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The Legacy and Contemporary Relevance of Nazi Physicians

Tom L. Beauchamp

The Cary M. Maguire Center
for Ethics & Public Responsibility
Southern Methodist University
Dallas, Texas

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Rita G. Kirk
Director

Tom L. Beauchamp

Tom L. Beauchamp serves as Professor of Philosophy and Senior Research Scholar in the Kennedy Institute of Ethics at Georgetown University. In 2011 he was given the Lifetime Achievement Award for Excellence in Research Ethics by Public Responsibility in Medicine and Research (PRIM&R). In 2010 he was presented the Henry Beecher Award of the Hastings Center, New York, for a lifetime of contributions to research ethics and other areas of bioethics. Beauchamp's research interests are in the ethics of human-subjects research, the place of universal principles and rights in biomedical ethics, methods of bioethics, Hume and the history of modern philosophy, and business ethics. Publications include the following co-authored works: *Principles of Biomedical Ethics* (6th edn. 2009), *A History and Theory of Informed Consent* (Oxford, 1986), and *The Human Use of Animals* (Oxford, 2nd edn. 2008, with four coauthors). *His Philosophical Ethics* (McGraw-Hill, third edn., 2001) is a work in ethical theory. Publications also include a number of edited and coedited anthologies and over 150 scholarly articles in journals and books.

The Legacy and Contemporary Relevance of the Crimes of Nazi Physicians

The Holocaust is not some one event or sequence of events. It is many events, policies, attitudes, and cultural configurations. At its core is a profoundly deep failure of moral sensitivity by some of the most prestigious and responsible members of German society and Polish society. The failure was at such a high level that it is difficult to comprehend the events. Why did it happen? How do we explain serial murders of this magnitude, especially at the hands of physicians? What is the philosophical importance of these events? Uncertainty plagues the answers we try to give.

The abnormality in German medicine was sufficiently great that we might try to brush it aside as a moral travesty of such an exceptional nature that it has little to teach us about our everyday conduct and our culture in the U.S. Such a shelving of history, as if it meant nothing to us in our affiliations and pursuits, is a moral mistake. The holocaust has much to teach us about moral insensitivity and moral evil within the bowels of our own society. Evil elements of culture in central Europe were the chief culprits, but we in the U.S. are not as free of the taint of the kind of moral insensitivity seen in the Holocaust as we may like to think. Some high officials of government in the U.S. worked day in and day out to keep desperately abused European Jews out of the United States—and to keep U.S. troops in Europe from aggressive movement toward liberation of concentration camps. A moral taint will forever hang over the actions of certain anti-Semitic officials in the Roosevelt administration for some of their inexcusable inactions. Roosevelt had a number of close Jewish advisers—Felix Frankfurter, Henry Morgenthau, Sam Rosenman, Ben Cohen, etc.—but they were under attack in the U. S. because of their race and because of their efforts to get Jews out of Europe. Bills before the U. S. Congress to help save German Jewish children all went down to defeat. This disappointing period in U.S. history needs to be weighed along with our noble ambitions and sacrifices in the Second World War. We were noble, but naive—and not entirely free of our own serious racial and religious discrimination.

That the Nazi regime was ghastly and that we fought valiantly against

it does not excuse the racial prejudice and discrimination in the U.S., which was abundant at the time. Gunnar Myrdal, the great Swedish economist, Nobel laureate, and expert on race relations, wrote in his wonderful book *An American Dilemma*, which was funded by the Carnegie Foundation, that American anti-Semitism in these years probably was slightly stronger in the U. S. than in Germany prior to the Nazi era. Myrdal presented another thesis as well: He thought that what protected the United States from the serious racial issues in Germany was what he regarded as a semi-official American Creed of liberty, equality, justice, and fair treatment of all people. This was the big difference between racial attitudes in the U. S. and Germany—hostile in both nations—and Myrdal regarded this creed as America's savior and protector. It kept us from stooping to the extremes of German, Austrian, and Polish society.

Much of what happened during the Holocaust, though certainly not all, was a racially motivated insensitivity and hostility. Warped racial theories were widely present not only in German society, but even in German medicine prior to the Hitler regime. The Holocaust will always be the extreme case—the perfect storm of a warped medicine, a warped politics, and a cruel leadership. But before we classify German society as so remote from life in the United States that it bears no relevance to us, we would do well to recall many of the attitudes present in the U. S. at the time, which is what Myrdal was cataloguing in 1944. Much of the U.S.—I think effectively all of the U.S.—was segregated by race. The segregation of what were then regarded as Negro or Colored populations was accompanied by a pervasive discrimination against Jews, Native Americans, Hispanics, and assorted others. Southern Methodist University, for example, was a segregated university (except for the Perkins School of Theology), and its fraternities and sororities almost uniformly did not allow Jews as members. Even though I lived through this entire period, including as a student at SMU, I still find it difficult to comprehend the moral insensitivity of and the stereotyping of some individuals that was widely present in American society at the time, and at SMU in particular. German society is, I repeat, the extreme case of moral insensitivity and outright evil, but it would be indefensible of us as Americans, then and now, to make the presumption that we were (or are) the extreme case at the other end of the continuum—as if we were somehow the beacon of

moral sensitivity and moral goodness in a racially segregated and racially intimidating society. If we take this attitude, then we shut ourselves off from what we might learn from the Holocaust.

