



The Advisory Committee on Human Radiation Experiments: Reflections on a Presidential Commission

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The Advisory Committee on Human Radiation Experiments (Advisory Committee) was created by President Clinton on 15 January 1994, in response to mounting allegations of human rights abuses in government-sponsored radiation experiments conducted during the cold war. The suspect research included a series of experiments in which patients, some terminally ill, were injected with plutonium at Oak Ridge Hospital, the University of Rochester, the University of Chicago, and the University of California, as well as two experiments in which seriously ill patients were injected with uranium at the University of Rochester and Massachusetts General Hospital.

In many respects, the Advisory Committee was in the tradition of national bioethics commissions exemplified by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (National Commission) created in 1975 and the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research (President's Commission) created in 1980. However, the Advisory Committee was also unlike these and other bioethics commissions in important respects. The purpose of this article is to highlight these similarities and differences and to bring some perspective to bear on the Advisory Committee's work and accomplishments.

Mission and Method of the Advisory Committee

The Advisory Committee was a presidential advisory commission. Like the President's Commission, committee members were appointed by the president. Our designated government liaison¹ was a member of the White House staff and our reports were submitted to the president through a working group of the cabinet. Presidential advisory commissions are not rare events in public policy. There were ninety-nine such commissions

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The Advisory Committee on Human Radiation Experiments

Reflections on a Presidential Commission

by Ruth Faden

Like the National Commission and the President's Commission, the Advisory Committee on Human Radiation Experiments was formed to carry out specific ethical tasks. Yet the committee also had an "openness" mission, a charge to investigate allegations that the U.S. government secretly exposed Americans to environmental releases of radiation. Eighteen months later—and after sixteen public meetings, more than 200 interviews, and the review of about 400,000 documents—the committee delivered a 925-page report to the president.

between 1945 and 1972. Yet, the creation of a presidential commission remains a noteworthy national event, signifying an extraordinary action by the president,² and the status and authority we enjoyed as a presidential commission were among our chief assets. Although federal advisory commissions with other mechanisms of appointment and reporting can have a profound effect on public policy—consider, for example, the National Commission, which was created by Congress and reported to the secretary of the Department of Health, Education and Welfare (now DHHS)—it is worth noting that thus far there have been very few presidential commissions in bioethics.

The Advisory Committee was charged with making determinations about the morality of actions and policies in the conduct of the human radiation experiments and intention-

al releases of radiation into the environment and assessing the extent to which current protections and practices are sufficient to guard against moral abuses of human subjects in the future. The role of bioethics was reflected in my selection as chair of the Advisory Committee, and in the appointment to the Advisory Committee of three eminent contributors to the field—Jay Katz, Patricia King, and Ruth Macklin. The bioethics mission was also reflected in the Advisory Committee's staff. The associate directors of the staff were Jeffrey Kahn and Anna Mastroianni; they were joined by Jonathan Moreno and Jeremy Sugarman as senior staff and Jeffrey Botkin, Allen Buchanan, Nancy Kass, and Gail Geller as consultants. Because our focus was the ethics of research with human subjects, we resembled the National Commission,³ which also was created in

part in response to a series of allegations about abuses in human subject research. We also share a common lineage with the Tuskegee Syphilis Study Ad Hoc Panel, appointed by the Department of Health, Education, and Welfare in 1972 to review that study as well as the department's policies and procedures for the protection of human subjects in general.

From our inception, however, it was clear that we had an additional mission. News reports alleged not only that biomedical scientists had acted unethically but also that, in the interests of national security, the U.S. government had deceived and used Americans in human experiments and had exposed them to secret environmental releases of radiation. These allegations went to the heart of the compact between citizens and their government. They also symbolized the worst of the cold war, evoking images of a secret government dominated by clandestine operations and manipulations of the truth.

The Clinton administration had undertaken a major initiative to reverse this image and with it the public's lack of confidence in government. As the first administration to begin its tenure in the post-cold war era, the committee fit directly into this initiative. As the president remarked in accepting our final report:

I saw this committee as an indispensable part of our effort to restore the confidence of the American people in the integrity of their government . . . When I became the president, I realized we had great new economic challenges, we had profound social problems, and that a lot . . . had to be done by an energized American citizenry, but that our national government had a role to play in moving our country through this period of transition. And in order to do it, we needed to increase the capacity of the government to do it through political reform, but we also needed . . . to increase the confidence of the American people so that . . . they could trust the government to tell the truth and to do the right things.

