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Jonathan D. Moreno

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REASSESSING THE INFLUENCE OF THE NUREMBERG CODE ON AMERICAN MEDICAL ETHICS

*Jonathan D. Moreno, Ph.D.**

John Fletcher's career is marked both by his vigilant defense of the rights of human research subjects, and by his determined insistence that important medical studies proceed under ethically acceptable conditions. Appropriately, this celebration of John Fletcher's career¹ coincides with the fiftieth anniversary of the Nuremberg Code ("Code"). The formulation of the Code by the judges in the war crimes trial of Nazi doctors following World War II marked the beginning of the modern effort to ensure ethical conduct in research. This Article considers the role of the Code and its effect upon certain aspects of the evolution of research standards in the United States, a process that John Fletcher greatly influenced. This Article argues that recent revelations about Cold War era deliberations among high ranking officials enable a far more deeper understanding of the Code's role during the years following the war than had been possible before this material was unclassified.

I. JUDGMENT AT NUREMBERG

On August 19, 1947, the war crimes trials of twenty-three Nazi physicians and bureaucrats in Nuremberg, West Germany, came to a close. Known variously as *United States v. Karl Brandt et al.*,² the Nuremberg Medical Trial, or the "Medical Case" (to distinguish it from the trials of Nazi political, industrial and military leaders),³ the trials began on De-

* The author worked on the staff of the Advisory Committee on Human Radiation Experiments. The enclosed views are those of the author and do not represent the views of the Advisory Committee.

1. Franklin G. Miller, *Dedicatory Essay on John C. Fletcher*, 13 J. CONTEMP. HEALTH L. & POL'Y ix-xiv (1996).

2. *The Medical Case, Trials of War Criminals before the Nuremberg Military Tribunals under Control Council Law No. 10* (U.S. Government Printing Office, 1949).

3. Advisory Committee on Human Radiation Experiments, *Final Report of the Advisory Committee on Human Radiation Experiments 75* (1996) [hereinafter *Advisory Committee*].

ember 9, 1946. The trials took far longer than the prosecution expected because the issues were more complex than they appreciated at the outset. The defense was able to argue and present evidence that the conventions or the common practice of human subject research were ambiguous, contrary to the claims of prosecution witnesses. In the end, however, the three judges, all Americans, found fifteen of the defendants guilty of atrocities, sentencing seven to death.⁴

The case presented by the defense apparently left a deep impression upon the Nuremberg judges. Rather than simply rule on the guilt or innocence of the defendants, the judges decided to formulate a set of statements that would leave no doubt about which ethical principles must govern the use of human beings in medical science. In this effort, they were influenced strongly by Dr. Andrew Ivy, an expert witness sent by the American Medical Association ("AMA") to testify on medical ethics at the trials.⁵ Dr. Ivy conducted experiments in the United States on questions similar to those pursued by the Nazi researchers, including seawater desalination and the effects of high altitudes. More significantly, Dr. Ivy sometimes used human subjects.⁶

In August 1946, Ivy prepared a twenty-two page document setting out the rule of human experimentation, giving one copy to the AMA's Judicial Council and another to the Nuremberg prosecutors.⁷ On December 11, 1946, the AMA House of Delegates approved a somewhat shorter version of Ivy's rules, which were published subsequently along with other items of business in the *Journal of the American Medical Association*.⁸ The most important provisions of the Code itself, which was published along with the rest of the tribunal's judgment in August 1947, reproduced verbatim most of Ivy's language, as well as two contributions from a memorandum prepared by the other American expert witness, Dr. Leo Alexander.⁹ The Code also was accompanied by the judges' assertion that these principles already were widely understood in the scientific

4. *Id.* See also *The Medical Case*, *supra* note 2.

5. *Id.*

6. *Id.* at 75-76.

7. *Id.* at 76.

8. *Supplementary Report of the Judicial Council, Proceedings of the House of Delegates Annual Meeting, 9-11 Dec. 1946*, 132 JAMA 1090 (Dec. 28, 1946). See also William A. Coventry, *Report of the Reference Committee on Miscellaneous Business, Proceedings of the House of Delegates Meeting, 9-11 Dec. 1946*, 133 JAMA 35 (1947). See Advisory Committee, *supra* note 3, at 77.