I mention these matters to set a context so that what I say is not received as ancient history. I want to concentrate on one and only one area of the Holocaust and what happened after it in the U.S., namely, what occurred in German *medicine* and the subsequent history of the regulation of research with human subjects, especially the regulations that govern research involving vulnerable subjects in the U.S. American medicine and American society generally have tended to regard what happened in German medicine and public health as ancient and irrelevant history, as if the findings of an American Court sitting in judgment of German physicians had no relevance to American medicine. This reception is a mistake still in need of correction.

The Context of Events in the 1930s and 1940s

I will concentrate largely on the 1940s and developments thereafter, but this dating is not determined entirely by the dates of the Holocaust. Of no less importance is the fact that scientifically rigorous research involving human subjects became common in the United States and in other developed countries only in the mid twentieth century. Not until shortly before the outbreak of World War II was research, as we have come to know it, an established and thriving concern.

It is worth a moment at this point to reflect on the question of why we do research with human subjects. Why not stick with animals, computer models, and the like? The answer is that the ideal laboratory species for accumulating data on human functions and reactions is human, and so we become the so-called animal of necessity. Today in doing research with human subjects we have legitimate reason for saying that our systems of research oversight require that we minimize risk and that we obtain consent when doing research involving human subjects. This perspective cannot, however, be claimed for earlier times. Practicing physicians have traditionally been governed by minimalistic oaths and codes of ethics as well as by licensing and regulatory boards, none of which was specific in application to research. Careful controls for the biomedical researcher are recent phenomena. Classic works in medical ethics—such as Thomas

Percival's wonderful 1803 treatise *Medical Ethics*—had effectively nothing to say about medical experimentation with human subjects. There was in fact no broad interest in consent to research or in research ethics prior to the period after the end of the Second World War.

Apart from the horrors that occurred in Germany during the Nazi period, which I will come to in a moment, one reason the 1940s are interesting to study is that research ethics, by contrast to physician ethics, was just beginning to be developed and was clearly underdeveloped everywhere. This fact, together with the warped racial theories of the period, made medicine vulnerable to racism and to something like Nazi manipulation, but abuses of human subjects occurred in many nations, including ours—not at the levels of atrocities of the Nazis, but sad to behold nonetheless.

It would be overreaching on my part to suggest that issues in the ethics of research and consent *never* arose in pre-1940s periods. Sporadic outcries did at various points appear against the use of human subjects without their consent, and there were occasional published accounts critical of the ethics of experimentation. For example, a Russian physician named V. Smidovich, writing under the pseudonym V. Veresaeff, wrote an impassioned, carefully reasoned, and well documented critique of clinical and research practices that had been conducted throughout the world in a book published in Russia in 1901. This extraordinary work, entitled in English *The Confessions of a Physician*, received considerable attention in educated circles in Russia, but its actual cultural impact was effectively zero in any country.

However, not long thereafter, there were public protests in several nations—most notably Prussia—about experiments that had gone badly and that had abused human subjects. Because of these concerns, The U. S. Congress and several state legislatures considered bills to control experimentation with humans, none of which ever became law—not even in the District of Columbia, over which Congress had control.

Problems in Walter Reed's Research on Yellow Fever

Another historically rich example of moral problems in research many years before World War II is Walter Reed's famous research on yellow fever in 1900. Reed was an army physician assigned to discover the cause

of yellow fever. He created a scientific study in which one group of human subjects was intentionally exposed to the bite of the mosquito, which, as we all know today, was the vector of the disease. This work was ultimately a tremendous scientific success, and Reed achieved legendary fame and the naming of a prominent Army hospital after him. Reed is also famous for (allegedly) having devised the first true consent form. The problem is that some of these accounts of Reed are more the stuff of legend than historical fact. Moreover, Reed's experimental work raised then and today some serious moral issues.

First, the so-called consent form was not truly a consent, as has been claimed; it was principally an employment contract. Second, Reed's experimental design in the study had been in part anticipated and used by an Italian experimental investigator in Brazil, and Reed's main scientific hypothesis had already been developed and championed for 19 years by a Cuban physician. The experiment in Brazil had already been sharply criticized as unethical in the treatment of human subjects by the great Canadian physician William Osler (later at Johns Hopkins, where Reed would train under the legendary William Welch). Osler called it criminal to engage in the intentional injections and exposures in the research in Brazil, which was fundamentally similar to Reed's use of human subjects.