So you have to understand that, for me, one reason this is so important is that it is part of our ongoing effort to give this government back to the American people . . . We have declassified thousands of government documents, files from the Second World War, the cold war, President Kennedy's assassination. These actions are not only consistent with our national security, they are essential to advance our values.

So, to me, that's what this is all about.⁴

Arguably, it was the Advisory Committee's mission as an "openness commission," more than our mission as a bioethics commission, that animated our creation by the president. This mission highlighted our critical role as an investigative body, but it would be a mistake to draw too sharp a line between the bioethics and the investigative dimensions of our work. Central to our mission as a bioethics commission was the controversial problem of retrospective moral judgment—whether and how to assess the morality of past practices and the people responsible for them. The framework adopted by the committee for this difficult task identified three kinds of ethical standards as relevant. One standard, basic ethical principles, was understood not to be limited by time or context. By contrast, the other two standards, the policies of government agencies at the time and the rules of professional ethics at the time, required the committee to investigate not only the facts of the events themselves but the professional and cultural context in which the events took place. The investigative dimension of the committee's work was, moreover, typical of presidential commissions. Commissions are generally created to provide careful analysis of a complex problem, and that analysis necessarily requires an investigation of relevant data and perspectives. Many of the President's Commission's reports, for example, relied heavily on fact finding as well as moral and legal analysis.

That said, however, the significance of our openness mission cannot be overstated. Allegations of grave signifi-

cance had been lodged against the government. The creation of the Advisory Committee as a presidential commission was intended to symbolize concern for the situation at the highest level of government. Moreover, it was recognized that any inquiry into these allegations that was advisory to the specific federal agencies at issue, let alone any inquiry internal to those agencies, would lack credibility. Thus, although the Advisory Committee was in the tradition of bioethics commissions, it also was in the tradition of crisis-oriented commissions such as the President's Commission on the Accident at Three Mile Island, the Presidential Commission on the Space Shuttle Challenger Accident, and the Advisory Commission on Civil Disorders (Kerner Commission). Such commissions are intended to bolster public trust in government candor in the face of scandal or disaster.

Like other crisis-oriented commissions, we were expected to complete our work quickly. The committee's initial term was for twelve months, later extended to eighteen months. By contrast, the National Commission existed for over three years and the President's Commission for over four years. In number of commissioners, we were somewhat larger than either the National Commission or President's Commission, both of which had eleven members; we had fourteen. In addition to the four members with expertise in bioethics, the members of the committee included a representative of the general public and experts in radiation oncology and biology, nuclear medicine, epidemiology and biostatistics, public health, history of science and medicine, and law. These same disciplines were mirrored on the Advisory Committee's forty-member professional staff. Like the National Commission and the President's Commission, the Advisory Committee's staff was headed by a lawyer, Daniel Guttman.

The scope of the committee's charge was enormous. We were asked to investigate events that spanned administrations from Franklin Roosevelt to Gerald Ford and that involved the highest echelons of both the defense establishment and the scientific community. We were to examine the con-

duct and policies of six federal agencies including the Departments of Defense, Energy, Health and Human Services and Veterans Affairs, NASA, and the CIA.

Between April 1994 and July 1995, the Advisory Committee held sixteen public meetings, most in Washington, D.C. In addition, subsets of committee members presided over public fora in cities throughout the country. The committee heard from more than 200 witnesses and interviewed dozens of professionals who were familiar with experiments involving radiation. A special effort, called the Ethics Oral History Project, was undertaken to learn from eminent physician-investigators how research with human subjects was conducted in the 1940s, 1950s, and 1960s.

We were granted unprecedented access to government documents. The president directed all the federal agencies involved to make available to the committee any documents that might further our inquiry, wherever they might be located and whether or not they were still secret. With the assistance of hundreds of federal officials and agency staff, the committee retrieved and reviewed approximately 400,000 government documents, many of which were buried in obscure locations throughout the United States. Some of the most important documents were secret and were declassified at our request.

