metal plating to be implanted under the skins of their forehead to look more like a dinosaur, I advice them to go and see a tattoo artist. Or better yet, a psychologist.” There was one person in the audience who responded and said: “Wait, but how do you decide that the second example is ethically problematic and the first one is not?”, but no real discussion took off after that. For the majority of the audience, that the wishes of the second patient did not qualify as a proper medical request seemed to be self-evident.

It was after that symposium that I started thinking that the focus of historians of medical ethics on the veracity of medico-ethical principles is rather misleading. After all, the promulgation of medico-ethical principles is only ever

an answer to some fundamental set of problems imagined in certain societies at certain times. To better understand the historical embedding of ethics in society therefore, it is much more interesting to investigate how certain issues come to crystallize as either morally problematic or acceptable in public debates and performances. Why is it that a plastic surgeon anno 2012 finds it self-evident that he does not operate to give someone a 'dinosaur-head', while it is simultaneously unproblematic for him to submit a healthy woman to intensive surgery to size her up with that desired DD cup? To that end, by historically seeking to understand which set of problems medico-ethical documents like the Nuremberg Code and the 1955 Dutch *Guidelines* fundamentally aimed to solve, I hope to offer some modest insights into the nitty-gritty of how meaningful ethical frameworks come to 'be made'. And who knows, in that process this thesis might even inspire present-day medical ethicists, as well as physicians, to similarly reflect upon the intricacies of their own patterns of thought when it comes to deciding which medical cases presented to them they consider to be ethically problematic and which they ultimately qualify as morally just.

· Introduction ·

In 1958, the 70-year-old internist Cornelis Douwe de Langen (1887-1967) wrote an article for the *Dutch Journal for Medicine*[1] wherein he expressed a deep concern over the 'shifting standards for tests upon human beings' within the Dutch medical profession.[2] Interestingly, to illustrate that the ethical standards for human experimentation were strongly subject to 'the changing of time', De Langen made use of a historical case-study. In the year 1903, medical students of the University of Groningen had rebelled against internist Karel Frederik Wenckebach, for they felt he had conducted unacceptable experiments upon his patients. The students' complaints were picked up by a local newspaper and caused a minor medical scandal. What had happened? For his research on cardiac arrhythmias, Wenckebach had placed pads on the heart area, neck and wrists of patients under his care, which allowed him to measure the activity of the human heart. The professor's students objected to this procedure for it required the research subjects to lay still for long periods of time, which proved to be difficult for some of the heart patients. Because Wenckebach's tests had no therapeutic or diagnostic benefits, the students considered them to be indefensible.[3]

Comparing this example to the status quo of medical experimentation in his own day, De Langen wrote:

> Wenckebach did not prick his patients in the veins or other organs. Neither did he apply unpleasant technical devises in their bodies. […] These days, one can research the circulation [of blood] with a catheter in one of the

[1] Trans.: Nederlands Tijdschrift voor Geneeskunde. Translations are mine, unless otherwise stated.

[2] C.D. de Langen, 'Proeven op mensen en de verschuiving van te stellen normen', in *Nederlands Tijdschrift voor Geneeskunde* Vol. 102 (1958), pp. 25-27.

[3] Ibidem, p. 26.

> compartments of the heart of a sick man, of a healthy human being, or of a patient that suffers from an entirely different illness. One can stick needles in his veins and arteries, without being afraid that emotions will run high or that a medical scandal will develop. Norms have shifted, not just for the medical practitioner or student, but for the human being who is subjected to medical research in general.[4]

What De Langen sought to demonstrate with this historical example is that what comes to be recognized as a medico-ethical problem is not naturally given. Instead, what passes as either 'problematic' or 'normal', the Dutch internist believed to be dependent upon the norms and values that prevail in certain societies at certain times.

A few years earlier, from 1953 to 1955, De Langen had been a member of an official Health Council committee titled 'tests upon human beings', installed by the Dutch State Secretary of Public Health to develop a scientific advice on the ethics of human experimentation.[5] On 10 October 1955, this committee promulgated the *Guidelines for Tests upon Human Beings*, a twelve-page document containing fourteen principles for those 'medical tests which could result in any form of risk, extraordinary distress or pain for the human being'.[6] While the medico-ethical document is largely forgotten or neglected by medical ethicists today, in the mid-1950s the *Guidelines* was envisioned to play an important standard-setting role for the ethics of clinical research in the Netherlands. For a little while the Health Council document was even internationally famous. In 1970 for example, the eminent Professor of Research in Anesthesia Henry K. Beecher[7] listed the *Guidelines for Tests upon Human Beings*

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4 Ibidem, p. 27.

5 The phrase 'tests upon human beings' is a translation from the Dutch 'proeven op mensen'.

6 J. Wester, 'Advies van de Voorzitter van de Gezondheidsraad, d.d. 10 oktober 1955 uitgebracht aan de Minister van Sociale Zaken en Volksgezondheid betreffende proeven op mensen', p. 10.

7 Every history of (Western) clinical research ethics of the twentieth century will mention the name of Henry K. Beecher, the American whistle-blower who gained world fame in 1966 by publishing 22 examples of research studies which had risked 'the health or the life of their subjects without informing them of the dangers or obtaining their permission'. He is often remembered with the highest praise. Historian David Rothman has written for example: 'In June 1966, Henry Beecher, Dorr Professor of Research in Anesthesia at Harvard Medical School, published […] his analysis of 'Ethics and Clinical Research' and thereby joined the ranks of such noted muckrakers as Harriet Beecher Stowe, Upton Sinclair, and Rachael Carson.' In: D.J. Rothman, *Strangers at the Bedside: A History of How Law and Bioethics Transformed Medical Decision Making* (New York, 1991), p. 15.

right next to medico-ethical documents such as the *Hippocratic Oath* (470-360 B.C.), *Percival's Code* (1803) and the *Declaration of Helsinki* (1964) in his famous book *Research and the Individual*.[8]

De Langen was a prominent member of the Health Council committee 'tests upon human beings'. He never neglected to ventilate his personal point of view on the subject and openly wondered during some of the committee meetings whereto it was that the relationship between patient and practitioner was drifting under the influence of the modern biomedical sciences.[9] Had physicians not become alienated from their position at the bedside of the patient? And, vice versa, did patients not expect too much from the healing capacities of their physician?[10] At the same time, De Langen also reflected upon his own subject position in being capable of separating moral rights from moral wrongs. Already during the very first committee meeting, he put forward that in his opinion 'the appreciation of what a physician can reasonably do with his fellow human being heavily depends upon the historical setting in which he operates'.[11]

With this assertion, the Dutch internist arguably tapped into one of the most fundamental debates cutting through all of the humanistic disciplines: i.e. whether ideas, utterances, conceptions, statements, beliefs can be meaningfully understood and interpreted outside of the historical context in which they have first been formulated (the *historism* dilemma).[12] While such is a philosophical dilemma that should be debated rather than solved, its outcome forms a pressing concern for an academic field like medical ethics, which is specifically concerned with the epistemological status of normative principles. After all, if a document like the 1948 Universal Declaration of Human Rights is argued to have no transcultural or transtemporal validity, it becomes a theoretical impossibility to rightfully uphold it in any other situation than its initial promulgation – a consequence of cultural relativism which seems undesirable to many. For this reason, a fair amount of scholarly publications has been devoted to prove the

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8 Henry K. Beecher, 'Ethics and Clinical Research', in *New England Journal of Medicine* Vol. 74 (1966), pp. 1354-1360; Henry K. Beecher, *Research and the Individual* (Boston, 1970).

9 National Achive, The Hague (henceforth: NL-HaNA), Gezondheidsraad, 1920-1956, 2.15.33, Inv.nr. 548, 'Notulen van de vergadering van de commissie uit de gezondheidsraad inzake proeven op mensen' (henceforth: Not. comm. proeven op mensen), 14 December 1953, p. 3.

10 He repeated these worries in his 1958 article: De Langen, 'Proeven op mensen', p. 27.

11 NL-HaNA, Gezondheidsraad, 1920-1956, 2.15.33, Inv.nr. 548, 14 December 1953, p. 2.

12 See: Herman Paul, *Het moeras van de geschiedenis. Nederlandse debatten over historisme, 1920-1970* (Amsterdam, 2012); Frederick C. Beiser, *The German Historicist Tradition* (Oxford, 2011).

universality of such codes, because, as bioethicist Ruth Macklin for example wrote in 1992:

> If moral beliefs and practices of other cultures and earlier eras cannot be criticized or compared from an ethical point of view, the notion of moral progress is conceptually incoherent. But it *does* make sense to be able to say that the practices of one time or place are more or less ethically acceptable than those of another.[13]

It is unsurprising therefore, that the 'course of life' taken by prominent codes of ethics has become an important area of investigation within the scholarly body of work that represents the history of medical ethics. After all, in order to establish that codes of ethics do indeed have transcultural and transtemporal validity, one needs to demonstrate the historical significance of such documents, not just for the specific society where, at one definite point in history, they have been promulgated, but also for times and places that are disconnected from the ethic codes' original contexts.

The most prominent document in this regard is the 1947 Nuremberg Code, widely recognized to be the first ever international code of medical ethics. Promulgated on the ruins of the Second World War, the document was formulated by the four American judges of the 1946-1947 Doctors' Trial, a tribunal held to prosecute those responsible for the gruesome Nazi concentration camp experiments that took place during the war. In the canonical publication *The Nazi Doctors and the Nuremberg Code* for example, ethicists George Annas and Michael Grodin describe the Nuremberg Code as 'an attempt to provide a natural law based universal set of ethical principles […] which must be considered in any ethical use of humans as experimental subjects'.[14] Interestingly, in order to

[13] Ruth Macklin, 'Universality of the Nuremberg Code', in George J. Annas & Michael A. Grodin (eds.), *The Nazi Doctors and the Nuremberg Code. Human Rights in Human Experimentation* (Oxford, 1992), pp. 240-257, there: p. 241. Italics added.

[14] Michael A. Grodin, 'Historical Origins of the Nuremberg Code', in Annas & Grodin, *The Nazi Doctors*, pp. 121-144, there: pp. 137-139. The passing of time has not made Annas and Grodin waver from this point of view. Sixteen years later, in the influential 2008 *Oxford Textbook of Clinical Research Ethics*, the two influential ethicists stand by their 1992 observation and put forward that also in the twenty-first century the Nuremberg Code remains the 'primary foundational document informing all ethical codes on research with humans'. In: George J. Annas & Michael A. Grodin, 'The Nuremberg Code', in Ezekiel J. Emanuel, Christine Grady, Robert A. Crouch, Reider K. Lie, Franklin G. Miller & David Wendler (eds.), *The Oxford Textbook of Clinical Research Ethics* (Oxford, 2008), pp. 136-140, there: p. 136. That the

demonstrate how the 1947 document slowly, but gradually gained the status of a universal code of ethics, historians have pointed to the 1955 Dutch *Guidelines for Tests upon Human Beings* as one of the first instances where the Nuremberg principles were locally implemented. In the 1998 article 'Transcultural Medical Ethics and Human Rights' for example, historian of medical ethics Robert Baker argued that the Dutch were the first to accept the 1954 World Medical Association (WMA) *Principles for those in Research and Experimentation*, which 'reiterated the main themes of the Nuremberg Code, particularly in their requirement that each person who submits to experimentation be informed of the nature of, the reasons for, and the risk of the proposed experiment and consent in writing'.[15]

This thesis will establish that this historical claim is false. The *Guidelines* promulgated by the Dutch Health Council in 1955 had little to do with either the 1947 Nuremberg Code or the 1954 WMA *Principles*. Instead, it was a response to complaints by the Dutch antivivisectionist movement, which argued that the misuse of human beings for biomedical experiments was the only logical outcome of the widespread use of laboratory animals for scientific research, a practice which had clouded physicians' minds and hardened their senses. In addition, the Health Council never referred to the Code and disagreed with most of the medico-ethical norms codified in the *Principles* (see chapter 4 of this thesis). It is surprising therefore, that Baker evaluated the work of the Dutch Health Council as one of the first attempts to implement the Nuremberg Code. Because he did not document any sources for his claim, it is difficult to assert on which documents he based his findings. Nevertheless, his analysis has been taken up by others, and as recently as 2007, historians have written that the 1955 Dutch *Guidelines* were meant to adopt the WMA *Principles for those in Research and Experimentation*, which were in turn designed to implement the Nuremberg Code.[16]

To correct this historical misconception, this thesis will reconstruct the actual relationship between the 1947 Nuremberg Code and the 1955 Dutch *Guidelines*. The main research question to which this thesis seeks to provide an

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Nuremberg Code is the most important document in the history of the ethics of medical research is accepted by many. See chapter 1 of this thesis for more examples.

15 Robert Baker, 'Transcultural Medical Ethics and Human Rights', in Ulrich Tröhler & Stella Reiter-Theil (eds.), *Ethics Codes in Medicine. Foundations and achievements of codification since 1947* (Aldershot, 1998), pp. 312-331, there: p. 319.

16 Ulrich Tröhler, 'The Long Road of Moral Concern: Doctors' Ethos and Statute Law Relating to Human Research in Europe', in Andreas Frewer & Ulf Schmidt (eds.), *History and Theory of Human Experimentation: The Declaration of Helsinki and Modern Medical Ethics* (Frankfurt, 2007), pp. 27-54, there: p. 34.

answer with this analysis is how the relation between the two medico-ethical documents is to be understood if the historical evaluation provided by Baker and others cannot be maintained. This question is meaningful, precisely because – as has hopefully been established above – history is an important tool for ethicists to develop a meaningful conceptual framework for their philosophical theories.[17] This means that if the legacy of the Nuremberg Code turns out to be imagined rather than real, this inevitably has consequences for the idea that the Nuremberg principles ever had any transcultural or transtemporal validity. At the same time however, merely accepting that a document like the Nuremberg Code can only be understood in its specific spatial and temporal setting is unsatisfactory. If that would be true, ethicists should just discard history as a means of reflection, since nothing could be learned from past medico-ethical practices in the first place. Importantly, this is not the mission of this thesis. Instead, it is written with the idea in mind that a heuristic understanding of the past can be useful for the present. More specifically, this thesis is written with the belief that mapping how biomedical experimentation has historically come to crystallize as either ethically just or problematic can offer valuable insights for present-day attempts of formulating a meaningful theoretical framework for clinical research ethics.

Despite its factual shortcomings for example, Baker's 1998 article puts forward an interesting point of view that is insightful for the discussion about the transhistorical validity of medico-ethical principles. What the historian of medical ethics argued was that, 'it is the commonality, not of principles and values, but of problems and conflicts, and the correlative need for a solution, that prompts one culture to accept a conflict-resolving norm invented by another'.[18] It should not be forgotten, the historian explained, that the need to articulate a formal agreement between various parties presupposes the presence of conflict. After all, if there is no absence of trust between members of a society, there would be no reason to hold all individuals to agreed-upon rules. Conflict, not consensus, therefore underlies morality and law. This also explains, according to Baker, why in the first two decades after the Second World War, the Nuremberg Code was virtually

[17] Of all ethicists, medical ethicists in particular make use of historical case-studies (i.e. casuistry) to shed light on present-day medico-ethical dilemma's. In 1982, philosopher Steven Toulmin famously argued therefore that the pragmatic oriented approach within medicine had salvaged 'ethics' as an academic discipline, which had come to reach a dead-end in the twentieth-century by trying to postulate meta-ethical theories that had little bearing upon everyday reality. Steven Toulmin, 'How Medicine Saved the Life of Ethics', in *Perspectives in Biology and Medicine* Vol. 25 (1982), pp. 736-750.

[18] Baker, 'Transcultural Medical Ethics', p. 319.

ignored by the international medical community, which, as medical ethicist Jay Katz has famously remarked, regarded the document as 'a good code for barbarians, but unnecessary for ordinary physicians'.[19] If Nuremberg-type restrictions were needed at all, medical practitioners evaluated them to only apply to so-called non-therapeutic experiments, which most of the post-war tests upon human beings were not. Only when a society recognizes that medical research on human subjects poses a medico-ethical problem, Baker therefore concluded, correlating principles like the Nuremberg Code can come to be implemented.[20]

For Robert Baker, the specific *conflicts* to which the Nuremberg Code was a response, do have a transcultural and transtemporal nature. The Nazi concentration camp experiments did not just become unethical within the court room of the Nazi Doctors' Trial, the historian argues, but were violations of basic human rights in any spatial and temporal setting imaginable. Similarly, that the Code's fundamental principles thereafter became part of a wide variety of cultures over a longer period of time is proof, according to Baker, that the Code successfully solved the fundamental medico-ethical problems that stood at its base. It was only because the Nuremberg principles successfully addressed a set of universal human problems, that the 1947 code of ethics could become one of the most important documents in the history of clinical research ethics.[21] Admittedly, this argumentative structure is somewhat circular, which might explain why the historian has pointed to the *Guidelines* as one of the first attempts to implement the Nuremberg Code. By promulgating the medico-ethical document, the Dutch Health Council did after all acknowledge that the practice of human experimentation was in need of some form of external regulation. In addition, the Health Council explicitly differentiated between therapeutic and non-therapeutic interventions and acknowledged that certain medico-ethical principles are applicable to both. In other words, the mere existence of the *Guidelines* would prove that the Dutch medical profession recognized in the 1950s that medical research on human subjects poses some fundamental medico-ethical problems.

The problem with this analysis is that one only needs to compare the first principle of the Nuremberg Code with that of the *Guidelines* to realise that the two documents have a fundamentally different understanding of the nature of medico-

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[19] Jay Katz, 'The Consent Principle of the Nuremberg Code: Its Significance Then and Now', in Annas & Grodin, *The Nazi Doctors*, pp. 227-239, there: p. 228.

[20] Baker, 'Transcultural Medical Ethics', pp. 319-320.

[21] Baker points for example to the fact that 'in-form-ed-(o) con-sen-t-(o)' has become a standard term in the Japanese language. In: Ibidem, pp. 328-329, there: p. 329.

ethical violations. Where the Code speaks of 'the absolute necessity of the voluntary consent of the human subject' (see Appendix I), the *Guidelines* put forward that 'the responsibility of the researcher, not the willingness of the subject, is primary in experiments upon human beings' (see Appendix V). In addition, what Baker's thesis also fails to solve, is how the shift from principles to problems negates the dilemma put forward by the historism perspective: who decides, and on what grounds, which medical interventions are ethically problematic and which are not? Or, as De Langen wondered in 1958, why did Wenckebach's students find it highly problematic in 1903 to force heart patients to lay still for longer periods of time, while by the end of the 1950s it was possible to place catheters directly in the heart without causing a similar stir?

By investigating the early Dutch crystallization of clinical research ethics in the first decade after the Second World War, this thesis wants to build on these questions. The aim is to therewith contribute to a deeper understanding of how some forms of medical experimentation have historically come to crystallize as medico-ethical *problems* and, following Baker's analysis, for what reasons they have consequently come to be translated in medico-ethical *principles*. One might call this a study of 'ethics-in-the-making' – a phrase this thesis borrows from the well-known concept of 'science-in-the-making' developed by social scientists like Bruno Latour and Steve Woolgar in the 1980s.[22] Science-in-action stands for the idea that, instead of studying the *products* of science, one should study the *processes* by which scientific knowledge comes to be generated. In addition, this perspective puts forward that going back in time and deconstructing how certain scientific ideas and facts have historically come to materialize leads to a better understanding of the nature of scientific knowledge itself. Thus, treating the scientific laboratory as an anthropological site where the discovery of scientific knowledge is an ongoing process can show that the direction of scientific progress is not self-evident, but rather a tight knit between theoretical convictions (e.g. concerning methodology) and practical limitations (e.g. available work space and research funds). Finally, studying the 'production-processes' by which scientific knowledge comes to be generated contributes not only to a better understanding of the nature of scientific knowledge itself, but also of how scientific claims ultimately gain authority. On what grounds does the scientific community for

[22] Bruno Latour, *Science in Action: How to Follow Scientists and Engineers Through Society* (Harvard, 1987); Bruno Latour & Steve Woolgar, *Laboratory Life: The Construction of Scientific Facts* (Princeton, 1979).

example accept or reject scientific claims? Or, which distribution mechanisms play a role in these processes and in what way do scientific theories interact with the cultural society in which they should come to be embedded?

By historically unwrapping such processes, the seemingly 'universal' status of scientific knowledge becomes more temporal, more specific and sometimes therefore surprisingly fragile. After all, scientific facts and theories which are generally accepted in the present, once needed to be produced from scratch. They thus knew a period of uncertain fluidity before they historically came to crystallize as universally self-evident. This goes the same for codes of ethics. Philosophical theories in particular are never formulated in a socio-cultural vacuum. As medical historian Charles Rosenberg wrote in 1988, 'specific ideas and academic values exist not in some realm of disembodied cognition, but in the minds and emotional priorities of particular individuals'.[23] Such individuals are confronted with cultural notions and practical challenges that are inevitably time and place specific, which is as true for the present as it was for the past. Reflecting upon the apparent strangeness of medico-ethical conceptions that seemed natural to past historical actors can therefore unhinge some present-day assumptions which have similarly been taken for granted as self-evident. In other words, like the Dutch internist Cornelis Douwe de Langen did in the 1950s, this thesis thus ultimately uses history as a tool to study the present at the remove of the past.

Chapter 1 of this thesis will outline and evaluate the current historiographical field of medical ethics as relevant for this thesis and argue how the primary focus on medico-ethical *problems* instead of medico-ethical *principles* offers an alternative and possibly more fruitful historiographical approach than those currently dominant in the sub-discipline. In addition it will indicate the main heuristic tools that have been used to provide the necessary theoretical structure for this object of study. The remaining chapters of this thesis revolve around the historical relationship between the 1947 Nuremberg Code and the 1955 *Guidelines*. The Health Council did consider the Nuremberg principles in 1953, but discarded them because she evaluated the Nazi concentration camp experiments to be incongruous with the practice of human experimentation in the Netherlands. As will be shown in chapter 2 of this thesis, this assessment became possible, because of the manner in which the Nuremberg Code itself had been framed by the prosecutors of the Doctors' Trial. In fact, given the narrow

[23] Charles E. Rosenberg, 'Wood or Trees? Ideas and Actors in the History of Science', in *Isis* Vol. 79 (1988), pp. 564-570,there: p. 568.

conceptualization in the Doctors' Trial of the problematic nature of human experimentation, it is unsurprising that the Code was at the time evaluated as a 'good code for barbarians, but an unnecessary document for ordinary physicians'. The Nazi physicians were argued to not have been true scientists, but only monstrous criminals. Chapter 2 will also make clear that, despite Baker's claims to the contrary, this attitude was no different for most medical practitioners in the Netherlands in the first decade after the Second World War.

Chapter 3 will establish how not every stakeholder in the Dutch arena on biomedical experimentation shared the belief that a true scientific identity was synonymous with ethically just behaviour. After the Second World War, Dutch antivivisectionists persistently argued that the defendants of the Doctors' Trial instead represented the pinnacle of the modern research-based laboratory sciences. They did so to gain a stronghold in the Dutch academy for their reform agenda and to establish professorial chairs in vivisection-free medicine and homoeopathy. With these actions, the Dutch antivivisectionists forced the established medical profession to pay attention to the potential medico-ethical problems of human experimentation. But because the practice simultaneously became the battleground for discussions over the humanistic value of the research laboratory and the merits of alternative ways of knowing, the established medical profession became very defensive of the method and, at least publicly, almost oblivious to the medico-ethical problems it might harbour.

This thesis will argue that it is in this socio-political climate that the promulgation of the *Guidelines* needs to be understood. As will be shown in chapter 4, the Health Council committee 'tests upon human beings' was only established after the Dutch antivivisectionist movement had once again made the headlines with news of questionable biomedical experiments that were conducted on innocent patients in the Leiden academic hospital. With this immediate cause for its mandate in mind, the Health Council became very careful in framing the discussion on the topic. Each of the committee members was aware that organizations such as the Dutch Anti-Vivisection Foundation might be able to further their cause with the guidelines the Health Council was about to promulgate – a development which was evaluated to be highly undesirable. De Langen for example repeatedly emphasized that it was of vital importance to preserve the right of Dutch physicians to make autonomous decisions, free from governmental or any other form of interference.[24]

[24] NL-HaNA, Gezondheidsraad, 1920-1956, 2.15.33, Inv.nr. 548, Not. comm. proeven op

To argue that the Dutch Health Council was only concerned with the standing of medicine in society would be a mistake however. The committee 'tests upon human beings' was genuinely convinced that no *communis opinio* existed in the Netherlands concerning the proper ethical standards for tests upon human beings and that their guidelines would come to set the national standard for the ethics of clinical research.[25] During one of the committee meetings for example, deputy chairman Jean Jacques Brutel de la Rivière remarked that generally accepted guidelines for permissible tests upon human beings simply did not exist within the Dutch medical profession and that the outcome of the committee's deliberations was therefore extremely important.[26] This proved to be a difficult undertaking, because in order to draw up appropriate principles the committee members first needed to agree upon the precise problems it aimed to be addressing. As chapter 4 of this thesis will therefore also show, the medico-ethical problems the committee thought to be solving with the *Guidelines* changed and evolved during nine meetings that took place between December 1953 and September 1955, until they had become a careful conceptual and rhetorical construction which allowed the Dutch Health Council to balance between the innovation of biomedical science and the regulation of human experimentation.

In short, by mapping both the relationship between the 1947 Nuremberg Code and the 1955 Dutch *Guidelines for Tests upon Human Beings* as well as the production-processes that were involved in the formulation of both medico-ethical documents, the history of the early crystallization of clinical research ethics in the Netherlands after the Second World War can hopefully offer present-day medical ethicists and physicians an interesting framework for reflecting upon their own subject position in the arena of 'ethics-in-action', while at the same time offer food for thought in the ongoing debate on the extent to which individual conceptions of moral rights and wrongs are ultimately entangled with the socio-cultural conceptions and beliefs that prevail in certain societies at certain times.

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mensen, 14 December 1953, p. 9.

25 An therewith become the baseline for decisions made by the Dutch medical disciplinary tribunal, which based its rulings on the existing ethics of the Dutch medical profession.

26 NL-HaNA, Gezondheidsraad, 1920-1956, 2.15.33, Inv.nr. 548, Not. comm. proeven op mensen, 13 April 1954, pp. 10-11.

1. From Principle to Problem: Perspective and Methodology

Human problems do not spring up, full-blown and announced, into the consciousness of bystanders. Even to recognize a situation as painful requires a system for categorizing and defining events.[27]

There can be various reasons for reading or writing works of history. As for the history of medicine, the subdiscipline this thesis is most likely to be categorized under, these reasons tend to vary depending upon the epistemological perspective and disciplinary affiliation of the respective historian or individual reader. As medical historians Frank Huisman and John Warner have succinctly summarized, histories of health, sickness and healing can serve a better understanding of present-day interpretations and interventions, as well as ease medical students into their profession; they can make intimate bodily processes tangible by enlightening past cultural traditions, rituals and meanings to sickness and health, as well as offer intellectual satisfaction and reassurance to clinicians in their daily undertakings.[28] This multitude of aims has contributed to the existence of a wide range of historiographical traditions, of which 'traditional medical history', 'social history of medicine' and 'cultural history of medicine' are arguably the most influential.[29]

[27] Joseph R. Gusfield, *The Culture of Public Problems: Drinking-Driving and the Symbolic Order* (London, 1981), p. 3.

[28] Frank Huisman & John H. Warner, 'Medical Histories', in Frank Huisman & John H. Warner (eds.), *Locating Medical History. The Stories and Their Meanings* (London, 2006), pp.1-30.

[29] See for example: S. B. Nuland, 'Medical History for the General Reader', in Huisman & Warner, *Locating Medical History*, pp. 450-459; C. Webster, 'The historiography of medicine', in P. Corsi & P. Weindling (eds.), *Information Sources in the History of Science and Medicine* (1983), pp. 29-43; T. Ashplant & A. Wilson, 'Whig history and present-centred history', in *Historical Journal* Vol.31 (1988), pp. 1-16; R. Cooter, 'After Death/After-"Life": The Social

In academic debates over the value of each of these ways of remembering, historians have displayed a tendency of representing the opposing point of view as products of bad scholarship in order to establish the superiority of their own epistemological position. While it would be too strong to therefore tax all historiographical criticism as mere rhetorical boundary-work, the value of such polemics needs to be critically scrutinized if these debates end up creating more problems than the ones they aim to solve. As Huisman has argued, the mutual denouncing of the protagonists of these various approaches results in an encapsulation and isolation of 'sub-subdisciplines' that do not benefit the overall objectives of the field – an observation which has led him to advocate 'a dialectic of understanding': i.e. a constructive confrontation between various positions that cherishes the merits as much as the weaknesses of opposing standpoints.[30]

There are some footnotes to this approach. In order to establish a functional dialectic of understanding, it is indispensable (a) for a multitude of perspectives to exist and thrive, and (b) for their respective protagonists to actually engage in conversation. In the historiography of medical ethics however, two distinctly different perspectives have tended to dominate the field, narrowing the range of credible topics of investigation and pushing alternative approaches into the margins. Because these two genres are furthermore utilized by scholars with different institutional homes as well as professional aims, there has been little cross-fertilisation that can qualify as a dialectic of understanding in the manner Huisman envisions it. In addition, a 'constructive confrontation' between various standpoints should neither be taken as a euphemism for the thought-terminating cliché 'let's agree to disagree'. This thesis is written with the belief that a history of medical ethics is most valuable (or valorizable – to use a popular term), if it can provide greater insight into how medico-ethical conceptual frameworks and institutional practices are interwoven with the fabric of certain social groups in specific historical time-periods. It is towards the understanding of these provisos that this thesis seeks to make a contribution.

This chapter will first outline and evaluate the current historiographical field as relevant for this thesis. In the introduction to the 2009 *Cambridge World*

History of Medicine in Post-Modernity', in *Social History of Medicine* Vol.20 (2007), pp. 441-464; L.J. Jordanova, 'The Social Construction of Medical Knowledge', in *Social History of Medicine* Vol 8. (1995), pp. 361-381; D. Porter, 'The Mission of Social History of Medicine: An Historical Overview', *Social History of Medicine* Vol.8 (1995), pp. 349-359.

[30] Frank Huisman, 'The dialectics of understanding. On genres and the use of debate in medical history', in *History and Philosophy of the Life Sciences* Vol.27 (2005), pp. 13-40.

History of Medical Ethics, editors Baker and McCullough provide an overview of the main textbooks, monographs and edited volumes that have been procured on the topic since the early nineteenth century.[31] Although Baker and McCullough have not sought to categorize these historical works as specific styles of remembering, it appears from their overview that two historiographical approaches to medical ethics have been dominant, in this thesis respectively denoted as 'essentialist' and 'fig leaf' histories of medical ethics. Secondly, this chapter will defend the merits of a third and alternative way of remembering medical ethics, one in which not medico-ethical principles but medico-ethical problems take centre stage for the medical historian. Finally, this chapter will explicate the main epistemological and methodological tools that underpin the historical analyses in the remaining chapters of this thesis.

An essentialist approach to the history of medical ethics

Essentialist histories conceptualize medico-ethical 'problems' as having an *essence* to them that is bound to neither time nor space (i.e. transhistorical).[32] What changes under the influence of passing time can therefore not be these problems themselves, but only their treatment by physicians or philosophers. Consequently, it is unproblematic from an essentialist perspective to assert that both the moral concerns in the classical Hippocratic corpus or in the eighteenth-century philosophies of Immanuel Kant are ancient predecessors of contemporary medico-ethical reflections, for they all sought to tackle the same medico-ethical problems (even if the wording 'medical ethics' itself only stems from 1803).[33] This approach is popular among professional ethicists, according to Baker and McCullough, because it allows them to utilize past understandings of medico-ethical problems as a defence for present-day theories and practices, either by appealing to an ancient tradition or by denouncing the past in order to dignify the present.[34]

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[31] Robert B. Baker & Laurence B. McCullough, 'What Is the History of Medical Ethics?', in Robert B. Baker & Laurence B. McCullough (eds.), *The Cambridge World History of Medical Ethics* (Cambridge, 2009), pp. 3-15.

[32] Darrel W. Amundsen, 'History', in Jeremy Sugerman & Daniel P. Sulmasy (eds.), *Methods in Medical Ethics* (Washington DC, 2001), pp. 126-145, there: p. 134.

[33] Baker & McCullough, 'What Is the History', p. 3. The wording 'medical ethics' was for the first time used in: Thomas Percival (ed. by Chester R. Burns), *Medical Ethics: A Code of Institutes and Precepts, Adapted to the Professional Conduct of Physicians and Surgeons* (Huntington New York, 1975: 1803).

[34] Baker and McCullough for example look to: Stanley J. Reiser, Arthur J. Dyck & William J.

Criticism of this approach by professional historians is that such histories circumvent methodological questions generated by differences in linguistic and conceptual frameworks of medico-ethical problems throughout recorded history.[35] Whether past physicians or philosophers correctly handled or even understood these problems, is irrelevant for the essentialist conceptualization of these problems.

In essentialist histories, the significance that is accorded to certain historical developments, such as the promulgation of a code of ethics or the institutionalization of certain 'ethicist' practices, highly depends upon the medico-ethical principles valued by the historian at work.[36] The 1947 Nuremberg Code for example, has been portrayed in essentialist histories both (1) as a universal set of principles and (2) as a faulty and outdated document. When taken to be universal, the essentialist historian treats the Code in a manner reminiscent of the Durkheimian notion of totemism: i.e. by attributing quasi-divine and transcendent powers to the document, which at the same time functions in the historical narrative as a signifier for a specific time-period [i.e. 'modern' medical ethics] that can be separated from all that came before.[37] As described in the introduction to this thesis, the canonical 1992 volume *The Nazi Doctors and the Nuremberg Code* for example denotes the Code 'an attempt to provide a natural-law based universal set of ethical principles'.[38] Similarly, other volumes state that the Code is 'an

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Curran (eds.), *Ethics in Medicine: Historical Perspectives and Contemporary Concerns* (Cambridge Massachusetts, 1977); Warren T. Reich (ed.), *The Encyclopedia of Bioethics.* (New York, 2nd ed., 1995). See also: Todd Chambers, 'Retrodiction and the Histories of Bioethics', in *Medical Humanities Review* Vol.12 (1998), pp. 9-22.

