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**Executive Summary
and
Guide to Final Report**

*Advisory
Committee
on
Human Radiation
Experiments*

Advisory Committee on Human Radiation Experiments

Ruth R. Faden, Ph.D., M.P.H.-Chair

Philip Franklin Wagley Professor of Biomedical Ethics and Director
The Bioethics Institute
Johns Hopkins University
Baltimore, Maryland

Senior Research Scholar
Kennedy Institute of Ethics
Georgetown University
Washington, D.C.

Kenneth R. Feinberg, J.D.

Kenneth R. Feinberg & Associates
Washington, D.C.

Eli Glatstein, M.D.

Professor and Chair
Department of Radiation Oncology
The University of Texas
Southwestern Medical Center at Dallas
Dallas, Texas

Jay Katz, M.D.

Elizabeth K. Dollard Professor Emeritus
of Law, Medicine and Psychiatry
Harvey L. Karp Professorial Lecturer in Law
and Psychoanalysis
Yale Law School
New Haven, Connecticut

Patricia A. King, J.D.

Professor of Law
Georgetown University Law Center
Washington, D.C.

Susan E. Lederer, Ph.D.

Associate Professor
Department of Humanities
The Pennsylvania State University College of Medicine
Hershey, Pennsylvania

Ruth Macklin, Ph.D.

Professor of Bioethics
Department of Epidemiology & Social Medicine
Albert Einstein College of Medicine
Bronx, New York

Lois L. Norris

Second Vice President of Omaha National Bank
and Omaha National Corporation (Retired)
Omaha, Nebraska

Nancy L. Oleinick, Ph.D.

Professor of Radiation Biochemistry
Division of Radiation Biology
Case Western Reserve University School of Medicine
Cleveland, Ohio

Henry D. Royal, M.D.

Professor of Radiology
Associate Director; Division of Nuclear Medicine
Mallinckrodt Institute of Radiology
Washington University Medical Center
St. Louis, Missouri

Philip K. Russell, M.D.

Professor, Department of International Health
Johns Hopkins University
School of Hygiene and Public Health
Baltimore, Maryland

Mary Ann Stevenson, M.D., Ph.D.

Assistant Professor of Radiation Oncology
Joint Center for Radiation Therapy
Harvard Medical School
Boston, Massachusetts

Deputy Chief

New England Deaconess Hospital
Department of Radiation Oncology
Boston, Massachusetts

Duncan C. Thomas, Ph.D.

Director, Biostatistics Division
Department of Preventive Medicine
University of Southern California School of Medicine
Los Angeles, California

Reed V. Tuckson, M.D.

President
Charles Drew University of Medicine and Science
Los Angeles, California

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*Advisory Committee on Human
Radiation Experiments*

FINAL REPORT

EXECUTIVE SUMMARY

AND

GUIDE TO FINAL REPORT

Executive Summary

The Creation of the Advisory Committee	3
The President's Charge	4
The Committee's Approach	5
The Historical Context	8
Key Findings	10
Key Recommendations	16
What's Next: The Committee's Legacy	20

Guide to the Final Report	21
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THE CREATION OF THE ADVISORY COMMITTEE

On January 15, 1994, President Clinton appointed the Advisory Committee on Human Radiation Experiments. The President created the Committee to investigate reports of possibly unethical experiments funded by the government decades ago.

The members of the Advisory Committee were fourteen private citizens from around the country: a representative of the general public and thirteen experts in bioethics, radiation oncology and biology, nuclear medicine, epidemiology and biostatistics, public health, history of science and medicine, and law.

President Clinton asked us to deliver our recommendations to a Cabinet-level group, the Human Radiation Interagency Working Group, whose members are the Secretaries of Defense, Energy, Health and Human Services, and Veterans Affairs; the Attorney General; the Administrator of the National Aeronautics and Space Administration; the Director of Central Intelligence; and the Director of the Office of Management and Budget. Some of the experiments the Committee was asked to investigate, and particularly a series that included the injection of plutonium into unsuspecting hospital patients, were of special concern to Secretary of Energy Hazel O'Leary. Her department had its origins in the federal agencies that had sponsored the plutonium experiments. These agencies were responsible for the development of nuclear weapons and during the Cold War their

activities had been shrouded in secrecy. But now the Cold War was over.

The controversy surrounding the plutonium experiments and others like them brought basic questions to the fore: How many experiments were conducted or sponsored by the government, and why? How many were secret? Was anyone harmed? What was disclosed to those subjected to risk, and what opportunity did they have for consent? By what rules should the past be judged? What remedies are due those who were wronged or harmed by the government in the past? How well do federal rules that today govern human experimentation work? What lessons can be learned for application to the future? Our Final Report provides the details of the Committee's answers to these questions. This Executive Summary presents an overview of the work done by the Committee, our findings and recommendations, and the contents of the Final Report.

THE PRESIDENT'S CHARGE

The President directed the Advisory Committee to uncover the history of human radiation experiments during the period 1944 through 1974. It was in 1944 that the first known human radiation experiment of interest was planned, and in 1974 that the Department of Health, Education and Welfare adopted regulations governing the conduct of human research, a watershed event in the history of federal protections for human subjects.