The status and authority we enjoyed as a presidential committee were critical to our success in this discovery of the nation's past. The agencies were obligated by an executive order to comply with our requests, and some cabinet members, notably Hazel O'Leary of the Department of Energy, had made the recovering of these records a personal agency priority. Moreover, as a presidential commission we received extensive press coverage, which gave us leverage in our relationships with the agencies.

In addition to investigating experiments conducted decades ago, it was important to investigate the current conduct of human research. Insofar as wrongdoing may have occurred in the past, and in order to make policy recommendations for the future, we needed to examine the likelihood that similar events could happen to-

day. Toward this end, we undertook three projects to examine the current state of human research.

First, we studied how each agency of the federal government that currently conducts or funds research involving human subjects regulates this activity and oversees it. We focused in this inquiry on oversight of conventional human research and on current policies and practices with respect to secret or classified research with human subjects. Second, from among the large number of research projects involving human subjects currently supported by the federal government, we randomly selected 125 from both radiation- and nonradiation-related disciplines for scrutiny. Third, to learn from subjects themselves, the committee conducted the Subject Interview Study in which almost 1,900 patients receiving medical care in outpatient facilities of private and federal hospitals throughout the country were surveyed.

Here again, we benefited from our status as a presidential commission. The federal agencies were obligated to provide us with contemporary grant materials by executive order. By contrast, we did not have subpoena power, and thus universities and other private research institutions were under no legal obligation to provide us with either research documents or access to their patients. However, these institutions appreciated the implications of refusing to cooperate with a presidential commission, including negative press coverage, and compliance with our requests was high. Every university we approached furnished us with the documents we requested and most of the clinical facilities we approached permitted us to interview their patients.

The Advisory Committee's Work and Our Recommendations

On 3 October 1995 we delivered our final report to the president at a White House ceremony.⁵ Eighteen months of investigation, analysis, and deliberation were distilled into a document of more than 900 pages. The report is divided into four parts.

Part I, "Ethics of Human Subjects Research: A Historical Perspective," which contains four chapters, explores

how both federal government agencies and the medical profession approached human experimentation from 1944 to 1974. In the last chapter of Part I we present our framework for evaluating the ethics of human radiation experiments, grounded in both history and philosophical analysis.

Part II, "Case Studies," approaches particular experiments from several angles, each of which raises overlapping ethical questions. The chapters on the plutonium injections and total-body irradiation consider the use of sick patients to provide data needed to protect the health of workers engaged in the production of nuclear weapons; the chapter on prisoners considers the use of healthy subjects for this purpose; the chapter on children considers experimentation with particularly vulnerable people; and the chapter on the Atomic Energy Commission's program of radioisotope distribution considers the institutional safeguards that underlay the conduct of thousands of human radiation experiments. The chapters on intentional releases, atomic veterans, uranium miners, and Marshall Islanders consider, in common, situations in which entire groups of people were exposed to risk as a consequence of government-sponsored cold war programs. The section concludes with a review of the degree to which secrecy impaired, and may still impair, our ability to understand human radiation experiments and intentional releases conducted in the 1944-1974 period.

Part III, "Contemporary Projects," reports the results of our three inquiries into the present, as well as the committee's synthesis of the implications of these results for the current state of human subject research.

Part IV, "Coming to Terms with the Past, Looking Ahead to the Future," reports the Advisory Committee's findings and recommendations. Some of the highlights of these findings and recommendations are summarized below.

Based on a finding that wrongs had been committed, the Advisory Committee recommended that the government deliver an apology and provide financial compensation to the subjects (or their next of kin) of human radiation experiments conducted

under specified circumstances. We also concluded that a grave injustice had been done to uranium miners by the government and recommended the removal of barriers to compensation under existing legislation. Addi-

jects. Many of the Advisory Committee's recommendations are directed toward this finding. Specifically, we recommended that the institutional review board (IRB) component of the federal system be changed by creat-

protection of human subjects be subjected to regular, periodic evaluations that are based on an examination of outcomes and performance and that include the perspective and experiences of subjects of research as well as the research community; (2) the current structure of sanctions that can be imposed on investigators and grantee institutions for violations of research ethics rules be reviewed to determine if it is appropriate to the seriousness with which the nation takes violations of the rights and interests of human subjects; (3) human subjects protections be extended to nonfederally funded research; and (4) a mechanism be created for the satisfactory resolution of the long-standing social issue of compensation to subjects of federally funded research for research injuries. We also recommended specific steps to improve existing protections of the rights and interests of human subjects recruited from among military personnel.