35 Baker and McCullough, 'What Is the History', p. 4.

36 The adjective 'ethicist' seems more appropriate in this context than the adjective 'ethical', since the former denotes 'that which professional ethicists maintain', whereas the latter refers to 'that which is morally just'. Whether there is an actual difference between the two is subject to academic and philosophical debate. To compare two opposite approaches, see: Macklin, 'Universality and the Nuremberg Code'; and: Roger Cooter, 'The Resistible Rise of Medical Ethics', in *Social History of Medicine* Vol. 8, Nr. 2 (1995), pp. 257-270.

37 Émile Durkheim, *The Elementary Forms of Religious Life* (translated by Karen Fields, New York, 1912/1995); Steven Lukes, *Émile Durkheim; His Life and Work, A Historical and Critical Study* (New York, 1972). Durkheim referred to the concept of totemism as: “the attribution of quasi-divine and mysterious powers to a physical object, which in turn obtains the function of a sign or symbol that simultaneously denotes and distinguishes one group from another”.

38 Annas & Grodin, *The Nazi Doctors*, p. 137. Or: Evelyn Shuster, 'Fifty Years Later: The Significance of the Nuremberg Code' in *The New England Journal of Medicine* Vol. 337 (1997), pp. 1436-1440.

important set of basic ethical guidelines for research'[39]; that 'before [the Code], there were no internationally recognized standards of research ethics'[40]; or that the Code truly is the 'primary foundational document informing all ethical codes on research with humans', therefore remaining the 'most authoritative legal and human rights code on the subject of human experimentation'.[41] The Code is thus envisioned to embody the outward and visible form of 'an ethical ideal that is universally applicable' – a conceptualization of the legal document that is often invoked to justify the applicability of Code to the Nazi experiments, even if the principles were drawn up *post-hoc*.[42] At the same time however, these accounts attribute the Code such importance, because the document is envisioned to symbolize a paradigmatic break with traditional medical ethics and to signify the starting point of modern research ethics. As one historian has put it: 'Nuremberg marks the end of an epoch and the beginning of a new one at the same time, not only for culture and the political world, but also for ethics in general and for ethics in the natural sciences and medicine especially'.[43] In these type of essentialist narratives, Nuremberg is thus constructed as a totemic symbol: one which unites as well as differentiates and which signifies a belief system that is simultaneously transhistorical as well as temporal (but neither contextual nor contingent).

When the essentialist historian at work however evaluates the Nuremberg Code to be incongruous with the medico-ethical theories and principles he (or she) ascribes to, the document is faulted for being 'born in scandal' [i.e. as a response to the Nazi concentration camp experiments] and for overly focusing on what were at that time perceived to be the most outrageous transgressions of 'normal medico-ethical behaviour'. As such, Nuremberg served a specific and important practical purpose [i.e. convict the Nazi medical perpetrators], but failed to establish an overarching framework with universal principles that have the capacity to *a priori* govern ethical research.[44] This version of essentialist history denounces the Nuremberg Code for being a *past* faulty historical practice (subject to spatial and

[39] Tröhler & Reiter-Theil, *Ethics Codes in Medicine*, p.ix.
[40] Baker & McCullough, *The Cambridge World History*, p.460.
[41] Emanuel et al., *The Oxford Textbook*, p. 136.
[42] Macklin, 'Universality of the Nuremberg Code', p. 255.
[43] Dietrich von Engelhardt, 'Scientific Progress in Socio-Cultural Context: Natural Science, Medicine and Myth after Nuremberg', in Tröhler & Reiter-Theil, *Ethics Codes in Medicine*, pp. 109-118, there: p. 109.
[44] See: Ezekiel J. Emanuel, David Wendler & Christine Grady, 'An Ethical Framework for Biomedical Research', in Emanuel et al., *The Oxford Textbook*, pp. 123-135. Also: Jonathan D. Moreno, *Undue Risk: Secret State Experiments on Humans* (New York, 2000).

temporal contingencies), juxtaposing it to the *present* medico-ethical framework, which is in turn evaluated to be universally necessary and sufficient.[45] Again, what has changed are not the medico-ethical problems to be dealt with, but only those who can meaningfully deal with them.

Adam's fig leaf – a social history perspective

Since the early twentieth century an alternative historiographical tradition has been built which principally analyses codes of medical ethics as self-serving to the standing of the medical profession.[46] This approach became particularly popular among social historians of medicine from the 1940s onwards.[47] So-called 'social histories of medical ethics' have a tendency of constructing ethical claims as 'fig leaves', which would disguise assertions of monopolistic privilege and mask the fact that modern medicine is really a political enterprise.[48] To what extent historical actors are evaluated to have agency over this process, depends upon the sociological or philosophical tradition with which the historian at work identifies himself (or herself). While for example older historical narratives tend to display an understanding of social interactions that is close to a Goffmanian dramaturgical metaphor, present-day socio-cultural histories interpret the epistemological status of medical ethics much more according to a Foucauldian tradition.

Sociologist Erving Goffman was a twentieth century sociologist who famously conceptualized social life as a 'staged drama': i.e. “the individual in ordinary work situations presents himself and his activity to others, the ways in which he guides and controls the impression they form of him, and the kinds of things he may and may not do while sustaining his performance”.[49] This metaphor allowed Goffman to differentiate between so-called *backstage* intentions and *frontstage* performances: social actors can purposefully present an image of themselves in their interactions with the outward world (i.e. their audience) that is

[45] Emanuel et al., 'An Ethical Framework', p.132.

[46] Baker and McCullough let this tradition start with the American scholar Chauncey Leake (1896-1978). In: Baker & McCullough, 'What Is the History', p. 7.

[47] Ibidem, p. 8. See also: Porter, 'The Mission of Social History'; Cooter, 'After Death/After-“Life”'.

[48] See: Jeffrey L. Berlant, *Profession and Monopoly: A Study of Medicine in the United States and Great Britain* (Berkeley, 1975); Ivan Waddington, *The Medical Profession in the Industrial Revolution* (Dublin, 1984); Carleton B. Chapman, *Physicians, Law and Ethics* (New York, 1984).

[49] E. Goffman, *The Presentation of Self in Everyday Life* (8.ed., London, 1990 (1959)), p. xi.

congruent with their private motives, but at the same time effectively hides these intentions from view. In acting out their role, these actors can make use of 'props', which is how traditional social histories of medical ethics envision past codifications of medico-ethical principles. As sociologist Jeffrey Berlant wrote in 1975 of godfather of medical ethics Thomas Percival (1740-1804): "[his] ethics were […] the organizational tool […] for monopolistic traditions for all professions, [and] an important device for suppressing competition between different types of professions".[50]

Goffman thus envisioned individual actors to be capable of consciously shifting between frontstage and backstage personae, delivering a public performance that is congruent with the execution of a privately drawn-up business plan. In traditional fig leaf histories of medical ethics, physicians and philosophers are similarly portrayed as cunning masterminds, who purposefully utilize moral claims in order to achieve practical ends. Contemporary social historians of medicine, influenced by the cultural turn of the 1970s and 80s, tend to depart from this mastermind interpretation of the history of medical ethics and take instead a Foucauldian approach to history, emphasizing that human thoughts and actions are shaped by cultural codes rather than individual will.[51] Instead of all together rejecting the fig leaf hypothesis however, most socio-cultural historians arguably rather tend to tweak it.

Medical historian Roger Cooter for example, one of the few socio-cultural historians who has written about the historiography of medical ethics, evaluates the professionalization of medical ethics in the 1960s and 70s as 'part of the institutionalization and exercise of professional power'.[52] While he is too much of a structuralist to solely contribute this tendency to conscious and deliberate decisions on the part of power-hungry individuals, Cooter nevertheless maintains that medical ethics is 'an ideological construct and resource, a means to social authority'.[53] Instead of safe-guarding the ethical quality of modern biomedical practices, the present-day medico-ethical profession is thus, according to this perspective, just as much an attempt to monopolize intellectual ownership over the problems at hand. The one main difference with Goffmanian fig leaf

[50] Berlant, *Profession and Monopoly*, p. 56.
[51] See for example: Cooter, 'After Death/After-"Life"'; Porter, 'The Mission of Social History'; Jornanova, 'The Social Construction'.
[52] Roger Cooter, 'The Ethical Body', in Roger Cooter & John Pickstone (eds.), *Medicine in the 20th Century* (Amsterdam, 2000), pp. 451-468, there: p. 454.
[53] Ibidem, p. 466.

hypotheses, is that Cooter holds medico-ethical arbitration to be necessarily produced by the social, political and ideological context in which it is conducted, and is much less interested in the possibility of wilful agency on the part of individual historical characters. Thus, with regard to the Nuremberg Code, he finds it not so much interesting to historically investigate the parameters of the Doctors' Trial itself (which Cooter holds to be a show trial deliberately held to create an image of medicine as 'ideologically pristine and uniquely oriented to the defence of humanitarianism'), but to analyse the relation of medical ethics as a twentieth century intellectual paradigm to e.g. the waning influence of religion in the twentieth century and the simultaneous rise of civil rights and women's movements.[54]

As a prolific writer, Cooter is probably one of the most outspoken medical historians of his age. His essays on medical ethics function first and foremost as a critique of the dominant essentialist perspective, which he faults for 'hardly ever considering the socio-economic and political possibilities for and constraints upon asking the 'right' questions and arriving at the 'right' answers'.[55] What seems striking therefore, is that despite Cooter's polemical writing style and his utter rejection of essentialist histories, his conceptualization of a proper history of medical ethics is not necessarily incongruous with the historiographical vision of an essentialist historian who evaluates the past to be incommensurable from the present: the latter will also want to prove that in the past, medical ethics was dependent upon spatial and temporal contingencies. What both approaches furthermore have in common, is their privileging of historical actors' categories and perceptions over the ontological status of medico-ethical problems themselves. In the essentialist tradition, as medico-ethical issues are taken to be historically static, focus lies on the changing theories and practices of physicians or philosophers. For social historians of science, for whom historical actors' backstage motives and frontstage rhetoric take centre stage, the actual existence and perceived importance of medico-ethical problems have similarly received little scholarly attention. Although Cooter hinges towards such an interpretation, by arguing that 'like *nature*, the *ethical* is what society and culture attribute to it at any particular historical moment', he chooses to interpret this attribution-process as first and foremost a politico-ideological struggle, thereby leaving little room for the genuine beliefs and traditions of historical actors in differentiating between

[54] Ibidem, pp. 460-465.
[55] Cooter, 'The Resistible Rise', p. 260.

moral 'rights' and 'wrongs'.[56] With that, a serious treatment of the nature of medico-ethical problems themselves remains just as much absent as in the essentialist tradition. The only difference is that for the essentialist medico-ethical problems are pivotal, whereas for fig leaf historians they appear to be irrelevant.

A third way of remembering: from principle to problem

In the 1998 article 'Transcultural Medical Ethics and Human Rights', Robert Baker cried out that it is impossible to evaluate the Nazi concentration camps as having been morally unproblematic in any given historical setting:

> Whatever rules or regulations may, or may not, have been in place at the time, these [Nazi] *doctors* had violated a fundamental obligation. They should not have needed a formalism, a rule, a law, to tell them that they had trespassed upon a primary good and thus had violated the fundamental terms, not merely of a given societal conception of the physician-patient contract, but of any possible contract. […] Any such trespass is transtemporal and can be condemned even when there is no formal rule of morality or law expressively forbidding it.[57]

In the present-day globalized world, the debate over the cultural relativity of medico-ethical problems has become ever more important. It has become common practice that Western pharmaceutical companies and research institutions outsource their clinical trials to so-called Contract Research Organizations (CROs), which conduct trials-on-demand in developing countries where both disease and test subjects appear to be abound. Philosophical claims of locality and contextuality are in danger of appearing to be mere rhetoric (frontstage) for double standards of individual worth (backstage): i.e. that what Western patients do not want to be subjected to, can be tried out on the anonymous masses in 'the Third World'.[58] In these debates it is important to maintain that certain medical interventions are ethically problematic everywhere, not just where patient rights are better established and organized.

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[56] Cooter, 'The Ethical Body', p. 466.

[57] Baker, 'Transcultural Medical Ethics', p. 328. Italics in original. See also: Macklin, Universality of the Nuremberg Code'.

[58] See: Soniah Shah, *The Body Hunters. Testing New Drugs on the World's Poorest Patients* (New York, 2006) – a 242 page pamphlet against the 21st century international politics of CROs.

However worthily intended, the danger of this essentialist assessment is that it ignores that medico-ethical 'problems' first need to be culturally recognized as such, before they can become the subject of meaningful philosophical analysis and appropriate laws and regulations.[59] In the case of the Nazi experiments, all the defendants of the Doctors' Trial pleaded not guilty, despite the overwhelming factual evidence to the contrary.[60] Reich Commissioner for Health and Sanitation Karl Brandt for example, who was sentenced to death by hanging in 1947, maintained to the very end that the euthanasia programs which he had led, had truly been acts of mercy. Sometimes it was more humane, Brandt argued, to actively end 'suffering' than to let a 'patient' carry on 'struggling'.[61]

Although such words appear to be euphemisms for blatant murder in light of the 70.000 victims that were put to death under the Nazi 'Euthanasia Programme' between 1939 and 1941 (see chapter 2), it would be a mistake to evaluate the Nazi doctors' actions to be utterly incommensurable with their medical ethic. As historian of science Robert N. Proctor has convincingly argued, doctors like Karl Brandt were not without values. On the contrary, their ethics were crystal clear (e.g. Nordic supremacy, 'total war demands extreme measures', 'instrumental rationality demands it', 'Jews are lesser creatures', etc.) and they acted in surprising accordance with those values.[62] If historical research wants to make a contribution to present-day dilemmas over human experimentation, it might therefore be more productive to investigate *why* the Nazi doctors considered the experiments to be perfectly compatible with their professional morals than repeating the essentialist question if these experiments were ethical or not.

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[59] Does the historian Robert Baker qualify as an essentialist? Given his outstanding introduction to the 2009 *Cambridge World History of Medical Ethics* (i.e. 'What is the History of Medical Ethics', written together with Laurence McCullough) I would argue not. His analysis of the weaknesses of the essentialist point of view are too poignant for him to ascribe to this epistemological perspective. However, his Rawlsian conceptualization of (some) medico-ethical problems as 'fundamental' primary goods in his 1998 article 'Transcultural Medical Ethics' does in my opinion, as set forth in the introduction of this thesis, perpetuate an essentialist perspective. It would be interesting therefore to see whether Baker still ascribes to his 1998 assessment of (the history of) the Nuremberg Code.

[60] Alexander Mitscherlich & Fred Mielke, 'Epilogue: Seven Were Hanged', in Annas & Grodin, *The Nazi Doctors*, pp. 105-107.

[61] Ulf Schmidt, *Karl Brandt: The Nazi Doctor. Medicine and Power in the Third Reich* (London, 2007).

[62] Robert N. Proctor, 'Nazi Doctors, Racial Medicine, and Human Experimentation', in Annas & Grodin, *The Nazi Doctors*, pp. 17-31, there: p. 26. See also: Michael H. Kater, *Doctors under Hitler* (Chapel Hill, 1989); Michael Burleigh, *Death and Deliverance: 'Euthanasia' in Germany, c.1900-1945* (Cambridge, 1994).

Similarly, if one is to accept that the Nazi experiments were necessarily unethical because they were conducted upon unwilling 'patients', inflicted disproportionate pains and often resulted in death, the question arises why this evaluation is not often extended to similar forms of *animal* experimentation. While present-day scholars concerned with the epistemological status of the Nuremberg Code rarely address this dilemma, for antivivisectionists in the immediate post-war era this was the only sensible question to ask with respect to the Nazi experiments (see chapter 3). For this particular social group, it was inconceivable that forced human experimentation was generally acknowledged to be an ethical problem, while animal experimentation (which antivivisectionists evaluated to be necessarily forced) was not.

To gain insights therefore, in the ways in which certain medical issues have historically come to be *formulated* as medico-ethical problems while others have not, this thesis will investigate the reception of the Nuremberg Code in the Netherlands in the first decade after the Second World War. The Code, which was supposed to be an answer to some fundamental tension between the goals of the clinical practitioner and the biomedical researcher, was virtually ignored by the Dutch medical community in the post-War decade, until – quite suddenly – the Dutch Health Council promulgated a set of principles for human experimentation in 1955. The following chapters will lay bare that the Council's promulgation of the *Guidelines* was first and foremost a response to the accusation of the Dutch antivivisectionist movement that animal experimentation clouded the senses of the medical experimenter, which led him to loose his sense of humanity and conduct cruel and unlawful experiments on humans (see chapters 3 and 4). Which issues the *Guidelines* thus ultimately addressed, is dependent upon the problems the Health Council envisioned to be solving. Understanding of this production-process of ethics-in-the-making can shed important light on the parameters and limitations of medico-ethical regulations.

The word 'formulation' in the above problem statement is purposefully chosen. It leaves room for both framed as well as genuine expressions by historically relevant stakeholders in debates over proper clinical research ethics. The following chapters will on the one hand relate instances where a clear Goffmanian discrepancy can in fact be noted between backstage ideas and frontstage rhetoric: politicians, physicians and other stakeholders often purposefully framed a certain version of a medico-ethical issue in order to influence public opinion of the parameters of the problem at hand (and by

extension tip the scales in political decision-making to their favour). To that extent, appeals to medical ethics did indeed function as fig leaves to keep other more pragmatic interests from view. On the other hand however, those involved were also often sincerely concerned over the future standing of medicine in society or the dangers of biomedical experimentations. Although their use of arguments and expression of worries might appear to be alien from a present-day perspective, it would be anachronistic to argue that these were therefore nothing more than fig leaves to merely further professional needs. By allowing for both framed and genuine expressions and actions of historical actors, some of the seemingly incommensurable differences between essentialist and social histories of medical ethics might possibly be neutralized.

The culture of public problems: concept clarification

To structure historical actors' arguments and thought-patterns, this thesis makes use of a number of sociologically inspired concepts. While these have to be taken more as heuristic tools than anything else, they are nevertheless useful to achieve clarity in the analyses of the historical material under investigation. In the remaining pages of this chapter therefore, a number of sociologists and their theories will pass in review.

In the 1981 research essay *The Culture of Public Problems*, sociologist Joseph Gusfield developed a theoretical perspective with which to examine the 'social phenomenon of public problems'.[63] While Gusfield takes the American drinking/driving-problem as his object of investigation, his thesis that *ways of seeing* have histories (i.e. human situations and problems have not always been construed and recognized as they are today or will be in the future) is highly useful for this thesis. Gusfield defines a public problem as 'a condition that is considered by a group of people to be simultaneously deplorable and capable of being relieved by and requiring public – communal/state – action'.[64]

[63] Gusfield, *The Culture of Public Problems*.

[64] Joseph R. Gusfield, 'Constructing the Ownership of Social Problems: Fun and Profit in the Welfare State', in *Social Problems* Vol.36, No.5 (1989), pp. 431-441, there: p. 431. Gusfield differentiates 'public' problems from 'private' ones. Problems are only public, according to Gusfield, when they become matters of controversy in the arenas where public action is taken. In 1981, Gusfield thus wrote that marital happiness and sexual frustration would not count as public problems, because there existed no public agencies to assure their resolution (in Gusfield, *The Culture of Public Problems*). In 1989 (in 'Constructing the Ownership'), he revoked this point of view, but only because 'sexual therapy had become a recognized field that

There are two dimensions to defining a given situation as a public problem. At the cultural level, drinking while driving can be conceptualized as 'perfectly normal' (it therefore being *not* a problem), a wilful choice of deviant behaviour (it therefore requiring punishment), or an act of insanity (and thus needing medical treatment). However, while in theory any number of cause-effect conceptualizations is possible (e.g. the driver was possessed by an alien force), not any theory is viable as a *public* problem. Individual actors are born into arenas wherein pre-existing cultural beliefs, scientific theories as well as traditions reign. In order to influence public conceptions, the actor therefore first needs to have the ability to create and influence the public definition of a problem, a subject position which Gusfield denotes with the term *ownership*.

The concept of ownership ties into the second dimension of defining a situation as a public problem. The public arena is not a field on which all can play on equal terms: i.e. not only theories and beliefs play a role, but also self-interests, needs and practices. Some actors and institutions are stakeholders with more authority and control than others, and therefore have more ownership of the public definition of the problem. This part of Gusfield's conceptual framework is thus similar to Goffman's differentiation between frontstage and backstage: some phenomena can be privately recognized as problems, but publicly denied as such because off the interests involved (an example being the strong tobacco lobby in the United States which claims that its products are non-harmful to the human physique). The main difference with Goffman however – and this is where the conceptual framework *The Culture of Public Problems* is most in line with this thesis – is that Gusfield is only willing to attribute limited agency to the role of needs and practices in obtaining public ownership over a problem. Interest groups do not stand apart from society, working upon public perceptions from 'the outside'; they are themselves just as much influenced by reigning cultural beliefs and scientific theories. Therefore, theories (beliefs) and practices *co-constitute* possible conceptions and solutions of public problems.[65]

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required training, and had medical insurance extended to it'. (p. 432). Sexual satisfaction thereby had become 'a social responsibility and a citizen's right' (p. 432). This analysis is problematic, given the fact that evaluating an affair as private (i.e. not requiring public action) is not an individual decision. Communal perceptions, beliefs and traditions, even if they do not inspire public actions, are just as much a public affair if so-called 'private frustrations' are the result of internalized ideals about what is normal and what is deviant behaviour. As feminists have often argued 'the personal is political'.

[65] See: Gusfield, *The Culture of Public Problems*, pp. 1-23. Co-constitution is not a term that Gusfield uses himself. This thesis borrows it from the epistemological perspective of STS.

Whatever qualifies as a public problem is thus constantly in flux. Not only do needs and practices vary over time, scientific theories and cultural beliefs are also subject to historical change. Once a certain phenomenon has come to crystallize as a public problem however, those who are publicly recognized to have authority on the issue are in charge of determining its possible solution. Since the late nineteenth century, this role has been increasingly reserved for the 'professional expert', who is envisioned to possess the relevant know-how and appropriate authority to deal with the matter at hand.[66] The stronghold of this socio-cultural position should not be underestimated. Historians have argued for example, that the Nuremberg Code was of little influence in the first two decades after the Second World War, because it was promulgated by legal instead of medical authorities (even if it was drawn up by two distinguished physicians: one physiologist and one neurologist).[67] Because the Nuremberg judges were not recognized to possess professional expertise on the ethics of clinical research, the international medical community would not accept the Code as an authoritative document (see chapter 2).

At the same time, the social status of the expert has never been uncontested and tends to vary per profession and per historical context.[68] In the Netherlands in the early twentieth century for example, respected jurists submitted a petition to Dutch parliament wherein they requested a neutralization of the existing 'doctors monopoly' to practice medicine, on the grounds that patients should have the right to individually choose the healer they preferred.[69] Similarly, many of the stakeholders in the Dutch euthanasia debate of the late twentieth century were unhappy that physicians obtained the exclusive right to 'administer' active euthanasia and assisted suicide. Enabling a dignified death, these stakeholders argued, was a process that should not be allocated to a small group of experts.[70]

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66 Eliot Freidson, *Profession of Medicine. A Study of the Sociology of Applied Knowledge* (New York, 1970).

67 Paul Weindling, 'The Origins of Informed Consent: The International Scientific Commission on Medical War Crimes, and the Nuremberg Code', in *Bulletin of the History of Medicine* Vol.75, No.1 (Spring, 2001), pp. 37-71.

68 See: Frans van Luntheren, Bert Theunissen & Rienk Vermij (eds.), *De opmars van deskundigen. Souffleurs van de samenleving* (Amsterdam, 2002); E.H. Tonkens, *Mondige burgers, getemde professionals: marktwerking, vraagsturing en professionaliteit in de publieke sector* (Utrecht, 2003).

69 Frank Huisman, 'Wie Geneest? De Strijd om Culturele Autoriteit in de Nederlandse Gezondheidszorg', in Luntheren et al., *De opmars van deskundigen*, pp. 99-118.

70 James C. Kennedy, *Een weloverwogen dood: euthanasie in Nederland* (Amsterdam, 2002).

In the process of determining who has the proper expertise to come up with a reliable solution to a public problem, already existing categories which are believed to carry weight are invoked to demarcate the parameters of the problem (and thus define what the problem precisely is). Depending for example on whether a medico-ethical problem is evaluated to be scientific or social (two categories which are by no means clear-cut), different sorts of professional expertise will be called upon. As will be explicated in chapter 3 of this thesis, it was highly ambiguous in the 1940s and 50s in the Netherlands whether ethical reflections over human experimentations were first and foremost scientific (and thus the ownership of the medical profession), or if they were inherently social (and therefore required the involvement of social institutions). In particular, when the Minister of Social Affairs started differentiating institutionally between 'scientific health care matters' and 'social health care matters' after the Second World War, it became a subject of debate who had the authority to define the boundaries of medico-ethical problems and establish appropriate regulations.

Philosophers of science have baptised this difficulty of establishing rigorous delineations between what is 'science' and what is 'non-science' as the 'demarcation-problem'. In 1983, sociologist Thomas F. Gieryn proposed that scientists purposefully construct social boundaries to distinguish their intellectual activities from ways of knowing that do not fit their criteria of 'proper science'. As such, they seek to obtain a monopoly upon the production of 'objective knowledge statements' and therewith establish strict limitations to the sort of activity that is allowed to participate in scientific and public debates. According to Gieryn, this *boundary-work* is mainly ideological: depending on the directed audience, scientists attribute only a certain selection of qualifying characteristics to the institution of science. Because science has no essential definition, it can be described as either 'pure' or 'applied', as either 'theoretical' or 'empirical', depending on the goal and opponent of the scientist.[71]

This thesis only partially accepts Gieryn's assessment of scientists' motives and goals, because it is similar to the earlier discussed fig leaf hypothesis: i.e. it emphasizes self-interested social practices and leaves little room for genuine theoretical convictions. However, the idea that the historical boundaries of science

[71] Thomas F. Gieryn, 'Boundary-Work and the Demarcation of Science from Non-Science: Strains and Interests in Professional Ideologies of Scientists', in: *American Sociological Review*, Vol.48, No.6 (Dec., 1982), pp. 781-795. See also: Thomas F. Gieryn, *Cultural Boundaries of Science. Credibility on the line* (London: The University of Chicago Press, 1999).

are not self-evident but subject to political debate (for the historian at work as well as the historical actor), is a useful concept to keep in mind. In discussions over the merits of live experimentation for example, both the Dutch antivivisectionist movement and the Dutch medical profession sought to delineate a different conception of proper science that was congruent with their point of view (see chapter 3). While antivivisectionists argued that human as well as animal experimentation degraded the spirit of the humane scientist (and therefore degraded science itself), those in favour of the practice argued that it was in fact the capstone of the research-based laboratory (and thus the very essence of modern science). When this debate turned into a discussion over the establishment of a vivisection-free professorship at a Dutch university, the boundary between science and non-science became the battle ground for both parties to defend their respective views concerning human and animal experimentation.

Finally, this thesis provisionally accepts that the expertise over what counts as proper medico-ethical principles has proceeded through distinct *research programmes*.[72] In different institutional settings and historical time periods, there have been defining characteristics of what constituted as the *hard core* of medical ethics: i.e. the absolute fundamentals of morally just behaviour towards patients, research subjects and other medical professionals. Presently, the principles of informed consent and patient autonomy arguably form this hard core, internationally as well as in the Netherlands. This thesis will defend however that this has not always been so (see chapter 4). In addition, this thesis provisionally accepts that the ownership over these research programmes was handed over from the medical profession to professional ethicists somewhere after the 1960s and 70s, at least in the public domain (frontstage) and at least in most Western countries. This is how historians have recorded it for the United States (both essentialists as well as social historians), and this is how textbooks in general

[72] Ethicists Ezekiel Emanuel and Christine Grady argue that medical ethics since Nuremberg has proceeded through distinct *paradigms*. They emphasize however that these paradigms should not be thought of a Kuhnian paradigms with radical, instantaneous paradigm shifts. Rather, transitions between paradigms evolved over time, were subsequently espoused and had antecedents in the prior paradigm. The Lakatosian concept of 'research programmes' therefore seems more appropriate. In: Ezekiel Emanuel & Christine Grady, 'Four Paradigms of Clinical Research and Research Oversight', in Emanuel et al., *The Oxford Textbook*, p. 222-230. See also: Imre Lakatos, 'Falsification and the Methodology of Scientific Research Programmes', in: Imre Lakatos & Alan Musgrave (eds.), *Criticism and the Growth of Knowledge* (Cambridge: Cambridge University Press, 1971), pp. 91-196; Imre Lakatos, 'History of Science and its Rational Reconstructions', in: J. Worrall & G. Currie (eds.), *The Methodology of Scientific Research Programmes* (Cambridge: Cambridge University Press, 1974), pp. 102-138.

conceive of past and present-day medico-ethical expertise.[73] Whether this is true for the Netherlands, is something that remains to be investigated. This thesis will defend however, that at least between 1947 and 1955, it were physicians in the Netherlands who decided what counted as proper medico-ethical solutions to experienced medico-ethical problems.

Accepting however that medical professionals had the ownership over the definition of medico-ethical issues and principles, does not mean that they had the exclusive ownership over the formulation of medico-ethical problems. Other social groups had significant influence in determining the agenda of medico-ethical discussions, and this limited the possible solutions the medical profession could offer. This is true for the past as well as the present. Historically investigating the socio-cultural crystallization processes of medico-ethical problems is therefore an important alternative approach to the dominant 'essentialist' and 'fig leaf' traditions in the history of medical ethics. As such, it has the possibility to contribute to a better dialectic of understanding between the merits of various ways of remembering the history of medical ethics, as will hopefully become clear from the following chapters of this thesis.

[73] Rothman, *Strangers at the Bedside*; Cooter, 'The Ethical Body'; Emanuel & Grady, 'Four Paradigms'.

2. A Good Code for Barbarians: Nuremberg and the Netherlands

> *The defendants in the dock are charged with murder, but this is no mere murder trial.* […] *Some of them may be sadists who killed and tortured for sport, but they are not all perverts. They are not ignorant men. Most of them are trained physicians and some of them are distinguished scientists*.[74]

The 1947 Nuremberg Code (see Appendix I) formed the capstone of the Doctors' Trial, the first of twelve American military tribunals trying those surviving members of the military, political, and economic leadership of Nazi Germany, who had not been dealt with in the Trial of the Major War Criminals before the International Military Tribunal. The court case, officially known as *United States of America v. Karl Brandt et al.*, ran from 9 December 1946 to 20 August 1947 and brought 20 physicians and three Nazi officials before four American judges. While seven of the 23 received the death sentence, seven others were acquitted. The remaining nine all returned to freedom between 1953 and 1955.[75]

Despite the historical relevancy that is often attributed to the Code (see chapter 1), the principles codified by the Nuremberg judges were largely ignored in the first two decades after the Second World War by both national and international medical organizations, including arguably the World Medical Association. In the Netherlands, the Code was hardly reported upon in the official organs of the Dutch medical profession. When the Dutch Health Council

[74] Telford Taylor, 'Opening Statement of the Prosecution. December 9, 1946' reprinted in Annas & Grodin, *The Nazi Doctors*, pp. 67-93, there: p.68.

[75] For an overview of the defendants and their verdict, see: Paul J. Weindling, 'The Nazi Medical Experiments', in Emanuel et al., *The Oxford Textbook*, pp. 18-30, there: p. 27.

promulgated principles for human experimentation in 1955, the Nuremberg Code was not referenced, despite prior investigations into the proceedings of the Doctors' Trial by the Council's President (see chapter 4).

This chapter will plead that given the narrow conceptualization in the Doctors' Trial's indictments of the medico-ethical problems at hand, it is unsurprising that the Code was evaluated at the time as a 'good code for barbarians but an unnecessary code for ordinary physicians'.[76] In other words, instead of claiming ownership over the medico-ethical dilemmas put forward by the Doctors' Trial, medical professionals in the immediate post-war era sought to *disown* the problem of unlawful human experimentation, which the parameters of permissible (i.e. ethical) biomedical research established during the Doctors' Trial (and by extension in the Nuremberg Code) enabled them to do so.

To do so, this chapter will outline how the indictments of the Doctors' Trial sought to reconcile two conflicting problems: to prosecute Nazi physicians for committed crimes, while simultaneously preserving the idea that the practice of human experimentation is highly useful for the progress of science and should not be thwarted by negative public exposure to biomedical research in general. In addition, it will evaluate the reception of the Nuremberg Code in the Netherlands by the Dutch government and the organized Dutch medical profession in the first decade after the Second World War. In the following chapter, it will be investigated how other stakeholders sought to claim ownership over the potentially problematic nature of clinical research in the Netherlands. First however, this chapter will give a short summary of the Nazi experiments and their rationale themselves.

The rationale behind the Nazi experiments

Not all medical experiments conducted in the Nazi concentration camps, were brought to the fore during the Doctors' Trial, the principal reason being that not all major perpetrators were still alive or had been caught. *Todesengel* Joseph Mengele for example, escaped prosecution and his infamous eugenicist experiments using twins did thus not form a part of the indictments at Nuremberg.[77] The experiments that were included, can generally be divided into three categories: (1) furthering

[76] Katz, 'The Consent Principle'.

[77] Michael R. Marrus, 'The Nuremberg Doctors' Trial in Historical Context' in *Bulletin for the History of Medicine* Vol.73 (1999), pp. 106-123, there: pp. 110-111.

the Nazi war mission, (2) procuring better means of population control and (3) understanding and cataloguing racial differences.[78]

The first category refers to those experiments that were conducted to research and improve German soldiers' survival chances when hurt in combat. These include the high-altitude, sea-water and freezing experiments that took place at the Dachau concentration camp; the studies into the physiological effects of mustard gas, and the aetiology and treatment of wound infections; research into bone, muscle, and nerve regeneration and into bone transplantation; understanding the epidemiology of malaria, typhus and epidemic jaundice; and finally the experimental trials to test the effectiveness of war weapons, such as incendiary bombs and poisonous bullets. The second category includes the studies into more effective ways of 'administering' euthanasia and enabling large-scale sterilization. The third and final category denotes the Jewish Skeleton Collection, a collection of heads and bodies of murdered Jews. The Skeleton Collection is an apparent stranger in the midst of the other experiments in the Doctors' Trial indictment, because it was not exactly an experiment itself, but an anthropological display to showcase the inferiority of the Jewish race. It was nevertheless an 'act of science' and a gruesome one at that, making it therefore a useful case to show the degenerate nature of Nazi medicine. It is questionable however to what extent it had anything to do with the ethics of biomedical experimentation.