Nonetheless, Walter Reed persisted and tried to get around some criticisms through his mechanism of the employment contract. However, this alleged consent form was tainted, and he used (as roughly 50% of his subjects), poor Spanish immigrants. His employment contract overpromised the likely benefits of being a research subject and promised payment for services in a high amount that was never paid as promised. These are still problems in biomedical research in the U. S. today; but the moral problems get worse with Reed. It has often been reported that Reed exposed himself to the bite of the mosquito and even that he was a martyr for science. In fact, however, Reed did not expose himself to the mosquito and did not die of yellow fever. In a structure of military chain of command, he allowed—or possibly asked—two members of his investigative team to voluntarily expose themselves to the mosquito, which they did, and died as a result. This is a paradigm early case in the now long struggle in the U. S. with the use of experimental subjects who are easily available and vulnerable to abuse.

Reed is a case of looming moral problems and of moral insensitivity—made all the more interesting because Reed is generally presented, still today, as an American hero. But I've said enough now about the history of moral insensitivity in medical research as the background for my theses in this paper, and I need to return at this point to the research in Germany and to the findings at Nuremberg.

Nazi Physicians, the Nuremberg Trials, and the Nuremberg Code

Nuremberg is the most important watershed event in the more than 2000 years of research involving human subjects. The unprecedented cruelties in Germany were often administered by well trained and prominent physicians. Their extraordinary evil was to change how we view the use of human subjects in scientific research, and we hope the change is forever. But one of the conclusions for which I will be arguing is that we have not resolved all of the problems that became so obvious in Nazi Germany.

The Nuremberg Trials and the Nuremberg Code constituted the first major curbs on research in any nation. The succinct Nuremberg Code was prescribed in 1948 as part of the judgment in *United States v. Karl Brandt*, the Nuremberg trial of 23 Nazi physicians and bureaucrats who engaged in so-called biomedical experiments during the war. Although it is a common misconception that these were the earliest examples of willfully harmful, vicious research on unwilling human subjects, the Nazi experiments were indeed unprecedented in the extensiveness and extremity of the harm and suffering to which they knowingly exposed their many victims. Using subjects drawn from the populations of concentration camps (Jews, gypsies, Poles, and Russians), Nazi scientists explored the effects of ingesting poisons, intravenous injections of gasoline, immersion in ice water, and the like. Infection with epidemic jaundice and spotted fever virus, as well as killing people to obtain organs and brains for study, were common parts of an extensive pattern of "medical" experiments.

Nazi euthanasia (a dreadful euphemism for the original meaning of the term "euthanasia") programs involving physicians also killed an estimated 256,000 people. These programs were explicitly directed at persons who had "worthless lives" and were social "undesirables." Often doctors made a decision whether someone was a social undesirable, and therefore whether

euthanasia was appropriate. Being sick or being Jewish could be enough for the classification as an undesirable. Some physicians and researchers engaged in killing these individuals in a manner that facilitated their research plans of autopsies. Karl Brandt was Hitler's escort surgeon, and he had convinced Hitler of the need for the killing of "incurables." Brandt, like others of his persuasion, was convicted of crimes against humanity at Nuremberg and hanged.

It has often been said that German doctors were Nazified and then manipulated by the new German government, but the historical situation was more complicated. Heinrich Himmler brought German medicine, in part, under SS control and transformed medical faculties in universities into centers of racial ideology. There was clearly collaboration between the SS and a large number of physicians. However, the orthodox view that aggressive medical researchers were only to be found in SS-sponsored research is implausible. The proposed research was conducted at many levels of German society and at many locations. Racial characteristics and behavior were a common focus of studies. These studies were sometimes more anthropological than medical, and their scientific merit was almost always questionable.

Many German physicians had racial theories that led them to support a program of eugenics, euthanasia, or autopsy while also supporting the idea of a eugenically planned society. Many were believers in sterilization and helped draw up sterilization laws. Around 340,000 persons were forcibly sterilized in Germany and German-annexed Austria between 1933 and 1945. Moreover, medical researchers and textbook writers were hard at work stigmatizing particular racial groups and persons with disabilities. Sometimes these theories were created by physicians, at other times merely endorsed by physicians. The point is that there was as much a Nazi adoption of pre-existing theories in medicine as there was an adoption by medical professionals of Nazi ideology.