Our report also called for the establishment of a mechanism to provide for the continuing interpretation and application of ethics rules and principles for the conduct of human subject research in an open and public forum, an essential process if research involving human subjects is to have an ethical framework responsive to changing scientific and social times.

We realize, however, that regulations and policies are no guarantee of ethical conduct. If the events of the past are not to be repeated, it is essential that the research community increasingly come to value the ethics of research involving human subjects. Thus, one of our key recommendations is that efforts be undertaken on a national scale to ensure the centrality of ethics in the conduct of scientists whose research involves human subjects.

Significance of the Advisory Committee for Bioethics

At this writing, it is less than a year since the Advisory Committee submitted its final report. The nature and extent of its impact, and thus the extent to which the Advisory Committee was a success, cannot yet be assessed. Nevertheless, some preliminary ob-

Perhaps most central to the field of bioethics is our finding that there are serious deficiencies in the current system for the protection of the rights and interests of human subjects.

tional recommendations addressed government responsibilities to populations environmentally exposed to radiation from government operations conducted in support of nuclear weapons, and to atomic veterans and the people of the Marshall Islands.

Based on a finding that current research involving human subjects sponsored by the government may be classified and conducted in secret, and a finding that environmental releases can still take place in secret under current environmental laws and regulations, we recommended specific changes in applicable federal policy to safeguard the rights and interests of human subjects and communities. We called especially for the adoption of a federal policy requiring the informed consent of all human subjects of classified research and propose that this requirement not be subject to exemption or waiver. We called further for the creation of an independent panel of appropriate nongovernmental experts and citizen representatives to review and approve all classified research with human subjects and all secret environmental releases.

Perhaps most central to the field of bioethics is our finding, based primarily on our review of contemporary research documents and the results of the Subject Interview Study, that there are serious deficiencies in the current system for the protection of the rights and interests of human sub-

jects. Many of the Advisory Committee's recommendations are directed toward this finding. Specifically, we recommended that the institutional review board (IRB) component of the federal system be changed by creating mechanisms for ensuring that: (1) IRBs appropriately allocate their time so they can adequately review studies that pose more than minimal risk to human subjects; (2) the information provided to potential subjects clearly distinguishes research from treatment, realistically portrays the likelihood that subjects may benefit medically from their participation and the nature of the potential benefit, and clearly explains the potential for discomfort and pain that may accompany participation in the research; (3) the information provided to potential subjects clearly identifies the federal agency or agencies sponsoring or supporting the research project and all purposes for which the research is being conducted or supported; and (4) the information provided to potential subjects clearly identifies the financial implications of deciding to consent or refuse to participate in research. We argued that IRBs have the responsibility to determine that the science is of a quality to warrant imposing risk or inconvenience on human subjects and, in the case of research that purports to offer a prospect of medical benefit to subjects, to determine that participating in the research affords patient-subjects at least as good an opportunity of securing this medical benefit as would be available to them without participating in research.

We recommended further that: (1) the current federal system for the

servations can be made about initial effects and responses, particularly with respect to the field of bioethics.

According to one scholar of presidential commissions, a critical standard for assessing a commission's impact is the degree to which the president supports the commission's findings and recommendations through such measures as the issuance of presidential statements, the introduction of legislation, and administrative action taken by the president or within the executive branch.⁶ By this criterion, the Advisory Committee already has achieved success. The president issued a powerful public statement in accepting our final report in which he endorsed our findings and recommendations. The statement included a moving public apology to former subjects and their families, thereby implementing one of our principal recommendations. The statement announced the issuance of an executive order instructing every agency of the federal government that supports or conducts human research to review their procedures in light of the Advisory Committee's recommendations and report their findings to the president. The executive order also created the National Bioethics Advisory Commission, a new presidential commission with a broad mandate for research ethics.