In defence of their actions, the Nazi physicians put forward that their experiments had served the war efforts and that their individual moral judgement had thus been made subject to the needs of the nation. As Karl Brandt argued in front of the Nuremberg judges: “any personal code of ethics must give way to the total character of the war”, an approach which the defence argued to be similar to the rationale utilized by American researchers who had during the war conducted experiments on prisoners, mentally incompetent patients and other research subjects.[79] As sociologist Zygmund Bauman has explained, this rationale can be denoted as a utilitarian attitude imbued with the Weberian notion of instrumental rationality: i.e. choosing the most efficient means to achieve a specific end, without in itself reflecting on the value of that end (i.e. focusing on the 'how' of

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[78] All the experiments are described in: Taylor, 'Opening Statement'; Weindling, 'The Nazi Medical Experiments'; Ulf Schmidt, 'Medical Ethics and Nazism', in Baker & McCullough, *The Cambridge World History*, pp. 595-608.

[79] Charles Hamilton, *Leaders and Personalities of the Third Reich: Their Biographies, Portraits, and Autographs, Vol. 1* (San Jose, 1984), p. 138.

the action instead of the 'why').[80] Thus, in the case of the Nazi experiments, the use of a 'few' human subjects in order to possibly realize extensive benefits for the community, was evaluated by the Nazi physicians to be only rational.

One of the reasons historians and ethicists have so fervently argued that the principles in the Nuremberg Code are indeed transhistorical (see chapter 1), is to counter precisely this use of argumentation by the defendants of the Doctors' Trial: that the concentration camp experiments were not unethical under the Nazi regime and that the Trial was nothing more than victor's justice. Already during the Trial, the prosecution sought to prove that the German physicians had not only violated the rules of war, but also their very own professional codes of conduct. For this reason, the Trial's indictment was grafted on pre-existing German codes of clinical research ethics, aiming to establish that the defendants had knowingly trespassed upon their own well-established medico-ethical principles and could thus be held legally responsible for their crimes.[81] If anything, it made their choice of actions even worse, for these were not 'ignorant men', they were 'trained physicians, and some of them even distinguished scientists'.[82]

Neither the concept of instrumental rationality nor the accusation of 'lawlessness' sufficiently explains however, why the Nazis justified the use of concentration camp prisoners for their experiments, but not the use of other members of society. It is not true that in the Third Reich biomedical experimentation was value-free. Significantly, upon their rise to power in 1933, the Nazis had past strict regulations for the use of animals in biomedical research. As Chief Counsel Telford Taylor (head of prosecution) remarked during the opening statement of the Doctors' Trial:

> This [1933] law states explicitly that it is designed to prevent cruelty and indifference of man towards animals and to awaken and develop sympathy and understanding for animals as one of the highest moral values of a

[80] Zygmunt Bauman, *Modernity and the Holocaust* (New York, 1989), p. 22.

[81] Tröhler, 'The Long Road', pp. 31-32. In December 1900 the Prussian Minister of Religious, Educational and Medical Affairs issued a specific Directive wherein physicians and surgeons were advised to obtain informed consent for any intervention other than diagnostic or therapeutic ones. In 1931, this Directive was further elaborated as *Guidelines for Novel Therapeutic Trials and for Performing Scientific Experiments in Humans*, which included both therapeutic and non-therapeutic research. See also: J. Vollman & R. Winau, 'Informed Consent in Human Experimentation before the Nuremberg Code, in *British Medical Journal* Vol. 313 (1996), pp. 1445-1447.

[82] Taylor, 'Opening Statement', p. 68.

> people. The soul of the German people should *abhor* the principle of *mere utility* without consideration of *the moral aspects*. […] If the principles announced in this law had been followed for human beings as well, this indictment would never have been filed. It is perhaps the deepest shame of the defendants that it probably never even occurred to them that human beings should be treated with at least equal humanity.[83]

The thing to be investigated therefore, is why Nazis did not feel that concentration camp prisoners were entitled to the same kind of rights as animals. The medico-ethical principles which they did have, did apparently not apply to Jews, gypsies and others.

In explaining the overwhelming absence of any moral reflection on the implementation of the Holocaust in Nazi Germany, Bauman invokes (among other things) the sociological notion of the *universe of obligation*: i.e. 'the circle of people with reciprocal obligations to protect each other whose bonds arise from their relation to a deity or sacred source of authority'.[84] The universe of obligation created within the Third Reich separated those who stood within the Nazi vision of the world from those to whom the moral precepts of that world were not applicable (and moral evaluations therefore meaningless).[85] Applying this concept to the concentration camp experiments illuminates how an apparent uneven discrepancy between animal and human rights did thus not exist for the Nazi physicians: animals were envisioned to be part of the Nazi world, whereas Jews and other deviant members of the Third Reich were not. Using this latter group for medical experimentation was not considered to be a transgression of medical ethics, because the Nazi physicians did not have any obligations towards them. As Bauman so succinctly puts it: 'The struggle over moral issues never takes place, as the moral aspects of actions are not immediately obvious or are deliberately prevented from discovery and discussion. In other words, the moral character of action is either invisible or purposefully concealed'.[86] In Nazi Germany, human experimentation on concentration camp prisoners did *not* surface as a public problem.

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[83] Ibidem, pp. 89-90. Italics added.
[84] Bauman, *Modernity and the Holocaust*, p. 26. See also: Helen Fein, *Accounting for Genocide: National Response and Jewish Victimization during the Holocaust* (New York, 1979), p. 4.
[85] Ibidem, p. 27.
[86] Ibidem, p. 24.

Framing the problem: the limiting indictment of the Doctors' Trial

In August 1945, the four Allied Powers issued the London Charter of the International Military Tribunal (IMT), in which it was decided that the 'major war criminals of the European axis' had to be tried and punished.[87] Already during the preparations of the IMT however, the question arose whether there should not be subsequent international trials to prosecute other 'lesser war criminals', such as representatives of the Third Reich ministeries, the I.G. Farben, the judiciary, and the *Einsatzgruppen*.[88] In November 1945, one month after the opening of the IMT, the Allied Control Council in charge of overseeing Germany's occupation therefore passed Control Council Law No.10, which established a legal framework to try alleged war criminals who had not been brought before the judges of the IMT.[89] Members of the German medical profession quickly became a suspect category, when damning evidence of a biomedical nature was brought to the fore during the IMT. Evidence against Hermann Wilhelm Göring, leading member of the NSDAP and Commander-in-Chief of the German *Luftwaffe*, for example included his involvement in the Dachau high-altitude researches. Similarly, during the cross-examination of Wolfram Sievers, the General Secretary of the SS Ahnenerbe (a Nazi think tank), the Jewish Skeleton Collection was brought to light.[90] When more evidence was uncovered by members of the Field Information Agency, Technical (FIAT) and the International Scientific Commission for the Investigation of War Crimes of a Medical Nature (ISC), the United States decided in mid-August 1946 that a trial against medical perpetrators of the Third Reich would be held.[91]

Because of the nature of the concentration camp experiments, the Doctors' Trial became the first of the subsequent American military tribunals. In light of the incriminating evidence available, a trial against German doctors was evaluated to

87 See: Kevin Jon Heller, *The Nuremberg Military Tribunals and the Origins of International Criminal Law* (Oxford, 2011).

88 Ulf Schmidt, 'The Nuremberg Doctors' Trial and the Nuremberg Code', in Frewer & Schmidt, *History and Theory of Human Experimentation*, pp. 71-116. See also: Marrus, 'The Nuremberg Doctors' Trial'; Weindling, 'The Origins of Informed Consent', pp. 37-71

89 Schmidt, 'The Nuremberg Doctors' Trial', p. 72. Control Council Law No. 10 was purposefully based on both German criminal law and international treaties which Germany had signed: i.e. the 1907 Hague Regulation on Warfare, the Kellogg-Briand Pact of 1928 (which condemns aggressive wars) and the Geneva Convention of 1929 (which are rules for the protection of prisoners of war).

90 Ibidem, pp. 73-74. NB. Schmidt refers to *Wolfgang* Sievers. This has to be a typo.

91 Ibidem, pp. 74-75.

be the most likely to succeed, whereas the cases against German finance and industry encountered much more obstacles.[92] Importantly, the Doctors' Trial thus served as a prototype-trial, and the indictment therefore as an important policy-making document. By the end of October 1946, the United States charged 20 German doctors and three bureaucrats with 'war crimes and crimes against humanity'.[93] All 23 defendants were held to have acted 'in complete disregard of international conventions, the laws and customs of war, and the general principles of criminal law as derived from the criminal laws of all civilized nations'.[94] In addition, some individual defendants were charged with the organization of health services in the Third Reich, the use of fraudulent methodology for criminal experiments, and obligation in the face of superior orders.[95]

A number of historians has remarked that the indictment of only 23 individuals is inexplicable in the face of the thousands of German doctors who were in one way or another involved in the forced sterilization and euthanasia programs on German nationals before and during the war.[96] The focus on human experimentation during the Doctors' Trial would fail to understand the integral part of medicine to the Nazi program. Medical theories of race and eugenics preceded the Third Reich rather than following it and the sterilization and euthanasia programs were carried out by the medical profession at large, not just a group of 23 individuals. According to historian Robert Proctor, the Trial neglects the relation between the rise of Nazism and the early twentieth century crisis in modern science and medicine that was associated with the increasing specialization and bureaucratization of science. When Hitler came to power, he promised Germany a future with 'more Goethe and less Newton' – a feeling that, as will be explored in chapter 3 of this thesis, was shared by more social groups than just the Nazis. Historian of Holocaust studies Michael R. Marrus argues that the narrow construction of the Trial's charges has facilitated the evasion of responsibility that characterizes much of the immediate post-war treatment of medicine in society. As such, the focus on human experimentation has resulted in a failure to live up to 'a grand historic assessment of medicine in the Third Reich and the human dimension of the catastrophe'.[97]

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92 Ibidem, pp. 73-74.
93 Ibidem, p. 75.
94 Marrus, 'The Nuremberg Doctors' Trial', p. 108.
95 Ibidem, p. 109.
96 Ibidem, p. 105; Proctor, 'Nazi Doctors', pp. 26-29.
97 Marrus, 'The Nuremberg Doctors' Trial', p. 105.

At the time however, there were a number of specific reasons to focus only on medico-ethical problems of an experimental nature in the Doctors' Trial. Firstly, the Nuremberg trials in general served to stigmatize the criminality of the Nazi regime and thereby contribute to the democratization of Germany. In this context, it was better to single out a few individuals than condemn a considerable segment of society at large. Secondly, legal restrictions anchored in the London Charter and Control Council Law No.10 forced the prosecution to focus on medical crimes committed in the face of the war.[98] When the prosecution had initially sought to emphasize that the organization of the medical services in the Third Reich was part of the core of the Nazi enterprise, the defence had argued successfully that the American tribunals had no jurisdiction over such an offence, because of the ruling of the IMT that conspiracy charges had to be linked with 'crimes against peace', something which the medical crimes were not.[99] This also meant that the forced sterilizations (more than 400.000 victims) before the war could not be included in the indictment.

Thirdly, in congruence with the Doctor's Trial function as a prototype-trial, the prosecution wanted to approach the medical crimes as variations in the overall scheme of the principle of genocide. The concentration camp experiments aimed at procuring better means of population control, had been conducted to develop methods that could efficiently and systematically murder ethnic and religious groups, which was a crime against humanity for which the Nazi physicians could be prosecuted. This focus on the intention and execution of murdering *another* people however, meant that emphasis during the Doctors' Trial lay with crimes committed on non-German nationals. When Karl Brandt put forward during the Trial that there had been a legal and even humanitarian basis for the euthanasia programs, the judges responded:

> Whether or not a state may validly enact legislation which imposes euthanasia upon certain classes of its citizens is a question which does not enter into the issues. *Assuming that it may do so*, the Family of Nations is not obligated to give recognition to such legislation when it manifestly gives legality to plain murder and torture of defenceless and powerless human beings *of other nations*.[100]

[98] Schmidt, 'The Nuremberg Doctors' Trial', pp. 81-82.
[99] Marrus, 'The Nuremberg Doctors' Trial', p. 112.
[100] Ibidem, p. 117. Italics added.

The focus on genocide thus excluded those criminal medical actions which had been undertaken upon German victims. Next to the forced sterilizations, the 1939-1941 euthanasia program upon German nationals (more than 70.000 victims) was therefore largely ignored during the trial – developments which the Nuremberg Code itself embodies by its exclusive focus on clinical research ethics.

The focus on human experimentation itself was neither free from danger however. Before the start of the trial, the prosecution had received information that both American and British researchers had performed experiments on human subjects during and after the war that could similarly be regarded as unethical. In 1945, *Life* magazine in the United States had reported on dangerous malaria experiments which had been conducted on American prisoners (many of whom were black) during the Second World War. The British Medical Research Council had condoned experimental studies on infants suffering from spina bifida, which would 'most likely not harm them, but should nonetheless not be carried out on perfectly healthy children'.[101] It had to be prevented that the defence could put forward an argument of *tu quoque*: i.e. that the Allied nations were likewise guilty of unethical conduct when it came to experimenting upon human beings and were thus not morally entitled to condemn the work of Nazi physicians. Taylor's office therefore set out to prove that the concentration camp experiments had not been scientific and therefore unnecessary. Throughout 1946, American attorneys sought to answer questions concerning the character of the Nazi experiments: if they had really been necessary, if they had been adequately designed and carried out and if they had produced any valuable results.[102]

But fear for acquittal was not the only reason to carefully construct the Nazi medical experiments as criminal. Surviving minutes of a meeting held on 31 July 1946 between British, French and U.S. medical investigators forming FIAT, show that the prosecutors feared that:

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[101] Schmidt, 'The Nuremberg Doctors' Trial', p. 76-77. A more detailed study of the wartime experiments on United States prisoners can be found in: Jon M. Harkness, 'Nuremberg and the Issue of Wartime Experiments on U.S. Prisoners: The Green Committee', in *Journal of the American Medical Association* Vol. 276 (1996), pp. 1672-1675. Also chapter 2 'Research at War' of David J. Rothman, *Strangers at the Bedside* (1991), pp. 30-50, is insightful. It shows for example that the rationale behind both the Nazi experiments and the U.S. prison experiments were congruent: if soldiers, drafted into the military, were obliged to make sacrifices for their countries, prisoners should not be exempt from similar duties. Participating in clinical trials was a way to redeem oneself and serve one's nation.

[102] Ibidem, p. 76.

> …unless appropriate care is taken, the publicity associated with the trial of the experimenters in question, and also the publicity which is bound to be attached to the official report of this meeting, may so stir public opinion against the use of humans in any experimental manner whatsoever that a hindrance will therefore result to the progress of science.[103]

The prosecution wanted to make sure that condemnation of the Nazi medical experiments would not result in general unrest over human experimentation. The indictment of the Doctors' Trial therefore preserved the idea that the act of human experimentation, when performed ethically, is essential for the progress of science. In order to do so, the prosecution sought to establish clear boundaries between what was generally regarded as legitimate medical science and the criminal Nazi experiments. It sought to create a perception of science as being synonymous with ethical behaviour (and criminal acts as therefore necessarily non-scientific) – a strategy which stood at the base of the Nuremberg Code.

The boundary-work of Andrew Ivy and Leo Alexander

The first tactic utilized by the prosecution in order to draw up boundaries between American and Nazi science, was to establish that the American medical profession – in contrast with the Nazi physicians – did possess clear defined ethics for human experimentation. The man who came to play an essential role in this process was the well-respected American professor of physiology Andrew Ivy (who also voiced the above quoted concern over the Trial's hindrance to scientific progress during the FIAT meeting of 31 July 1946). His involvement in the Doctors' Trial would become central to the eventual promulgation of the Nuremberg Code.[104]

On 1 August 1946, Ivy wrote down a list of three principles which he held to be essential in clinical experimentation. In these 'Principles and Rules of Experimentation on Human Subjects', the physiologist addressed the issue of voluntary consent, the necessity of the experiment's usefulness, the scientific validity of the experiment, and the prohibition of the experiment if there are *a*

[103] In: Weindling, 'The Origins of Informed Consent', p. 49. Cited original: Minutes of Meeting to Discuss War Crimes of Medical Nature Executed in Germany under the Nazi Regime, 31 July 1946, PRO WO 309/471 (n.39).

[104] Both Schmidt (2007) and Weindling (2001) provide elaborate descriptions of Ivy's work and philosophy, as well as his involvement in the Doctors' Trial.

priori reasons to believe that death or disabling injury will occur.[105] In December 1946, shortly after the opening of the Doctor's Trial, a shortened and modified form of these principles was adopted by the American Medical Association's (AMA) House of Delegates.[106]

During the trial, from 12 to 16 June 1947, Ivy was called to the stand to testify on behalf of the prosecution in defence of the controversial malaria experiments. Earlier in the trial, the prosecution had suffered a setback, when its medical expert witness, the psychiatrist and medical historian Werner Leibbrand, had stated after cross-examination by the defence, that the American malaria experiments were also 'excesses and outgrowths of biological thinking' and should similarly be condemned as unethical human experimentation.[107] In his testimony, Ivy aimed to rebut Leibbrand's claim by arguing that the United States did have specific standards for research with humans which were codified by the AMA and represented the accepted medical practice of the United States in general.[108] When examined by the defence however, Ivy was forced to admit that the principles he was referring to had not existed in the American research context before 1946 (see also chapter 3) and that the AMA's publication on experimental medical ethics had been made in anticipation of Ivy's testimony in the trial.[109]

Ivy also deliberately tried to exonerate the American medical profession from the accusations made in context of the malaria experiments by offering false evidence. In early 1947, the American physiologist had established a committee on the ethics of the experiments (the so-called Green Committee). In Nuremberg, he presented the most important 'findings' of that committee, which at that time had never met once.[110] When asked by the defence if there was any relation between the Doctors' Trial and the formation of the Green Committee, Ivy responded negatively, stating that there was no relation whatsoever.[111]

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[105] Schmidt, 'The Nuremberg Doctors' Trial', p. 77.

[106] Ibidem, p.78. Cited original: 'Report of Reference committee on Miscellaneous Business', in *Journal of the American Medical Association* Vol. 133 (1946), p. 33. Interestingly, they appeared in small print and without comment in JAMA.

[107] Ibidem, pp. 95-96. Leibbrand had been called to the stand to represent the conscience of the 'normal' (i.e. non-Nazi) German medical profession, but instead ended up providing important ammunition for the defence.

[108] Ibidem, p. 98. See also: John D. Moreno, *Undue Risk*.

[109] Ibidem, p. 98.

[110] The final report of the committee was only submitted in December 1947, after the end of the Doctors' Trial. In: Harkness, 'Nuremberg'.

[111] Medical historian Paul Weindling has suggested that Ivy, whose testimony was a clear attempt to manipulate the trial, went to this length because it was unacceptable for him that biologically

But although his testimony was not very successful, Ivy played an important role in establishing the Trial's boundaries between permissible and non-permissible human experimentation. His 'Principles and Rules' had been presented to the American judges before the start of the trial and would form the core of the later Nuremberg Code: nine of the physiologist's points were eventually adopted by the judges (see Appendix II). In addition, Ivy had lunch with at least some of the judges in January 1947, who indicated during that meeting that the prosecution had at that stage not yet convincingly argued that the malaria experiments were crucially different from the Nazi experiments. At that lunch, Ivy set forth his conviction that 'something of a preventative nature had to come out of the Trial of the Medical Atrocities' (i.e. a code or declaration).[112] His involvement in the Doctors' Trial was thus clearly instrumental to the establishment of the Code.

The second tactic to establish proper science as being incommensurable with the criminal Nazi experiments was developed by another important player in the development of the Code.[113] In early November 1946, American neurologist Leo Alexander was appointed chief medical expert for the prosecution. Taking Ivy's 'Principles and Rules' as his point of departure, Alexander single-handedly developed three documents that – together with the 'Principles and Rules' – were to become the blueprint of the Nuremberg Code (the final document containing eight of the Code's ten principles, see Appendix II).[114] Upon arriving in Nuremberg, Alexander's first assignment was to explore the differences between Allied and German medical science. There were defendants who argued that the Nazi medical experiments had been carried out to search for the most effective treatment of illnesses and solutions to war problems such as dehydration – the utilitarian approach of which American doctors could arguably also be accused.[115]

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based medical research was being portrayed as objectifying the patient. It had been the criminal ideology of Nazism that corrupted medicine in the Third Reich, not ethical flaws internal to science. Later in his career, when the physiologist became discredited as a scientific researcher in the United States because he defended the medical use of the alternative cancer treatment Krebiozen (of which there was no known therapeutic value), he accused President Lyndon B. Johnson of Nazi practices because the government had employed federal measures to suppress the distribution of Krebiozen. Medicine necessarily had to be a free profession, according to Ivy, or it was in danger of being misused for sinister ends. In: Weindling, 'The Origins of Informed Consent', p. 57, pp. 70-71

112 Ibidem, p. 67.

113 Ulf Schmidt, *Justice at Nuremberg. Leo Alexander and the Nazi Doctors' Trial* (Basingstoke, 2004).

114 Weindling, The Origins of Informed Consent', p. 55.

115 Historian David J. Rothman has shown that it is true that the rationale behind both the Nazi

To differentiate between American and Nazi biomedical research, Alexander invoked the concept of 'thanatology' – the study of death. According to the neurologist, the majority of the Nazi research experiments were meant to establish efficient methods of killing or maiming, as for example the experiments to test new ways to sterilize and euthanize large groups of people at the same time.[116] During the opening statement of the Doctors' Trial, anticipating upon the defence arguing that the concentration camp experiments had been conducted in service of the war effort, Taylor used Alexander's concept to shift the attention from the rationale behind these experiments (i.e. the means to be used in achieving victory) to the manner in which potential research results would have been put to use:

> Our proof will show that a quite different and even more sinister objective runs like a red thread through these hideous researches. We will show that in some instances the true object of these experiments was not how to rescue or to cure, but to destroy and kill […] Mankind has not heretofore felt the need of a word to denominate the science of how to kill prisoners most rapidly and subjugated people in large numbers. This case and these defendants have created this gruesome question for the lexicographer. For the moment we will christen this macabre science *thanatology*, the science of producing death.[117]

Although Taylor did not state it explicitly, the concept of thanatology allowed the prosecution to differentiate the concentration camp experiments from the American malaria experiments, which were argued to have been conducted to discover new methods of healing (and were thus for the benefit of mankind).

While it served its purpose in the Doctors' Trial, it is problematic that Alexander fashioned the concept of thanatology to be interpreted only negatively. Firstly, in contemporary medical ethics as well as medical practice, the study of

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experiments and the U.S. prison experiments is strikingly congruent: both were defended on the principle that if soldiers, drafted into the military, were obliged to make sacrifices for their countries, prisoners should not be exempt from similar duties. To use Rothman's expressive wording: 'some people were ordered to face bullets and storm a hill; others were told to take an injection and test a vaccine'. Rothman, *Strangers at the Bedside*, pp. 30-50, there: pp. 49-50.

[116] For a description of the Nazi experiments, see: Weindling, 'The Nazi Medical Experiments'; Ulf Schmidt, 'Medical Ethics and Nazism', in Baker & McCullough, *The Cambridge World History*, pp. 595-608.

[117] Taylor, 'Opening Statement', p. 70. Italics in original.

death is often interpreted positively, because it allows human beings to better understand processes of mortality, natural as well as cultural ones. On the website for the Dutch Centre for Thanatology at the Radboud University in Nijmegen for example, one can read: 'the issue of death throws into relief the most important cultural values by which people live their lives and evaluate their experiences. Life becomes transparent against the background of death, and fundamental social and cultural issues are revealed'.[118] The contrast of this quote with the 'macabre science of thanatology', as portrayed by Alexander and Taylor, is in itself evidence that what is taken to be a medico-ethical problem is not naturally given, but depends to a large extent on which social group or institution takes ownership of the 'problem'. Unfortunately, the negative connotation that came to be attributed to the concept of thanatology through the Doctors' Trial has contributed to the idea that the study of death is essentially problematic, which can be a prohibiting factor in contemporary debates concerning humane ways of administering euthanasia.[119] Secondly, as Schmidt has argued, because Alexander framed the medico-ethical problem at stake in the Doctors' Trial to be mainly the obscure *goals* of Nazi physicians, critical analyses of the methods used by the Nazi researchers, of their cumulative radicalization and of the relation between modern medicine and the industry of war, came to be excluded.[120]

The instrumental boundary-work by both Ivy and Alexander is seen in the overall ambiguous conceptualization of the medico-ethical problems the Doctors' Trial (and thus the Nuremberg Code) was supposed to address. On the one hand the prosecution sought to establish the German medical scientists as a special type of perpetrator, while on the other it wanted to differentiate medical crimes from 'proper' ('real', 'normal') science. Thus, on the one hand, the Doctors' Trial was envisioned to be 'no mere murder trial', because the Nazi physicians had knowingly trespassed upon their professional code of ethics. During the opening statement, Taylor argued:

> The thanatological knowledge, derived in part from these experiments, supplied the techniques for genocide, a policy of the Third Reich, exemplified in the 'euthanasia' program and in the widespread slaughter of Jews, Gypsies, Poles, and Russians. This policy of mass extermination could

[118] http://www.ru.nl/ct/english/. Retrieved from the web on 10 April 2012.
[119] See for example www.thanatology.org.
[120] Schmidt, 'The Nuremberg Doctors' Trial', p. 87.

> not have been so effectively carried out without the *active participation* of German *medical scientists*.[121]

At the same time, the prosecution aimed to establish that the problem at hand had nothing to do with science, that the German physicians were nothing more than gruesome criminals. During the opening statement, Taylor thus also remarked:

> The Nazis have, to a certain extent, succeeded in convincing the peoples of the world that the Nazi system, although ruthless, was absolutely efficient; that although savage, it was completely scientific; that although entirely devoid of humanity, it was highly systematic – that 'it got things done'. The evidence which this Tribunal will hear will explode this myth. The Nazi methods of investigation were inefficient and unscientific, and their techniques were unsystematic. These experiments revealed nothing which civilized medicine can use.[122]

This contradiction exemplifies how the prosecution struggled with successfully prosecuting Nazi physicians for committed crimes, while simultaneously preserving the idea that human experimentation was highly useful for the progress of science (and thus humanity). The awkward frontstage conceptualization of the medico-ethical problem at hand, served to reconcile conflicting backstage interests.

Disowning the problem: the legacy of the Nuremberg Code

Together with the verdict against *Karl Brandt et al*., the Nuremberg Code was issued on 19 August 1947. It set forth principles of informed consent, the necessity of prior animal experimentation, the need for properly trained researchers and fruitful results for the good of society. It stipulated that unnecessary physical and mental suffering should be avoided, that the degree of risk should not exceed the humanitarian importance of the problem, and that no experiment should be conducted where there was an *a priori* reason to believe that death or disabling injury could occur (except, perhaps, in those instances where the researcher also served as subject). Finally, it prescribed that the research

[121] Taylor, 'Opening Statement', pp. 70-71. Italics added.
[122] Ibidem, p. 91.

subject should be at liberty to end the experiment and that the researcher had the obligation to do so when injuries, death or disabilities were likely to occur (these latter two principles being the only ones neither Ivy nor Alexander had already suggested, see Appendix II). Before enunciating the Code, the judges stated:

> The great weight of the evidence before us is to the effect that certain types of medical experiments on human beings, when kept within reasonably well-defined bounds, conform to the ethics of the medical profession generally. The protagonists of the practice of human experimentation justify their views on the basis that such experiments yield results for the good of society that are unprocurable by other methods or means of study. All agree, however, that certain basic principles must be observed in order to satisfy moral, ethical and legal concepts.[123]

To what extent the Code became influential after the Doctors' Trial, has been the subject of heavy historical debate. As recent as 2008, it has been asserted in the *Oxford Textbook of Clinical Research Ethics* that 'the Nuremberg Code has informed every major code of conduct regarding human experimentation since its promulgation in 1947'.[124] Similarly, in a 1992 study into the influence of the Nuremberg Code on subsequent medico-ethical declarations and documents, the authors claimed that the principles enumerated in the Code were 'adopted, interpreted and applied on an international scale within 10 years of the Doctors' Trial'.[125] In a 1998 study conducted by ethicist Gonzalo Herranz however, who contacted national medical associations of 22 European countries and 18 Latin American countries to collect and revise codes of regulations in the medical profession published after 1947, the argument is made that the Nuremberg Code remained practically unknown prior to the 1964 Helsinki Declaration in at least Europe, the United States, and South America.[126]

The divergence in these historical assessments can partially be explained by the variety of epistemological perspectives informing them. From an

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[123] 'Judgment and Aftermath', in Annas & Grodin, *The Nazi Doctors*, pp. 94-104, there: p. 102.
[124] Annas & Grodin, 'The Nuremberg Code', p. 139.
[125] Sharon Perly, Sev. S. Fluss, Zbigniew Bankowski & Françoise Simon, 'The Nuremberg Code: An International Overview', in Annas & Grodin, *The Nazi Doctors*, pp. 149-173, there: p. 155.
[126] Gonzalo Herranz, 'The Inclusion of the Ten Principles of Nuremberg in Professional Codes of Ethics: An International Comparison', in Tröhler & Reiter-Theil, *Ethics Codes in Medicine*, pp. 127-139.

essentialist perspective, when the content of the Nuremberg Code is evaluated to be congruent with 'natural-law based principles', it becomes plausible that other codes with similar contents are both members of the same family-tree. From the fig leaf point of view, it is appealing to argue that the Code was kept anonymous until the public arousal caused by scandals such as Tuskegee and Willowbrook made physicians need a document to assert the existence of a professional code of ethical conduct (articles on the Code were practically non-existent in the United States until the rise of the bioethics movement in the 1970s).[127] But invoking historiographical differences can only go so far. Ethicist Herranz for one, does not qualify as a fig leaf historian. His work, as an in-depth empirical study that traces networks of reference between various medico-ethical codes and declarations, lays bare that medical professionals in the immediate post-war decade were little concerned with the principles codified by the Nuremberg judges. A significant number had probably never even heard of the Code or did not understand its consequences. The Journal of the American Medical Association (JAMA) for example, published the sentencing against the Nazi doctors only in the form of a letter 'from the correspondent in Berlin', which Herranz describes as 'containing a journalistic, non-technical version of the ruling of the Code'.[128]

What is generally agreed upon however among historians of medical ethics, is that in the first two decades after the Second World War, medical practitioners evaluated the concentration camp experiments as a form of Nazi exceptionalism.[129] During the Doctors' Trial, Taylor, Ivy and Alexander had painted a picture of proper science as being necessarily democratic or even apolitical. It was only by succumbing to a political ideology, that German physicians had given up their scientific integrity and *transformed* into Nazi criminals. As Alexander wrote in 1949: "Science under dictatorship becomes subordinated to the guiding philosophy of the dictatorship."[130] What was therefore important was not so much to keep medical professionals under control, but to ensure scientific and clinical freedom.

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[127] Ibidem, p. 138. Referenced bibliography: I. Ladimer & R.W. Newman (eds.), *Clinical Investigation in Medicine: Legal, Ethical, and Moral Aspects. An Anthology and Bibliography* (Boston: 1963).

[128] Ibidem, p. 138.

[129] See for example: Rothman, *Strangers at the Bedside*, pp. 62-63; Baker, 'Transcultural Medical Ethics', pp. 319-320; Jay Katz, *Experimentation with Human Beings* (New Haven, 1972); Susan M. Reverby, *Examining Tuskegee, The Infamous Syphilis Study and its Legacy* (Chapel Hill, 2009).

[130] Marrus, 'The Nuremberg Doctors' Trial', p. 111.

It is of course difficult to pinpoint precisely to what came first: the instrumental framing on behalf of men like Ivy and Alexander during the Doctors' Trial or the socio-cultural belief that proper science is incommensurable from the Nazi crimes. It can be safely asserted however, that the Nuremberg proceedings did not make it difficult for the post-war medical profession to take this path. The medico-ethical problem that came to surface in public discussions after the Second World War, was not the existence of an essential tension between biomedical research and clinical practice, but the role of medicine with respect to the democratic or totalitarian state. With that, medical professionals could relatively easy disown the medico-ethical problems and principles put forward by the Doctors' Trial and the Nuremberg Code, because they were evaluated *not* to pertain to physicians of a free society.[131]

The Nuremberg Code in the Netherlands

Virtually every comment made about the immediate post-war treatment of the Nuremberg code by the 'medical profession' or 'ordinary physicians' (themselves already strong generalizations) in the last few paragraphs, should be read with the adjective 'American'. Little in-depth research has been conducted for the legacy of the Doctors' Trial in other countries, with the possible exception of the study by Herranz and the history of clinical research ethics in Germany, which, because of its exceptional role in the Second World War, should be treated as a separate case. For the Netherlands, only Lucas Bergkamp has made a detailed study of the history of relevant norms and rules for human experimentation since the Second World War.[132] Bergkamp's work is geared however, towards an audience interested in health law, and his historical overview is an enumeration of relevant legal documents rather than an analysis of their social impact during the time in which they were drawn up.

As put forward in the introduction to this thesis however, historians have pointed to the Netherlands as one of the first countries to enforce the Nuremberg Code. As Baker stated in 1998:

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[131] As historian David Rothman has nicely summarized it: 'The defendants were Nazis first and last; by definition nothing they did, and no code drawn up in response to them, was relevant to the United States'. In: Rothman, *Strangers at the Bedside*, pp. 62-63.

[132] L. Bergkamp, *Het proefdier mens. De normering en regulering van medische experimenten met mensen* (Alphen aan de Rijn, 1988).

> In 1954, [the World Medical Association, WMA] issued formal *Principles for those in Research and Experimentation*, that reiterated the main themes of the Nuremberg Code […] A year later the Public Health Council of the Netherlands issued guidelines that also attempted to implement and enforce the WMA *Principles* in clinical contexts through the institution of local research councils (later to be called institutional review boards, or IRBs).[133]

The decision of the Dutch Health Council to issue guidelines for human experimentation however, preceded the 1954 WMA *Principles* (see Appendix IV) and only paid lip-service to the document in its final evaluation. If anything, the WMA *Principles* and the Dutch *Guidelines* were both influenced by the work of the two Dutch physicians De Langen and Hamburger, who were commissioned by the Royal Dutch Medical Association (KNMG)[134] to prepare a number of statements concerning ethical human experimentation. The Health Council also never sought to install local research councils. Instead, it wanted to implement a national review committee for all Dutch clinical research, an objective in which it was unsuccessful (for all, see chapter 4).