In addition to asking us to investigate human radiation experiments, the President directed us to examine cases in which the government had intentionally released radiation into the

environment for research purposes. He further charged us with identifying the ethical and scientific standards for evaluating these events, and with making recommendations to ensure that whatever wrongdoing may have occurred in the past cannot be repeated.

We were asked to address human experiments and intentional releases that involved radiation. The ethical issues we addressed and the moral framework we developed are, however, applicable to all research involving human subjects.

The breadth of the Committee's charge was remarkable. We were called on to review government programs that spanned administrations from Franklin Roosevelt to Gerald Ford. As an independent advisory committee, we were free to pursue our charge as we saw fit. The decisions we reached regarding the course of our inquiry and the nature of our findings and recommendations were entirely our own.

THE COMMITTEE'S APPROACH

At our first meeting, we immediately realized that we were embarking on an intense and challenging investigation of an important aspect of our nation's past and present, a task that required new insights and difficult judgments about ethical questions that persist even today.

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 forums 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 physicians about how research with human subjects was conducted in the 1940s and 1950s.

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.

As we began our search into the past, we quickly discovered that it was going to be extremely difficult to piece together a coherent picture. Many critical documents had long since been forgotten and were stored in obscure locations throughout the country. Often they were buried in collections that bore no obvious connection to human radiation experiments. There was no easy way to identify how many experiments had been conducted, where they took place, and which government agencies had sponsored them. Nor was there a quick way to learn what rules applied to these experiments for the period prior to the mid-1960s. With the assistance of hundreds of federal officials and agency staff, the Committee retrieved and reviewed hundreds of thousands of government documents. Some of the most important documents were secret and were declassified at our request. Even after this extraordinary effort, the historical record remains incomplete. Some potentially important collections could not be located and were evidently lost or destroyed years ago.

Nevertheless, the documents that were recovered enabled us to identify nearly 4,000 human radiation experiments sponsored

by the federal government between 1944 and 1974. In the great majority of cases, only fragmentary data was locatable; the identity of subjects and the specific radiation exposures involved were typically unavailable. Given the constraints of information, even more so than time, it was impossible for the Committee to review all these experiments, nor could we evaluate the experiences of countless individual subjects. We thus decided to focus our investigation on representative case studies reflecting eight different categories of experiments that together addressed our charge and priorities. These case studies included:

- experiments with plutonium and other atomic bomb materials
- the Atomic Energy Commission's program of radioisotope distribution
- nontherapeutic research on children
- total body irradiation
- research on prisoners
- human experimentation in connection with nuclear weapons testing
- intentional environmental releases of radiation
- observational research involving uranium miners and residents of the Marshall Islands

In addition to assessing the ethics of human radiation experiments conducted decades ago, it was also important to explore the current conduct of human radiation research. Insofar as wrongdoing may have occurred in the past, we needed to examine the likelihood that such things could happen today. We therefore undertook three projects:

- A review of how each agency of the federal government that currently conducts or funds research involving human subjects regulates this activity and oversees it.
- An examination of the documents and consent forms of research projects that are today sponsored by the federal government in order to develop insight into the current status of protections for the rights and interests of human subjects.
- Interviews of nearly 1,900 patients receiving out-patient medical care in private hospitals and federal facilities throughout the country. We asked them whether they were currently, or had been, subjects of research, and why they had agreed to participate in research or had refused.

THE HISTORICAL CONTEXT

Since its discovery 100 years ago, radioactivity has been a basic tool of medical research and diagnosis. In addition to the many uses of the x ray, it was soon discovered that radiation could be used to treat cancer and that the introduction of "tracer" amounts of radioisotopes into the human body could help to diagnose disease and understand bodily processes. At the same time, the perils of overexposure to radiation were becoming apparent.

During World War II the new field of radiation science was at the center of one of the most ambitious and secret research efforts the world has known--the Manhattan Project. Human radiation experiments were undertaken in secret to help under

stand radiation risks to workers engaged in the development of the atomic bomb.

Following the war, the new Atomic Energy Commission used facilities built to make the atomic bomb to produce radioisotopes for medical research and other peacetime uses. This highly publicized program provided the radioisotopes that were used in thousands of human experiments conducted in research facilities throughout the country and the world. This research, in turn, was part of a larger postwar transformation of biomedical research through the infusion of substantial government monies and technical support.

The intersection of government and biomedical research brought with it new roles and new ethical questions for medical researchers. Many of these researchers were also physicians who operated within a tradition of medical ethics that enjoined them to put the interests of their patients first. When the doctor also was a researcher, however, the potential for conflict emerged between the advancement of science and the advancement of the patient's well-being.

Other ethical issues were posed as medical researchers were called on by government officials to play new roles in the development and testing of nuclear weapons. For example, as advisers they were asked to provide human research data that could reassure officials about the effects of radiation, but as scientists they were not always convinced that human research could provide scientifically useful data. Similarly, as scientists, they came from a tradition in which research results were freely debated. In their capacity as advisers to and officials of the government, however, these researchers found that the openness of science now needed to be constrained.