Twenty doctors and three administrators, several of whom occupied responsible positions within the Third Reich's medical hierarchy, were indicted before the war crimes tribunal at Nuremberg late in 1946. In its opening statement the prosecution—the United States government—declared as follows:

> The defendants in this case are charged with murders, tortures,

> and other atrocities committed in the name of medical science. . . . In many cases experiments were performed by unqualified persons; were conducted at random for no adequate scientific reason, and under revolting physical conditions. All of the experiments were conducted with unnecessary suffering and injury and but very little, if any, precautions were taken to protect or safeguard the human subjects from the possibilities of injury, disability or death. In every one of the experiments the subjects experienced extreme pain or torture, and in most of them they suffered permanent injury, mutilation, or death, either as a direct result of the experiments or because of lack of adequate follow up care.

Dr. Andrew Ivy, who served during the trial as an expert witness on scientific and ethical questions, criticized the research that had been done for its poor scientific design, irrelevance, and extreme cruelty. He argued that the medical tragedies were magnified by the invalidity of the experiments, which revealed nothing of use to "civilized medicine."

The extreme disregard of ethics in the Nazis' exploitation and abuse of subjects is all the more remarkable in light of the fact that in 1931 Germany had enacted, on moral grounds, strict regulations or guidelines (Richtlinien) to control both human experimentation and the use of innovative therapies in medicine. Issued by the Reich's Health Department, these regulations remained binding law throughout the period of the Third Reich, but there is no evidence of any serious attempt to understand or enforce this law, either in medicine or government, after the Nazis came to power in 1933. It was demanded under this law that consent (first party or proxy consent, as appropriate) must always be given "in a clear and undebatable manner." Questions of the nature of appropriate information, bona fide consent, careful research design, and special protections for vulnerable subjects were all delineated in these guidelines. Human experimentation was declared impermissible without consent, and absolutely impermissible with dying patients.

It is a special irony—a phenomenal historical oddity—that no other nation appears to have had such morally and legally advanced regulations at the time of the Nazi abuses. A second irony is that although the Nuremberg Code is widely assumed to be the first major document in the history of research ethics to deal with consent in a specific manner, the

1931 regulations actually contain no less adequate provisions than those in the Code itself.

At the Nuremberg trial it became evident that in no respect were the victims of the Nazi experiments volunteers, much less *informed* volunteers. The Nuremberg Military Tribunals unambiguously condemned the sinister motivation behind the experiments, calling them "crimes against humanity." The defendants were found to have corrupted the ethics of the medical profession and of science, and to have repeatedly and deliberately violated their subjects' rights. During testimony the accused defended their actions by an aggressive attack on the thesis that voluntary participation by human subjects *generally* occurs in medical experimentation. One defendant—formerly head of a reputed [Robert Koch] Hygiene Institute—stated:

> The extent to which subjects are volunteers is often deceptive. At the very best they amount to self deceit on the part of the physician who conducts the experiment, but very frequently to a deliberate misleading of the public. In the majority of such cases, if we ethically examine facts, we find an exploitation [by physicians] of the ignorance, the frivolity, the economic distress, or other emergency on the part of the experimental subjects.

The Nazi defendants argued, similarly, that the allies were in no position to judge them because the allies had themselves engaged in questionable research without consent. However, setting aside any errors of judgment and action that might have occurred on the side of the allies, the scale of what the Nazis had done was an unprecedented evil. The tribunal forthrightly rejected the Nazi's defense and gave a central role to the voluntary participation and consent of research subjects. The judges took responsibility for establishing what they called the "basic principles [that] must be observed in order to satisfy moral, ethical and legal concepts" in the conduct of human subjects research. A list of ten principles was crafted as the core of the Nuremberg Code.

Principle One of the Code states, without qualification, that the primary consideration in research is the subject's voluntary consent, which is "absolutely essential." It requires that consent have at least four characteristics: It must be voluntary, competent, informed, and comprehending. The rest of the Code sets general bounds within which

an investigator may conduct research and delineates the conditions under which a subject has the ability to volunteer and, in all cases, to withdraw from the research even after it has begun.

Whether the Nuremberg Code was influential in the years after 1948 is historically controversial, but, somewhat embarrassingly, it does not appear to have had much of an effect in the United States, even though our judges had delivered the judgment in the trials and had fixed the terms of the Code. There is one apparent, but not profoundly important, exception to this point about influence: The U. S. Dept. of Defense adopted the Nuremberg Code, but it was a distant and veiled adoption: Having accepted the Code, the Dept. of Defense never seriously attempted to implement the Code in its conduct. This might seem ludicrous and hypocritical, but when we come below to the Declaration of Helsinki, it will become apparent that most countries and institutions have behaved roughly as the Department of Defense did: Adopt a code and then do little to implement it.

In any event, to bring this discussion of Nuremberg to a conclusion, the Nuremberg Code served as a model background condition for the development of modern research ethics, but I do not think that it actually served as the model use for the professional and governmental codes formulated throughout the 1950s and 1960s. The Code was limited in scope and specificity, and eventually it came to be viewed, understandably, as inadequate to govern the complex variety of situations arising in the expanding fields of biomedical and social scientific research. Pressure to develop less general guidelines for specific disciplines began to mount, but only about a decade and a half after Nuremberg.