It is not easy to assert what impact the Code did have on ordinary medical practice in the Netherlands in the first decade after the Second World War. The document was hardly ever mentioned in Dutch newspapers and entirely omitted from the two main mouthpieces of the KNMG: the academic journals *Medical Contact* (MC)[135] and *Dutch Journal for Medicine* (NTvG). Judging from a discussion among members of the KNMG on the 1948 WMA Declaration of Geneva (i.e. a document which was envisioned as a new version of the Hippocratic Oath, see Appendix III) that took place at a members meeting in 1949, it appears as if Dutch medical professionals had never even heard of the Code at all.[136] According to some historians, the Geneva Declaration was an attempt to implement the principles pertaining to human experimentation of the Code. As medical historian Ulrich Tröhler puts it: 'the Declaration stipulated that 'even under threat […] I will not use my medical knowledge contrary to the laws of humanity' – 'laws' on which the Nuremberg Code had been based'.[137] But the

[133] Baker, 'Transcultural Medical Ethics', pp. 319-320. See also: Tröhler, 'The Long Road', p. 34; Henry K. Beecher, *Research and the Individual* (Boston, 1970).
[134] Trans.: Koninklijke Nederlandsche Maatschappij der Geneeskunde.
[135] Trans.: Medisch Contact.
[136] 'Notulen vergadering 5 februari 1949', in *Medisch Contact* Vol. 4 (1949), pp. 22-27.
[137] Tröhler, 'The Long Road', p. 34.

Nuremberg Code was not referenced in the Declaration and neither were the limitations of human experimentation explicitly addressed. Instead, the Declaration stressed (among other things) that medical doctors would dedicate themselves to the 'humanitarian goals of medicine', that they should give their teachers respect and gratitude and maintain the utmost respect for human life and the noble traditions of the medical profession (see Appendix III).[138]

During the 1949 KNMG meeting, the organisation's central committee proposed to oblige new members of the organization to formally promise upon accepting their membership that they would act according to the principles set forth in the Declaration of Geneva. During the subsequent discussion however, a number of the KNMG members professed to have been not too impressed with the provisions made in the Geneva Declaration, especially towards the use of human beings for biomedical research. In particular the local division of Alkmaar questioned whether documents like the Declaration of Geneva were adequate to guarantee the safety of the research subject in this modern day and age:

> More and more it has become a fact, that tests upon humans are being conducted for the purpose of medical-clinical or other scientific research. The circumstance, that as a rule only volunteers are used, should not be taken as an apology, because in many of the cases the researchers are unable to oversee all the possible consequences of the experiments, let alone the test subjects. Also in the Netherlands this way of conducting research has made its appearance.[139]

Alkmaar therefore proposed to request the WMA to amend the Declaration of Geneva, adding that medical doctors should promise to consider the health of 'anyone who has been trusted to my care, either as physician or as scientific researcher, as the most important concern'.[140] In response to these complaints, the KNMG's central committee promised to further investigate how the WMA could better take the rights of the research subject into account. It professed that it could agree with the intentions of Alkmaar, but that it was not convinced of the chosen wording of the proposed amendment. The committee's proposal of swearing to the Declaration of Geneva as a new member of the KNMG, was subsequently

[138] Baker, 'Transcultural Medical Ethics', p. 319.
[139] Ibidem, p. 27.
[140] Ibidem, p. 27.

accepted with nineteen votes in favour and fifteen against.[141] No member present at the meeting mentioned the Nuremberg Code.[142]

How can this lack of engagement by the Dutch medical profession with the principles set forth in the Nuremberg Code be explained? Physicians reading NTvG knew about the concentration camp experiments, for they were summarized by Frits Dekking – a microbiologist and survivor of the Dachau concentration camp – in NTvG in two different articles, one in 1946 (one page) and one in 1947 (four pages).[143] In the 1947 article, Dekking provided a summary of the Trial's indictment and contemplated upon the possible reasons the Nazi physicians could have had for their crimes.[144] What the microbiologist could not comprehend, was how confident the defendants of the Doctors' Trial had been: how entitled they felt to their actions and how they did not consider the concentration camp experiments to be a medico-ethical problem. 'It is as if a Mohammedan stands trial for polygamy in the court of Zutphen!', Dekking exclaimed.[145] He then ended his article by stating that the death sentence could be the only solution, not as retribution, but as a 'palliative measure of social hygiene'. In addition, overall vigilance remained absolutely necessary, according to the microbiologist. Even with the triumph of good, the roots of evil were still in existence all over the world, and it was by no means unthinkable that crimes of this size would be repeated once more.[146] The promulgation of the Code itself however, was not mentioned in either NTvG or MC.

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[141] A substantial minority of the KNMG-members was worried that the Geneva Declaration would devalue the Dutch 'doctor's oath' (trans.: artseneed), sworn by young medical doctors upon receiving their medical degree. In addition, the Declaration was evaluated to be a 'typically American, sentimental promise' that was little realistic. In: 'Kort verslag van de 99ste algemene vergadering (openbaar gedeelte) der Ned. Maatschappij tot Bevordering der Geneeskunst, gehouden op zaterdag 4 februari 1949 in 'Esplanade' te Utrecht', in *Medisch Contact* Vol. 4 (1949), pp. 245-266, there: pp. 253-254.

[142] 'Notulen vergadering 5 februari 1949', pp. 22-27.

[143] Frits Dekking, "Medische' experimenten in Duitsche concentratiekampen', in *Nederlandsch Tijdschrift voor Geneeskunde* Vol. 90 (1946), p. 1011; Frits Dekking, 'Het proces der Duitse artsen', in *Nederlandsch Tijdschrift voor Geneeskunde* Vol. 91 (1947), pp. 1830-1833. Dekking was arrested during the Second World War as a member of the Dutch resistance and spent time in concentration camp Dachau because of it. He published his memoires under the pen-name Yvo Pannekoek, a moving memory of the war which has gone through multiple reprints. See: Yvo Pannekoek, *Memoires van Yvo Pannekoek* (Amsterdam 4th ed., 1983); J. van der Noordaa & R.A. Coutinho, 'In memoriam prof.dr. F. Dekking', in *Nederlands Tijdschrift voor Geneeskunde* Vol. 148 (2004), p. 2093.

[144] Dekking, 'Het proces der Duitse artsen'.

[145] Ibidem, p. 1832.

[146] Ibidem, p. 1833.

Other than the possibility that Dutch physicians simply did not know about the existence of the Code, there are a number of possibilities which could explain the absence of any public discussion among members of the Dutch medical profession over the consequences of the Nuremberg Code – a document which after all, when actively upheld by the Dutch medical profession, could have contributed to Dekking's call for vigilance. The first reason could be that Dutch physicians also regarded the Code as a 'good code for barbarians', as historical research has shown for the United States. There is no known evidence to back up this claim, but Dekking would for example put the term 'medical' between quotation marks when he referred to the concentration camp experiments, indicating that he evaluated them as incongruous with proper scientific behaviour. Similarly, when the Dutch antivivisection movement suggested in 1947 that unethical human experimentation also took place in the Netherlands, the President of the Dutch Health Council responded highly offended to the comparison with Nazi practices (see chapter 3).[147]

A second possibility is that Dutch physicians could not imagine their own professional community, which had a high social standing in the Netherlands, to succumb to a Nazi-type ideology. In particular after the Second World War, the spirits were high among Dutch physicians, for they considered themselves to have played an important and effective part in the Dutch resistance.[148] During the final meeting of Medical Contact in 1946 for example (the Dutch medical resistance movement after which the academic journal is named), speeches were made wherein Dutch physicians were celebrated as the conscience of Dutch society, for retaining a positive attitude 'during times when most Dutch citizens had remained passive and let the storms pass with their head bowed'.[149] Such a group of honourable men (and a few women) could not be seduced to dogmatism and ideology, and therefore did not need to be regulated by documents stipulated by a legal authority (an assessment with which not everyone agreed, see chapter 3).

A more practical reason for the neglect of the Nuremberg Code, is that Dutch physicians simply had other things on their mind. In 1941, the Dutch government had – under Nazi rule – proclaimed the so-called 'Health Insurance

[147] See: Dekking, "Medische' experimenten'.

[148] This is how the role of the Dutch physicians during the Second World War is still remembered. See for example the episode of *Andere Tijden* of 26 March 2009: 'Artsen in Oorlogstijd'. To be viewed online at: http://www.uitzendinggemist.nl/programmas/215-andere-tijden. Derived from the web on 12 April 2012.

[149] 'Opheffing M.C.', in *Medisch Contact* Vol.1. (1946), pp. 64-66.

Decision'[150], a decision which entailed profound changes for the manner in which the Dutch health care system was socio-economically organized. In the first years after the war, when it became clear that the Health Insurance Decision would not be reversed, the pages of MC were filled with complaints by medical professionals who feared for their financial situation and for a waning influence of the KNMG in the organisation of Dutch health care. Similarly, the repatriation of medical practitioners from the Dutch East Indies after the Indonesia's declaration of independence, made many physicians worry over a potential overcrowding of the market for medical professionals. After the war, the social structures of the Netherlands needed to be 'rebuilt' and the legacy of the concentration camps, the war crimes and the Holocaust, was often considered to impede this process.[151] That does not mean that Dutch physicians sought to downplay to horrors of the medical experiments – the words of Dekking leave little to the imagination. The editors of NTvG also did not refrain from publishing in full detail a number of gruesome gynaecological experiments conducted upon prisoners of the concentration camp Auschwitz.[152] But it is very well imaginable that the exceptional cruelty inflicted by Nazi physicians was like an alien side-show: conducted on a different planet and of little use when trying to return to the normal order of the day.

Finally, it is of course possible that the organized Dutch medical profession purposefully kept discussions about regulations for clinical research out of the limelight, similar to Ivy's actions during the Doctor's Trial. As will be shown in subsequent chapters, also Dutch medical professionals were often afraid that negative publicity on the subject matter would endanger the progress of science, by instigating governmental restrictions for human (and animal) experimentation. Organized discussions on the subject matter, by e.g. the Dutch Health Council and the KNMG, regularly took place behind closed doors (backstage) to prevent their doubts and conclusions from being interpreted in an undesired fashion (frontstage) by stakeholders with different interests (see chapter 3 and 4). However, it would be a mistake to evaluate the actions of the Dutch

[150] Trans.: Ziekenfondsenbesluit.

[151] See: Wijnand Mijnhardt, *Dutch Perceptions of World War II: The Struggle with an 'Unredeemable' Past* (Unpublished Lecture given at UCLA, 2006). More general: Ian Kershaw, *The Nazi Dictatorship. Problems & Perspectives of Interpretation* (London 4th ed., 2000).

[152] E. de Wind, 'Mededeelingen over de gynaecologische proeven verricht in het concentratiekamp 'Auschwitz' tussen Maart 1943 en Augustus 1944, in *Nederlandsch Tijdschrift der Geneeskunde* Vol.89 (1946), pp. 364-366.

medical profession in the immediate post-war era as only self-serving. Many prominent members of the Dutch medical community did not refrain from participating in public debates (e.g. on the pages of MC) over the dangers of human experimentation and the need for strong medico-ethical principles (see the conclusion of this thesis). But they mostly did not envision the possible medico-ethical problems that come with clinical research in the same manner as became dominant after the 1960s and 1970s in most Western countries. That the first principle of the 1955 *Guidelines* (see Appendix V) negates the necessity of obtain informed consent for example, should not so much be read as an unwillingness of the Health Council to take patient rights into account, but as the expression of a strong belief that a medical professional was primarily responsible for the health of all those under his care, patient as well as research subject. The solution to unethical human experimentation was therefore not to be found in restrictive measures, but in the proper education of young men and women who aspired to be scientific researchers. The relevant medico-ethical problem was for the Health Council not so much an essential tension between research and practice, but the waning influence of the physician at the bedside (see chapter 4).

Not all stakeholders in the Dutch debate over human experimentation were of the opinion that clinical research was, when properly conducted, necessarily ethical. After the Second World War, one social group utilized the Nazi concentration camp experiments to remind the Dutch people that the atrocities committed under the rule of the Third Reich were only the final – but inevitable – station of the express train that was called the 'modern research-based laboratory sciences'. In 1947, the Dutch antivivisectionist movement handed in a petition to the Dutch Minister of Social Affairs, wherein it requested a chair in vivisection-free medicine to counter the negative influence the research-based laboratory had on the moral of the medical researcher. The antivivisectionists argued that the judgement of the biomedical scientist became increasingly blurred as he did more vivisections on animals – a development of which eventually all weak (human) members of society would become a victim. It was the Dutch antivivisectionist movement which argued after the Second World War that human experimentation was inherently problematic, and it was their manner of campaigning that would eventually inspire the Dutch Health Council to draw up the Regulations for Human Experimentation. Not the Declaration of Geneva, not the WMA's *Principles for those in Research and Experimentation,* and certainly not the Nuremberg Code.

3. Research in the Laboratory: a Slippery Slope

> *It are the sucklings in the children's clinics, the little children in the orphanages; it are the little or non-paying patients in the hospitals, the less wealthy women in childbed; it are the tuberculosis patients and the insane in the sanatoriums; it is all that stands defenceless in life, from which the scientific experimenter above all recruits his material*.[153]

In 1946, the Dutch Anti-Vivisection Foundation (AVS) commemorated its struggles of the past fifteen years in an anniversary edition of *Announcements*[154], the Foundation's monthly journal. With the atrocities of the Second World War fresh in mind, members of the Foundation were urged to fight the practice of medical vivisection with renewed vigour:

> During the trials of war criminals in Nuremberg it has been discovered to which horrible vivisection-experiments the prisoners in Germany have been exposed. This has to be another reason for us to continue our actions with utmost fortitude, so that such terrors will forever be ended![155]

For Dutch antivivisectionists, the medical experiments in the Nazi concentration camps were proof that the disregard of animal suffering at the hands of biomedical

[153] NL-HaNA, Afdeling Volksgezondheid, (1902) 1918-1950 (1976), nummer toegang 2.15.37, inv.nr. 2357, letter of the secretary of the Dutch Health Council to the Minister of Social Affairs, 17 July 1947.

[154] Trans.: Meededeelingen. Translations are mine, unless stated otherwise.

[155] J.J. Theling, 'Vijftien jaren van strijd tegen de vivisectie', in *Meededeelingen Lustrum-Nummer* Vol.15 (1946), pp. 3-4, there: p.4.

researchers ultimately led to cruelty among men. In the first decade after the Second World War therefore, during a period when various organisations pushed the Dutch government to establish a professorial chair in vivisection-free medicine, the AVS systematically utilized the Nuremberg Doctors' Trial to justify the battle against animal experimentation. And, as will be shown in chapter 4 of this thesis, it were the persistent complaints by the Dutch antivivisectionist movement over the use of human beings for experimental biomedical tests, which ultimately led to the instalment of the Health Council committee responsible for the promulgation of the 1955 *Guidelines*.

To better situate the impact of this immediate cause upon the content of the *Guidelines*, this chapter will first situate in which manner the debate over animal vivisection and human experimentation came to develop in the first decade after the Second World War. During a period when medical professions tried their best to portray the Nazi experiments as first and foremost criminal activities which had little to do with modern science (see chapter 2), antivivisectionists persistently argued that such biomedical atrocities had in fact been a long time in coming. According to them, the defendants of the Doctors' Trial merely represented the pinnacle of research-based laboratory medicine. This idea was based on the belief that the reductionistic and deterministic thinking employed by scientific researchers since the rise of the research laboratory and the experimental method in the nineteenth century, had persistently downplayed the importance of the psyche and neglected the integrity of the individual. As a result, physicians' respect for animal and human life had become lost. To reawaken the humanity of the medical profession therefore, antivivisectionists argued that all human and animal experimentation had to become prohibited. To this end, the AVS requested in 1947 the establishment of a professorial chair in vivisection-free medicine. According to the Foundation, only doctors who were trained to respect organic life would be able to pay proper respect to their patients in the clinic.

In the ensuing debates however, vivisection-free medicine came to be associated not only with the opposition to certain type of *practices* (i.e. animal and human experimentation), but also with alternative ways of *knowing*, which were perceived by the established medical profession to denounce all of the labours and fruits of the modern research-based laboratory. In that process, human as well as animal vivisection turned signifier for the modern biomedical sciences, and vivisection-free medicine for everything the research laboratory was not. Both animal vivisection and human experimentation thus became boundary-objects in

establishing the borders between what was regarded as 'proper science' and what was called 'charlatanism'. To keep antivivisectionism out of the academy therefore, became a goal in itself for the established Dutch medical profession, an attitude which, as the next chapter will show, would be of great influence to the establishment of rules and regulations for clinical research in the Netherlands.

The 1947 request for a chair in vivisection-free medicine

Until 1985 in the Netherlands, the Crown was responsible for appointing professorial chairs at the open universities. Dutch ministers thus had the last word in decisions concerning the establishment of a professorship, even if private organizations offered to subsidize an endowed chair. For this reason, the AVS sent a petition to Minister Willem Drees of Social Affairs on 1 March 1947, wherein the Foundation pleaded for the establishment of a Dutch professorship in vivisection-free medicine and defended its request as follows:

> It should not be forgotten, that animal experiments have a coarsening effect upon those who conduct them. We ensure your Excellence that the notorious experiments on human beings in the concentration camps just take up a tiny part of the countless experiments, which are also in normal times frequently conducted upon those of special means. This is a logical consequence of the animal experiment, but will eventually not lead to satisfactory results. It are the sucklings in the children's clinics, the little children in the orphanages; it are the little or non-paying patients in the hospitals, the less wealthy women in childbed; it are the tuberculosis patients and the insane in the sanatoriums; it is all that stands defenceless in life, from which the scientific experimenter above all recruits his material.[156]

For consultation on the matter, Minister Drees sent the petition to the Dutch Health Council, a scientific advisory body established in 1902 to advice the government on issues concerning medicine and public health.[157]

[156] NL-HaNA , Afdeling Volksgezondheid, (1902) 1918-1950 (1976), nummer toegang 2.15.37, inv.nr. 2357, letter of the secretary, 17 July 1947.

[157] The Health Council still exists (2012) and is widely regarded to be one of the most important Dutch advisory bodies on medicine and public health. See: Roland Bal, Wiebe E. Bijker & Rudolf P.J. Hendriks, *Paradox van wetenschappelijk gezag: over de maatschappelijke invloed van adviezen van de Gezondheidsraad* (Den Haag, 2002); R.B.M. Rigter, *Met raad en daad.*

The Council considered the comparison of Dutch medical research to the Nazi concentration camp experiments to be a very serious accusation and demanded the AVS via a letter to Drees to provide proper evidence to substantiate its claim.[158] In response, Mary Stuart, then president of the AVS, sent a document to the Minister with nine cases of human experimentation in the Netherlands, each of which was considered by the members of the Foundation to be in breach with every existing medico-ethical standard. All examples had been recorded from either Dutch medical dissertations or journal articles in the NTvG. In conclusion, as if she wanted to say that these case-studies only represented the tip of the iceberg, Stuart apologized for the fact that she could only provide a limited amount of data because the larger part of the Foundation's library had been lost during evacuations in the Second World War.[159]

Some of the studies described repeated blood tests on infants, such as the 1923 dissertation on digestion-leukopenia in children, wherein a four-and-a-half month old baby – 'the ill and nervous Johanna' – was subjected to 56 blood tests in a period of two months.[160] Another example referred to a doctoral study wherein the elimination of exogenous causes to climate asthma was investigated as a possible therapeutic intervention. The doctoral student, P.N. van Patot, had described in his dissertation how 'traditional desensitization agents' could very easily worsen the condition of the patient, a development which was difficult to reverse. He had nevertheless gone ahead with his research and repeatedly injected the traditional agents under the skin of 'outpatient material' (his research subjects) without obtaining *informed* consent: 'It was completely unknown to most patients with what they had been injected'.[161] The experiments produced no satisfactory results and, as written in the dissertation, failed entirely. While no clear changes were perceived to take place in some subjects, in others a clear worsening of their condition could be observed: 'Once in a while a patient told us spontaneously that he had never felt this terrible in his life'.[162]

Another case of human experimentation described by the AVS, was a 1929 Dutch research on the merits of inoculation with the Bacillus Calmette Guérin

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De geschiedenis van de gezondheidsraad 1902-1985 (Rotterdam, 1992).

158 NL-HaNA , Afdeling Volksgezondheid, (1902) 1918-1950 (1976), nummer toegang 2.15.37, inv.nr. 2357, letter of the secretary, 17 July 1947.

159 Ibidem, letter of M.Stuart to the Minister of Social Affairs, 16 September 1947.

160 Ibidem, appendix to the letter of Mr.M Stuart, p. 1.

161 Ibidem, pp. 2-3.

162 Ibidem, p. 3.

(BCG) vaccine. The study used children as research subjects. In criticizing the study's experiments, Stuart compared them to the 'notorious catastrophe of Lübeck'.[163] In the first half of the twentieth century it was still uncertain whether BCG was a harmless and effective prophylactic to tuberculosis. In particular, it was ambiguous whether the inoculated bacterium was truly non-virulent.[164] In 1930, 251 healthy infants were vaccinated with BCG in Lübeck, Germany. Shortly thereafter, many of them became seriously ill and within the first year of life 72 had died of tuberculosis.[165] Later investigations of the 'Lübeck disaster' brought to light that the infants had received a faulty mix of the bacterium, leaving the relevant vaccines to contain virulent strains. In the Dutch study, such misfortunes were absent, but from publications in NTvG, the AVS deduced that also in the Netherlands researchers were not always certain how safe these experimental inoculations really were. The Dutch antivivisectionists found it unacceptable that healthy children, free of tuberculosis, were subjected to significant risks in the form of repeated inoculations, multiple x-rays and frequent blood tests.[166] In addition, the Dutch BCG researchers had experimented on children which had either been ill already, or were recovering from sickness, and thus had their weakened immune-systems exposed to new active bacterial agents. One child by the name Dina K. was inoculated with the BCG vaccine for the study in December 1928. On 1 February 1929, she had developed an abscess where she had been vaccinated, in combination with whooping cough. In a short period of time, Dina started suffering from bronchitis, whereafter she died in early April 1929 of acute meningitis.[167]

One dissertation, used by the AVS to prove that unethical experimentation on human beings did indeed exist in the Netherlands, was of school medical

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[163] NB. The Lübeck disaster was the catalyst for the 1931 German Guidelines for Novel Therapeutic Trials and for Performing Scientific Experiments in Humans (see chapter 2). See: Tröhler, 'The Long Road of Moral Concern'.

[164] John D. McKinney, William R. Jacobs Jr. & Barry R. Bloom, 'Persisting Problems in Tuberculosis', in *Emerging Infections Volume I* (London, 1998), pp. 51-146.

[165] C. Bonah & P. Menut, 'BCG Vaccination around 1930 – Dangerous Experiment or Established Prevention? Practices and Debates in France and Germany', in Volker Roelcke & Giovanni Maio (eds.), *Twentieth Century Ethics of Human Subjects Research, Historical Perspectives on Values, Practices, and Regulations* (Stuttgart, 2004), pp. 111-128; Daniel S. Nadav, 'The 'Death Dance of Lübeck': Julius Moses and the German Guidelines for Human Experimentation, 1930', in Volker Roelcke & Giovanni Maio (eds.), *Twentieth Century Ethics*, pp. 129-136.

[166] NL-HaNA , Afdeling Volksgezondheid, (1902) 1918-1950 (1976), nummer toegang 2.15.37, inv.nr. 2357, appendix to the letter of Mr. M. Stuart, p. 5.

[167] Ibidem, p. 5.

officer Jan Jacques Brutel de la Rivière. In 1932, Brutel had received his doctoral title for research conducted on allergic skin reactions in non-allergic subjects.[168] To obtain his desired results, Brutel had injected a variety of substances, such as a preparation of the pneumococcus bacterium (which can lead to pneumonia) and a suspension of certain spirochaetes (one of which can theoretically lead to syphilis), into sanatorium patients.[169] Initially, Brutel had mainly used subjects from homes for the insane, but a large number of positive test results had led him to question whether these patients were fit for his research purposes. He therefore proceeded to continue his experiments on patients of women's clinics, most of whom were pregnant.[170] In the mid-1950s, when Brutel became an influential member of the Health Council committee 'tests upon human beings', he openly wondered during the committee meetings to what extent his doctoral research had been ethical, a contemplation that resulted in uneasy discussions among members of the Health Council (see chapter 4).

In 1947, when the AVS filed its petition to Minister Drees, Brutel de la Rivière was President of the Health Council. That the Foundation had referred to his work specifically as evidence for unethical Dutch human experimentation, is significant, for Brutel de la Rivière was a particularly well-respected physician in his day. During the Second World War, the physician had in fact been the leading authority of the Dutch resistance.[171] After the war, he similarly became one of the most important authorities of the Dutch medical community. This is reflected for example in the fact that Brutel in 1945 simultaneously became the President of the KNMG, President of the Health Council and President of the newly established Central Committee for Public Health (CCV)[172], an advisory body installed by the Dutch government to reflect upon social matters concerning medicine and public health.[173] The accusations made by the AVS appear not to have prohibited Brutel in any way from participating in subsequent deliberations by the Health Council.

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168 'Personalia', in *Nederlands Tijdschrift voor Geneeskunde* Vol. 116, No. 14 (1972), pp. 585-586.

169 NL-HaNA , Afdeling Volksgezondheid, (1902) 1918-1950 (1976), nummer toegang 2.15.37, inv.nr. 2357, appendix to the letter of Mr. M. Stuart, p. 6.

170 Ibidem, p. 7.

171 Dutch medical historian Mart van Lieburg has even referred to Brutel de la Rivière as the 'primus inter pares' of Dutch medical resistance during the Second World War. In: M.J. van Lieburg, 'Vergeten helden', in *Medisch Contact* Vol. 64 (2009), pp. 812-815.

172 Trans.: de Centrale Commissie voor de Volksgezondheid. Later renamed as the Council for Public Health and Care (trans.: de Raad voor Volksgezondheid en Zorg).

173 'Dr. J.J. Brutel de la Rivière 60 jaar arts', in *Nederlands Tijdschrift voor Geneeskunde* Vol. 116 (1972), pp. 585-586; Rigter, *Met raad en daad*, p. 125.

On the contrary, as President, he became solely responsible for organizing the 'advisory committee on the establishment of chairs for vivisection-free medicine'. There are no recorded documents which indicate that his position became in any way contested after the letter by Mary Stuart.

Perhaps it is unsurprising that the most eminent representative of the Dutch medical profession was not asked to step down after accusations made by the Dutch antivivisectionists, a social group which was arguably not very popular in the immediate aftermath of the Second World War. While Brutel could be regarded as the 'primus inter pares' of the medical profession for his role in the Dutch resistance, the AVS had been connected to prominent Dutch national-socialists such as Anton Mussert and Meinoud Rost van Tonningen, who had both been members of the Foundation. Similarly, the AVS had been one of the first organized societies to actively encourage Jews during the war to terminate their membership.[174] It must have been a slap in the face for the proud Dutch medical profession (see chapter 2) that someone like Brutel de la Rivière was accused of Nazi-like activities by an organization which was known to have been 'on the wrong side of the war'. In any case, the fact that Brutel had come to be of such a high social standing makes it all the more striking that the AVS did choose to use Brutel's dissertation as an example of the claim that 'the notorious experiments on human beings in the concentration camps just take up a tiny part of the countless experiments, which are also in normal times conducted continuously upon those of special means'. With his position as figurehead of the medical profession, an attack upon Brutel was a direct attack upon Dutch medicine itself.

The letter by Mary Stuart thus illustrates that the mutual relationship between the Dutch anti-vivisectionist movement and the Dutch medical profession was precarious to say the least. This is also suggested by the manner in which Brutel, as President of the Health Council, went about electing members of the 'advisory committee on the establishment of chairs for vivisection-free medicine'. After consultation with Minister Drees, Brutel decided to invite two homoeopathic doctors by the name of Gerard Bakker and J.C. Wolterbeek to take up a position in the committee. The two men, recommended by the AVS, were specifically asked in their invitation letters to defend the proposition that 'vivisection-free medicine could be of more benefit to Dutch public health than a medicine based on the

[174] Amanda Kluveld, *Reis door de hel der onschuldigen, de expressieve politiek van de Nederlandse antivivisectionisten, 1890-1940* (Amsterdam, 2000), pp. 219-220.

natural sciences'.[175] In contrast, the residual members of the committee, which were all physicians, could all participate in the Health Council without preparing a defence for their point of view.[176]

It is clear that the two antivivisectionists Bakker and Wolterbeek were regarded with great suspicion by Brutel. Even if the two men were practising physicians, the President of the Health Council perceived them as outsiders to the Dutch medical profession. In order to survey who the two homoeopaths were for example, Brutel sent letters to some of his medical colleagues for some background screening. On Gerard Bakker, he received a letter from neurologist L.F.C. van Erp Taalman Kip, former president of the KNMG and a personal friend.[177] According to Taalman Kip, Bakker was a 'somewhat unusual figure like most homoeopaths', who had previously been a general practitioner without much success.[178] As far as he knew, Bakker had never acted in a clearly unethical manner and was generally accepted by his colleagues, who sometimes allowed him to give presentations on homoeopathy in a local division of the KNMG. Nevertheless, Taalman Kip added that as far as he was concerned, all homoeopaths were continuously in conflict with any form of medical ethic and therefore a genuine danger to their patients. Taalman Kip had furthermore heard that Bakker, who was known for not wanting to operate on an appendicitis, had called a surgeon within the hour when his own child had a stomach ache with 'somewhat suspicious symptoms'. Finally, the neurologist wrote that he had recently treated a patient for an abscess in the brain, which had been told for years by Bakker that she was suffering from a chronic ear infection. 'While this might be plain common among these sort of gentlemen', Taalman Kip complained to Brutel, 'I consider such actions to be nothing more than criminal behaviour'.[179]

In preparation of the first meeting, Brutel asked Bakker to write an introduction for the Health Council which could serve as a basis for discussion over the need for a professional chair in vivisection-free medicine. The homoeopath was expected to take up three issues: (a) whether vivisection-free

[175] NL-HaNA, Gezondheidsraad, 1920-1956, 2.15.33, Inv.nr. 547, letter 'betreffende: leerstoelen vivisectie-vrije geneeskunde', 28 May 1948.

[176] Each of these members was a physician which qualified as 'adhering to the norms and values of the established medical profession'.

[177] See also: E.G. van Heusden, 'Ter herdenking van L.F.C. van Erp Taalman Kip', in *Nederlands Tijdschrift voor Geneeskunde* Vol. 114 (1970), pp. 1472-1473.

[178] NL-HaNA, Gezondheidsraad, 1920-1956, 2.15.33, Inv.nr. 547, letter from L.F.C.van Erp Taalman Kip to J.J. Brutel de la Rivière, 27 December 1947.

[179] Ibidem.

would in his opinion serve as either an addition to, or a replacement of, the current Dutch educational system, (b) if existing medical treatments based on experiments with animals or humans should be rejected and (c) what the position of antivivisectionists was concerning 'physiology and the other basic sciences of medicine', of which Brutel emphasized that they 'were built to a significant extent on human and animal experimentation'.[180] With their request for a professorial chair in vivisection-free medicine, the homoeopaths were thus perceived to challenge modern medicine in its entirety. Bakker nevertheless took up the challenge and prepared the requested document, obliging even when Brutel asked him to revise his vision a number of times.[181] In the end, Bakker handed in a four-page document wherein he postulated eight statements for discussion.[182]

The homoeopath also travelled, on the expenses of the Health Council, to the United States to investigate the institutionalization of homoeopathy at American universities and to take additional courses in the homoeopathic doctrine.[183] Despite this obvious enthusiasm however, Bakker specifically requested Brutel before accepting his position in the Health Council, to guarantee him and Wolterbeek that they could hand in an alternative advice to the Minister of Social Affairs if they did not agree with the opinions of the majority of the committee.[184] He made it clear that he knew such was a right of individual Health Council members as stipulated in the by-laws of the advisory body of 1920. This indicates that Bakker seems to have been aware even before the commence of the Health Council's 'advisory committee on the establishment of chairs for vivisection-free medicine', that it would be difficult to convince his fellow

[180] Ibidem, letter of J.J. Brutel de la Rivière to Gerard Bakker, 26 January 1948.

[181] After having read the first version, the Health Council President complained that the homoeopath's arguments were not well structured and did not hold up against some arguments Brutel himself considered to be important. In: Ibidem, letter of Gerard Bakker to J.J. Brutel de la Rivière, 15 March 1948; Gerard Bakker, 'Stellingen met Toelichting behorende bij de inleiding tot de discussie', 39 March 1948; Gerard Bakker, 'Afschrift', 28 May 1948.

[182] The two statements which for example received most additional explanation were (1) that 'the serving character of medicine should always take precedence over scientific purposes' and (2) that 'vivisection-free medicine should not become a mandatory subject, for it will naturally become an indispensable subject within the Dutch medical faculties'. In: Ibidem, 'Stellingen met toelichting behorende bij de inleiding tot de discussie'.

[183] Brutel himself gave permission for this trip. In: Ibidem, letter of J.J. Brutel de la Rivière to the Medical Superintendent of Public Health, 4 February 1948; letter of Gerard Bakker to J.J. Brutel de la Rivière, 7 February 1948.

[184] Ibidem, letter of Gerard Bakker to J.J. Brutel de la Rivière, 28 January 1948. Response: Ibidem, letter of J. J. Brutel de la Rivière to Gerard Bakker 'Betreffende: leerstoel vivisectievrije geneeskunde', 4 February 1948.

committee members of his antivivisectionist convictions. That he was not far from wrong, became clear quickly after the start of the first committee meeting.