9. Advisory Committee, *supra* note 3, at 76-77.

community.¹⁰ Were that the case, a critic might wonder why was it necessary to formulate them in this context. Why would a simple declaration of guilt or innocence based on the facts of the matter not be sufficient?

II. THE NUREMBERG CODE IN THE UNITED STATES: THE STANDARD VIEW

Although the trials themselves were not followed closely in the United States, the guilty verdicts did make the front page of the *New York Times*.¹¹ What then, was the influence of the Code in the United States, especially in the years immediately following the trials? Most commentators believe the influence of the Code in the United States was imperceptible. According to historian David Rothman, "the prevailing view was that [the Nuremberg medical 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."¹²

At least four rationales supported this attitude. First, once the conduct of the Nazi doctors became known, it was regarded as so extreme and *sui generis* as to have little or no bearing on civilized people who conducted scientific research according to their consciences. Second, the concentration camps were regarded as a radically different environment from anything resembling a normal setting for medical studies, far more cruel than even a conventional prison. Third, the longstanding tradition of medical ethics, embodied in the beneficent philosophy of the Hippocratic Oath, was regarded as a generally adequate basis upon which the medical profession could police itself. Fourth, the Code's absolute requirement for the "voluntary consent of the subject" obviously was inapplicable to populations upon whom important medical research was being done, and had been done for some time, including children.¹³

To be sure, there were some exceptions to the perception that the Code did not apply to normal medical research with human subjects. Although most popular press coverage of human-subject research was highly sensational, there were occasional critical articles exposing the use of "human

10. *Id.* at 77.

11. *Id.* at 85.

12. David Rothman, *Strangers at the Bedside: A History of How Law and Bioethics Transformed Medical Decision Making* 62, 62-63 (1994).

13. Susan E. Lederer & Michael A. Grodin, *Historical Overview: Pediatric Experimentation*, in MICHAEL A. GRODIN & LEONARD H. GLANTZ, *CHILDREN AS RESEARCH SUBJECTS* 3-28 (1994).

guinea pigs" in the years following World War II.¹⁴ In the early 1950's, sociologist Renee Fox found that physician-scientists in a metabolic research ward were highly sensitive to the ethical dilemmas they faced, and paraphrased the Nuremberg Code as the principle upon which the researchers she observed based their use of human subjects.¹⁵ But as medical researcher Jay Katz has observed, most of the medical research community has adopted this view: "[The Nuremberg Code] was a good code for barbarians but an unnecessary code for ordinary physicians."¹⁶

More pertinent to the territory staked out in this Article is the influence of the Code in the legal sphere. Professor Leonard Glantz has argued that the Code has had little influence on federal regulations for the conduct of human subjects research,¹⁷ though his survey does not include the defense establishment, which is the focus of this Article. Professor George Annas has noted that the first United States court citation of the Code was in 1973, and concludes from his analysis of its subsequent influence in court decisions that national security generally has trumped the Code in cases involving the abuse of human beings by defense-related federal agencies during the Cold War.¹⁸

Stanley v. United States,¹⁹ is the only United States Supreme Court case that comments on the Code, and then only in dissent.²⁰ In *Stanley*, an Army sergeant attempted to bring suit against the government for subjecting him to illegal drug experimentation, but his case was dismissed under the *Feres* doctrine which prohibits members of the Armed Forces from suing the government for harms inflicted "incident to service."²¹

14. See e.g., John L. O'Hara, *The Most Unforgettable Character I've Met*, READER'S DIGEST, May 1948, at 30, 31; Thomas Koritz, J.M.D., *I Was a Human Guinea Pig*, SATURDAY EVENING POST, July 25, 1953, at 27.

15. RENEE C. FOX, EXPERIMENT PERILOUS: PHYSICIANS AND PATIENTS FACING THE UNKNOWN 69, 69-71, 112 n.16, 227-29 (1959).

16. Advisory Committee, *supra* note 3, at 86 (op. Jay Katz).

17. LEONARD H. GLANTZ, *The Influence of the Nuremberg Code on U.S. Statutes and Regulations*, in THE NAZI DOCTORS AND THE NUREMBERG CODE 183 (George J. Annas & Michael A. Grodin eds., 1992). See Claire A. Milner, Comment, *Gulf War Guinea Pigs: Is Informed Consent Optional During War*, 13 J. CONTEMP. HEALTH L. & POL'Y 199, 211-18 (1996) (discussing the extent to which the principles of the Code have been incorporated into the law of the United States).