One of the questions that perhaps no one knows how to answer is why the allies condemned the Nazis at Nuremberg and then failed to apply their provisions to their own conduct. I will be working in various ways on this problem in the last half of this paper, and here I note only that I find it deeply disappointing that, in our own conduct, we in the United States took to heart in our public and institutional policies so little of what we should have learned from the Holocaust and the Nuremberg Trials.

The Declaration of Helsinki

Not until around 1960 did a number of physicians around the world get organized to address the fact that medicine was everywhere vulnerable

to abuses of the sort we had seen in Germany. Partially in response to this perceived threat, the World Medical Association (WMA) began in the early 1960s (after some prior discussion in the 1950s) to draft a more suitable code to distinguish ethical from unethical clinical research. A draft of the WMA's code was produced in 1961, but the code was not adopted until a meeting at Helsinki in 1964. Let me say bluntly that I do not believe that the Declaration of Helsinki was entirely motivated by the moral purity of western allies seeking to do the right thing in research involving human subjects. Some of the motivation, indeed, seems to be that the wording in the Nuremberg Code was too constraining of biomedical research, particularly in taking discretion away from medical investigators about whether their research was justified.

The Declaration of Helsinki was proposed as the proper set of ethical principles to guide the international medical community in regulating human experimentation. It was drafted in June 1964 in Helsinki, Finland, and has since undergone six revisions (the most recent at the General Assembly in October 2008) and two clarifications, growing considerably in length from 11 paragraphs to its present size. It is today widely regarded throughout the world by many major research enterprises, government agencies concerned with research, and research universities as *the* authoritative cornerstone—*the* cornerstone, unrivalled—of human research ethics, although it is not a legally binding instrument in international law. It draws its authority from the degree to which it has been codified in, or has influenced, national or regional legislation and regulations.

The document has had a remarkable success. Most medical associations have endorsed the Declaration or established ethical requirements consonant with its provisions; and officials at federal agencies in the United States often looked first to Helsinki before developing their own provisions, some of which were close to verbatim reformulations of Helsinki. Many corporations endorsed it. In substance, however, the Declaration of Helsinki is now, and from the start has been, a remarkably weak and nonspecific set of guidelines. The primary problem is that it is so short on specifics—that is, on the specification of what its principles require. Moreover, we are seeing at the present time the erosion and perhaps the collapse of the Declaration of Helsinki. On October 27, 2008 the U. S. FDA withdrew its support for a reference to the Declaration, substituting

a relatively new and untested code of the International Conference on Harmonization (orig. 1996).

The FDA has determined, as I do, that the Declaration is a weak and incomplete document. I have no time to go into the details, but the messages are two: (1) First, even in 1964, almost 20 years after the end of the Second World War, little had been done to develop research ethics in a detailed form in any country. Nuremberg had not been taken to heart. The World Medical Association had only a skeletal framework of an idea and little had been done in the United States, which had vigorously attacked German abuses, but then failed to take the message home. (2) Second, we find ourselves still today a bit confused and adrift about the right anchors and specific provisions of research ethics. We are uncertain about how we can make efficient advances in science while also properly protecting human subjects.

The Jewish Chronic Disease Hospital Case

One of the first incidents to achieve notoriety in research ethics in the United States, was a study conducted at the Jewish Chronic Disease Hospital (JCDH) in Brooklyn, New York. It occurred in the same year of the publication of the Declaration of Helsinki.

In July 1963, Dr. Chester Southam of the Sloan Kettering Institute for Cancer Research persuaded the hospital's medical director, Emmanuel E. Mandel, to permit research involving injection of a suspension of foreign, live cancer cells into 22 patients at the JCDH. The objective was to discover whether a decline in the body's capacity to reject cancer transplants was caused by their cancer or by debilitation. Patients without cancer were needed to supply the answer. Southam had convinced Mandel that although the research was nontherapeutic, such research was routinely done without consent. Some patients were informed orally that they were involved in an experiment, but it was not disclosed that they were being given injections of cancer cells. No written consent was attempted, and some subjects were incompetent to give informed consent. In 1966 the Board of Regents of the State University of New York censured Drs. Southam and Mandel for their role in the research. They were found guilty of fraud, deceit, and unprofessional conduct.