The staged drama of a Health Council committee

In the two years that it took the Health Council to advise the Minister of Social Affairs on the issue, the committee on vivisection-free medicine only gathered twice. During the first meeting, on 2 June 1948, the Health Council discussed whether a medical practice based on animal experimentation blurred the boundaries between permissible and non-permissible interventions.[185] Bakker brought up that experiments like those conducted by Hans Eppinger, the Nazi doctor who had forced prisoners of the Dachau concentration camp to drink nothing but sea water in order to study the physical symptoms of dehydration, were proof of what physicians could turn into if they conducted too much animal vivisections.[186] Other committee members were not convinced. One remarked that the Nazi experiments were political crimes and had little to do with medicine. If anything, naturopathy, a form of alternative medicine based on a belief in vitalism, had been much popular in Germany before the Second World War.[187] Similarly, when Bakker mentioned the Dutch BCG experiments, the response was that inoculations with the vaccine were now generally used to control tuberculosis, proving that the experiments had not been conducted to benefit science, but to help mankind.[188] In addition, it was argued that the fact that therapies with insulin and liver preparations had come to be realized, was only because biomedical researchers practised vivisection.[189]

Bakker and Wolterbeek emphasized however, that they did not seek to challenge the substantial results which had been achieved through the incorporation of the natural sciences within medical practice. Their problem lay instead with the exclusiveness of research-based laboratory medicine. According to the homoeopaths, the reductionistic scientific method did not fully appreciate the role of the psyche in health and illness. Instead, it relied solely on causal reasoning and neglected intuitive thinking. Medicine has always been an art as well as a science and Bakker and Wolterbeek believed that the Dutch academy

[185] Ibidem, Notulen van de vergadering van de commissie, 2 June 1948, p. 2.
[186] Ibidem, p. 2.
[187] Ibidem, p. 2.
[188] Ibidem, p. 2.
[189] Ibidem, p. 2.

should continue to represent both. A chair in vivisection-free medicine could ensure that students were free to choose individually which method they found more convincing and in addition make them aware that vivisection was not the only natural approach to medicine, but a deliberate choice on the part of certain type of scientists. Finally, if doctrines like homoeopathy were truly unscientific, Bakker and Wolterbeek were convinced that their teachings would soon be rejected by students and that the subject would thus automatically bleed to death. However, as long as homoeopaths did not get a proper chance to convince medical colleagues of their approach (e.g. NTvG refused to publish articles on homoeopathy), modern medicine was a dogma rather than a science.[190]

After this first meeting, Brutel sent a concept of the advice to the Minister. He explained how two committee members felt that the official science of healing had wandered from its original goal. Physicians had a duty to help, not harm.[191] The rest of the committee was convinced however, that modern medicine could not have achieved such a high scientific standing if experiments on animals had not been undertaken. Neither could this majority be convinced of the merits that a chair in vivisection-free medicine would seek to promote. In addition, they found it incorrect to state that official medicine had excluded other directions than the 'natural scientific way of knowing'. In earlier times, homoeopathy used to be practised by all sorts of physicians and had simply lost that place when science had moved forward. If it wanted to reclaim its former position within medicine, it was the duty of those who were in favour of the suggested approach to convince those who thought differently of their beliefs. That this had not happened was proof that the established medical community did not actively have to support other ways of knowing.[192] In conclusion, Brutel wrote however:

> This majority also feels that when a group of persons wants to realize professorial chairs in vivisection-free medicine at the university, this initiative must not be suppressed and that this group should be allowed to let its voice be heard in the academy.[193]

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[190] See also: J.C. Wolterbeek, 'Een leerstoel voor de Homeopathie', in *Medisch Contact* Vol. 5, No. 15 (13 April, 1950), pp. 272-274; Gerard Bakker, 'Een leerstoel voor Homoeopathie?' in *Medisch Contact* Vol. 5, No. 17 (27 April, 1950), pp. 319-320.

[191] NL-HaNA, Gezondheidsraad, 1920-1956, 2.15.33, Inv.nr. 547, 'Concept betreffende: vivisectie', 8 October 1948, pp. 1-2.

[192] Ibidem, p. 2.

[193] Ibidem, p. 3.

Bakker responded highly disappointed to the concept advice. He felt that Brutel was suggesting that he and Wolterbeek did not have a scientific approach to their work, an assertion that he found offending for a large number of reasons: during the committee meeting, none of his prepared statements on homoeopathy and vivisection-free medicine had been falsified on substantive grounds; both he and Wolterbeek were graduates from a Dutch university (and he himself now even from an American university); both he and Wolterbeek possessed a healthy state of mind; both had an orderly service record and both were always willing to defend their medical field in the established professional circles of the Dutch medical profession. Taking all this into account, how could Brutel possibly suggest that the homoeopaths were no true scientists? According to Bakker, the derogatory attitude of his fellow committee members could only be explained by a limited conception of mental freedom on their part, a state of mind that he had never expected from professionals which were known to have fought heavily for the freedom of thought and speech under the infamous Nazi regime.[194]

From a rather different source, the concept advice received additional criticism. In November 1948, Floor Wibaut, the secretary-treasurer of the KNMG, wrote a letter to Brutel to express his concern over the fact that the Health Council acknowledged in the concept advice that a professional chair in vivisection-free medicine should not be suppressed.[195] Since the late middle-ages, Wibaut wrote, science had been free of religion and dogma. With the exception of the universities of Nijmegen and Amsterdam, Dutch universities had established an academic community that was free from normative motives in the choice of offered educational programs. According to Wibaut, the antivivisectionist cause could therefore be compared to physicists denying the existence of atoms because nuclear energy could be used for undesired ends.[196] To exclude data on the basis of

[194] Ibidem, letter of Gerard Bakker to Jan Jacques Brutel de la Rivière 'betreffende leerstoelen vivisectievrije geneeskunde', 30 November 1948.

[195] Ibidem, letter of F. Wibaut to Jan Jacques Brutel de la Rivière, 23 November 1948. Floor Wibaut Jr. was named after his father, the famous business man and SDAP-politician Floor Wibaut, of whom a statue has been erected in Amsterdam. Wibaut Jr. became a well-respected ophthalmologist and member of the Dutch Senate after the Second World War. See: G.C. Heringa, 'Dr. F. Wibaut zestig jaar arts', in *Medisch Contact* Vol. 26 (1971), pp. 711-713; G.W.B. Borrie, 'Wibaut, Florentinus Marinus (1859-1936)', in *Biografisch Woordenboek van Nederland* (place online on 10 February 2012). Also: On 25 March 1954 *Medical Contact* dedicated an entire edition of the journal to the contributions of Wibaut to the Dutch resistance during the war and to the Dutch medical profession in general, in: *Medical Contact* Vol. 9 No. 12 (25 March 1954).

[196] A comparison which is a bit odd, given that vivisection is a *means* to an end (i.e. obtain valid

objections raised against the way they had been obtained, Wibaut held to be contrary to the essence of science.[197] This meant that a chair in vivisection-free medicine was based on a negative foundation: it was *against* vivisection and *against* research-based laboratory medicine. As such, it could never function as an addition to the existing Dutch educational system in medical faculties.

After this letter, Brutel de la Rivière decided to convene a second meeting, which took place on 19 January 1949. Unsurprisingly, the most important point on the agenda was that one final sentence of the concept-version: i.e. the admission that a chair in vivisection-free medicine should not be hindered by the Dutch government. Although he did not mention the existence of Wibaut's letter, Brutel's reasons for this new debating point corresponded almost literally to the objections raised by secretary-treasurer of the KNMG: vivisection-free medicine went against everything modern medicine stood for and could therefore not be integrated into the existing medical curricula of Dutch universities.[198] It was thus impertinent for the final sentence in the concept advice to be removed. Because the majority of the committee agreed, Bakker and Wolterbeek had to settle for writing an alternative advice to the Minister, which they handed in as an appendix to the official advice of the Health Council, presented on 17 March 1949 to the newly installed Minister of Social Affairs Dolf Joekes.[199]

From the frontstage/backstage perspective, it is significant that the Health Council first sent a concept advice to the Minister of Social Affairs, its effective 'commissioner', and then decided to depart from it after a letter from an outside party with no relevant authority. In this regard, Drees and Joekes should thus not be seen as the respective 'audience' of the Health Council, but rather as fellow 'actors', participating in the 'staged drama' that was the 'advisory committee on the establishment of chairs for vivisection-free medicine'. The real audience was 'the larger lay public in the Netherlands', practically represented by the Dutch parliament who was to vote upon the establishment of a chair in vivisection-free

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scientific knowledge), whereas an understanding of atoms and nuclear energy is 'the end itself (i.e. scientific knowledge), which in turn can be used as a means to other ends.

197 Significantly, it was precisely this problem that scientists after World War II had to face: would it be ethical to either use or destroy the research findings obtained through Nazi experiments? In that debate, the manner in which the scientific data was obtain was the crux of the dilemma. See: Ulf Schmidt, 'Medical Ethics and Nazism'.

198 NL-HaNA, Gezondheidsraad, 1920-1956, 2.15.33, Inv.nr. 547, Notulen van de vergadering van de commissie van advies inzake het instellen van leerstoelen voor vivisectie-vrije geneeskunde, 19 January 1949.

199 Their advice can be found in: Ibidem, 'Afschrift', 29 January 1949.

medicine at one of the Dutch universities. Significantly, in parliamentary debates (the actual frontstage) upon the subject matter, the Health Council's advice effectively functioned as a 'prop': providing important support to the Minister's standpoint against a chair in vivisection-free medicine, since the Council's vision counted as a scientific assessment by an objective authority. Thus, when political parties favouring a chair in vivisection-free medicine confronted the Minister with his refusal to establish such a professorship, the latter could argue that the Health Council, 'an objective scientific authority', had advised against it.[200]

Backstage, it turns out that this so-called 'scientific advice' was heavily framed by protests of outsiders with obvious interests in the outcome of the committee's discussions. What is important to realize for example, is that Brutel was not allowed officially to send the confidential concept-advice to the KNMG for revision, which had theoretically no stake in the matter. In contrast, when Bakker asked permission to Brutel for using some of what was discussed by the Health Council in publications, Brutel explicitly forbade Bakker to mention anything of what was communicated among the members of the Health Council to third parties, reminding him that the Council's by-laws stipulated utmost confidentiality and Bakker infringing upon them would be highly unethical.[201] Although Bakker did not mention which information he wanted to put to use, it is fairly safe to assume that he was referring to the original standpoint of the Health Council in the concept-version. Earlier petitions to establish professorships in vivisection-free medicine had been denied on grounds that the expenses were simply too high for the State to be able to act upon educational requests which were not absolutely essential. But by the end of the 1940s, the AVS had raised enough funds to fully subsidize an endowed chair. If it became publicly known that the Health Council had originally not opposed a professorial chair in vivisection-free medicine, this would provide undesired support to the antivivisectionists' goals. Brutel's strong reaction to Bakker's request indicates that he realized in which ways the advice could potentially provide undesired support to the antivivisectionist cause. He therefore strategically invoked the by-laws to refrain Bakker from using the authority of the Health Council against the wishes of the established medical community.

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[200] Handelingen der Staten Generaal, 1949-1950, 37ste Vergadering, 16 December 1949, Vel 279, p. 1100.

[201] NL-HaNA, Gezondheidsraad, 1920-1956, 2.15.33, Inv.nr. 547, letter of Jan Jacques Brutel de la Rivière to Gerard Bakker, 12 March 1949.

The historical crystallization of vivisection as a medico-ethical problem

The fact that the Dutch antivivisectionist movement pointed to *human* experimentation in 1947 to establish the morally problematic nature of *animal* vivisection is historiographically significant. The role of animal experimentation is often neglected in histories of clinical research ethics, which tend to focus instead on the growing influence of monitoring committees for clinical research and medical decision making after the 1960s.[202] The rise of external governing agencies is evaluated in such narratives, as *determined* by scientific and technological advances: i.e. as the self-evident outcome of vast changes in the biomedical landscape after the 1940s, such as the institutionalization of randomized controlled trials and the development of new medical technologies (e.g. the invention of the hemodialysis and hart-lung machines). In the influential 1991 monograph *Strangers at the Bedside* for example, the American historian David Rothman maintained that the ethics of human experimentation did not command much attention prior to World War II, because medical research had only been conducted on a small scale and had been almost always therapeutic in intent.[203] In other words, clinical research did not constitute a public problem, because violations were too few to produce corrective legislation or new professional review policies.[204]

Such an analysis glosses over the fact however that already in the seventeenth century scholars argued that animal experiments caused such intolerable suffering that they would inevitably lead to cruelty among men.[205] Or

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[202] It is either neglected or human and animal experimentation are taken to be two distinct historical phenomena, which need to be treated separately from one another.

[203] Rothman, *Strangers at the Bedside*, pp. 18-29. Rothman later revoked this position in the 1998 article, 'The Nuremberg Code in Light of Previous Principles and Practices in Human Experimentation', in Tröhler & Reither-Theil, *Ethics Codes in Medicine*, pp. 50-59. Drawing on the work of Susan E. Lederer, Rothman asserted in this article that professional disciplinary action or some collective expression of censure or disapproval almost never occurred before the Second World War. Investigators could freely disobey set norms and paid no price for it (a fig leaf analysis). According to Lederer herself however, already in the early twentieth century a growing number of lawsuits in the United States over unauthorized surgical procedures resulted in the standardization of written consent forms for a physician or surgeon in order for him to undertake any for of biomedical intervention. See: Susan E. Lederer, *Subjected to Science. Human Experimentation in America Before the Second World War* (London, 1995).

[204] For a thorough discussion on technological determinism, see the articles in the edited volume: Merrit Roe Smith & Leo Marx, *Does Technology Drive History? The Dilemma of Technological Determinism* (Baskerville, 1994).

[205] Andreas-Holger Maehle & Ulrich Tröhler, 'Animal Experimentation from Antiquity to the End

that already in the eighteenth century, the famous and well-respected philosopher Immanuel Kant put forward in one of his essays on ethics that animal vivisection would eventually weaken man's compassion for his fellow human being.[206] Similarly in the late nineteenth century, organized antivivisectionist movements gained a respectable following by arguing that the treatment of animals in research-based laboratories increasingly butchered the humanity of the scientific researcher, making him insensible to the suffering of his patients.[207] Such historical evidence suggests that human experimentation was a 'public problem' long before the rise of randomized controlled trials or large pharmaceutical companies.

Nevertheless, it is true that the existence of 'clinical research ethics' as a separate research programme within the larger scholarly field of ethics or even medical science is a development of the second half of the twentieth century. One possible explanation for this phenomenon is, as will be explored in chapter 4 of this thesis, that it was not until the 1960s and 1970s that the 'research-subject relationship' came to be differentiated from the 'doctor-patient relationship'. In the title of the Health Council committee 'tests upon human beings' for example, the wording 'experimentation' is purposefully avoided. Experimental interventions were perceived by the committee members to be not essentially different from other biomedical tests which were continuously undertaken upon patients to diagnose their illness or provide a treatment that would hopefully result in complete recovery of the patient (an end state which no medical doctor could ever fully guarantee). What was important therefore was not to establish an ethic specifically geared toward experimental tests, but to properly educate aspiring physicians to treat all of those under their care humanely and to be capable of making morally responsible decisions in any given medical situation.

Significantly however, the AVS did specifically campaign against biomedical experimentation in 1947. According to the antivivisectionists, to subject living beings to possibly risky tests without immediate diagnostic or therapeutic benefits was diametrically opposed to the art of medicine itself. Experimental vivisection was essentially a perversion of medicine. This suggests

of the Eighteenth Century: Attitudes and Arguments' in Nicolaas A. Rupke (ed.), *Vivisection in Historical Perspective* (London, 1987), pp. 14-47, there: pp. 21-22. For the long history of animal vivisection, see also: Andreas-Holger Maehle, 'The Ethics of Experimenting on Animal Subjects', in Baker & McCullough, *The Cambridge World History*, pp. 552-557; Anita Guerrini, *Experimenting with Humans and Animals: From Galen to Animal Rights* (Baltimore, 2003).

206 Maehle & Tröhler, 'Animal Experimentation', pp. 36-37.

207 Ibidem, p. 54.

that the antivivisectionist stance should be understood as more than a mere protest against the practice of animal experimentation. This hypothesis is supported by the fact that organized antivivisection movements can only be traced back to the second half of the nineteenth century, while the practice of animal experimentation itself was publicly criticized long before the year 1800. Already in the seventeenth century for example, Jean Riolan Jr. (1560-1657), a professor of anatomy and botany in Paris, dismissed the use of animal experimentation by arguing that the anatomical differences between man and animal were much too vast to render any meaningful comparison possible.[208] Also in the seventeenth century, the French Jesuit Gabriel Daniel (1649-1728) argued that the animal experiment could not be defended on moral grounds, because it caused intolerable suffering to animals themselves.[209] In the early eighteenth century, English newspapers such as *The Spectator* and *The Gentleman's Magazine* wrote critically of the famous Boylean air pump experiments, because they required animals to be repeatedly subjected to painful procedures without generating any novel facts.[210] And towards the end of the eighteenth century, it was the social reformer Jeremy Bentham (1748-1832) who opposed animal vivisection by comparing animal rights to the abolition of slavery, famously stating 'the question is not, Can they *reason*? nor, Can they *talk*? but, Can they *suffer*?'[211]

In explaining this seemingly late rise of organized protests against animal experimentation, historians have pointed to the simultaneous rise of the academic discipline 'experimental physiology' after 1800.[212] The Dutch historian Nicolaas Rupke for example, has argued that the origination of antivivisectionist movements in the nineteenth century fundamentally has to be understood as one of the first organized socio-cultural protests against the increasing professionalization and institutionalization of the biomedical sciences. When vivisection was attacked by such groups, Rupke argues, it was not actually the welfare of animals which took centre stage, but that what animal experimentation had come to represent: i.e. a criterion of proper science with specific career opportunities that excludes other ways of knowing.[213]

[208] Ibidem, pp. 21-22.
[209] Ibidem, pp. 27-28.
[210] Ibidem, pp. 29-30.
[211] Ibidem, pp. 37-38.
[212] See for example: Richard French's *Antivivisection and Medical Science in Victorian Society* (London, 1975); Jan Romein, *Op het breukvlak van twee eeuwen*. Tweede druk (Amsterdam, 1976).
[213] N. Rupke, 'Introduction', in Rupke, *Vivisection in Historical Perspective*, pp. 1-13, there: p. 5.

It should be noted that this historiographical assessment is not uncontested. The American historian Susan Lederer for example, who has written extensively on both animal and human experimentation in modern history, disagrees with the equation of antivivisection to anti-science sentiments.[214] According to her, such an analysis flattens the understanding of multiple and fluid meanings that medical science came to embody throughout the nineteenth and twentieth century. Neither in use of arguments, nor in desired political actions, Lederer feels that an easy dichotomy between anti-modernists and scientific progressives can be established. Similarly, the Dutch cultural historian Amanda Kluveld (2000) has persuasively argued that Dutch antivivisectionists in the late nineteenth and early twentieth century did seek to integrate important aspects of modern life into their respective world views.[215] Instead of turning away from modernity, Kluveld believes antivivisectionist movements to have co-constituted modern life, albeit through a different conceptualization of the relationship between science, religion and philosophy than the – by then – established scientific order.[216] That their efforts to unite these various ways of knowing did not pass the test of time is therein not relevant, argues Kluveld. It is the aims of these social groups that have to be considered, not their outcome – any other treatment of the antivivisection movement would be anachronistic.[217]

But while both Lederer and Kluveld convincingly argue against a dichotomy between the actual *epistemological perspectives* of the so-called 'anti-modern antivivisectionists' and 'scientific progressives', their work does not overthrow Rupke's observation that antivivisectionist movements did at least *culturally position* themselves to be in opposition to the modern sciences. And in

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[214] Lederer, *Subjected to Science*, pp. 58-59.

[215] Kluveld, *Reis door de hel der onschuldigen*, p. 25.

[216] Ibidem, p. 144. Kluveld discusses for example the world view of civil engineer Felix Ortt (1866-1959). While being one of founding fathers of the Dutch antivivisection movement and a convinced vitalist, Ortt was also a strong supporter of the modern sciences and in particular valued physics and the established laws of thermodynamics. He believed all activity to be a conversion of energy, but found it difficult to accept that this necessarily resulted in an increase of entropy, or randomness. From the electron, the molecule and the cell, to the organism, society and the state, Ortt believed a mysterious and inconceivable order to exist, which could only be explained if an ordering principle – which the Christian anarchist Ortt called 'God' – was operating upon and through it. This principle, which he envisioned to be eternal and universal, existed in everything and thus included both humans and animals. A scientist who conducted experiments upon animals, thereby lost his connection to the ordering principle. See also: F. Ortt, *Het pneumat-energetisch monisme* ('s-Gravenhage, 1917).

[217] Ibidem, p. 144.

turn, they were actively denounced by the newly established biomedical profession for being an 'unscientific group of quacks'. In her 1995 book *Subjected to Science*, Lederer outlines how the American antivivisectionist movement grew in the nineteenth century out of the fear that the rise of the research-based laboratory had displaced the ideal of the clinically sensitive practitioner.[218] It was in particular the establishment of institutions solely dedicated to scientific research (e.g. the Rockefeller Institute of Medical Research) that did little good to the public perceptions of medical practitioners. Members of both the elite and the poorer classes became afraid that they would be unwittingly experimented upon in hospitals or that grave diggers would sell their corpses to medical students needing to practice their dissecting skills.[219] It was only by the 1930s, when medical research had started to deliver actual therapeutic and prophylactic results, that the American public's confidence in the biomedical sciences grew strong enough to defend human experimentation on the grounds of the advances in medicine and the trustworthiness of the medical profession.[220]

In turn, Lederer describes how the American medical profession responded to the antivivisectionist accusations by equating the success of laboratory medicine to the practice of animal vivisection.[221] Thus, to attack the practice of animal vivisection was to attack science itself. When antivivisectionists for example tried to restrict animal experimentation at a federal level between 1896 and 1900 (NB. by accusing the American medical community of frequently experimenting upon orphans, blacks, the elderly and other weak members of society), the leaders of the organized medical profession complained that such accusations damaged the newly established cultural authority of 'laboratory medicine' and thereby endangered the entire public health of the United States. The American Medical Association (AMA), representing the American medical community, even established an official 'Council on the Defence of Medical Research' to counter such 'erroneous and exaggerated perceptions of medical science as propagated by the American antivivisectionist movement'.[222] The

[218] See also: E. Shorter, *Bedside Manners: the Troubled History of Doctors and Patients* (New York, 1985); J. H. Warner, *The Therapeutic Perspective: Medical Practice, Knowledge and Identity in America, 1820-1885* (Cambridge, 1986); C. E. Rosenberg, *The Care of Strangers: The Rise of America's Hospital System* (New York, 1987); A. Cunningham & P. Williams (eds.), *The Laboratory Revolution in Medicine* (Cambridge, 1992).
[219] See also: Ruth Richardson, *Death, Dissection and the Destitute* (London, 1987).
[220] Lederer, *Subjected to Science*, pp. 137-138.
[221] Ibidem, p. 57.
[222] Ibidem, pp. 51-72.

antivivisectionist accusations were nevertheless effective. To prove that American researchers were truly concerned with the ethics of animal experimentation, the Defence Council circulated guidelines for permissible animal vivisection in 1909 among all American laboratories and medical schools. Similarly, after continuing accusations by the American antivivisectionist movement, the chair of the Defence Council proposed to amend the AMA's Code of Ethics (1847) in 1916, to include a statement about the necessity of voluntary patient cooperation in medical experimentation with humans.[223] This proposal found great opposition however within the AMA. A majority of the organisation's members was of the opinion that the critical safeguard for patient welfare was not to be found in a guideline written down on a piece of paper, but only in the outstanding character of the clinical researcher. The AMA therefore dismissed the proposed amendment. It was only in 1946, with the lobbying of physiologist Andrew Ivy (see chapter 2 of this thesis), that the AMA would for the first time accept formal guidelines for the use of human beings in medical experimentation. Nevertheless, the American medical profession was forced to engage with human experimentation as a public problem long before the advent of the Second World War.

For the Netherlands, Kluveld has shown that antivivisectionists similarly utilized the threat of human experimentation to establish formal regulations concerning animal vivisection in the late nineteenth and early twentieth century. In 1903 for example, the Dutch anti-revolutionary member of parliament M.A. Brants (a zoologist) pleaded that legal regulation of vivisection was essential to protect those weak members of society who came into contact with the medical profession.[224] In 1881, animal cruelty had become a criminal offence under 'offences against morality' in the Dutch Penal Code.[225] When the 'sorrows of the animal' were not the goal however, but only 'a means to a rational end', the section of the law did not apply.[226] This changed somewhat in 1903, when Prime Minister Abraham Kuyper established further limitations by ordaining that animal vivisection could only take place when it was indispensable for scientific research or education. In addition, any vivisection had to be conducted by either professors,

[223] In: Ibidem, pp. 73-100. See also: Donald Konold, *A History of American Medical Ethics, 1847-1912* (Madison, 1962); Robert B. Baker, Arthur L. Caplan, Linda L. Emanuel, Stephen, R. Latham (eds.), *The American medical ethics revolution: how the AMA's code of ethics has transformed physicians' relationships to patients, professionals, and society (*London, 1999).
[224] Ibidem, pp. 168-169.
[225] Ibidem, p. 165.
[226] Ibidem, p. 165.

lecturers or teachers.[227] But since Kuyper's Ministerial Decision contained only guidelines, the measures had no legal standing, leading antivivisectionists to argue that animal vivisection would continue to darken the researcher's mind and harden his senses, eventually culminating in atrocious human experimentation.[228]

It was particularly from the 1930s onwards, that the antivivisectionist movement came to position itself explicitly *against* the established Dutch medical profession. In 1931, under direction of the wealthy general practitioner Pieter Pijl, a number of antivivisectionists left the Dutch Society for the Prevention of Vivisection (NBBV)[229] to establish the Foundation Anti-Vivisection League (SAVB)[230] – later renamed as the aforementioned AVS. Pijl was highly successful in committing others to his antivivisectionist cause and often used the press to alert the public of – what he believed to be – scientific misdemeanour of medical practitioners. Significantly, he also summoned two medical practitioners to the Dutch Medical Disciplinary Committee for having conducted experiments on children, an action which was hitherto unknown in Dutch antivivisectionist circles. In turn, he was subsequently summoned himself for having slandered the medical profession.[231] While the Disciplinary Committee dismissed both claims, Kluveld uses these cases as indicators of how, with the rise of the AVS, the Dutch medical profession and Dutch antivivisectionists increasingly came to position themselves as diametrically opposed to one another, as two forces with completely different visions on the role of medicine in society and on life itself in general.

In such debates, the practice of human experimentation came to play an important role. If tests on animals were in themselves not horrific enough to generate appropriate legislation, the additional threat of unethical human experimentation might make all the difference in raising the necessary awareness for the antivivisectionist cause. One can wonder however to what extent the Dutch

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227 Or, when a professor assumed responsibility, by doctorates, doctors and possible assistants. In any case, professional expertise thus became a prerequisite for permissible animal experimentation. In: Ibidem, p. 171.

228 NB. In parliament, Brants questioned why the Prime Minister sought to maintain the sovereign rights of scientists, treating them as if they stood apart from the laws of society. Kuyper responded that science should be a free profession in order for it to thrive. Kluveld notes however that the orthodox-Protestant Kuyper was probably also afraid legal regulations of vivisection would promote an acceptance of a medical science based on the physiological processes of animals – creatures which he believed to be incommensurably different from God's creation of human kind. Ibidem, p. 171.

229 Trans.: Nederlandse Bond ter Bestrijding der Vivisectie.

230 Trans.: Stichting Anti-Vivisectie Bond.

231 Kluveld, *Reis door de hel*, p. 216.

antivivisectionist movement was truly concerned with the dangers of human experimentation. For the 1947 request for example, the AVS instrumentally joined forces with organized political ideologies, religious factions and alternative medical belief systems in order to establish a vivisection-free medicine in the Netherlands. Some of these organisations, such as the Dutch *Association of Homoeopathic Healers*, actually promoted the use of human subjects for biomedical experimentation, because they believed human and animal physiology to be incommensurable (see below). This indicates that Dutch antivivisectionists increasingly deployed utilitarian-instrumental politics in order to establish a vivisection-free medicine.[232] In that process, for opponents as well as supporters of animal vivisection, philosophy and method – i.e. ways of knowing and ways of doing – often became interchangeable. As will be explored in the remaining pages of this chapter, this had the result that the post-war crystallization of clinical research ethics in the Netherlands (and with that the promulgation of the *Guidelines*) became just as much a debate about what medical experimentation had come to signify, as about the protection of research participants or the traditional doctor-patient relationship.

The post-war equation of antivivisectionism with 'anti-science'

That the antivivisectionist stance turned signifier for everything the research laboratory was not, is exemplified by the fact that it were two homoeopaths who represented the AVS in the Health Council meetings. Importantly, the connection between antivivisection and homoeopathy is by no means as self-evident as it appears from the Health Council meetings on vivisection-free medicine. Instead, the latter illustrate how a number of Dutch organisations sympathizing with one of the two causes strategically decided to join forces after the Second World War in

[232] In order to analyse the history of antivivisectionism in the Netherlands, Kluveld uses a classificatory system for political activity put forward by the British sociologist Frank Parkin. For the political style of Dutch antivivisectionists in the late nineteenth and early twentieth century, Kluveld invokes the Parkinian term 'expressive activity', which denotes actions and argumentations that are less concerned with specific achievements than with the benefits and satisfactions which the activity itself affords. Their main goal was not so much to obtain political power or establish legal regulations, but to express their beliefs and enter into a meaningful debate with their political opponents. In contrast, Pieter Pijl and the AVS much more focussed on 'instrumental activity', which Parkin has described as those actions which are geared toward the ends to be achieved rather than the means employed in attaining them. See: Frank Parkin, *Middle Class Radicalism. The social bases of the British campaign for nuclear disarmement* (New York, 1968); Kluveld, *Reis door de hel*, p. 20.

order to decrease the influence of the natural sciences in the practice of medicine and society more generally. The 1947 petition for example, was supported by organizations such as the *Dutch Society of Naturopathy*[233], the *Foundation Professional Chair in Vivisection-Free Medicine*[234] and the *Dutch Vegetarian Association*[235]. These organizations defended their cooperation on the basis of a communal anxiety over the analytical and technical nature of modern medicine, arguing that it 'neglected medicine's synthetic element and treated sickness instead of the sick'.[236] The AVS framed treatments using natural remedies in such a way that their methods would not need animal experimentation and thus be more ethical than natural scientific interventions – a conceptualization of homoeopathy that became dominant in parliamentary discussion, but was not accurate. In 1950 for example, amidst one of the parliamentary discussions over a professorship in vivisection-free medicine, the *Association of Homoeopathic Healers in the Netherlands*[237] sent a letter to the Minister of Social Affairs and Public Health, to correct the idea that homoeopathy (i.e. a way of knowing) and vivisection-free medicine (i.e. a way of doing) could simply be equated. Although the *Association* could endorse the attempts of the AVS from a 'business standpoint', it wanted to make clear that it did not believe a proper understanding of medications could be established without animal experimentation. If anything, Dutch pharmacologists experimented too little on healthy *human beings*, a prerequisite for the safety of medicaments that was indispensable according to the homoeopathic doctrine.[238]

Also during debates in Dutch parliament, it were particularly members from religious factions, such as the Reformed Political Party (SGP)[239], which used homoeopathy and antivivisection interchangeably in pushing for a professorial chair in vivisection-free medicine. For them such a professorship was important, because they believed it might be successful in challenging 'a medicine based on the modern sciences of nature'. The SGP believed, for example, that a vivisection-free medicine would rightfully challenge vaccination campaigns of biomedical scientists – a prophylactic intervention the Reformed Party felt to be in direct

[233] Trans.: Nederlandse Vereniging voor Natuurgeneeswijze.
[234] Trans.: Stichting Leerstoel Vivisectie-vrije Geneeskunde.
[235] Trans.: Nederlandse Vegetariërsbond.
[236] NL-HaNA, Gezondheidsraad, 1920-1956, 2.15.33, Inv.nr. 547, Anti-Vivisectie-Stichting 'Aan de leden van de 1ste en 2de Kamer der Staten Generaal, date unknown, p. 1
[237] Trans.: Vereeniging van Homoeopathische Geneesheeren in Nederland.
[238] This letter was published in *Medisch Contact*: 'Homoeopathie', in *Medisch Contact* Vol. 5, No.24 (15 June 1950), pp. 438-440.
[239] Trans.: Staatkundig Gereformeerde Partij.

opposition to God's providence.[240] Thus, during a parliamentary discussion on the State Budget of 1950, the SGP-er Van Zandt demanded to know from Minister Theo Rutten of Education, Arts and Sciences why he would not establish a professorship in vivisection-free medicine.[241] Van Zandt argued that the AVS had offered to pay for all costs and a substantial number of Dutch citizens desired it, so there was no valid reason for the Minister to keep on refusing the instalment of such a professorship. Rutten responded however that, after extensive discussion with members of the AVS, he had come to the conclusion that antivivisectionists did not simply want to add a specialization to the Dutch medical faculties, but establish an entirely different system of education, which the Minister felt was not 'practically realisable for the time being'. Notably, Rutten also defended his position against vivisection-free medicine on the grounds that the Health Council, a 'scientific and objective advisory body', had advised against it.[242] Nevertheless, after subsequent discussions with Van Zandt, Rutten admitted that an academic climate should be open to multiple philosophies, and agreed to take the proposal of the AVS into consideration.[243]

This statement led to considerable commotion among the ranks of the KNMG. On the pages of MC, the journal's editor-in-chief complained that antivivisectionists simply denounced all results of modern medical science, which meant that the establishment of a chair in vivisection-free medicine would entail an experiment of 'massive gruesomeness that far surpassed any human or animal vivisection'.[244] Was the Minister sincerely willing to expose young students to a form of medicine that violated its own objectives?[245] Similarly, the central committee of the KNMG wrote an official letter to the Prime Minister, the Minister of Social Affairs, the State Secretary of Public Health and the Minister of Education, Arts and Social Sciences, wherein it warned that the establishment of a vivisection-free professorship would not only endanger the general level of scholarship in the Dutch academy, but also cause major damage to Dutch public

[240] Handelingen der Staten Generaal, 1949-1950, 37ste Vergadering, 16 December 1949, Vel 279, pp. 1097-1098.
[241] Ibidem, p. 1096.
[242] Ibidem, p. 1100.
[243] Ibidem, p. 1101.
[244] G.C. Heringa, 'Een leerstoel voor de homoeopathie?', in *Medisch Contact* Vol. 5 (1950), pp. 191-193, there: p. 193. See also: J.J. van Loghem, 'De Vivisectie-vrije Geneeskunde in de Tweede Kamer', in *Nederlandsch Tijdschrift voor Geneeskunde* Vol. 94 (1950), pp. 18-19.
[245] Ibidem, p. 193. NB. Trans. of 'violation': verkrachten.

health.[246] The antivivisectionist stance was against everything the modern natural sciences had achieved and should therefore be considered as highly dangerous. In addition, the central committee argued that homoeopaths denounced a large number of therapeutic and prophylactic measures, such as vaccination, which experience had undoubtedly proven to be useful. Finally, Minister Joekes of Social Affairs himself sent a letter to Rutten, wherein he emphasized that all Dutch medical faculties were explicitly against the establishment of a chair in vivisection-free medicine. He reminded his colleague of the 1949 scientific advice of the Health Council and asked to be included in any upcoming decision concerning the matter on grounds of the effect it could have on the public health of the Netherlands.[247] Each of these responses from the 'established Dutch medical profession' illustrates that antivivisectionism thus in itself had come to crystallize as ethically problematic, as it was envisioned to go against the very core of modern science, which had brought so much relief to human kind.