The impact of these presidential actions is not yet known. A working group of officials from all six of the agencies that fell under the Advisory Committee's mandate, together with staff from the Domestic Policy Council, have been charged by the president with formalizing the administration's responses to the full range of the committee's recommendations. Although federal agencies have already taken steps to implement some of our recommendations, no official actions have been made public. A formal response is expected by the one-year anniversary of the release of our report.

Public policies typically have complicated histories and the creation of a National Bioethics Advisory Commission is no exception. Efforts to create such a commission predate the Advisory Committee; at the same time, however, it is likely that the committee was instrumental in the com-

mission's actual authorization. The committee did not recommend that any specific body be established, and some committee members were not supportive of the creation of another ad hoc, advisory group. The charter of the National Bioethics Advisory Commission is responsive, however, to the Advisory Committee's recommendation that a public mechanism be established to interpret and apply ethical rules and principles in research with human subjects.

The extent to which the Advisory Committee succeeded in our openness mission to contribute to the national effort to "give this government back to its people" is perhaps clearer. We are particularly proud to be responsible for the declassification of so many significant documents of interest not only to scholars of the ethics and history of biomedical science, but also to scholars of the cold war and the national security establishment. The entire document collection of the Advisory Committee, including the oral histories and the data tapes of the Subject Interview Study, now is available to the public through the National Archives and Records Administration. In an unprecedented step, much of this collection is to be available electronically. In a further effort to assist citizens as well as scholars and journalists interested in conducting their own investigations into the past, we included in our final report a "Citizen's Guide to the Nation's Archives," which provides instructions for accessing federal records as well as the Advisory Committee's collection.

There are several important respects in which the committee's experience is also of immediate significance for bioethics. Although I have already noted that the president's interest in creating the committee was animated by his commitment to openness in government, the Advisory Committee did bring questions of bioethics to the president's attention. It is likely that the Advisory Committee occasioned the first public comment by an American president on the subjects of informed consent and the ethics of human research:

Medical and scientific progress depends upon learning about

people's responses to new medicines, to new cutting-edge treatments . . . We have to continue to research, but there is a right way and a wrong way to do it.

There are local citizen's review boards, there are regulations that establish proper informed consent and ensure that experiments are conducted ethically. But in overseeing this necessary research, we must never relax our vigilance.

The breathtaking advances in science and technology demand that we always keep our ethical watch light burning . . . Science is not ever simply objective. It emerges from the crucible of historical circumstances and personal experience. Times of crisis and fear call forth bad science, even science we know in retrospect to be unethical . . . Let these pages serve as an internal reminder to hold humility and moral accountability in higher esteem than we do the latest development in technology.

The Advisory Committee also brought to the attention of bioethics issues that have curiously received little attention within the field—the relationship of science to the state and the role of secrecy in government-sponsored research. In 1975, congressional hearings and the report of another presidential advisory committee, the Rockefeller Commission, revealed to the public the details of a CIA program, known principally by the codename MKULTRA, involving secret experiments on unwitting human subjects conducted as part of an extensive effort to develop techniques to influence and control human behavior. Although these revelations prompted President Ford to issue an executive order in 1976 requiring informed consent in human experimentation with drugs, in accordance with guidelines issued by the National Commission, MKULTRA occasioned little discussion in the then burgeoning bioethics literature.

In 1986 a congressional subcommittee headed by U.S. Representative Edward Markey released what was in fact the first federal report on human radiation experiments, "American

Nuclear Guinea Pigs: Three Decades of Radiation Experiments on U.S. Citizens." At a time in bioethics when there was keen interest in the topics of informed consent and research ethics, this report alleged that unwitting human subjects had been used in (sometimes) secret government research. However, for reasons that remain obscure, the Markey Report, as well as the issues the report raised, went virtually unnoticed in the field. As has already been noted, some of the Advisory Committee's most strongly worded recommendations are directed at serious gaps in public policy governing the conduct of secret government research.

Also largely unexamined in the bioethics literature prior to the Advisory Committee is the history of policies governing human research in federal agencies other than the Department of Health and Human Services (and its predecessor, the Department of Health, Education and Welfare). As we now know, other agencies, including most notably the Department of Defense, had a long tradition of internal debate and policy development with respect to human research that was of substantial concern not only to military scientists but to the many university medical researchers whose work was supported by the Defense Department.