An Influential Scholar: Henry Beecher

Immediately after these events unfolded in New York—in 1965-66—the perception of a threat both to science and a threat of abuse of human subjects came to the attention of the Director of the U. S. National Institutes of Health (NIH). The United States cannot claim, prior to 1965, an abiding and serious interest in protecting against the kinds of abuses it had discovered, and then prosecuted, in Germany. But 1966 can be taken to be an important year in the development of moral sensitivity in the U. S. to problems of research ethics. It was important for several reasons, but I will mention only one. The point of my comments is to foster appreciation of how underdeveloped our moral sensitivity was more than two decades after the discovery of Nazi abuses. It is remarkable how little we seem to have learned at this point from the Holocaust.

The 1966 work of an influential writer in the United States named Henry Beecher is the perfect starting point. Beecher wrote a 1959 monograph entitled *Experimentation in Man*. In this little book he announced that the atrocities disclosed at Nuremberg and the continuing advance into new areas of human biomedical research called for "a long, straight look at our current practices," which he was convinced were headed in the direction of medical disasters that would constitute significant abuses.

In 1966 that Beecher published a truly landmark document entitled "Ethics and Clinical Research" (published in the internationally acclaimed and widely read *New England Journal of Medicine*). In this article he presented detailed case accounts of contemporary biomedical research that contained serious or potentially serious ethical violations. Several of these experiments had been performed with a high ratio of risk to benefit and involved vulnerable or disadvantaged subjects who were unaware of their participation in research. Most of the subjects had not consented, or at least consent was not documented. In one experiment, physicians substituted placebos for an established and effective treatment without notification to patients. In another, physicians administered (chloramphenicol) a known inducer of (potentially fatal) aplastic anemia, to patients without their knowledge. Beecher argued that the ease with which he had collected samples from published articles in medical journals meant that if only one quarter of the cases show truly unethical behavior, medicine still would be

faced with a seriously wrong situation.

It turns out that he was right and that the abuses reached up to the highest levels of American medicine—in particular, to our greatest medical schools and our highest government officials. More than two decades after Nuremberg American physicians had not taken the Holocaust's most important lessons to heart. Beecher's discoveries were widely read and soon became considered an American disgrace.

Tuskegee

Using Beecher as a guide, I have just claimed that the development of research ethics in the U. S. is, with few exceptions, a post-1966 phenomenon. In truth, only a small advance in research ethics had occurred in the U. S. by 1973—almost thirty years after the discovery of German abuses. 1973 is a date that will go down as perhaps the most important single year in the history of research abuses and developments in research ethics in the United States. What happened in that year can almost be summed up in one word: Tuskegee.

The Tuskegee Syphilis Study is the most notorious case of prolonged and knowing violation of subjects' rights to emerge in the 1970s. It was a Public Health Service study initiated in the early 1930s. Originally designed as one of the first syphilis control demonstrations in the United States, the stated purpose of the Tuskegee Study was to compare the health and longevity of an untreated syphilitic population with a nonsyphilitic, but otherwise similar population. Beginning in 1932, the physicians running the study traced the pathological evolution of syphilis in approximately 400 black males. Another 200 without syphilis served as controls. That all of the subjects were black—said to be "Negro males" in the study—was the result of racist attitudes and racial discrimination at the highest levels of American medicine and federal agencies. The subjects of these experiments knew neither the name nor the nature of their disease. That they were participants in a non-therapeutic experiment also went undisclosed. They were informed only that they were receiving free treatment for "bad blood," a term local blacks associated with a host of unrelated ailments, but which the white physicians allegedly assumed was a local euphemism for syphilis. The investigators assumed that the subjects would comply without question; their deference to authority and desire to receive free

medical attention made them readily available subjects. The subjects were also misinformed that research procedures such as painful spinal taps were a "special free treatment," a patently false statement. As historians James Jones and David Rothman have both argued, the investigators manipulated the subjects into "consenting." These subjects were in such a state of social deprivation that manipulation came effortlessly. This experiment was a 40-year deathwatch, as Jones called it, in which treatable subjects intentionally were not treated.

Although the experiment was designed to last only six to eight months, a few investigators believed—evidently with some scientific warrant—that it had unrivalled potential as a study. They pushed to extend it indefinitely, and they got their way. It was extended for years and then more years and then more years still. Meanwhile, untreated subjects were systematically blocked from receiving available treatments. Whatever treatment the men received prior to 1973 came from physicians who were not connected with the study. The PHS—our public health service—gave them treatment only after the experiment was exposed and brought to public light. They had never been given even penicillin when it became available in the 1950s.

Although the study was reviewed many times between 1932 and 1970 by PHS officials and medical societies, as well as being reported in 13 public, published articles in prestigious medical and public health journals, it continued uninterrupted and without serious challenge. However, in 1972, a Public Health Service employee became a whistleblower and the story hit the news. Suddenly, almost overnight, the old justifications of the science that had been offered for forty years no longer worked. The physicians were embarrassed, the public health service was embarrassed, and the United States was embarrassed.