18. GEORGE J. ANNAS, *The Nuremberg Code in U.S. Courts: Ethics versus Expediency*, in THE NAZI DOCTORS AND THE NUREMBERG CODE 201 (George J. Annas & Michael A. Grodin eds., 1992).

19. *United States v. Stanley*, 483 U.S. 669 (1987).

20. *Id.* at 687 (Brennan, J., dissenting).

21. *Stanley*, 483 U.S. at 669. For a more detailed discussion of *Stanley* and the *Feres* doctrine, see Milner, *supra* note 17, at 219-23.

The remainder of this Article reassesses the influence of the Code on American medical ethics in the decade immediately following the Medical Trials, especially in the national security establishment. Recent information suggests that the Code was influential in quarters that many would find surprising. For example, although the Code's influence did not reach the medical profession or research community, it did flourish in the councils of the national security establishment as part of planning for defense against unconventional atomic, biological, and chemical weaponry during the decade following World War II.

This reassessment is both prompted and justified by the Final Report of the President's Advisory Committee on Human Radiation Experiments, released by President Clinton on October 3, 1995. The appointment of the Committee was followed by press reports of government sponsored, unethical and often secret experiments on human beings conducted between 1944 and 1974. These experiments included injecting hospitalized patients with plutonium, feeding radiation-laced breakfast cereal to institutionalized adolescents, exposing cancer patients to total-body irradiation, and irradiating the testicles of prisoners in state penitentiaries. In order to determine whether the experiments conformed to the ethical standards of the day, or those currently recognized, the Advisory Committee was granted unprecedented access to thousands of pages of formerly classified documents relating to the development of human research policies within the national security establishment. As a member of the Committee staff, I was charged with helping the Committee come to an understanding of the nature and significance of these historical standards.

III. POST-WAR NOTICE OF NUREMBERG IN THE ATOMIC ENERGY COMMISSION

In its investigation of the post-war period, 1946 to 1948, the Committee found that there was a flurry of activity surrounding the use of human subjects in 1947 in the newly formed Atomic Energy Commission ("AEC"), the civilian entity that inherited many of the programs and contracts of the Manhattan Project.²² This activity was inspired in part, by a series of plutonium injections administered to hospitalized patients

22. The Manhattan Project was the code name for the World War II-era, U.S. government-sponsored research and development program that led to the atomic bomb. It continues as a common informal reference to the project. Advisory Committee, *supra* note 3, at 46-53.

with diagnoses of bone cancer during the war; which apparently were intended to help provide the AEC information about safe levels of exposure for laboratory workers handling fission products.²³ While the Committee did not conclude that the AEC was influenced directly by the Nuremberg Trials or the subsequent Code, the AEC's response to the injection project was an attempt to ensure that its contractor physicians agreed to certain standards in the use of human subjects.²⁴ These standards were expressed in the AEC General Manager's response to two different inquiries.²⁵

The first response, a letter written in April 1947, indicated the AEC's "expectation that [research with human subjects] may have therapeutic effect,"²⁶ as well as the requirement of proof that "each individual patient, being in an understanding state of mind, was clearly informed of the nature of the treatment and its possible effects, and expressed his willingness to receive the treatment."²⁷ The April letter also required that two physicians must certify in writing that these conditions were satisfied.²⁸ The second response, a November 1947 letter, went even further; requiring that the "patient give his complete and informed consent in writing"²⁹

As an advisor to a subcommittee of the President's cabinet, the Committee had to analyze carefully the surviving documentary evidence from the agency during that period at hand. That evidence did not include specific reference to the Medical Trials that were still taking place at Nuremberg in April 1947, nor did it include the fact that the trials were concluded by November of that year. The most that the Committee could conclude with certainty was that the AEC was aware of the potentially negative legal and public relations effects of publicity surrounding the plutonium injections. The AEC's concern was evidenced by the March 1947 recommendation of AEC's Medical Division and Public Relations

23. *Id.*

24. *Id.*

25. Letter from Carroll L. Wilson, General Manager of the AEC to Stafford Warren, the University of California at Los Angeles, (Apr. 30, 1947) (on file with National Archives & Records Admin., College Park, Md., in Record Group 220 by ACHRE No. DOE-052094-A-439). See also Letter from Carroll L. Wilson, General Manager of the AEC, to Robert Stone, University of California, (Nov. 5, 1947) (on file with National Archives & Records Admin., College Park, Md., in Record Group 220 by ACHRE No. DOE-052295-A-1).