The work of the Advisory Committee underscores what is I believe already recognized by many in bioethics: the importance of history and historical context to bioethics scholarship. There is no question that the committee's assessment of the current state of human research, and particularly our approach toward improving the future, was affected in profound ways by our historical investigation of the policies and practices of the 1940s and '50s. Our reading of that history caused us to view with skepticism the ultimate effectiveness of rules and regulations to ensure ethical conduct in the use of human subjects, particularly when the culture of the institutions and professions that control the enterprise runs counter to those rules. When we looked toward the future, although we called

for changes in public policy, we reserved our strongest recommendations for changes in the culture of human subjects research and in the values and commitments of biomedical scientists.

History is important not only for its lessons for the future, but also because of obligations to be accountable for and responsive to the moral failings of the past. A public apology by the president is a significant national act intended, in the words of one Advisory Committee member, to "bind the nation's wounds," wounds of distrust rooted in historical circumstances. In the history of American science, there is at least one other episode, the Tuskegee Syphilis Study, where wounds linger and a public apology is called for. The precedent set by our work and the president's response to it will, I hope, be extended in just this way.

Finally, the Advisory Committee has significance for bioethics as a lesson in power. Our review of contemporary research documents and the Subject Interview Study were by no means flawless efforts, but they were also remarkable achievements. Conducted in less than a year, they provide the first systematic effort to obtain national data bearing on the effectiveness of the current system of human subject protections since the work of the National Commission. That this kind of probing evaluation has been provided only by presidential commissions is no coincidence. Absent specific federal authority and public prominence, it is difficult, if not impossible, to garner the access, the cooperation, and the resources necessary to conduct a meaningful, outcomes-based, assessment of human subjects protections.

A central asset of a presidential commission is its political clout; it is difficult for institutions, both within and outside of government, to say no to a presidential commission. This power permitted us to do in eighteen months what a generation of historians and scholars of bioethics might never have achieved. We opened the door on mountains of the nation's records and we opened a window

onto the current state of human subject research. In the end, one critical measure of a presidential commission is whether it uses its power as wisely as possible to advance the public good. Whether we did remains to be seen.

References

1. Under the Federal Advisory Committees Act, each advisory committee must have a "designated federal official" whose role includes the official opening and closing of every meeting. Our designated federal official was Philip Caplan, deputy assistant to the president.
2. Thomas R. Wolanin, *Presidential Advisory Commissions: Truman to Nixon* (Madison, Wis.: University of Wisconsin Press, 1975) p. 31.
3. Although the National Commission's clear focus was the ethics of human research, it also issued less well known reports on other topics. See Bradford Gray, "Bioethics Commissions: What Can We Learn from Past Successes and Failures?" in *Society's Choices: Social and Ethical Decision Making in Biomedicine*, ed. Ruth Bulgar, Elizabeth Bobby, and Harvey Fineberg (Washington, D.C.: National Academy Press, 1995).
4. Remarks by President William J. Clinton in Acceptance of Human Radiation Final Report, *The Human Radiation Experiments: Final Report of the President's Advisory Committee* (New York: Oxford University Press, 1996), p.xvii.
5. The Final Report was originally issued by the U.S. Government Printing Office (stock number 061-000-00-848-9). The *Executive Summary and Guide to the Final Report* (stock number 061-000-00849-7) and the three supplemental volumes to the Final Report (061-000-00850-1, 061-000-00851-9, and 061-000-00852-7) may be purchased from the Superintendent of Documents, U.S. Government Printing Office. The Final Report is now available from Oxford University Press, *The Human Radiation Experiments*.
6. Wolanin, *Presidential Advisory Commissions*, p. 132.
7. Remarks by President William J. Clinton in Acceptance of Human Radiation Final Report, *The Human Radiation Experiments*, p. xix.
8. U.S. House of Representatives, Committee on Energy and Commerce, Subcommittee on Energy Conservation and Power, November 1986, "American Nuclear Guinea Pigs: Three Decades of Radiation Experiments on U.S. Citizens" (ACHRE No. Con-050594-A-1).