The Dutch antivivisectionists were not entirely unsuccessful however, for Minister Joekes did decide in 1949 to research the frequency of vivisection in the Netherlands and the manner in which these experiments were conducted.[248] In 1953, his successor presented the report to the Health Council for comments. For the subsequent committee that was to be erected, Brutel de la Rivière asked representatives of the AVS, the NBBV and the *Dutch Society for the Protection of Animals*[249] to preside at the meetings. Again however, the majority of the committee decided that legal regulations for vivisection were unnecessary, this time because Joekes' research results showed that animal vivisection hardly occurred in the Netherlands.[250] But the Dutch antivivisectionist movement did not leave it at that. In parliament, Van Zandt would continue on a yearly basis to request the establishment of a professorial chair in either homoeopathy or vivisection-free medicine. The AVS itself continued to emphasize in publications that vivisection hardened the senses of young physicians, presenting a slippery slope that would eventually result in a blurring of the boundaries between permissible and non-permissible medical interventions. In these publications,

[246] The letter was published in *Medisch Contact*: 'Leerstoel voor de homoeopathie?', in *Medisch Contact* Vol. 5, No. 17 (27 April, 1950), pp. 303-306.

[247] NL-HaNA, Gezondheidsraad, 1920-1956, 2.15.33, Inv.nr. 547, letter of the Minister of Social Affairs A.M. Joekes to the Minister of Education, Arts and Sciences, 'leerstoel homoeopathische geneeskunde', 13 April 1950.

[248] Rigter, *Met raad en daad*, p. 136.

[249] Trans.: Nederlandse Vereniging ter Bescherming van Dieren.

[250] Rigter, *Met raad en daad*, p. 136. See also: NA, GR, Inv.nr. 546, 'Commissie inzake Vivisectie'.

human experimentation consistently continued to function as a prime example of the importance of governmental regulation for *animal* vivisection. In 1953 for example, on a propaganda evening organized by the AVS, Mary Stuart accused the Leiden academic hospital of conducting horrific medical experiments on both innocent babies and the defenceless insane. These accusations were so serious, that the then State Secretary of Public Health decided to ask the Health Council for new advice on the subject matter. It was to this end, that the advisory body decided to establish the committee 'tests upon human beings', which would eventually, in 1955, produce a set of ethical principles that has become known as the Dutch *Guidelines for Tests upon Human Beings*.

4. Tests upon Human Beings: Defining the Dutch Problem

With these guidelines the Health Council committee appeals to the landmarks for tests upon human beings, which simultaneously function as warning signs.[251]

In 1950, medical researcher A.A. Botter published a treatise on the aetiology of nettle-rash in children, for which he had conducted experimental clinical research in the academic hospital of Leiden.[252] To prove that the disease was caused by a virus, Botter had dripped bacteriological sterile filtrates of throat rinses, urine and faeces into the noses of admitted children and a number of the little research subjects infected with 'throat rinse filtrates' did indeed successfully develop rashes. Simultaneous tests conducted upon animals however, did not conclusively demonstrate the existence of a virus. Botter's hypothesis therefore remained conjectural.[253]

When the AVS learned of Botter's research, it became a prime example for the Dutch antivivisectionists to demonstrate the degeneracy of the modern research-based laboratory sciences. In 1953, on a meeting organized by the AVS, president Mary Stuart and head of personnel and public affairs Willem Groen argued that both the dissertations of Botter and Brutel de la Rivière (see chapter 3) proved which effect the practice of animal experimentation ultimately had on the

[251] Statement of M.G. Neurdenburg, in: NL-HaNA, Gezondheidsraad, 1920-1956, 2.15.33, Inv.nr. 548, Not. comm. proeven op mensen, 5 April 1955, p. 17. Trans.: De heer Neurdenburg vindt de indeling van de richtlijnen wel gelukkig. Spreker meent dat de Commissie hier een appèl doet op de grenspalen, welke tevens de waarschuwingsborden zijn.

[252] A.A. Botter, 'Over de aetiologie van de strophulus infantum', in: *Verhandelingen van het Instituut voor Praeventieve Geneeskunde* Vol. 16 (1950).

[253] J.R. Prakken, 'A.A. Botter, *Over de aetiologie van de strophulus infantum*', in *Nederlandsch Tijdschrift voor Geneeskunde* Vol. 94 (1950), p. 2766.

ethical conduct of the members of the Dutch medical profession. These accusations were recorded in the Dutch newspaper *The Free People*[254] in an article titled 'Serious accusation against Leiden hospital. Babies and the insane used for experiments?'.[255] The names of Botter and Brutel were not mentioned in the article, but the fact that a national daily wrote about perceived abuses of the Dutch medical profession, led the then State Secretary of Public Health Piet Muntendam to take action and ask the Health Council to advise him on the subject matter.[256]

This chapter will establish that the fact it had been the AVS which had provoked the State Secretary to ask for an advice on the ethics of human experimentation, significantly narrowed the scope of the deliberations undertaken by the Dutch Health Council upon the subject. The *Guidelines for Tests upon Human Beings* had to be formulated very carefully, said the committee members, so not to provide any undesired public support to the antivivisectionist cause. As one member put it, 'the one percent of negative consequences that the research laboratory might have, should not be allowed to negate the 99 percent of positive effects generated by modern science'.[257] The promulgation of the *Guidelines* therefore turned into an attempt to protect the standing of medicine in Dutch society and as a result, the legacy of the *Guidelines* was one that purposely downplayed the dangers of biomedical clinical research.

At the same time however, it would be a mistake to remember the *Guidelines* as a mere 'fig leaf' to keep critics of laboratory science at bay. Most of the Health Council members sincerely felt that human experimentation was in need of some form of regulation. They therefore envisioned themselves an important societal task: i.e. to formulate for the first time a public ethic for clinical research and therewith set the moral standard for all physicians aiming to undertake biomedical tests upon human beings. This chapter will therefore also outline how the Health Council's perception of the precise problematic nature of clinical research gradually came to crystallize in the nine committee meetings that took place between 1953 and 1955. During those gatherings, the committee 'tests

[254] Trans.: Het Vrije Volk.

[255] Trans.: Ernstige beschuldiging tegen Leids Ziekenhuis. Baby's en krankzinnigen gebruikt bij proeven? See also: NL-HaNA, Gezondheidsraad, 1920-1956, 2.15.33, Inv.nr. 548, Not. comm. proeven op mensen, 9 Februari 1954, p. 7.

[256] NL-HaNA, Gezondheidsraad, 1920-1956, 2.15.33, Inv.nr. 548, NL-HaNA, Gezondheidsraad, 1920-1956, 2.15.33, Inv.nr. 548, Not. comm. proeven op mensen, 14 December 1953, p. 1. See also: Inv.nr. 549, letter of State Secretary of Public Health P. Muntendam to the central committee of the KNMG, 17 June 1953.

[257] Ibidem, 27 Januari 1955, p. 2. The comment was made paediatrician Willem Karel Dicke.

upon human beings' came to reflect not only upon the boundaries of the medical experiment in relation to other medical interventions, but also upon the proper hierarchy within the medical profession itself, upon the relationship between practitioner and patient, and upon the role and responsibilities of the modern-day individual in and towards his society. With that, the *Guidelines for Tests upon Human Beings* became one of the first public reflections by the organized medical profession upon its position and responsibilities within the modern Dutch state and forms an excellent case-study to study the processes of ethics-in-the-making.

The honoured representatives of the Dutch medical profession

If one wants to claim that the *Guidelines for Tests upon Human Beings* are a response of the organized Dutch medical profession to the antivivisectionist stance, one first needs to establish that the governmental advisory body represents that medical profession. Apart from the serving President and the Council's secretariat however, the advisory body only exists by means of working committees, whose members are elected depending upon the specific subject the Health Council is asked to advise upon.[258] As has been demonstrated in chapter 3 of this thesis, these experts do not necessarily have to be representatives of medical organizations. On the occasions that the Health Council was asked to develop an advice on medical vivisection, also representatives of other social organizations such as the AVS were invited. While it is questionable how much influence men like Bakker and Wolterbeek actually had on the official Health Council advice, they did extensively contribute to the committee's discussions and were allowed to hand in an alternative advice to the Minister.

For the committee 'tests upon human beings' however, only medical practitioners were invited (with the exception of one statistician), each of which had gained his spurs as specialist in his (or her) medical field of expertise or had become a well-known authority within organisations such as the KNMG, the *Royal Dutch Academy of Sciences*[259] or other medical and scientific organizations (see below). No critics of human experimentation received an invitation, nor were any ethicists or theologians asked to take place in the Health Council committee. The committee itself ran from 1953 to 1955 and during that time it saw three chairmen. Upon commencement in 1953, Pieter Adrianus van Luijt was president

[258] Bal et al, *Paradox van Wetenschappelijk Gezag*, pp. 83-132.
[259] Trans.: Koninklijke Academie der Wetenschappen.

of the Health Council. After the fourth meeting of 13 April 1954 however, Van Luijt turned seriously ill and could not resume his responsibilities.[260] Because subsequent president J. Wester would not take office until April 1955 (after which he did lead the final two committee meetings), Jean Jacques Brutel de la Rivière presided as deputy chairman over one third of the Health Council meetings on human experimentation.[261]

Similar to the 'advisory committee on the establishment of chairs for vivisection-free medicine' (see chapter 3), it seems not to have mattered that Brutel was one of the principal objects of the antivivisectionists' complaints. If anything, when his dissertation was discussed, Brutel seemed to be one of the only committee members remotely interested in debating the ethics of his past work. In contrast, most members considered the evaluation of past research studies to be somewhat irrelevant for the promulgation of present-day principles.[262] These members preferred to refrain from medical casuistry, as the discussion of individual cases was argued to be of little use for the composition of general principles. In addition, these members were afraid that if such material would come to be included in the *Guidelines* (which the committee intended to publish on a broad scale), the lay media would only misrepresent the discussed cases as exposed skeletons from a dusty old cupboard – negative publicity which the Dutch medical profession could very well do without.[263] At one point, one of the committee members commented: "If we include examples of ethically dubious studies in the advice, the lay press will pick up on it. Considering what the reason has been for the congregation of this Health Council committee, this could prove to be quite a dangerous development."[264]

Brutel set the agenda for most of the committee meetings and, even before the retreat of Van Luijt, he did most of the necessary preparatory work. He for example drew up the principal statements used by the Health Council for its initial

[260] F. Bezemer, 'In memoriam P.A. van Luijt', in *Nederlandsch Tijdschrift der Geneeskunde* Vol. 98 (1954), pp. 3513-3514. Van Luijt died in October 1954.

[261] Van Luijt led meeting one, Brutel de la Rivière meeting two to seven, and Wester meeting eight and nine. See: NL-HaNA, Gezondheidsraad, 1920-1956, 2.15.33, Inv.nr. 548, Not. comm. proeven op mensen; J. Wester, 'Advies van de Voorzitter van der Gezondheidsraad d.d. 10 oktober 1955', p. 2. See also: J.R. Prakken, 'Dr. J. Wester 65 jaar', in *Nederlands Tijdschrift voor Geneeskunde* Vol. 110 (1966), p. 595.

[262] NL-HaNA, Gezondheidsraad, 1920-1956, 2.15.33, Inv.nr. 548, Not. comm. proeven op mensen, 9 Februari 1954, pp. 7-8.

[263] Ibidem, 9 Februari 1954, p. 7.

[264] Ibidem, 23 December 1954, p. 16.

deliberations and wrote the first few concept versions of the final advice.[265] This does not mean however that Brutel's standpoints prevailed in the 1955 *Guidelines*. His views were often divergent from the rest of the committee, in particular on patient consent and on the use of prisoners as research subjects. Whereas Brutel for example considered the permission of patients to be essential for communal trust in the doctor-patient relationship, other members felt patient consent to be of only secondary importance.[266] Similarly, whereas Brutel found experiments upon prison inmates very well acceptable in order for them to repay their debts to society, all the other members were of the opinion that such experiments should never be undertaken, because free consent was impossible for individuals in such a dependent position.[267] One member even argued that if such had been allowed by the Dutch medical profession during the Second World War, the Nazis had would have had a field-day.[268] Brutel's concept versions of the *Guidelines* were therefore subjected to thorough revisions.

Apart from the three chairmen, the committee consisted of fourteen official members, including State Secretary Muntendam and Superintendent of Public Health Cornelis Banning, both of whom were not present at any of the meetings except for a short visit during the eight committee meeting to install President Wester.[269] Overall, these physicians represented a variety of specializations. On the following pages, this chapter will discuss in more detail the names of five of these historical characters in order to gain a better understanding of the various attitudes and opinions that dominated in the Health Council. In addition, some of the details of each of these five men are worth mentioning, because each of them played a significant role in the construction and formulation of the final *Guidelines for Tests upon Human Beings* (as relevant for this thesis).[270]

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[265] NL-HaNA, Gezondheidsraad, 1920-1956, 2.15.33, Inv.nr. 548, Not. comm. proeven op mensen, 14 December 1953, p. 1; NL-HaNA, Gezondheidsraad, 1920-1956, 2.15.33, Inv.nr. 549, J.J. Brutel de la Rivière aan de Leden van de Commissie inzake Proeven op Mensen, 'No.15 Betreffende: Proeven op Mensen', 17 Januari 1955; Ibidem, 8 Februari 1955.

[266] This difference in standpoints became clear throughout the first seven meetings. In this chapter, these differences will be discussed in more detail. References to specific meetings, and note pages will follow then.

[267] NL-HaNA, Gezondheidsraad, 1920-1956, 2.15.33, Inv.nr. 548, Not. comm. proeven op mensen, 13 April 1954, p. 6.

[268] Ibidem, 5 April 1955, p. 10.

[269] Ibidem, 5 April 1955, p. 1.

[270] Furthermore installed were professor in bacteriology and serology Pondman of the University of Groningen, professor of internal medicine and physician-director of the Nijmegen Canisius hospital Enneking, professor of psychiatry and experimental physiology Van der Horst of the

The first committee member of this group of five is Cornelis Douwe de Langen (66 years old in 1953). By the 1950s, the internist had become a highly honoured member of the Dutch medical profession. He was in possession of multiple medals of honour[271] and honorary member of organizations such as the *Royal Dutch Academy of Sciences*[272] and the *International Internist Association*.[273] De Langen was a man of outspoken opinions. He was the committee member who most explicitly condemned acts of human experimentation he considered to be unethical and was a strong advocate of stringent restrictions for biomedical researchers. The Dutch internist complained at length for example, about the loose attitude of his medical contemporaries in their treatment of patients and research subjects.[274] To illustrate this, he spoke of a recent discussion between him and an American bacteriologist who had subjected 200 orphans to medical experiments. De Langen was outraged that the American scientist had only wanted to admit after much pressure from the side of the Dutch internist that his choice of research subjects arguably passed the borderline of permissible human experimentation.[275] De Langen therefore felt that if medical practitioners did not have the courage to experiment upon themselves, they should not be entitled to conduct them upon others. In fact, society should, as far as the internist was concerned, demand for tests to be undertaken upon the descendants of such researchers. Norms for ethical human experimentation were shifting in the Netherlands and De Langen believed this development to be dangerous for the safety of patients and for the societal reputation of the Dutch medical establishment in general.[276]

Free University of Amsterdam, professor in obstetrics and gynaecology (and obstetrician to the Dutch Royal family) Plate of the University of Utrecht, paediatrician Koenen from Maastricht, lung specialist Ms. Hallo, and secretary Kettlitz. See: F. Westendorp Boerma, 'Prof. Dr. A. Pondman 70 jaar', in *Nederlands Tijdschrift voor Geneeskunde* Vol. 104 (1960), pp. 1008-1010; C.L. Majoor, 'In memoriam Prof. Jules A.M.J. Enneking', in *Folia Medica Neerlandica* Vol. 8 (1965), pp. 163-166; F.C. Stam, 'Prof. Dr. L. van der Horst 50 jaar arts', in *Nederlands Tijdschrift voor Geneeskunde* Vol. 114 (1970), pp. 785-786; P.G. Hart, 'In memoriam Prof. Dr. W.P. Plate', in *Nederlands Tijdschrift voor Geneeskunde* Vol. 127 (1983), pp. 1269-1270.

[271] De Langen was Knight in the Order of the Dutch Lion, Officer in the Order of Oranje Nassau, Officer in the Legion of Honour, Commander in the Royal Order of Siam, Commander in the Order of China and Commander in the Order of the Emperor of Cambodia.

[272] Trans.: Koninklijke Nederlandse Maatschappij der Wetenschappen.

[273] L. Schalm, 'Prof. Dr. C.D. de Langen 75 jaar', in *Nederlands Tijdschrift der Geneeskunde* Vol.106 (1962), pp. 1825-1826; N.H. Swellengrebel, Levensbericht C.D. de Langen, in: Jaarboek KNAW, 1966-1967, Amsterdam, pp. 353-357.

[274] NL-HaNA, Gezondheidsraad, 1920-1956, 2.15.33, Inv.nr. 548, Not. comm. proeven op mensen, 14 December 1953, p. 2.

[275] Ibidem, 14 December 1953, p. 2.

[276] Ibidem, 14 December 1953, p. 2.See also: De Langen, 'Proeven op mensen'.

A committee member with a rather opposing point of view was Willem Karel Dicke, medical director of the Juliana Children's Hospital in The Hague and later professor in paediatrics at the University of Utrecht.[277] Dicke felt that the committee painted a much too rosy picture of medicine's past in comparison to its present.[278] It was important for medicine to move forward, said the paediatrician, and the committee had to ensure that its final advice would not in any way provide ammunition to the guns of 'those who sought to ban medical experiments from society'. It should not come to pass, Dicke exclaimed during one meeting, that modern biomedical science becomes halted 'like the man who buried his talents in order for nothing evil to happen'.[279] If anything, the patient was in debt to past experimental research and had a moral obligation to contribute to the progress of medical science.[280] Dicke did admit however that there existed experimental studies for which he would not lend his children, but this was an emotional argument he considered to be irrelevant for the discussion. What mattered was how the Dutch medical profession would take action against the excesses that took place in the Netherlands, not discuss cases of unethical conduct in the United States or Nazi Germany.[281] The paediatrician strongly felt that as long as human experimentation did not pose a medico-ethical problem on Dutch soil, the Health Council should be very restrained in restricting biomedical research.[282] During the discussions of the final wording of the advice, Dicke would therefore request many changes which served to minimize a negative evaluation of Dutch medical practice and scientific research.

One member that was particularly influential in establishing the structure of the Health Council advice, was Samuel Elsevier de Jongh. De Jongh had become professor in pharmacology at the University of Leiden in 1952 and would take up the position as Head of that same university in 1957.[283] In addition, he was an advisor of the State Defence Organisation (RVO-TNO) and the Dutch

[277] F.Th. van Genderen, 'In Memoriam Prof. Dr. W.K. Dicke', in *Nederlands Tijdschrift voor Geneeskunde* Vol. 106 (1962), p. 1108.
[278] NL-HaNA, Gezondheidsraad, 1920-1956, 2.15.33, Inv.nr. 548, Not. comm. proeven op mensen, 23 December 1954, p. 13.
[279] Ibidem, 14 December 1953, p. 4.
[280] Ibidem, 5 Maart 1955, p. 7.
[281] Ibidem, 23 December 1954, p. 17.
[282] Ibidem, 14 December 1953, p. 4.
[283] P.J. Gaillard, 'Levensbericht S.E. De Jongh', in *Jaarboek Huygens Institute – Royal Netherlands Academy of Arts and Sciences* (1976), pp. 200-202; E.L. Noach, 'In memoriam Prof.Dr. S.E. de Jongh', in *Nederlands Tijdschrift voor Geneeskunde* Vol. 120 (1976), pp. 1226-1228.

pharmaceutical company Organon. As a man who spent most of his days in the laboratory, De Jongh was highly sensitive to the accusations made by the AVS and severely opposed the idea that unlawful human experimentation was the only logical outcome of the institutionalized practice of animal vivisection. Instead, the pharmacologist was convinced that as many biomedical experiments as possible should make use of animal subjects and as few as possible upon human subjects. At the pharmacologist's request, Brutel added this prerequisite to the advice.[284]

Notably, simultaneous to his involvement in the committee 'tests upon human beings', De Jongh was also a member of the Health Council committee on vivisection, installed in 1953 to evaluate the frequency of the practice in the Netherlands (see chapter 3).[285] The pharmacologist caused a disturbance in that committee when he decided to leave the conference room during the first meeting after he had found out that the antivivisectionist Willem Groen was also present.[286] De Jongh did so, because he refused to have any contact whatsoever with the AVS. He considered the Foundation to be a scandalous organization, guilty of smear campaigns against the Dutch medical profession.[287] After that first meeting therefore, deputy chairman Brutel asked the AVS to retreat from the Health Council and allowed the pharmacologist to retake his position.[288] This affair became significant in 1956, when Groen decided to review the *Guidelines* for the monthly journal of the AVS. The fact that his opponent De Jongh had been a member of the committee 'tests upon human beings' illustrated for Groen that the *Guidelines* were drawn-up in a fashion typical for the established Dutch medical profession: i.e. behind closed doors and blind to any reasonable criticism uttered by non-medical professionals (see below).

A fourth influential committee member was the internist Job Pannekoek.[289] Also Pannekoek was a well respected member of the post-war Dutch medical

[284] Ibidem, 11 Maart 1954, p. 9; J. Wester, 'Advies van de Voorzitter van der Gezondheidsraad d.d. 10 oktober 1955', p. 5.

[285] Rigter, *Met raad en daad*, p. 136, 261; NL-HaNA, Gezondheidsraad, 1920-1956, 2.15.33, Inv.nr. 546, Commissie inzake Vivisectie.

[286] NL-HaNA, Gezondheidsraad, 1920-1956, 2.15.33, Inv.nr. 546, 'Notulen van de vergadering van de commissie inzake vivisectie, gehouden op 13 October 1953 des namiddags te 2 uur in het gebouw van de gezondheidsraad te 's-Gravenhage', p. 4.

[287] Ibidem, p. 4.

[288] Ibidem, 'letter of J.J. Brutel de la Rivière aan de heer W. Groen, 'No.53 Betreffende: vivisectie', 20 October 1953'; 'letter of J.J. Brutel de la Rivière aan Mevrouw Mr. M. Stuart, 19 October 1953'. See also: Rigter, *Met raad en daad*, p. 313.

[289] J.B. Scholten, 'J.H. Pannekoek 50 jaar arts', in *Nederlands Tijdschrift voor Geneeskunde* Vol.123 (1979), pp. 1359-1360.

community. During the Second World War, he had been one of two medical practitioners to start a massive and successful resistance of the Dutch medical profession against the corrupted central committee of the (K)NMG.[290] In 1946, Pannekoek was promoted to 'internist physician-director' of the Sint Geertruiden Hospital in Deventer.[291] During the fifth committee meeting, the internist brought up a dilemma to which the Health Council members came to attribute 'cardinal importance': i.e. were medical practitioners and researchers allowed to victimise a few in order to save the many? Personally, Pannekoek could answer this question in the affirmative.[292] When the Health Council discussed the use of narcotics for example, the internist argued that while patients in general experienced more negative side effects from modern narcotics than from traditional aether narcotics, the use of modern narcotics was justified because they were more effective, therefore allowed safer surgeries on more individuals and thus contributed to an overall decreasing mortality rate.[293] The internist's opinions carried weight and became the subject of many a discussion in the Health Council.

The fifth committee member was statistician and supporter of social medicine M.G. Neurdenburg. Neurdenburg was a man of a different professional calibre than the other Health Council members.[294] He did not occupy honorary positions such as men like Brutel or De Langen and, in theory, his role in the Health Council was only to function as substitute for Superintendent Banning.[295] Nevertheless, Neurdenburg played in important role in steering the discussions on human experimentation, in particular towards a general acknowledgement of the fact that 'scientific soundness' is an essential prerequisite of ethical experimental research to take place. With his background as statistician, Neurdenburg had a thorough understanding of research mechanisms. He therefore frequently complained that much of what had come to pass as so-called 'biomedical research' in recent years were actually scientifically flawed studies of physicians who did

[290] NB. The medical organization had agreed in 1941 to accept a member of the *National Socialistic Movement* (NSB) in its midst. Trans.: Nationaal Socialistische Beweging. In: Van Lieburg, 'Vergeten Helden'.

[291] Scholten, 'J.H Pannekoek', p. 1359.

[292] NL-HaNA, Gezondheidsraad, 1920-1956, 2.15.33, Inv.nr. 548, Not. comm. proeven op mensen, 23 December 1954, p. 6, p. 7.

[293] Ibidem, 23 December 1954, p. 7.

[294] There is no bibliography of Neurdenburg available, but NTvG contains an extensive review of his dissertation 'Cause of Death and Statistics': H.J. Coert, 'Dr. M.G. Neurdenburg, *Doodsoorzaak en Statistiek*, uitg. H.J. Paris, Amsterdam, 1929. Prijs: f 7.50' in *Nederlandsch Tijdschrift voor Geneeskunde* Vol. 74 (1930), pp. 2544-2548.

[295] J. Wester, 'Advies van de Voorzitter van der Gezondheidsraad d.d. 10 oktober 1955', p. 2.

not possess the skills to conduct serious scientific work.[296] Such studies had no value for the progress of science, argued the statistician, which meant that research subjects were needlessly subjected to risks. What was important therefore was that physicians were encouraged to develop better research plans before starting any clinical study.[297] If the 'cerebral phase' of a research plan would acquire the same stature as the 'manual phase', Neurdenburg believed that many of the current ethical problems with human experimentation would be alleviated.[298] In his opinion, this could only be achieved however by establishing a national and permanent advisory committee that could assist individual researchers in creating scientifically sound research plans (see below).

The looming presence of the Anti-Vivisection Foundation

From the outset, the looming presence of the Dutch antivivisectionist movement proved to be of significant influence on the course of the discussions which took place in the Health Council. During the second committee meeting, Dicke asked Van Luijt what the exact reason had been of the State Secretary of Health to ask for an official advice on the ethics of human experimentation. It was then that the members learned of the accusations made by the AVS.[299] The physicians present instantly became very cautious. Even De Langen, who was a fervent proponent of the promulgation of strict guidelines, immediately responded that this meant that the final text should be edited in such a way that it could not in any way be misused by the Dutch antivivisectionist movement. The committee had to carefully consider, the internist put forward, which provisions towards human experimentation it was willing to defend in public and which discussions had to remain absolutely confidential.[300] A number of backstage deliberations were not to be repeated in front of a public audience.

To this end, the committee members repeatedly emphasized that each of their discussions had to remain absolutely confidential. When it was for example decided to cancel some sentences from the concept version of the advice that were

[296] NL-HaNA, Gezondheidsraad, 1920-1956, 2.15.33, Inv.nr. 548, Not. comm. proeven op mensen, 23 December 1954, pp. 1-2.
[297] Ibidem, 27 Januari 1955, p. 17.
[298] See: J. Wester, 'Advies van de Voorzitter van der Gezondheidsraad d.d. 10 oktober 1955', p. 4.
[299] NL-HaNA, Gezondheidsraad, 1920-1956, 2.15.33, Inv.nr. 548, Not. comm. proeven op mensen, 9 Februari 1954, p. 7.
[300] Ibidem, 9 Februari 1954, p. 7.

considered to be too explicit in its condemnation of certain medical practices, the members were asked to burn the original pages in their possession.[301] One of the members even suggested to only sent a strictly confidential explanatory note to the Minister in order to ensure that the lay press would not in any way come to write about the Health Council's deliberations.[302] This was an extreme point of view however, since most members felt that such secrecy would take away any purpose in formulating guidelines for clinical research. The request was therefore ignored, but Brutel did promise that the Health Council would act with utmost caution in approaching the lay public.[303]

This secretive behaviour is also illustrated by a correspondence between Van Luijt and Floor Wibaut (see chapter 3). Wibaut had written a personal reflection on the practice of human experimentation in 1949, but never got around to publishing it, because the MC's editor-in-chief had convinced him that the subject matter was unfit for public discussion during such 'times of turmoil'. With 'turmoil' the editor-in-chief meant the debate over a professorial chair in vivisection-free medicine (see chapter 3).[304] In 1953 however, Van Luijt requested Wibaut to use his unpublished article for the committee 'tests upon human beings' as reading material for the committee members and asked why he had never gotten around to publish it. In a letter to the Health Council's President, Wibaut explained his reasons, but also wrote that the recent turn of events had made him feel encouraged to publish the article after all.[305] Van Luijt quickly responded however that Wibaut should seriously reconsider this new initiative. This was not the time to discuss the ethics of human experimentation publicly.[306]

The Health Council shared this attitude with the rest of the organized Dutch medical profession. In 1953 for example, De Langen had co-written a short reflection paper on clinical research for the central committee of the KNMG.[307]

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[301] Ibidem, 5 April 1955, p. 21.
[302] Ibidem, 5 Maart 1955, p. 14.
[303] Ibidem, 5 Maart 1955, p. 14.
[304] NL-HaNA, Gezondheidsraad, 1920-1956, 2.15.33, Inv.nr. 549, letter of F. Wibaut to P.A. van Luijt', 11 February 1954. MC's editor-in-chief was G.C. Heringa, the man who wrote in 1950 that the establishment of a chair in vivisection-free medicine would entail an experiment of 'massive gruesomeness' that far surpassed any human or animal vivisection (see chapter 3).
[305] Ibidem, letter of F. Wibaut to P.A. van Luijt', 11 February 1954.
[306] Ibidem, letter of P.A. van Luijt to F. Wibaut, 27 February 1954.
[307] This 'report' was sent in translation to the WMA as preparation for the 1954 *Principles for those in Research and Experimentation* (see chapter 2)NL-HaNA, Gezondheidsraad, 1920-1956, 2.15.33, Inv.nr. 549, 'Rapport, uitgebracht door Dr. R.J. Hamburger en Prof. Dr. C.D. de Langen inzake experimenten op mensen, aan het Hoofdbestuur der Maatschappij', 11 April

When Van Luijt requested the document for use in the Health Council, he had to solemnly promise the KNMG to reveal nothing from the report's content in its final advice, before he could have access to the document.[308] The content of the report itself however was anything but spectacular.[309] It was only a two-page letter sent in 1953 to the WMA in order to submit three points of discussion for the international debate on human experimentation.[310] Arguably, its most significant provision was that the Dutch medical profession did not ascribe much value to the idea of 'informed patient consent'. This was something that the Dutch medical profession was willing to defend publicly however and would in fact become the core principle of the 1955 *Guidelines*, which were published for a wide audience to read (see below). Yet, the fear that the ethics of human experimentation would become subject to public discussion before the organized medical profession was ready to make a well thought-through statement about it, appears to have predominated. The KNMG and the Health Council first wanted to carefully deliberate upon the wording in which they would convey their point of view to the outside world in order to prevent an organization like the AVS to use their public statement in an unintended manner.

For the same reason, much attention went into formulating the precise wording of the final advice. In particular Dicke repeatedly reminded the other committee members that the reason for their congregation had been accusations made by the AVS. If the Health Council did not emphasize how important the modern biomedical sciences were for the welfare of the entire Dutch population,

1953; Ibidem, Dr. L.A. Hulst to the World Medical Association, 'Experiments on Human Beings', on April 10, 1953.

308 Ibidem, letter of G. Dekker, secretary of the central committee of the KNMG, to J.J. Brutel de la Rivière, debuty president of the Health Council, on 11 December 1953.

309 Ibidem, Dr. L.A. Hulst to the World Medical Association, 'Experiments on Human Beings', on April 10, 1953.

310 Respectively these three points were (1) only experiments should be permitted on human beings in which the research worker is convinced, from reasonable evidence, that the results for the patient as to the nature and the duration of the experiment are controllable, (2) the responsibility of the research worker who experiments on human beings, and not the willingness of the person submitting to the experiment is primary, (3) except in degree, no principal difference exists between individuals who submit to experiments voluntarily and those who submit compulsively. In addition, the Nazi concentration camp experiments were explicitly condemned as criminal acts and the report emphasized that, as far as the Netherlands was concerned, the WMA should request editors of medical journals to refuse publication of articles of which the research data had been obtained in an unethical manner. The latter provision was later accepted by the WMA. In: Ibidem, p. 2. See also: Susan E. Lederer, 'Research Without Borders: The Origins of the Declaration of Helsinki', in Frewer & Schmidt, *History and Theory of Human Experimentation*, pp. 145-164.

the paediatrician put forward, the antivivisectionists might gain a stronghold in the academy by convincing the Dutch lay public that human experimentation had gotten out of hand.[311] According to Dicke, the medical profession had to claim the right to undertake experimental procedures. They had to insist upon it for the good of mankind.[312] Significant changes were therefore made to the concept versions of the *Guidelines*. Words like 'many' [dangerous interventions] were changed into 'some', terms like 'often' into 'sometimes'.[313] Or, where one of the concept versions contained the sentence 'if the doctor uses his patient [unwittingly] for a different goal [than recovering his health], the doctor violates his position of trust', this sentence was deleted after Dicke made critical comments about it.[314] In addition, to ensure that it was clear to those reading the advice that the Health Council did not in any way criticize the modern research laboratory, the final advice included segments such as:

> The natural scientific methods have, in particular during the last 50 years, been accepted as responsible. Their value for science and humanity has been proven. They need no defence and the committee only needs to verify whether their application has led in exceptional cases to irresponsible actions and declare the means to combat these excesses.[315]

Neither this rhetorical boundary-work nor the deployed secrecy by the KNMG and the Health Council was very effective however. It did at least not silence the AVS in any way. On the contrary, when Willem Groen wrote a review of the *Guidelines* in 1956, the secretive behaviour of the Dutch medical establishment was the first thing he noted. According to Groen, it actually proved that even the most fervent proponents of the research laboratory knew that the practice was, in reality, morally dubious:

> This strict confidentiality is such a pity! We would have very much liked to examine the KNMG report. It undoubtedly contains interesting information

[311] NL-HaNA, Gezondheidsraad, 1920-1956, 2.15.33, Inv.nr. 548, Not. comm. proeven op mensen, 27 Januari 1955, p. 2.
[312] Ibidem, 27 Januari 1955, p. 5.
[313] Ibidem, 22 September 1955, p. 3; See also: NL-HaNA, Gezondheidsraad, 1920-1956, 2.15.33, Inv.nr. 549, 'No.15 Betreffende: Proeven op Mensen, Concept', June 1955.
[314] Ibidem, 27 Januari 1955, p. 8.
[315] J. Wester, 'Advies van de Voorzitter van der Gezondheidsraad d.d. 10 oktober 1955', p. 5.