26. Letter from Wilson to Warren, *supra* note 25.

27. *Id.*

28. *Id.*

29. Letter from Wilson to Stone, *supra* note 25.

department to continue the classified status of a paper about the experiment.³⁰ Similarly, an unsigned October 1947 memorandum to the AEC's Advisory Board on Biology and Medicine suggested that "[t]here is perhaps a greater responsibility if a federal agency condones human guinea pig experimentation."³¹

It is reasonable to assume based on the evidence before the Committee, that the national security establishment was aware of the Nuremberg proceedings and the implications of Nuremberg on human subject research. Yet it would have been remarkable if the lawyers and administrators who were charged with responsibility for the nation's nuclear arsenal, and whose agency had a virtual monopoly control over the availability of radioisotopes for medical or any other purposes, had not taken note of the proceedings then taking place in Nuremberg. The likelihood that they did take note is given credence by a remark made by an AEC official several years later, in 1950.³² The AEC and the Department of Defense ("DOD") were engaged in planning a joint project called Nuclear Energy for the Propulsion of Aircraft ("NEPA").³³ Of particular concern was the amount of radiation to which an air crew could safely be exposed by the energy source of the aircraft.³⁴ One of the physician consultants was Robert Stone, who was the recipient of the November 1947 letter from the AEC general manager that required "informed consent."³⁵ Stone proposed that human experimentation was the only method of obtaining the needed information.³⁶ But the AEC's Division of Biology and Medicine chief, Shields Warren, objected.³⁷ In a meeting of the AEC-

30. Letter from Major B. M. Brundage, Chief of Medical Division of the AEC to the Declassification Section, (Mar. 19, 1947) ("Clearance of Technical Documents") (on file with National Archives & Records Admin., College Park, Md., in Record Group 220 by ACHRE No. DOE-113094-B-4).

31. Memorandum from unknown author to the Advisory Board on Biology and Medicine, (Oct. 8, 1947) (on file with National Archives & Records Admin., College Park, Md., in Record Group 220 by ACHRE No. DOE-0151094-A-502).

32. Memorandum from the Assistant Secretary of the Army to the Director of Medical Services, Office of the Secretary of Defense, (May 3, 1950) (on file with the National Archives & Records Admin., College Park, Md., in Record Group 220 by ACHRE No. DOE-113094-B-4).

33. Shields Warren, at the Meeting of the AEC-DOD Joint Panel on the Medical Aspects of Atomic Warfare 28, transcript available in the National Archives, (Nov. 10, 1950) (on file with National Archives & Records Admin., College Park, Md., in Record Group 220 by ACHRE No. DOE-012795-C-1).

34. *Id.*

35. Letter from Wilson to Stone, *supra* note 25.

36. Warren, *supra* note 33.

37. *Id.*

DOD Joint Panel on the Medical Aspects of Atomic Warfare, during which the use of "prisoner volunteers" was proposed, Warren replied: "It's not very long since we got through trying Germans for doing exactly the same thing."³⁸

Further, a 1951 exchange, between the AEC's Division of Biology and Medicine and the Commission's Los Alamos Laboratory, indicates that the spirit, if not the letter, of the Nuremberg Code was known outside AEC's central office.³⁹ A Los Alamos information officer, Leslie Redman, inquired about the AEC's policies on human experimentation, which were known only vaguely at the Lab (and which strongly suggests that neither of the sets of rules in the two 1947 letters was widely disseminated).⁴⁰ Redman said that his understanding was that "these regulations are comparable to those of the American Medical Association . . ."⁴¹ Thus, although Redman was not familiar with the two 1947 letters, the AMA principles, which were in essence the same as those expressed in the Code, did make an impression on the "culture" of radiation research.