The Department of Health, Education, and Welfare (DHEW) quickly appointed an ad hoc advisory panel to review the study as well as the Department's policies and procedures for the protection of human subjects in general. The panel found that neither DHEW nor any other government agency had a uniform or adequate policy for reviewing experimental procedures or securing subjects' consents. This finding occurred more than three decades after the discovery of and the successful prosecution by U. S. of Nazi abuses. The ad hoc panel recommended that the Tuskegee study be terminated at once, and that the remaining subjects be given the

care necessary to treat them (that is, to treat whatever could be treated of the disabilities that resulted from participation). In 1973 DHEW did end the study, but without offering any form treatment for the survivors. Tuskegee had become a true American tragedy, but at least we learned something from this tragedy and almost immediately began to reform the U. S. system of research—unlike the Holocaust, where it seems that U.S. medicine and public policy were unaffected.

Tuskegee would do more to stimulate protections for research subjects than any study ever conducted. The ad hoc advisory panel mentioned the need for improvements in resolving conflict between two strongly held but conflicting values: the dignity of the individual and freedom of scientific inquiry. It also recommended that Congress establish a permanent body that would regulate all federally supported research involving human subjects. This regulatory proposal was not enacted, and still today there is no permanent body. The ad hoc advisory report argued that despite Nuremberg, Helsinki, and related developments, mechanisms of the review and oversight of research were still in a primitive condition in the United States, and that more effective provisions were needed to protect the rights of subjects.

Although many abuses of subjects in American medicine were discovered in the 1970s, we had not at this point discovered many other abuses that would later come to light. Among the most interesting to me were the ways in which we, at the highest levels of government and medicine, had administered some form of radiation to a variety of human subjects—largely during the Cold War in the attempt to find out the risks involved in handling radioactive materials. These awful abuses of U. S. citizens and the citizens of other countries by the U.S. (the Marshall Islands, most notably) were not well understood until about half-way through the Clinton administration, when in 1995 President Clinton offered, for the first time in American history, a national apology as well as compensation for the abuses of federally funded radiation experimentation conducted at our best medical schools and hospitals.

Abuses such as those found in the Jewish Chronic Disease Hospital Case, Tuskegee, and the human radiation experiments cannot be excused on grounds of culturally induced ignorance, despite the pervasive opinion that the consent of human subjects is not morally required in a hospital

setting. Sometimes there are excusing conditions for wrong actions because alternative views are unavailable or are not taken seriously in the context, but alternative views were available in the 1960s and 1970s and were considered matters of the utmost significance in sources available to the relevant parties. It was known or easily knowable at the time (1) that a debate had occurred during the mid-1940s about experimentation in Nazi Germany; (2) that the American Medical Association's Judicial Council had sided in 1946 with what would soon be the Nuremberg view that voluntary consent to participation in research is essential; (3) that the Hippocratic tradition required physicians to put the care of patients first, not to deviate radically from accepted therapies, and not to risk harm to patients through nontherapeutic interventions; and (4) that there was a long tradition of post-Hippocratic writings in medical ethics of figures who recognized nontherapeutic experimentation as valid only if subjects had consented. Thus, requirements such as voluntary consent to experimentation and protection against harmful interventions had long been present in the medical community and even were present in some government policies traceable to the early 1940s.

In light of this history, neither physicians nor government and university officials who participated in the tragic events of the 1960s and 1970s in the U. S. could plausibly appeal to nonculpable moral blindness, because they and the officials at their institutions, as well as responsible higher officials in medicine, could have been expected to remedy contextual moral ignorance. There was ample opportunity for remediation of inadequate moral beliefs and therefore culpability for the continuance of those beliefs. The excuse of nonculpable ignorance, then, is not credible.

The Work of the National Commission for the Protection of Human Subjects

It is striking that a committee that revealed as many problems as the Tuskegee ad hoc advisory panel could have reported its findings as late as 1972-1973—and that we would not learn much about the human radiation abuses until 1995. Yet, as the final touches were put on the 1973 ad hoc advisory panel's report, and while national attention was focused on the Supreme Court's impending decision on the compelling abortion case of Roe v. Wade, newspapers began to publish reports that PHS-supported

investigators were using decapitated fetuses in metabolism research sponsored by NIH (when in fact they took place in Northern Europe). In the wake of Tuskegee, several other controversies mushroomed about research on prisoners, children, and "the institutionalized mentally infirm"—recalling some nightmarish abuses in Germany. Some claims of abuse turned out to be true, and some turned out to be false; but it became apparent to every impartial observer that the Tuskegee panel had opened rather than resolved the debate over human experimentation.