> and I just cannot shake the idea that it contains material which confirms the accusations made publicly by us in 1953 [i.e. the accusations against Botter and Brutel].[316]

To further substantiate this claim, Groen pointed to the fact that Samuel de Jongh had been a member of the committee 'tests upon human beings'. In his article Groen put forward that the pharmacologist regularly displayed suspicious behaviour when it came to public discussion of human experimentation. Recently, the pharmacologist had for example been asked to give a lecture on the subject matter to the members of the Leiden student association *Catena* on 13 May 1955. During the day of the event however, De Jongh had learned that members of the AVS would be present to hear what he had to say about human experimentation. When he opened his lecture therefore, the pharmacologist started with the announcement that members of the press would be present and that he was not comfortable to talk about such a delicate subject matter in front of outsiders who would only bring the medical profession in a predicament. He therefore changed the subject of his talk to a medical discussion of 'Addiction and Habituation'.[317] Such behaviour proved, according to Groen, that the research-based laboratory contained dark secrets which could not survive the light of day.[318]

What is striking in this regard, is that behind closed doors some Health Council members appear to have actually somewhat agreed with Groen on this particular point. Brutel for example repeatedly put forward during the committee meetings to worry that some of the additions to the concept versions of the final advice as proposed by Dicke would only come to be read by the general public as a pamphlet of a group of people that had something to hide. '*Qui s'excuse s'accuse*', the deputy chairman firmly stated.[319] This worry is also illustrated by a heated discussion the committee held on whether the Health Council should make explicit that academic hospitals were places where experimental tests were frequently conducted. Some members considered such a provision to be extremely dangerous. It would only frighten patients to go to hospitals, they argued, places where they after all received the best possible medical care available in the

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316 Willem Groen, 'Proeven op mensen', in *Mededelingen* Vol. 26 (1956), pp. 106-114, there: p. 110.
317 Ibidem, p. 111-112.
318 Ibidem, p. 112.
319 NL-HaNA, Gezondheidsraad, 1920-1956, 2.15.33, Inv.nr. 548, Not. comm. proeven op mensen, 27 Januari 1955, p. 3.

Netherlands.[320] Dicke for example recommended to omit such a section from the committee's final advice and was supported by Neurdenburg who argued that statistics already showed a decrease in hospital visits in the Netherlands, because patients generally feared that they would be used as guinea pigs within these walls.[321] This meant that if the Health Council would acknowledge that the medical profession used human beings like test animals, this would play directly into the hands of the antivivisectionists. However, Brutel for one considered it to be absolutely unworthy of the medical profession not to educate the public about matters like these and protested heavily against the point of view taken by Dicke and Neurdenburg.[322]

It took multiple gatherings for the committee members to come to an agreement. Consensus was only reached when De Jongh proposed to frame the relevant section of the advice in a reassuring tone. The Health Council had a duty to calm the Dutch people, argued the pharmacologist, and the *Guidelines* could fulfil an important function in easing the societal unrest concerning human experimentation.[323] This was an ideal that most committee members could agree with. The final advice therefore read:

> There have been public declarations that the ill are being used as guinea pigs in the Dutch hospitals. […] To combat such erroneous ideas and promote the bond of trust between the patient and the physician, the Committee wants the public to know that tests upon human beings will only be conducted if the most stringent scientific prerequisites have been fulfilled and the norms which are described in this advice are taken into account.[324]

Most committee members were confident that such provisions would enable a higher trust in the medical profession and with that, the *Guidelines* would prevent interventions that were immoral, while at the same time show that the medical profession was capable of regulating itself by establishing a professional code of conduct that was of a high ethical standard.[325]

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[320] Ibidem, 27 Januari 1955, p. 10.
[321] Ibidem, 27 Januari 1955, p. 10.
[322] Ibidem, 27 Januari 1955, pp. 10-11.
[323] Ibidem, 27 Januari 1955, p. 13; Ibidem, 5 Maart 1955, pp. 4-6.
[324] J. Wester, 'Advies van de Voorzitter van der Gezondheidsraad d.d. 10 oktober 1955', p. 7.
[325] NL-HaNA, Gezondheidsraad, 1920-1956, 2.15.33, Inv.nr. 548, Not. comm. proeven op mensen, 5 April 1955, p. 20.

Overall however, the fear of the antivivisectionist stance inspired the renowned representatives of the Dutch medical profession to frame their advice in such a manner that it could suppress any claims about the immoral nature of human experimentation. Nevertheless, while the obsession of the Health Council with the antivivisectionist stance certainly demonstrates that in the promulgation of the *Guidelines* other elements than only the ethics of clinical research played a role, the 1955 medico-ethical document should not be understood as nothing more than a dramaturgical 'prop' which allowed the organized medical profession to protect its standing in Dutch society. Although the antivivisectionist stance was perceived to be a serious threat and took up significant discussion time during the Council's meetings, it was certainly not the only matter the members discussed. If anything, the AVS forced the Dutch medical profession to for the first time systematically think about what an ethic for clinical research should precisely entail and how it might be separate from the ethics of other medical interventions. The Health Council literally had to 'produce' ethics, something which proved to be a difficult undertaking for the committee members. For in order to develop meaningful medico-ethical *principles* to govern human experimentation, they first had to decide what the medico-ethical *problems* of the practice precisely were.

The gradual emergence of the 'description of the problem'

Significantly, the actual guidelines in the eleven-page advice, presented by Wester to the Minister of Social Affairs and Public Health Ko Suurhoff in 1955, only take up about one page.[326] The other ten pages consist of additional explanation of terms used and justification of choices made. Significantly, the first nine pages – after a short introduction into the workings of the committee – carry the title 'description of the problem'. The first lines read:

> The mentioned press releases [by the AVS] in the introduction can give the impression that the words 'tests upon human beings' provide a sufficiently clear description of the subject. This is not the case and the committee will therefore start with an analysis of the subject. This analysis leads to a mission statement, which, as will become clear, includes much more than the expression 'tests upon human beings' superficially includes.[327]

[326] J. Wester, 'Advies van de Voorzitter van der Gezondheidsraad d.d. 10 oktober 1955', pp. 10-11.
[327] Ibidem, pp.2-10, there: p. 2.

The detailed description of biomedical tests following this introductory statement formed the end product of extensive discussion that took place during the first four committee meetings, wherein it became clear that there was no communal agreement between the members of the Health Council upon the definition of a medical experiment.

Partly, this confusion can be explained by the mandate of the committee 'tests upon human beings'. After the condemning *Free People* article of 1953, Muntendam had asked the Health Council to provide him with advice 'on the subject matter', without specifying any additional questions.[328] The subsequent deliberations of the committee could therefore take virtually any form. As a result, it was initially unclear to the committee members what exactly it was that they were supposed to be evaluating. Whereas De Langen wanted to discuss the use of heart catheters and the practice of liver punctures in modern hospitals under the banner of 'whereto is it that we are drifting?', Pannekoek brought forward that withholding treatment could also be an experiment and proposed to confine the discussion to those medical tests that carried a certain risk with them.[329] Whereas Dicke repeatedly emphasized that the whole of modern life was in itself an experiment with new applications such as laundry detergents and insecticides, Van Luijt concluded that although the practice of venipuncture was non-experimental, it was nevertheless far from innocent.[330] Importantly, this range in interpretations cannot be explained away as a lacking understanding of experiments in science on the part of the committee members. Each of them was, after all, a seasoned member of the Dutch medical profession and could relate past experimental studies in which he (or she) had been involved. Their problem lay instead with the *boundaries* of the scientific experiment and the idea that medical research needed a moral treatment separate from traditional medical practice. According to the committee, the medical experiment did not really possess qualities that made it intrinsically different from other modern technologies and scientific practices.

Initially, the committee had differentiated between human experimentation and other medical interventions. During the first meeting for example, Van Luijt had remarked that it might be good to distinguish between therapeutic tests and research work, because the goal of these two practices were arguably different.[331]

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328 Ibidem, p. 2.
329 NL-HaNA, Gezondheidsraad, 1920-1956, 2.15.33, Inv.nr. 548, Not. comm. proeven op mensen, 14 December 1953, p. 2, p. 5.
330 Ibidem, 14 December 1953, pp. 4-5.
331 Ibidem, 14 December 1953, p. 5.

Similarly, other committee members had put forward that in experimentation some unique factors, such as the desire to publish, played a role that required additional reflection.[332] During the subsequent meetings however, the Health Council physicians often interchanged experimental procedures with all sorts of medical interventions which they considered to be either ethically problematic or vitally important for the progress of science. By the fourth meeting, most committee members had come to the conclusion that the advice should also insert a warning against non-specific medical investigations such as routine liver punctures. In particular physicians like De Jongh and De Langen complained that many of this sort of tests had become routine in the last few years while they were often unnecessary to make a proper diagnosis.[333]

The Health Council was thus slowly broadening its mandate. What initially had been a discussion on human experimentation now became a discussion on the overall responsibilities of a medical practitioner in an age where the range of technologically invasive medical interventions was quickly expanding. At the same time however, this increasingly broad definition of 'tests upon human beings' resulted in uneasiness among the committee members. Brutel for one remarked that he found the discussion over diagnostic therapeutic tests to be somewhat peculiar. It was after all not as if the discussed invasive technologies were particularly novel. A test like the liver puncture, for example, had already been in use since 1939. Brutel professed to find it odd that a technology which had been in use for more than fifteen years suddenly came to be discussed as a medico-ethical problem by the Health Council. Are we not only discussing this, the deputy chairman asked the committee, because we now are asked to contemplate upon the subject of biomedical tests?[334] Were the committee members not starting to see medico-ethical problems where first there had been none? The Health Council should carefully consider to what sort of biomedical interventions it wanted to draw attention with its advice, argued Brutel, for the national medical disciplinary tribunal was based on the existing norms of the Dutch medical profession. When the Health Council would publish explicit guidelines on the ethics of tests upon human beings, it would stand to influence those existing norms and therewith influence which sort of medical interventions would remain legally permissible.[335]

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[332] Ibidem, 14 December 1953, p. 6.
[333] Ibidem, 13 April 1954, pp. 2-3.
[334] Ibidem, 13 April 1954, p. 3.
[335] Ibidem, 13 April 1954, pp. 10-11.

Brutel therefore considered it to be of great importance that the committee carefully weighted which boundaries and categorizations it sought to establish and in which format it would convey them to the general public.

After that fourth committee meeting Samuel the Jongh sent a memo to the members of the Health Council, wherein he outlined a principal reflection on the subject of 'medical tests upon human beings'. He did so, he later said, in order to elucidate some of the categorical issues the Health Council had been struggling with.[336] This memo would come to function as the backbone of the final advice. In it, De Jongh outlined how medical tests could be categorized as either therapeutic and diagnostic interventions or experimental researches and practice tests to gain additional experience. While diagnostic and therapeutic interventions were primarily aimed at the well-being of the patient, many routine investigations and interventions from a purely scientific point of view were only of secondary importance.[337] Yet, at the same time, both types of tests were ultimately aimed towards the benefit of the patient and it would be a mistake therefore to evaluate biomedical experiments as having intrinsic qualities which made them different from diagnostic observations (when these included an intervention to take place). On the contrary, De Jongh argued, whether an observation or experiment was ethically permissible was dependent not so much on the *nature* of any medical action, but on the *form* that intervention could take:

> It is not the definition of a problem or the experimental character that determines permissibility, but the intervention. An advantage of this way of reflecting is that the objections that are often heard against various medical actions, which do *not* serve to enrich scientific knowledge (e.g. some cases of diagnostic polypragmasy), have the same roots and can be judged according to the same criteria: i.e. that the intervention is inadequate for the prevailing situation.[338]

Thus, if a medical practitioner wanted to observe the influence of a pregnancy on the heart rate, this was a generally acceptable intervention, because taking one's

[336] Ibidem, 23 December 1954, pp. 3-17. The memo appears not to have been preserved. In the committee notes however, the content of the memo is discussed in great detail. In addition, Brutel de la Rivière successfully suggested to use the memo as the foundation of the first section of the final advice, which can thus be taken as written with De Jongh's memo in mind.
[337] J. Wester, 'Advies van de Voorzitter van der Gezondheidsraad d.d. 10 oktober 1955', pp. 5-6.
[338] Ibidem, p. 4. Italics in original.

pulse can cause no harm. But if the medical practitioner wanted to check whether the glycogen content of the liver is subject to change during a pregnancy, this should always be evaluated as ethically unacceptable, because the intervention required the patient to die for the measurement to take place.[339] Similarly, if the medical researcher wanted to investigate how the eye pupil responds to a small bundle of light, this was always ethically acceptable, because it caused no harm to the patient. However, if the researcher wanted to measure the influence of a one year protein-free diet on the human body, this was never ethically permissible.[340] The intensity of the intervention was the medico-ethical problem at stake, not the autonomy of the patient.

The responsibilities of both practitioner and patient in a modern society

This focus on the severity of medical interventions as opposed to the nature of medical tests proved to be defining in establishing the responsibilities of medical experimenters towards their patients and research subjects. When the committee had for example come to discuss the notion of *informed consent*, members like Brutel had expressed uneasiness over the fact that patients who went to the hospital confident to receive treatment could be used in non-beneficial scientific experiments without given their explicit permission. According to the deputy chairman, this was in conflict with any existing ideals and traditions of the medical profession.[341]

By equating medical experiments to diagnostic interventions however, the Health Council could maintain that the responsibility of the medical practitioner, not the willingness of the patient, was of primary importance for the ethical permissibility of medical interventions. The final advice for example read:

> Being aware of the fact that the physician is performing medical experiments is not self-evident when the patient has allowed himself to be medically treated by that doctor. In those cases, the patient has gone to the physician in order for everything that is beneficial for his recovery will be done. The Committee is of the opinion that the bond of trust between patient

[339] Ibidem, p. 3.
[340] Ibidem, p. 4.
[341] NL-HaNA, Gezondheidsraad, 1920-1956, 2.15.33, Inv.nr. 548, Not. comm. proeven op mensen, 23 December 1954, p. 8.

> and practitioner is not violated, when the physician, without actually asking permission, conducts additional interventions which serve to increase scientific knowledge or practical experience, as long as these interventions do not cause harm or delay recovery.[342]

This section was inspired by the idea that it was the physician who was ultimately responsible for the consequences of any medical intervention (irrespective of whether it was diagnostic, therapeutic or experimental) and that this responsibility could never be transferred to the patient. The majority of the committee was of the opinion that it was the medical practitioner who needed to decide whether the medical intervention in mind was *in degree* reasonably safe and therewith ethically permissible or not.[343] Committee members like Neurdenburg argued that patient *consent* would just come to function as a waiver of responsibility for the practitioner eager to conduct scientific research. In addition, the statistician put forward that the notion of *informed* consent was a practical impossibility. Patients simply did not possess sufficient scientific knowledge to understand the nature or implications of any biomedical intervention.[344] Similarly, other committee members argued that asking consent was ethically undesirable because if the intervention went wrong, the patient or the patient's family would endlessly blame itself for having given consent.[345] In the promulgation of the *Guidelines for Tests upon Human Beings*, the committee should therefore focus on the consciousness of the practitioner, not that of the patient.[346] Hence, it is unsurprising that the first principle of the *Guidelines* stated that 'the responsibility of the researcher, not the willingness of the participant is primary in experiments on human beings'.[347]

At the same time, it is fair to note however that the final *Guidelines* are somewhat ambiguous in this absolute responsibility of the medical practitioner over the consent of the informed patient. The final document for example also reads, that in case when risk, or 'more than normal' pain and inconvenience are expected to accompany the intervention, the experiment could take place if the patient gave consent:

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342 J. Wester, 'Advies van de Voorzitter van der Gezondheidsraad d.d. 10 oktober 1955, p. 7.
343 NL-HaNA, Gezondheidsraad, 1920-1956, 2.15.33, Inv.nr. 548, Not. comm. proeven op mensen, 13 April 1954, pp. 5-6.
344 Ibidem, 23 December 1954, pp. 9-10.
345 Ibidem, 23 December 1954, p. 10.
346 Ibidem, 23 December 1954, p. 10.
347 J. Wester, 'Advies van de Voorzitter van der Gezondheidsraad d.d. 10 oktober 1955, p. 10.

> The Committee is of the opinion that the right of an individual, who exposes himself to risk for a cause that he considers to be worthy, has to be recognized and the Committee finds that the researcher is principally entitled to make use of this state of mind. Whether this entitlement goes as far to allow a human being to risk his health, his validity or even his life, is a moral question from which the Committee refrains any value judgement.[348]

This addendum is significant, given the fact that most Health Council members were of the opinion that lay people were not capable of understanding the dangers of medical interventions. This incapacity only applied apparently to cases wherein the patient could refuse interventions the medical practitioner or researcher considered necessary.[349] In addition, in convincing the rest of the Health Council of the importance of this provision, Dicke argued that also in the other sciences pioneers had willingly exposed themselves to dangers in order to further science. He reminded the Health Council of those who had tried out fighter jets or developed the nuclear bomb. These were heroic and altruistic acts which should not be withheld from medical science.[350]

In general however, the Health Council came to the conclusion that the responsibilities of the medical practitioner towards his patient were absolute and final. Nevertheless, the members of the committee 'tests upon human beings' also felt that patients carried similar responsibilities, not only towards their own well-being, but also towards the progress of science which would eventually alleviate the suffering of future patients. Particularly Dicke was convinced that patients were morally in debt to the medical profession, which had brought so much relief to modern society. Most other committee members seemed to agree with the paediatrician. Only Neurdenberg professed that Dicke's words reminded him of the medical deeds which had come to pass in Nazi Germany.[351] In contrast, both Wester and De Jongh openly expressed sympathy with the paediatrician's point of view. They only felt that the wording 'moral obligation' should preferably not be used in the advice, given the fact that the lay public would also come to read it.[352]

[348] Ibidem, p. 8.
[349] Only the psychiatrist Van der Horst had expressed uneasiness over this addendum during the committee meetings, but his concern focussed on the possibility that it might be suicidal individuals who would volunteer for risky research studies. NL-HaNA, Gezondheidsraad, 1920-1956, 2.15.33, Inv.nr. 548, Not. comm. proeven op mensen, 5 April 1955, pp. 12-13.
[350] Ibidem, 5 April 1955, pp 7-8, p. 13.
[351] Ibidem, 5 April 1955, p. 7.
[352] Ibidem, 5 April 1955, p. 8.

To this end, Pannekoek proposed that the committee added a section to the final advice which emphasized that a patient who was admitted to a hospital highly profited from the medical experiences which had been gained from former patients. This would allow the Health Council to avoid the word 'duty', but nevertheless remind the public of one of the primary functions of hospitals.[353] The rest of the committee agreed. Also Neurdenberg acknowledged that in some ways the hospital patient could be compared to a prisoner: i.e. he could only be helped under certain pressure.[354] The final advice therefore read:

> The committee feels obliged to point out that the patient admitted in the hospital profits significantly from experiences the physician has gained from past patients. The public knows that hospitals do not only exist to nurse and treat the sick, but also to increase scientific knowledge.[355]

Similarly, the patient was envisioned by the Health Council to carry a responsibility to the society in which he participated. The majority of the committee felt that those who were willing to volunteer for medical experiments served society in similar ways as the soldier who was asked to fight for the greater good of his nation.[356] The members agreed that in this modern day and age the Hippocratic Oath of 'do not harm' was no longer fully applicable, meaning that with the growth of the modern state the responsibilities of the medical profession lay no longer so much with individual patients, but with the sick of society in general.[357] This meant that practitioners had responsibilities to patients, but patients also to practitioners.

Professional identity and the growing need for medical expertise

In debating the role of the individual patient towards his society, the Health Council sometimes came unsettlingly close to the utilitarian attitude deployed by the Nazi physicians in their defence of the concentration camp experiments during the Nuremberg Doctors' Trial (see chapter 2). During the fifth committee meeting

[353] Ibidem, 5 April 1955, p. 8.
[354] Ibidem, 23 December 1954, p. 10.
[355] J. Wester, 'Advies van de Voorzitter van der Gezondheidsraad d.d. 10 oktober 1955', p. 7.
[356] Ibidem, p. 9.
[357] NL-HaNA, Gezondheidsraad, 1920-1956, 2.15.33, Inv.nr. 548, Not. comm. proeven op mensen, 11 Maart 1954, pp. 2-3.

for example, when the discussion turned to the earlier mentioned dilemma of internist Pannekoek, the committee came to discuss what it was that the medical profession ultimately had to serve in this modern day an age: the community or the individual.[358] Dicke in particular was of the opinion that the differentiation between individual and communal interests was useless in modern states. Individuals simply needed to accept that the existence of risks had become part of the reality of everyday life in such complex societies. The individual who used a car for example was always in danger of getting killed in a road accident, but that did not mean that he should therefore abstain from societal participation in 'these modern times'. According to Dicke, the same rule of thumb applied for going to a hospital or participating in research experiments.[359] Some committee members agreed. Even the psychiatrist Van der Horst felt that life in a modern society had become 'group-minded' rather than 'individual-minded'.[360] Some physicians in the Health Council also strongly disagreed however with this utilitarian philosophy. De Langen for example fervently argued that there existed a crucial difference between the conscious acceptance of risk when riding a car and unconsciously being experimented upon when being admitted to a hospital. For him the doctor-patient relationship necessarily had to remain of an individual nature.[361]

As a solution to this dilemma, De Jongh proposed to separate the function of the treating physician from that of the medical researcher. He acknowledged that a medical practitioner could be tempted to conduct some useful experiments while he was treating a patient, which might blur his primary responsibilities and therewith endanger the safety of that patient.[362] The Health Council should therefore propose that in such cases the physician was required to consult a second doctor. If the latter would give consent, the treating physician could proceed with his experiments. Consent of the patient then remained unnecessary. This distinction is significant, given the fact that the Health Council had earlier come to the conclusion that no principle difference existed between diagnostic, therapeutic and experimental interventions. It now seemed to put forward that one could differentiate the so-called 'practising clinician' from the 'biomedical researcher'. This incongruence was noticed by Pannekoek, who argued that the concept of the 'treating doctor' [i.e. clinician] was internally ambiguous. Did this category for

[358] Ibidem, 23 December 1954, p. 12.
[359] Ibidem, 23 December 1954, p. 13.
[360] Ibidem, 23 December 1954, p. 12.
[361] Ibidem, 23 December 1954, p. 13.
[362] Ibidem, 23 December 1954, p. 13.

example include the professor who taught his students in the university hospitals? And if that was the case, did this mean that the university professor would no longer be allowed to conduct experimental tests? And in turn, did that not simply mean that the university would lose one of its core functions: i.e. furthering science by means of biomedical research?[363] Eventually the committee came to the conclusion that it was not so much a physician's professional identity which was essential in asserting whether certain experiments were ethically permissible, but the number of physicians making that decision. What was important, according to the majority of the Health Council, was that medical practitioners no longer individually decided whether experiments upon humans were ethically just.[364] This also solved Pannekoek's dilemma, for in university hospitals generally more than one physician resided at the bedside of a patient.[365]

The discussion over the professional identity of the medical practitioner points to one of the core medico-ethical problems the Health Council envisioned to be tackling with its promulgation of the *Guidelines for Tests upon Human Beings*. With the advancing of scientific knowledge and the increase in technological possibilities, the committee was convinced that specific professional expertise increasingly became a necessary prerequisite to conduct morally responsible experiments upon human beings. In other words, the progress of medical science forced the medical profession to differentiate not so much between clinicians and researchers, but between general practitioners and medical specialists. This is illustrated for example by De Langen, who argued that general practitioners and clinicians often unrighteously played the part of physiologist or pharmacologist.[366] In addition, he felt that the general assessment skills of physicians were slipping. The internist found it highly worrying that laparoscopies and gastroscopies – interventions that used to be taught on animals or corpses – were now generally practised directly on living human beings.[367] Brutel agreed. The deputy chairman also felt that a certain change in mentality had taken place among his colleagues. Cases which were considered to be ethically doubtful in the past, were no longer experienced to be in any way problematic in the present.[368]

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[363] Ibidem, 5 Maart 1955, p. 9.
[364] J. Wester, 'Advies van de Voorzitter van der Gezondheidsraad d.d. 10 oktober 1955', p. 9.
[365] NL-HaNA, Gezondheidsraad, 1920-1956, 2.15.33, Inv.nr. 548, Not. comm. proeven op mensen, 5 Maart 1955, p. 9.
[366] Ibidem, 11 Maart 1954, p. 11.
[367] Ibidem, 23 December 1954, p. 4.
[368] Ibidem, 23 December 1954, p. 4.

According to De Jongh, this change of mentality was caused by the strict separation which existed in the Netherlands between the clinic and the laboratory. This made it impossible for the general practitioner to practice his medical skills on laboratory animals, which not only had the result that he did not have the proper expertise to responsibly undertake tests upon human beings, but also made him lack a fundamental understanding of the moral risks scientific experiments harboured. A possible solution was therefore to establish a better functional relationship between clinical hospitals and physiological and pharmaceutical laboratories.[369] However, the growing need for specialised expertise also meant that the general practitioner needed to lean more on the shoulders of the medical specialist.[370] With the increasing specialization and technological possibilities of modern science, not every medical practitioner remained equipped to bear this responsibility. In its final advice, the committee therefore stated the following (and significantly, still under 'description of the problem'):

> Medical literature has shown that the number of cases, wherein human beings have been the object of research for other purposes than his recovery, are increasing and the modern methods and means, which medicine has at its disposal, have significantly enlarged the risk of these investigations […] Tests upon human beings may therefore only be conducted by physicians with special expertise concerning the issues at hand, or under their immediate supervision.[371]

In the eyes of the Health Council, certain boundaries thus needed to be established within the medical profession itself. For the majority of the committee members, specialized medical expertise had become a necessity to responsibly conduct a number of medical interventions.

If the lack of medical expertise was one of the core medico-ethical problems of tests upon human beings, the moral solution was to better educate young physicians. The Health Council therefore envisioned an essential role of Dutch medical faculties to ensure that the next generation of physicians would be capable of knowing when to intervene and when to withhold from undertaking invasive biomedical tests. Notably however, the committee did not think that

[369] Ibidem, 23 December 1954, p. 4.
[370] Ibidem, 23 December 1954, p. 5.
[371] J. Wester, 'Advies van de Voorzitter van der Gezondheidsraad d.d. 10 oktober 1955', pp. 9-10.

better education only meant more and earlier specialization. On the contrary, the committee acknowledged that there was a danger for aspiring medical doctors to become morally diluted as a result of technological modernization and scientific specialization.[372] Some members felt that whereas there used to exist an absolute ethic in the Dutch medical profession which governed the sacred doctor-patient relationship, now every practitioner simply seemed to make up his own rules. In their opinion, especially young medical assistants went ahead with invasive medical interventions without any reflection whatsoever on whether these tests were ethically justified or not.[373] The committee members therefore agreed with one another that it was essential to properly educate medical students not only on the details of human physiology and anatomy, but also on the particular ethics of medicine, on the proper doctor-patient relationship and on the importance of bedside intuition as opposed to extreme reductionistic thinking of the natural sciences. Perhaps surprisingly, this means that backstage the representatives of the Dutch medical profession came to similar conclusions as the Dutch antivivisectionists: both groups felt that the modern laboratory sciences hardened the senses of young medical practitioners, who, as a result, increasingly failed to grasp the virtues of the holistic bedside understanding of traditional medical practitioners (see chapter 3). It also indicates that the two culturally opposed social organisations in practice had rather similar ideas of how to oppose this intellectual trend: i.e. by installing checks and balances in the Dutch academy which would ensure that good doctors were first of all good people.[374]

Secondly, apart from revision of the medical curricula of Dutch universities, the committee 'tests upon human beings' also wanted the Dutch government to install a permanent advisory committee which could help individual physicians and biomedical researchers in checking whether their research plans were scientifically sound. In particular the statistician Neurdenburg was convinced that proper scientific advice of seasoned medical experts would alleviate many of the potential ethical problems that could arise in conducting experiments upon human beings.[375] It is this provision in the *Guidelines* that has

[372] NL-HaNA, Gezondheidsraad, 1920-1956, 2.15.33, Inv.nr. 548, Not. comm. proeven op mensen, 23 December 1954, pp. 8-13.
[373] Ibidem, 23 December 1954, p. 11.
[374] The Dutch antivivisectionist movement envisioned to do so by installing a professorial chair in vivisection free medicine, the committee 'tests upon human beings' by ensuring that medical students received medico-ethical education.
[375] J. Wester, 'Advies van de Voorzitter van der Gezondheidsraad d.d. 10 oktober 1955', p. 8, p. 11, p. 12.

probably led historians such as Robert Baker and Ulrich Tröhler to argue that the Netherlands was one of the first countries to establish IRBs. As far as historical evidence shows however, there was never any permanent advisory committee installed by the Dutch government. There are at least no documents to be found in any of the national archives that indicate that Minister Suurhoff even deliberated upon establishing such a council. In 1986, when Lucas Bergkamp (see chapter 2) wrote about the establishment of IRBs in the Netherlands, he concluded that the first such committee was only installed in 1970 at the Free University of Amsterdam.[376] It is therefore implausible that the Health Council was successful in this particular aim. What is certain however, is that it never sought to establish *local* research committees, as suggested by Baker (see chapter 2). Instead, it aimed to install a national council similar to the Medical Research Council (MRC) in Great Britain, but probably never succeeded.[377]

A reason for this failure might be that in particular the KNMG was not particularly enthusiastic about the idea.[378] In 1955, the Health Council had requested the medical organization to publish the final advice of the committee 'tests upon human beings' on the pages of MC. It did so, because it wanted to ensure that every medical practitioner in the Netherlands would learn of the *Guidelines* and implement them in their daily medical practice.[379] On 23 February 1956 however, secretary Dekker responded on behalf of the central committee that the KNMG 'did not agree with the suggestion that a national advisory committee is established to provide advice on matters of human experimentation'.[380] In addition, 'the KNMG would like the Health Council to insert into the advice that medical research remains the ultimate responsibility of the individual researcher, even when the researcher has asked such a committee for advice'.[381] It took two

[376] Lucas Bergkamp, 'American IRBs and Dutch Research Ethics Committees: How They Compare', in *IRB: Ethics and Human Research* Vol. 10 (Sep.-Oct., 1988), pp. 1-6.

[377] NL-HaNA, Gezondheidsraad, 1920-1956, 2.15.33, Inv.nr. 548, Not. comm. proeven op mensen, 9 Februari 1954, p. 6.

[378] NL-HaNA, Gezondheidsraad, 1920-1956, 2.15.33, Inv.nr. 549, letter of Health Council President J. Wester to the central committee of the KNMG, 23 December 1955.

[379] NB. In particular Brutel de la Rivière found it important that the *Guidelines for Tests upon Human Beings* reached as wide an audience as possible. This is noteworthy in comparison to his response to Bakker in 1949 when the homoeopath requested the then President of the Health Council to publish information about the content of the Health Council's advice on the establishment of a professorial chair in vivisection-free medicine (see chapter 3).

[380] NL-HaNA, Gezondheidsraad, 1920-1956, 2.15.33, Inv.nr. 549, letter of G. Dekker, on behalf of the central committee of the KNMG to Health Council President J Wester, 23 February 1956.