IV. THE NUREMBERG CODE IN THE PENTAGON

The Joint Panel's proposal to conduct prisoner experiments, opposed by the AEC's Shields Warren, was also hotly debated in the Pentagon; all of these discussions were, of course, highly classified. Interestingly, the two major uniformed services, the Army and the Navy, split on the question of prisoner experimentation in 1950, with the Army opposing the proposal and the Navy favoring it. The Assistant Secretary of the Army argued that animal studies should be continued instead of human subject research, and noted that the Joint Panel's proposal was rejected by the Committee on Medical Sciences of the Pentagon's Research and Development Board.⁴² While the Assistant Secretary technically was correct, the Committee did not close off the possibility of the proposal for human experiments entirely, but referred the matter back to the Joint Panel for further consideration.⁴³ At least two of the Committee's physician mem-

38. *Id.*

39. Letter from Leslie M. Redman, Los Alamos Laboratory, to Dr. Alberto F. Thompson, Chief of Technical Information Service, DBM, (Jan. 22, 1951) (on file with National Archives & Records Admin., College Park, Md., in Record Group 220 by ACHRE No. DOE-012795-C-1).

40. *Id.*

41. *Id.*

42. Memorandum from the Assistant Secretary of the Army to the Director of Medical Services, *supra* note 32.

43. *Id.*

bers seemed to agree that human studies could be done so long as they conformed with the December 1946 AMA principles.⁴⁴ Clearly, by 1950, the AMA-Nuremberg principles were on the minds of many medical advisors in the national security establishment.

The human experimentation debate raged on in the Pentagon for the following two years.⁴⁵ Finally, in mid-October 1952, a Defense Department lawyer named Stephen S. Jackson determined that the Nuremberg Code principles would have to be used in their entirety because they “already had international juridical sanction.”⁴⁶ Jackson so advised the Armed Forces Medical Policy Council (“AFMPC”), a high level Pentagon body that was chaired by Dr. Melvin Casberg.⁴⁷ At their October 13, 1952 meeting, the AFMPC recommended that the Department of Defense adopt the Code as its policy for the use of human experimental subjects, with one addition recommended by Jackson: that prisoners of war explicitly were ruled out as research participants.⁴⁸

The significance of Jackson’s conclusion should not be treated lightly. Jackson’s conclusion contrasts remarkably with the later rejections of the Code by courts that viewed its principles as superseded by national security considerations.⁴⁹ However, as the documentary evidence only recently available makes clear, in 1952, a Pentagon lawyer recognized the Code as good law that applied to the United States Department of Defense.⁵⁰ Justice Jackson’s conclusion was supported strongly by an Assistant Secretary of Defense for Manpower and Personnel, Anna M. Rosenberg.⁵¹ Rosenberg not only concurred in the Pentagon counsel’s view, but also recommended the addition of a clause that required the written consent of the potential subject.⁵² Thus, the AFMPC “strongly

44. Meeting of the Committee on Medical Sciences of the Research and Development Board, Department of Defense, transcript (partial), (May 23, 1950) (on file with National Archives & Records Admin., College Park, Md., in Record Group 220 by ACHRE No. DOE-012795-C-1).

45. *Id.*

46. Letter from Adam J. Rapalski, Administrator, Armed Forces Epidemiological Board, DOD, to Colin MacLeod, President, Armed Forces Epidemiological Board, DOD, (Mar. 2, 1953) (on file with National Archives & Records Admin., College Park, Md., in Record Group 220 by ACHRE No. NARA 012395-A-5).

47. Advisory Committee, *supra* note 3, at 57.

48. *Id.*; see also Letter from Stephen S. Jackson to Dr. Melvin A. Casberg, Advisory Committee on Human Radiation Experiments, Final Report 279 (Supp. 1995).

49. See ANNAS, *supra* note 18, at 209.

50. See Rapalski, *supra* note 46.

51. Advisory Committee, *supra* note 3, at 57.

52. See Stephen S. Jackson, Assistant General Counsel in the Office of the Secretary of Defense and Counsel for the Armed Forces Medical Policy Council, DOD, to Melvin A.

recommended that a policy be established for the use of human volunteers (military and civilian employees) in experimental research at Armed Forces facilities,"⁵³ and that such use "be subject to the principles and conditions laid down as a result of the Nuremberg Trials."⁵⁴