The U. S. Congress responded to Tuskegee and other abuses in 1974 by appointing a National Commission, whose deliberations and conclusions will be the final point in my account of the sequence of events from the Holocaust that led to serious reform in the U. S. System. The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research was established with a charge to identify the ethical principles that should govern the conduct of research involving human subjects and to develop guidelines for the conduct of research. It published its findings about proper principles in a document known as the *Belmont Report*, which has become—at least symbolically—the American ideal of responsible research. It sets out those principles and ideals that should govern all research. But the National Commission did not produce merely a set of general ideals; it published seventeen reports and appendix volumes, most focused on ethical issues in the use of vulnerable populations. Its more than one hundred recommendations for reform of the American system went directly to the Secretary of the Department of Health, Education, and Welfare (DHEW), and many were codified in federal regulations circa 1978 (US 45 CFR 46). They are something like the backbone of research ethics as we now understand it in the U.S.

This Commission had a transformative effect on the many years of morally insensitive research investigations in the U.S. It paid careful attention to the socioeconomic deprivation of the subjects who had been enrolled in the Tuskegee experiments and then looked for, and found, contemporary examples of similar abuses of vulnerable subjects in the U.S.

The law that created the Commission specified that no more than five of the Commission's eleven members could be research investigators. This stipulation is a bold way of Congress's determination at the time that

research activities of the biomedical and behavioral sciences be brought under the critical eye of, and possibly the control of, impartial persons who were not themselves scientists. At the time, the system was largely one that placed responsibility for the protection of human subjects on the shoulders of individual investigators. That is, federal policies relied on the discretion and good judgment of investigators to determine under which conditions research should be conducted. Federal involvement and review committees were then in the formative stages. They were destined to undergo rapid change toward protectionism under the guidance of the National Commission.

The lesson is this: When the Congress created the National Commission in 1973, there was considerable distrust of scientists and research physicians. Too much had gone badly. The Congress was in effect saying, "We will no longer allow scientists to self-regulate, because we have seen that self-regulation can lead to very problematic situations."

Conclusion: The Situation Today and The System Under Which We Operate

Despite Congress's message, we did not create a system and do not have one today in which scientists are not in control of their own deliberations about the particulars of research involving human subjects. On the contrary, we have created a system in which scientists are firmly in control of the review of the science that is conducted in their own institutions. The system is far more impartial and thorough today than it was in, say, 1973; but it still in 2011 is a system with relatively little outside oversight and a lot of problems. I cannot go deeply into the problems, but I will in conclusion mention a few reports that have been conducted and filed in the last decade.

In June of 1998 the Office of the Inspector General of DHHS issued a report in which it stated that the pillar of the US system of review—the IRB—is in serious jeopardy, and with it the protection of human subjects is in serious jeopardy. In 2003 the DHHS commissioned the Institute of Medicine to conduct a report of the system of research review in the U. S. The resulting analysis by IOM stated that major reforms are needed and that the system is sagging under the weight of far too many responsibilities

assigned to those engaged in the review of research. Several other reports, both before and after, reached similar conclusions. By the late-1990s it was apparent to every knowledgeable observer that the system of research review in the U. S. is seriously strained and seriously underfunded in many of our great medical research institutions. A number of them have been put on notice, and some have even had their federal funding withdrawn.

I have no time to go into what these problems are in particular, but I can say that they occur at multiple levels and that they affect our finest institutions of research medicine. The United States is not in jeopardy of being Germany in the 1940s, and it is not the seriously problematic U.S. of 1973. But one of the most important lessons to be learned from the Holocaust and from the entire history of biomedical research with human subjects is that our system has never been good enough. Moreover, our society and many others tend to forget the lesson to be learned from Nuremberg, which is that we should constantly be on guard against the victimization of the most vulnerable. It is extraordinary to me that now. more than 60 years after Nuremberg, we do not know the full extent of what happened in German medicine. Few victimizers were punished and many were promoted in the German system. We do not even know the identities of a great many of the victims, and all of our figures on how many victims there were are probably serious underestimates.

There are many reasons still today why we know so little, and often the reasons are sad to contemplate. One reason is that in most countries there was little will to pursue the war crimes of the Holocaust. Most of us quickly lost interest. Another reason is even sadder: Having won the war, we frequently capitulated to the protracted resistance by the German and Austrian governments to further investigations and to the providing of compensation for the victims of these medical experiments. West German legal authorities have never accepted the American judgment at Nuremberg, nor did the civil police or many academic officials in Germany. In post-war Germany both German officials and U. S. occupation forces were ineffective in coming to grips with the vast scope of war crimes. It was not until 1995 that we in the United States began to come to grips with our own history of experimental abuses to the point that we were willing to award compensation for the victims of human radiation experiments. Now more than a decade into the 21st century, there is still a great deal to

be learned from the Holocaust, not merely as a matter of history, but as a matter of current practice and policy.

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Cary M. Maguire Center for Ethics & Public Responsibility
Southern Methodist University
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