[381] Ibidem.

months for President Wester to respond. According to him, the *Guidelines* primarily aimed to promote medico-ethical norms and values that were accepted by the Dutch medical profession in general, a task to which a permanent advisory committee could only contribute positively. Wester therefore felt that the establishment of such a committee remained a good idea.[382] In late April 1956, Dekker wrote his reply. The KNMG's central committee had agreed to publish the *Guidelines* in MC, but only with the accompanying remark that an advisory committee would principally be useful for judicial courts, but not for individual biomedical researchers. Their autonomy had to be secured.[383] The advice was publish in MC on 31 May 1956.[384]

The actual legacy of the Nuremberg Code

So, did the Health Council committee in any way incorporate the 1947 Nuremberg Code into the 1955 *Guidelines for Tests upon Human Beings*? The answer to this question is short and simple: No. The Code was never once mentioned during any of the committee meetings and already during the first meeting, President Van Luijt stated that the Nazi concentration camp experiments needed no discussion by the Health Council, because they had little to do with the matters the committee needed to contemplate upon.[385]

Admittedly, this might have been different when other physicians had come to take place in the committee 'tests upon human beings'. In this regard, it is significant to point out, for example, that Van Luijt had asked some other medical professionals in 1953 to take place in the committee, who had to refuse the position because they were otherwise engaged. In this context, one important physician who had to decline a seat in the committee 'tests upon human beings' was Elie Aron Cohen, survivor of the Auschwitz concentration camp and author of the famous 1952 best-selling dissertation *The German concentration camp* (and later books such as *The nineteen trains to Sobibor*).[386] When Van Luijt requested

[382] Ibidem, letter of Health Council President J. Wester to the central committee of the KNMG, 6 April 1956.
[383] Ibidem, letter of G. Dekker, on behalf of the central committee of the KNMG to Health Council President J Wester, 27 April 1956.
[384] 'Proeven op mensen', in *Medisch Contact* Vol. 11 (1956), pp. 310-318.
[385] NL-HaNA, Gezondheidsraad, 1920-1956, 2.15.33, Inv.nr. 548, Not. comm. proeven op mensen, 14 December 1953 p. 7.
[386] E.A. Cohen, *Het Duitse concentratiekamp, een medische en psychologische studie* (Amsterdam, 1952); E.A. Cohen, *De negentien treinen naar Sobibor* (Amsterdam, 1979). See

Cohen in 1953 to offer a list of relevant literature on human experimentation, he provided the Health Council President with the following reference:

> Trials of War Criminals before the Nuremberg military Tribunals under Control Council Law No.10. For sale by the superintendent of Documents, U.S. Government printing office, Washington 25, D.C. ($2,75). Volume I en II: The medical case.[387]

Although it is difficult to make any certain statements about Cohen's possible influence on the formulation of the *Guidelines*, it is likely that his presence could have made an important difference. As an Auschwitz survivor and imprisoned camp doctor, Elie Cohen had experienced the Nazi cruelties first hand. In addition, he was in possession of the proceedings of the Doctors' Trial and probably knew therefore of the existence of the Nuremberg Code.[388] If Cohen had come to take place in the Health Council, he could have reminded the elite of the Dutch medical profession of the forced character of the concentration camp experiments and of the importance of informed consent – which was after all the foundation of the Code – to conduct ethically permissible research with human subjects. In Cohen's absence however, when his dissertation was brought up by Van Luijt during one of the first committee meetings, De Jongh put forward that Cohen's work needed no discussion, because it only concerned Nazi crimes and was therefore irrelevant for the subject matter the Health Council was tackling.[389] The Health Council president never once mentioned Cohen's reference to the Nuremberg proceedings. And although he did mention the Nazi concentration camp experiments during the first meeting, he argued that the committee did not need to discuss them, probably for the reason that they had little to do with the scientific subject of tests upon human beings.[390]

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also: W. Mooijman, 'Elie Aron Cohen', in *Jaarboek van de Maatschappij der Nederlandse Letterkunde* (1996), pp. 73-80; E. A. Cohen, *De afgrond: een egodocument* (Amsterdam, 1971).

387 NL-HaNA, Gezondheidsraad, 1920-1956, 2.15.33, Inv.nr. 549, note of E.A. Cohen to the President of the Health Council, 14 July 1953.

388 Cohen could have read about the medico-ethical document's promulgation in the case files. He mentioned that he personally possessed the Nuremberg proceedings in the note to Van Luijt, in: Ibidem, Cohen to the President of the Health Council, 14 July 1953.

389 NL-HaNA, Gezondheidsraad, 1920-1956, 2.15.33, Inv.nr. 548, Not. comm. proeven op mensen, 11 Maart 1954, p. 8.

390 In: Ibidem, 14 December 1953, p. 7.

To give weight to the advice however, the committee decided to insert in the introduction to the advice that the Health Council had made use of internationally promulgated documents, such as the 1948 Declaration of Geneva and the 1949 International Code of Medical Ethics of the WMA. It also mentioned that the committee had consulted the 1954 *Principles of those in Research and Experimentation*, the medico-ethical document of which historian Ulrich Tröhler has argued that it stipulated 'laws of humanity – 'laws' on which the Nuremberg Code was based' (see chapter 2).[391] It is probably the inclusion of this reference that has made historians argue that the Netherlands was one of the first countries to locally implement the Nuremberg Code. But the Health Council committee only paid lip-service to these documents in its final advice, which were in reality hardly ever discussed during the committee meetings. When the Declaration of Geneva was brought up, Van Luijt professed not even to know whether the KNMG was officially in support of these principles.[392] It was the internist Enneking who remembered that the local division of Alkmaar had asked questions about the Declaration in 1949, but he could not recall if this had led to any notable results (see chapter 2). The committee thereafter concluded that it would be useful to mention in the advice that the Health Council had discussed the document and then moved on to articles which it found more enlightening.[393] Such generally included statements which had been prepared by Brutel or articles containing morally dubious research studies which had appeared in NTvG.

The 1954 *Principles* themselves only came up during the eighth Health Council meeting and the committee members professed to disagree with multiple of the principles stipulated in the international medico-ethical document.[394] The lung specialist Hallo in particular considered the principles as promulgated by the WMA to be incongruous with the reality of everyday practice and argued that the *Guidelines* formulated by the Health Council were much stronger. None of the other committee members argued differently. When the doctors of the committee 'tests upon human beings' had to choose which principles for human experimentation they preferred, they professed to value their own down-to-earth assessment, of what constitutes as morally responsible research studies, much

[391] J. Wester, 'Advies van de Voorzitter van der Gezondheidsraad d.d. 10 oktober 1955', p. 2; Tröhler, 'The Long Road', p. 34.
[392] NL-HaNA, Gezondheidsraad, 1920-1956, 2.15.33, Inv.nr. 548, Not. comm. proeven op mensen, 11 Maart 1954, p. 7.
[393] Ibidem, 11 Maart 1954 p. 7.
[394] Ibidem, 5 April 1955, p. 3.

more than any internationally promulgated medico-ethical document.[395] The honoured representatives of the Dutch medical profession strongly believed that their *Guidelines for Tests upon Human Beings* were the only suitable solution to the medico-ethical problems they had identified for the existing clinical research practices of the biomedical and scientific landscape of the Netherlands.

[395] Ibidem, 22 September 1955, pp. 10-11.

· Conclusion ·

It is often in works of medical ethics that the famous Santayanian aphorism 'those who do not know history are bound to repeat it' is invoked. If that is true, there lies a mission to start *correctly* remembering the history of medical ethics. The first thing this thesis has therefore sought to establish, is that the historical claim that the 1955 Dutch *Guidelines for Tests upon Human Beings* was one of the first attempts to locally implement the in 1947 internationally promulgated Nuremberg Code, is utterly false. The members of the Health Council committee 'tests upon human beings' never once mentioned that they knew of the existence of the Code and consistently argued that the Nazi concentration camp experiments had little bearing on their discussions on the ethics of human experimentation. Of course, it would be a bridge too far to therefore conclude, based on this one case-study, that the Nuremberg Code never actually had any transcultural or transtemporal validity as a code of ethics. What it does prove however is that humanistic scholars sometimes all too easily use historical examples as mere food for theory in order to establish the validity of a predetermined philosophical claim. With this thesis has instead sought to establish, is that historical reality is complex and multi-layered and is not easily reduced to a preconceived theoretical template.

Merely showing however that the *Guidelines* did not reference the Code is unsatisfactory. After all, whether or not a national health council accepted or rejected the 1947 document in the first decade after the Second World War is practically of little use for physicians and ethicists confronted with the task of establishing meaningful medico-ethical principles in the increasingly globalist world of the twenty-first century. Even if such actors would aim to use history as a means of establishing the transcendent universality of medico-ethical principles, they could simply argue that either the Code or the *Guidelines* (or both) was a 'faulty document born in scandal' and therefore overly focused on what were in

those times perceived to be the most outrageous transgressions of 'normal medico-ethical behaviour'. This, as has been shown in chapter 1 of this thesis, has in fact become a popular mode of reasoning among essentialist historians who evaluate the Nuremberg Code to be incongruous with their personal vision on the present-day research programme of 'clinical research ethics'.

But what a historical analysis of both the 1947 Nuremberg Code and the 1955 *Guidelines for Tests upon Human Beings* can do for those concerned with the present-day ethics of human experimentation, is offer a projection screen for possible ways in which a research programme of clinical research can come to materialize. Studying the production-processes by which moral principles have historically 'been made' offers a better understanding both of the nature of ethical frameworks and of the manner in which they ultimately come to be recognized as 'universal' and 'self-evident'. It serves as a looking glass through which a better understanding can be gained of the ways in which some issues come to be recognized as public problems while others are not, while at the same time make the patterns visible in which theoretical convictions and practical limitations have historically interacted to co-constitute the eventual formulation of medico-ethical principles and guidelines. In other words, studying the early crystallization of clinical research ethics in the first decade after the Second World War – before medico-ethical documents like the Nuremberg Code and the Dutch *Guidelines* turned into so-called black boxes – forms an excellent case-study to gain a deeper understanding of the production-processes of 'ethics-in-action'.

As chapter 2 has shown, the Dutch medical profession was concerned with neither the Nuremberg Code nor the Nazi concentration camp experiments during this period. Due to its heroic role in the Dutch resistance, the organized medical profession could not imagine that anyone among them would succumb to Nazi-like activities. It was aided in this evasive attitude, by the fact that the category and concept of 'real' science was, by means of rhetorical boundary-work, framed as being incommensurable with unethical behaviour. For also in the Netherlands, the Nuremberg Code was considered to be a good code for barbarians, but superfluous for properly-trained physicians. The narrow conceptualization of the problems at hand in the Nuremberg Doctor's Trial facilitated this way of thinking. Above all, the Trial's indictment perpetuated the idea that the act of human experimentation is, when performed ethically, synonymous to the progress of science and with that to the benefit of humanity. In order to do so, the Trial's prosecution had to frame the Nazi concentration camp experiments in such a

manner that they had necessarily been unscientific and revealed nothing of use for civilized medicine. It had to establish that the seemingly comparable research studies of Allied scientists and Nazi criminals were in reality worlds apart. Overall, it was an awkward frontstage conceptualization that reconciled conflicting backstage interests.

At the same time however, the Dutch medical profession could not completely avoid any public discussion over the ethics of human experimentation. The Netherlands knew an active antivivisectionist movement which persistently argued after the Second World War that the Nazi concentration camp experiments were the inevitable product of the modern research-based laboratory sciences. Social organizations such as the AVS repeatedly made the headlines of national dailies with claims that medical doctors conducted horrific medical experiments on particularly the weak members of Dutch society. As a result, the Dutch antivivisectionists established human experimentation as a 'public problem', as a deplorable condition in dire need of national regulation. When they accused the Leiden university hospital in 1953 of abusing innocent babies and the defenceless insane in order to satisfy the needs of self-interested biomedical scientists, the State Secretary of Public Health had to take action and ask the Dutch Health Council to establish a scientific committee which could advise him on the ethics of human experimentation.

That it had been antivivisectionists who had taken ownership of the problematic nature of the Nazi experiments and human experimentation in general proved to be of significant influence on the proceedings of the Health Council committee 'tests upon human beings'. Already since the late nineteenth century, the Dutch antivivisectionist movement and the Dutch medical profession had come to position themselves in cultural opposition to one another. Also in the twentieth century, especially from the 1930s onwards, antivivisectionists had systemically accused the medical profession of possessing morally degenerated ideas and research practices. They argued that the reductionistic thinking which had become dominant after the rise of the research laboratory made Dutch physicians see sickness instead of the sick. In addition, the abundant use of animal vivisection had made their minds weak and their senses blunt. With its request for a chair in vivisection-free medicine in 1947 therefore, the AVS envisioned itself to cure the sacred art of medicine from the malignant tumours of modern medicine.

Unsurprisingly, the request was perceived by the Dutch medical profession as a direct attack on its professional identity and standing in society. On the pages

of the *Dutch Journal of Medicine* and *Medical Contact*, physicians cried out that all antivivisectionists were inherently unscientific and should at any cost be prevented from gaining a stronghold in the Dutch academy. The antivivisectionist stance went against everything modern science stood for and thus formed a direct threat for the public health of the Netherlands. In discussions such as these, antivivisectionism thus in itself came to crystallize as a public problem for the Dutch medical profession: i.e. it was a deplorable way of knowing and should, for the benefit of the Dutch nation, be banned from the all Dutch medical faculties. When the Health Council was therefore asked to establish guidelines for human experimentation in 1953, the committee 'tests upon human beings' paid attention to every little detail of its final advice to ensure that the AVS could not in any way misuse the *Guidelines* to further its antivivisectionist cause. In turn, the AVS argued that it was the Dutch medical profession which was truly unscientific. It was ridiculously reluctant to open up to the homoeopathic doctrine – as in the 'advisory committee on the establishment of chairs for vivisection-free medicine' – and had been suspiciously secretive in its dealings with the sources it had used for its advice on the ethics of clinical research in 1955. According to the Dutch antivivisectionist movement, this was all proof that documents like the *Guidelines* were only fig leaves to protect the standing of medicine in society.

Partially, the Dutch antivivisectionists were right. The Health Council did purposefully downplay the dangers of human experimentation in order to prevent the AVS from gaining a stronghold in the Dutch academy or provoking the Dutch government to establish legal restrictions for clinical research. In addition, the committee members heavily framed the wording of their final advice and omitted sections which they feared would publicly condemn (frontstage) too explicitly some biomedical research practices which they in private (backstage) sometimes also believed to be unethical. In *producing* an authoritative conceptual framework for the ethics of clinical research therefore, the antivivisectionist threat formed an important practical limitation. Even so, while it is difficult from a present-day perspective to imagine just how much the Dutch medical profession worried about the socio-political influence of the Dutch antivivisectionist movement, it would be a mistake to assume that the deliberations of the Health Council only served to protect the interests of Dutch medical practitioners. If anything, the AVS functioned as a catalyst in gathering for the first time a number of elite Dutch medical professionals to systematically consider the ethics and limitations of clinical research. As such, the committee 'tests upon human beings' can be thought

of as a miniature laboratory, where only gradually a tight knit was achieved between both theoretical convictions and practical limitations. The precise 'definition of the problem' that human experimentation posed, the intricacies of the modern doctor-patient relationship and the identity of the medical profession in the twentieth century, all were uncertain categories the Health Council members extensively debated during the committee meetings and reflected upon in memo's, personal letters and multiple concept versions of the final *Guidelines*.

It was only when the boundaries of the precise medico-ethical problems at stake had fully come to crystallize that the Health Council could establish which principles were appropriate to address them. The committee members carefully considered which responsibilities the medical practitioner had towards his patients and how he could balance between taking care of both the individual patient and society at large by conducting useful experiments which would ultimately alleviate the suffering of the future sick. The Health Council also strongly felt however that this obligation was not solely the responsibility of the medical profession. Both patient and practitioner had to ensure that biomedical science could progress, for only with an increase of scientific knowledge could the health of all Dutch citizens be ensured. Admittedly, in this conceptualization of modern society, the members of the committee 'tests upon human beings' sometimes came dangerously close to the arguments which had been put forward by the *defendants* of the Doctors' Trial in 1946 and 1947: i.e. that the needs of the individual had to be made subject to the greater needs of the nation. Simultaneously however, the Health Council deployed arguments and strategies which were largely similar to those of the *prosecution* of the Doctors Trial. For while the 1955 *Guidelines* can in no way be evaluated as a direct implementation of the 1947 Nuremberg Code, the rationale behind both documents was surprisingly similar: i.e. to reassure the lay public that medical professionals adhered to one unified code of moral conduct, while at the same time make visible that science is useful for society.

Ultimately, the Health Council did come to the conclusion that the health of the individual patient remained the highest goal for each medical practitioner and therefore formulated its principles as such. To ensure that medical doctors would still be capable of fulfilling such moral duties, even with the large increase of scientific and technological possibilities of the twentieth century, the committee 'tests upon human beings' gave much thought to the ways in which the trinity of medical practice, research and education should come to be institutionalized in the Netherlands. First of all, they felt that a better functional relationship needed to be

established between the clinic and the laboratory. Secondly, a stricter hierarchy within the medical profession itself needed to be realized. For the Health Council members, it was no longer self-evident that every medical practitioner was sufficiently qualified to responsibly conduct experiments upon human beings. Specific expertise therefore became a necessary prerequisite to guarantee a proper design of research studies and to judge whether a certain medical intervention was morally responsible or not. Finally, the Health Council argued that Dutch medical faculties needed to pay more attention to the education of aspiring physicians, to ensure that these young men and women were properly trained and remained capable of dealing with the responsibilities of being a medical professional in a modern era. Interestingly, the Health Council felt that this did not just mean more detailed and specialized knowledge of the human body. The advisory body also believed that physicians first had to be good human beings before they could become good doctors. Some committee members therefore argued that medical ethics had to become a separate teaching subject at the Dutch medical faculties. And with that provision, although they would probably never admit as much, the committee members actually agreed with the Dutch antivivisectionist movement that the reductionistic thinking deployed in the modern research laboratory had become too dominant within medicine.

The Health Council shared this uneasiness with the majority of the Dutch medical profession. After the Second World War, heated debates were often held on the discussion pages of *Medical Contact* over the ethics of medicine and the lack thereof within the Dutch medical profession. Eminent Dutch medical professionals professed to be greatly worried that in an age of increased specialization, advancing technologies and expanding bureaucracy, existing medico-ethical norms and values were no longer sufficient. When primus inter pares Jan Jacques Brutel de la Rivière had the honour to be the closing keynote of the centennial celebration of the – by then – *Royal* Dutch Medical Association, he ended his speech with a call for a written work which would 'adapt the existing medical ethics to the radical changes which have taken place in society at large as well as in the medical profession itself'.[396] Similarly, in 1947, letters of Brutel had been published in *Medical Contact* wherein he wrote to worry about the ethical morale among especially young physicians.[397] Admittedly, he did so at the time to

[396] G.C. Heringa, 'Medische ethiek, practische geneeskunde en wetenschap', in *Medisch Contact* Vol. 4 (1949), pp. 539-545, there: p. 539.

[397] Jan Jacques Brutel de la Rivière, 'Uitoefening der geneeskunst in vrij beroep tegenover deze

vent against the governmental interference in the organization of Dutch health care, a development which he believed to undermine the authority and influence of the KNMG. Nevertheless, Brutel also acknowledged that 'a robust professional tradition needed to be formed which would allow for both preventive and repressive measures to be taken to ensure proper ethical conduct by all Dutch medical practitioners and researchers'.[398]

Many others agreed. From time to time, letters appeared in *Medical Contact* wherein physicians argued for a new ethics, one which would remind medical professionals of their duties in times when temptations in the form of financial gain or academic prestige were strong. G.C. Heringa, the editor-in-chief of MC, who asked Floor Wibaut in 1949 not to publish his reflection paper on the ethics of clinical research (see chapter 4) and who wrote in 1950 that the establishment of a chair in vivisection-free medicine would entail 'an experiment of massive gruesomeness that far surpassed any human or animal vivisection' (see chapter 3), publicly stated on multiple occasions that 'the modern Dutch university failed its role as a medium of culture and institute of training'.[399] It was wrong to ascribe too much faith to the 'natural scientific method', Heringa argued, for the intuition of the bedside practitioner remained indispensable for the patient in the clinic. This meant that the medical profession had a responsibility in shaping the moral characters of young doctors, for which the education of medical ethics and culture in general was indispensable.[400]

For reasons such as these, a designated KNMG-committee drafted a complete new version of the 'ethics-booklet' between 1952 and 1955, a guide which the doctors' organization had issued for the first time in 1934.[401] Notably, each of the booklet's chapters appeared in full on the pages of *Medical Contact* to allow for public discussion and revision before the document would finally be published and distributed. Discussing its professional code of conduct was thus something that the Dutch medical profession felt it could do frontstage: out in the open for anyone interested to see and contribute. But the ethics of biomedical experimentation were not discussed in a separate entry. Apparently, the authors of

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uitoefening in dienstverband', in *Medisch Contact* Vol. 2 (1947), pp. 189-197.

398 Ibidem, p. 192.

399 See for example: G.C. Heringa, 'Gedachten over Medische Ethiek', in *Medisch Contact* Vol. 5 (1950), pp. 115-121.

400 G.C. Heringa, 'Medische ethiek, practische geneeskunde en wetenschap', in *Medisch Contact* Vol. 4 (1949), pp. 539-545.

401 See almost any issue of *Medical Contact* between 1952 and 1955.

the booklet did not feel it constituted a field of medicine which needed an ethical treatment separate from other medical issues and interventions. All in all however, in the course of the 1950s and early 1960s, Dutch physicians became increasingly interested not only in the ethics of their own profession, but also in the ethics of clinical research specifically. In the *Dutch Journal for Medicine* for example, the immunologist Joghem van Loghem started highlighting works and lectures on medical ethics on a regular basis and even wrote three published reflection papers on the subject of 'medical tests upon human beings' in the period 1953-54.[402] Significantly, in these articles Van Loghem also reflected upon the Nuremberg Doctors' Trial and discussed the implications of the Nazi concentration camp experiments for the public perception of clinical research in the Netherlands.[403] He did not mention the Nuremberg Code however. It was also during the 1950s, that the Dutch internist and medical historian Gerrit Arie Lindeboom started giving public lectures on the ethics of clinical research.[404] In the second half of the twentieth century, Lindeboom would come to play an important role in the Dutch formation of medical ethics and medical history as autonomous academic disciplines, as humanistic checks and balances in the ever-expanding Dutch medical system.

Arguably, it was the famous internist himself who inaugurated this era by publishing a collection of essays on the subject of medical ethics in 1960.[405] Significantly, the last chapter of this booklet specifically addressed the ethics of 'experimental tests upon human beings', which Lindeboom did believe to be

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[402] For highlighted works and lectures see for example: J.J. van Loghem, 'Drie onderwerpen der medische ethiek', in *Nederlandsch Tijdschrift voor Geneeskunde* Vol. 96 (1952), p. 1889; 'Medische ethiek in de totalitaire staat', Vol. 97 (1953), p. 2490; 'Internationaal congres voor de medische ethiek en medisch recht', Vol. 99 (1955), p. 1201; 'Congres voor medische ethiek', Vol. 99 (1955), p. 2165. For the reflection papers, see: J.J. Van Loghem', 'Geneeskundige proefnemingen bij mensen (I, II & III)', in *Nederlandsch Tijdschrift voor Geneeskunde* Vol. 97 (1953), pp. 518-520; Vol. 98 (1954), pp. 2266-2267; Vol. 98 (1954), pp. 3038-3039. For more information on Van Loghem himself, see: C.P. Engelfriet & H.W. Reesink, 'In memoriam prof.dr. J.J. Van Loghem', in *Nederlands Tijdschrift voor Geneeskunde* Vol. 149 (2005), pp. 2370-2371.

[403] Van Loghem referred for example to Alexander Mitscherlich & Fred Mielke, *Wissenschaft ohne Menschlichkeit* (Heidelberg, 1949).

[404] M.J. van Lieburg, 'Lindeboom, Gerrit Arie (1905-1986)', in *Biografisch Woordenboek van Nederland*. URL:http://www.historici.nl/Onderzoek/Projecten/BWN/lemmata/bwn4/lindebo [10-02-2012]. See also: G. A. Lindeboom, 'Geneeskundige proeven op mensen (Referaat Vrije Universiteit, 1957); G.A. Lindeboom, 'Ethiek in de medische wetenschap', in *Universiteit en Hogeschool* Vol. 3, p. 131.

[405] G.A. Lindeboom, *Opstellen over Medische Ethiek* (Kampen, 1960).

distinctly different from diagnostic and therapeutic tests upon human beings.[406] In this chapter, the Dutch internist argued that it had been the 1946-1947 Doctors' Trial which had shown the world what the reductionistic 'natural scientific approach' could amount to if it was all too eagerly incorporated in the practice of medicine. Physicians therefore had to remember that values, other than scientific ones, were just as important to become a good physician. Medical doctors needed return to their original position at the bedside of the patient. At the same time however, human experimentation had to continue, for also Lindeboom believed that the biomedical practice was essential for the progress of science and therewith indispensable for the cure of the future sick. '*Navigare necesse est!*', wrote the Dutch internist. Thus, similar to the Nuremberg Code and the *Guidelines for Tests upon Human Beings*, Lindeboom's chapter on human experimentation perpetuated the idea that the ethics of clinical research are ultimately a compromise between the belief that human experimentation is in need of certain ethical limitations and the conviction that biomedical science necessarily has to move forward.

This, of course, leaves only one question to be answered: which set of principles did this influential medical doctor and humanistic scholar in 1960 rely on to develop his conceptual framework for the ethics of clinical research? Perhaps surprisingly, Lindeboom neither mentioned nor referenced the *Guidelines for Tests upon Human Beings*, which the Dutch Health Council had envisioned only five years earlier to become the 'future national standard for the ethics of clinical research'. What the internist did reference however was that one document of which the committee 'tests upon human beings' had argued that it was quite a good code for barbarians, but rather unnecessary for ordinary physicians. It was with the work of Gerrit Arie Lindeboom that the Dutch medical profession was introduced to the 1947 Nuremberg Code.[407]

[406] Ibidem, pp. 135-153.

[407] 'Appendix 5: Regels in acht te nemen bij de experimenten op mensen (vastgesteld door het Tribunaal te Neurenburg op 19 augustus 1947)', in: Ibidem, pp. 173-174.

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Appendix I: The 1947 Nuremberg Code

1. The voluntary consent of the human subject is absolutely essential. This means that the person involved should have legal capacity to give consent; should be so situated as to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, over-reaching, or other ulterior form of constraint or coercion; and should have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him/her to make an understanding and enlightened decision. This latter element requires that before the acceptance of an affirmative decision by the experimental subject there should be made known to him the nature, duration, and purpose of the experiment; the method and means by which it is to be conducted; all inconveniences and hazards reasonable to be expected; and the effects upon his health or person which may possibly come from his participation in the experiment. The duty and responsibility for ascertaining the quality of the consent rests upon each individual who initiates, directs or engages in the experiment. It is a personal duty and responsibility which may not be delegated to another with impunity.

2. The experiment should be such as to yield fruitful results for the good of society, unprocurable by other methods or means of study, and not random and unnecessary in nature.

3. The experiment should be so designed and based on the results of animal experimentation and a knowledge of the natural history of the disease or other problem under study that the anticipated results will justify the performance of the experiment.

4. The experiment should be so conducted as to avoid all unnecessary physical and mental suffering and injury.

5. No experiment should be conducted where there is a prior reason to believe that death or disabling injury will occur; except, perhaps, in those experiments where the experimental physicians also serve as subjects.

6. The degree of risk to be taken should never exceed that determined by the humanitarian importance of the problem to be solved by the experiment.

7. Proper preparations should be made and adequate facilities provided to protect the experimental subject against even remote possibilities of injury, disability, or death.

8. The experiment should be conducted only by scientifically qualified persons. The highest degree of skill and care should be required through all stages of the experiment of those who conduct or engage in the experiment.

9. During the course of the experiment the human subject should be at liberty to bring the experiment to an end if he has reached the physical or mental state where continuation of the experiment seems to him to be impossible.

10. During the course of the experiment the scientist in charge must be prepared to terminate the experiment at any stage, if he has probable cause to believe, in the exercise of the good faith, superior skill and careful judgment required of him that a continuation of the experiment is likely to result in injury, disability, or death to the experimental subject.

Appendix II: Ivy and Alexander

NB. The following chart is derived from Paul J. Weindling, 'The Origins of Informed Consent: The International Scientific Commission on Medical War Crimes, and the Nuremberg Code', in *Bulletin of the History of Medicine* Vol. 75 (2001), pp. 37-71, there: p. 40.

Table 1. The Evolution of the Nuremberg Code

Nuremberg Code 19.8.47	Ivy I[a] 7/46	AMA 12/46	Alex. I[b] 12/46	Alex. II[c] 1/47	Alex. III[d] 3–4/47
1. Voluntary consent	X	X	X	X	X
Free power of choice			X	X	X
Sufficient knowledge & comprehension			X	X	X
Understanding & enlightened decision			X	X	X
Know nature, duration, purpose of experiment	X				
Know method & means					
Know inconveniences & hazards	X				
Know effects on health & person	X				
2. Fruitful results for good of society	X		X	X	X
3. Animal experimentation	X	X	X	X	X
4. Avoid unnecessary physical/ mental suffering, injury	X		X	X	X
5. No death or disabling injury except self-experiments	X		X	X	X
6. Degree of risk should not exceed humanitarian import of problem	X		X	X	X
7. Protect experimental subject			X	X	X
8. Proper preparations to be conducted by scientifically qualified persons		X	X	X	X
9. Subject at liberty to end experiment					
10. Scientist obliged to end experiment if injuries, disabilities, death likely					
ABSENT FROM CODE:					
Safeguards for mentally ill patients				X	X
Duty for quality of consent rests upon exp. director			X	X	X

[a]Ivy I = Pasteur Institute, 31 July–1 August 1946.
[b]Alexander I = "Ethical and Non-Ethical Experimentation on Human Beings," Nuremberg, 7 December 1946.
[c]Alexander II = Affidavit, 25 January 1947.
[d]Alexander III = "Ethical and Non-Ethical Experimentation on Human Beings," 15 April 1947.

Appendix III: The 1949 Declaration of Geneva

At the time of being admitted as a Member of the medical profession:

- I solemnly pledge to consecrate my life to the service of humanity;
- I will give to my teachers the respect and gratitude which is their due;
- I will practice my profession with conscience and dignity;
- The health and life of my patient will be my first consideration;
- I will respect the secrets which are confided in me;
- I will maintain by all means in my power, the honor and the noble traditions of the medical profession;
- My colleagues will be my brothers;
- I will not permit considerations of religion, nationality, race, party politics or social standing to intervene between my duty and my patient;
- I will maintain the utmost respect for human life, from the time of its conception, even under threat, I will not use my medical knowledge contrary to the laws of humanity;
- I make these promises solemnly, freely and upon my honor.

Appendix IV: The 1954 *Principles for Those in Research & Experimentation*

1. Scientific and Moral Aspects of Experimentation

The word experimentation applies not only to experimentation itself but also to the experimenter. An individual cannot and should not attempt any kind of experimentation. Scientific qualities are indisputable and must always be respected. Likewise, there must be strict adherence to the general rules of respect of the individual.

2. Prudence and Discretion in the Publication of the First Results of Experimentation

This principle applies primarily to the medical press and we are proud to note that in the majority of cases this rule has been adhered to by the editors of our journals. Then there is the general press which does not in every instance have the same rules of prudence and discretion as the medical press. The World Medical Association draws attention to the detrimental effects of premature or unjustified statements. In the interest of the public, each national association should consider methods of avoiding this danger.

3. Experimentation on Healthy Subjects

Every step must be taken in order to make sure that those who submit themselves to experimentation be fully informed. The paramount factor in experimentation on human beings is the responsibility of the research worker and not the willingness of the person submitting to the experiment.

4. Experimentation on Sick Subjects

Here it may be that in the presence of individual and desperate cases one may attempt an operation or a treatment of a rather daring nature. Such exceptions will

be rare and require the approval either of the person or his next of kin. In such a situation it is the doctor's conscience which will make the decision.

5. Necessity of Informing the Person Who Submits to Experimentation of the Nature of the Experimentation, the Reasons for the Experiment, and the Risks Involved

It should be required that each person who submits to experimentation be informed of the nature of, the reason for, and the risk of the proposed experiment. If the patient is irresponsible, consent should be obtained from the individual who is legally responsible for the individual. In both instances, consent should be obtained in writing.

Appendix V: The 1955 *Guidelines for Tests upon Human Beings*

1. Bij experimenten op mensen is de verantwoordelijkheid van de onderzoeker primair, niet de bereidheid van de proefpersoon.
2. Het is gewenst dat de onderzoeker andere deskundigen van zijn beraamd onderzoek op de hoogte brengt: het besef van verantwoordelijkheid wordt hierdoor vergroot.
3. Bij ingrepen gericht op vermeerdering van kennis en ter verkrijging van vaardigheid en ervaring waarbij risico, bijzonder ongerief op pijn aan de ingreep is verbonden, wordt toestemming van de vrij beslissende, volledige ingelichte proefpersoon noodzakelijk geacht.
4. Ingrepen waaraan een *aanzienlijk* risico is verbonden ook al is aan de voorwaarde van volstrekte vrijwilligheid en volledige voorlichting voldaan, acht de Commissie niet in overeenstemming met de aard en doelstelling van de medische wetenschap.
5. Indien de functie van experimentator en die van behandelend arts in één persoon is verenigd, zijn ingrepen die gevaar voor de proefpersoon met zich brengen niet geoorloofd zonder inschakeling van een adviescollege, aangezien de behandelend arts tevens experimentator niet de aangewezen persoon is de al of niet toelaatbaarheid van het risico te beoordelen.
6. Een proef op een mens moet onmiddellijk worden beëindigd als de proefpersoon dit wenst of indien onverwacht gevaar optreed, hetgeen inhoudt dat ingrepen waarvan de gevolgen niet ongedaan kunnen worden gemaakt (bijv. het inbrengen van geïnfecteerd plasma) niet toelaatbaar zijn.
7. Het behoeft nauwelijks te worden vermeld, dat elk niet strikt onvermijdelijk lichamelijk of geestelijk lijden en gevaar moet worden voorkomen.
8. Proeven (ingrepen) op kinderen gepaarde gaande met risico of bijzonder ongerief op zijn acht de Commissie niet aanvaardbaar.
9. Groepsonderzoekingen in kindertehuizen, rusthuizen en huizen voor ouden van dagen en dergelijke, welke onderzoekingen met risico, bijzonder ongerief of pijn gepaard gaan, zijn niet toelaatbaar.

10. Proeven op krankzinnigen, gepaard met ingrepen die meer dan normaal risico, bijzonder ongerief of pijn met zich brengen, acht de Commissie niet aanvaardbaar.
11. Proeven op gevangenen, gepaard met ingrepen die meer dan normaal risico, bijzonder ongerief of pijn met zich brengen, acht de Commissie niet aanvaardbaar.
12. Ten aanzien van proeven (ingrepen) op patiënten die geacht worden lijdende te zijn aan een onherstelbare ziekte, spoort de Commissie aan tot de meest mogelijke terughoudendheid ook al bieden dergelijke patiënten zich voor de proef (ingreep) aan.
13. Proeven op stervenden worden onder alle omstandigheden door de Commissie als ontoelaatbaar verworpen.
14. Een patiënt mag niet met *on*nodige onderzoekingen worden lastig gevallen. Diagnostische ingrepen, die enig gevaar voor de patiënt kunnen opleveren, zijn alleen verantwoord indien een doeltreffende therapie daarvan het gevolg kan zijn. De Commissie is daarom van mening, dat hij met het *routine*-onderzoek niet onder alle omstandigheden van allerlei nieuwe methoden, die niet zonder gevaar zijn, gebruikt behoort te maken.

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