But the path of the Code through the Pentagon hierarchy was still not a smooth one. Internal opposition to a written human subjects policy was considerable; its "controversial character" was admitted by George V. Underwood, the Director of the Executive Office of the Secretary of Defense early in 1953.⁵⁵ Underwood then attempted to win the strong endorsement of the proposal by the three uniformed service secretaries prior to the new administration of President-elect Eisenhower.⁵⁶ This effort failed, however, and it was agreed instead that the matter should be called to the attention of Eisenhower's incoming Secretary of Defense, Charles E. Wilson, as he was the one who would have to implement it.⁵⁷

When the new Secretary of Defense approved the AFMPC's recommendation on February 26, 1953, he could not have had much time to study what perhaps had been the single most debated subject in Pentagon medical circles for the previous three years. As the former Chief Executive of General Motors, Charles E. Wilson brought with him an expeditious management style, and was accustomed to relying on the judgment of responsible subordinates. Because he was not an expert on medical issues himself, Wilson must have appreciated the need to prepare for expected Soviet and Chinese challenges in unconventional atomic, biological, and chemical warfare. His experience in labor relations also might have taught him the importance of written contracts and protection from liability. The preamble to the Nuremberg Code-based memorandum specifies that the human experiments being contemplated were "the only feasible means for realistic evaluation and/or development of effective

Casberg, Chairman of the Armed Forces Medical Policy Council, (Oct. 22, 1952) (ACHRE No. NARA-101294-A) (stating that Assistant Secretary of Defense Rosenberg recommended the additional language).

53. Memorandum from Melvin A. Casberg, Chairman of the Armed Forces Medical Policy Council, DOD, to the Secretary of Defense, (Jan. 13, 1953) Advisory Committee on Human Radiation Experiments 305 (Supp. 1995).

54. *Id.*

55. Memorandum from George V. Underwood, Director of the Executive Office of the Secretary of Defense, to Deputy Secretary Foster, (Jan. 4, 1953) Advisory Committee on Human Radiation Experiments, Final Report 304 (Supp. 1995).

56. Memorandum from George V. Underwood, Director of the Executive Office of the Secretary of Defense, to Mr. Keys, Deputy Secretary of Defense, (Feb. 5, 1953) Advisory Committee on Human Radiation Experiments, Final Report 307 (Supp. 1995).

57. *Id.*

preventive measures of defense against atomic, biological or chemical agents”⁵⁸

V. THE NUREMBERG CODE MEETS HARVARD MEDICAL SCHOOL

As several commentators⁵⁹ have noted, the Code never established a firm foothold in United States statutes or regulations. This fact was the result of both the Code’s failure to address research on those who were unable to give “voluntary consent,” such as children, and to a cultural resistance towards external regulation on the part of the medical profession.

In 1959, the National Society for Medical Research (“NSMR”) held a conference at the University of Chicago on legal issues in medicine. An NSMR “Committee on the Re-Evaluation of the Nuremberg Experimental Principles” recommended that consent be understood as “either explicit or reasonably presumed,” and that third-parties be allowed to give permission for those who are incapable of consenting to research.⁶⁰

From 1954 to 1964, the World Medical Association discussed its own research code of ethics, generally referred to as the Declaration of Helsinki (“Declaration”).⁶¹ Developed by representatives of the medical research community itself, the Declaration differed from the Code in several important ways, which included a more flexible view of subject consent at such time as research participation can be considered to be potentially beneficial to the subject.⁶²

In 1961, several years before the Declaration, administrators at Harvard Medical School became concerned about a new clause in its Army medical research contracts. The language in this clause essentially reiterated the Code and applied it to the Army’s contract researchers, as well as to research conducted by the Army itself. An assistant dean of the medical school, Dr. Joseph W. Gardella, noted that “[t]he Nuremberg Code was conceived in reference to Nazi atrocities [T]he Code . . . is not necessarily pertinent to or adequate for the conduct of medical re-

58. Memorandum from Secretary of Defense to the Secretary of the Army, Secretary of the Navy, Secretary of the Air Force, (Feb. 26, 1953) (“Use of Human Volunteers in Experimental Research”) (ACHRE No. DOD-082394).

59. These commentators include George Annas and Leonard Glantz. *See* ANNAS, *supra* note 18, at 201; *see also* GLANTZ, *supra* note 17, at 183.

60. National Society for Medical Research, Report on the National Conference on the Legal Environment of Medicine 88 (May 27-28, 1959).

61. 21 C.F.R. § 312.120(c)(4) (1996).

62. *Id.* *See also* Milner, *supra* note 17, at 209-11 (outlining the differences between the Code and the Declaration and the history of the Declaration).

search in the United States.”⁶³ Dr. Gardella also questioned whether those who are sick are capable of understanding complex information, an issue that has been a concern of more recent scholarship in biomedical ethics.⁶⁴

When Dr. Gardella presented his discussion to the medical school administrative board in 1962, a board member, Dr. Henry Beecher, agreed to draft a statement of Harvard's principles concerning human research.⁶⁵ Dr. Beecher published a paper in the *New England Journal of Medicine* that contended there were numerous examples of the abuse of human subjects in the published medical literature.⁶⁶ Dr. Beecher's article, "Ethics and Clinical Research," proved to be one of the most influential events in the history of modern medical ethics.⁶⁷ However, Beecher relied less on subject consent as a protection for research participants, particularly those who are ill, than he did on the relationship between the patient and his or her physician.⁶⁸ In short order, Beecher and his Harvard colleagues succeeded in persuading the Army to permit them to substitute their principles for the Nuremberg Code language in their research contracts.⁶⁹

VI. CHANGING A PROFESSIONAL CULTURE

The failure of the AEC and Pentagon policies to penetrate the cultures of their respective professional communities provides an important lesson about the reform of deeply ingrained practices among highly trained experts. In both cases, lawyers and non-physician administrators attempted to impose conditions that were regarded as irrelevant or unrealistic by medical researchers. Although there was apparent willingness to accept AEC central office research requirements at the contract laboratories, it is important to appreciate that, by the early 1950's, the human subjects exposed to ionizing radiation for experimental purposes were mainly normal healthy research volunteers. By contrast, in the late 1940's, those who were subjects in radiation experiments were often sick patients, for whom the appropriateness of a consent process was met with much skep-

63. Advisory Committee, *supra* note 3, at 90.

64. *Id.* at 91.

65. *Id.*

66. Henry K. Beecher, M.D., *Ethics and Clinical Research*, 274 *NEW ENG. J. MED.* 1354, 1354-55 (1966).

67. *Id.* at 1354-60.

68. *Id.* at 1355.

69. Advisory Committee, *supra* note 3, at 91.

ticism. We saw the same dynamic at work fifteen years later in the NSMR committee report, Harvard Medical School's reception of the Nuremberg Code clause in its Army contracts, and in the Declaration of Helsinki.⁷⁰

To appreciate the true influence of the Code, one must abandon the expectation that, to be influential, it would have to be accepted immediately and openly and integrated into the actual practices of the research community. Instead, the Code's attempt to articulate the ethics of research was flawed, and the initial reception given it by most researchers was also flawed. Nevertheless, the root principle of consent proved hard to ignore. Even as efforts were made to massage and transform it, events such as the Thalidomide tragedy⁷¹ and the Tuskegee study,⁷² in the 1960's and 1970's,⁷³ brought home its forceful truth, however poorly expressed. With a logic that seems inexorable in retrospect, the Code first was seen as obviously applying to imprisoned and oppressed persons, then to all healthy subjects, then to those who were sick but would not benefit from an experiment, and then finally to those who were sick but stood a chance of benefitting from research participation. In fact, it was not logic that was operative in this evolution, but a growth in moral perception.

VII. CONCLUSION

Although the principle of informed consent to research participation is now well established even for those who are sick there is still reluctance among many medical professionals to accept that patients facing serious medical problems are able to process information about innovative therapies. The Advisory Committee's Subject Interview Study of hundreds of patients throughout the country found varying levels of understanding of research, but widespread trust among research subjects in medical professionals and medical institutions.⁷⁴ The juxtaposition of limited understanding and exceptional trust gives reason for concern about the consequences if the public begins to discern reasons for more skepticism of the research enterprise. John Fletcher's career has been marked by an unyielding commitment to the advancement of scientific knowledge, but

70. *Id.*

71. *Id.* at 92. See RUTH FADEN & TOM BEAUCHAMP, A HISTORY AND THEORY OF INFORMED CONSENT 203 (1986) (discussing the Thalidomide tragedy).

72. FADEN & BEAUCHAMP, *supra* note 71, at 167.

73. *Id.*

74. *Id.* at 475-76.

only under conditions in which the trust of research subjects has been earned.