None of these tensions were unique to radiation research. Radiation represents just one of several examples of the exploration of the weapons potential of new scientific discoveries during and after World War II. Similarly, the tensions between clinical research and the treatment of patients were emerging throughout medical science, and were not found only in research involving radiation. Not only were these issues not unique to radiation, but they were not unique to the 1940s and 1950s. Today society still struggles with conflicts between the openness of science and the preservation of national security, as well as with conflicts between the advancement of medical science and the rights and interests of patients.

KEY FINDINGS

Human Radiation Experiments

- Between 1944 and 1974 the federal government sponsored several thousand human radiation experiments. In the great majority of cases, the experiments were conducted to advance biomedical science; some experiments were conducted to advance national interests in defense or space exploration; and some experiments served both biomedical and defense or space exploration purposes. As noted, in the great majority of cases only fragmentary data are available.
- The majority of human radiation experiments identified by the Advisory Committee involved radioactive tracers administered in amounts that are likely to be similar to those used in research today. Most of these tracer studies involved adult subjects and are unlikely to have caused physical harm. However, in some nontherapeutic tracer

studies involving children, radioisotope exposures were associated with increases in the potential lifetime risk for developing thyroid cancer that would be considered unacceptable today. The Advisory Committee also identified several studies in which patients died soon after receiving external radiation or radioisotope doses in the therapeutic range that were associated with acute radiation effects.

- Although the AEC, the Defense Department and the National Institutes of Health recognized at an early date that research should proceed only with the consent of the human subject, there is little evidence of rules or practices of consent except in research with healthy subjects. It was commonplace during the 1940s and 1950s for physicians to use patients as subjects of research without their awareness or consent. By contrast, the government and its researchers focused with substantial success on the minimization of risk in the conduct of experiments, particularly with respect to research involving radioisotopes. But little attention was paid during this period to issues of fairness in the selection of subjects.
- Government officials and investigators are blameworthy for not having had policies and practices in place to protect the rights and interests of human subjects who were used in research from which the subjects could not possibly derive direct medical benefit. To the extent that there was reason to believe that research might provide a direct medical benefit to subjects, government officials and biomedical professionals are less blameworthy for not having had such protections and practices in place.

Intentional Releases

- During the 1944-1974 period, the government conducted several hundred intentional releases of radiation into the environment for research purposes. Generally, these releases were not conducted for the purpose of studying the effects of radiation on humans. Instead they were usually conducted to test the operation of weapons, the safety of equipment, or the dispersal of radiation into the environment.
- For those intentional releases where dose reconstructions have been undertaken, it is unlikely that members of the public were directly harmed solely as a consequence of these tests. However, these releases were conducted in secret and despite continued requests from the public that stretch back well over a decade, some information about them was made public only during the life of the Advisory Committee.

Uranium Miners

- As a consequence of exposure to radon and its daughter products in underground uranium mines, at least several hundred miners died of lung cancer and surviving miners remain at elevated risk. These men, who were the subject of government study as they mined uranium for use in weapons manufacturing, were subject to radon exposures well in excess of levels known to be hazardous. The government failed to act to require the reduction of the hazard by ventilating the mines, and it failed to adequately warn the miners of the hazard to which they were being exposed.

Secrecy and the Public Trust

- The greatest harm from past experiments and intentional releases may be the legacy of distrust they created. Hundreds of intentional releases took place in secret, and remained secret for decades. Important discussion of the policies to govern human experimentation also took place in secret. Information about human experiments was kept secret out of concern for embarrassment to the government, potential legal liability, and worry that public misunderstanding would jeopardize government programs.
- In a few instances, people used as experimental subjects and their families were denied the opportunity to pursue redress for possible wrongdoing because of actions taken by the government to keep the truth from them. Where programs were legitimately kept secret for national security reasons, the government often did not create or maintain adequate records, thereby preventing the public, and those most at risk, from learning the facts in a timely and complete fashion.

Contemporary Human Subjects Research

- Human research involving radioisotopes is currently subjected to more safeguards and levels of review than most other areas of research involving human subjects. There are no apparent differences between the treatment of human subjects of radiation research and human subjects of other biomedical research.
- Based on the Advisory Committee's review, it appears that much of human subjects research poses only minimal risk

of harm to subjects. In our review of research documents that bear on human subjects issues, we found no problems or only minor problems in most of the minimal-risk studies we examined.

- Our review of documents identified examples of complicated, higher-risk studies in which human subjects issues were carefully and adequately addressed and that included excellent consent forms. In our interview project, there was little evidence that patient-subjects felt coerced or pressured by investigators to participate in research. We interviewed patients who had declined offers to become research subjects, reinforcing the impression that there are often contexts in which potential research subjects have a genuine choice.
- At the same time, however, we also found evidence suggesting serious deficiencies in aspects of the current system for the protection of the rights and interests of human subjects. For example, consent forms do not always provide adequate information and may be misleading about the impact of research participation on people's lives. Some patients with serious illnesses appear to have unrealistic expectations about the benefits of being subjects in research.

Current Regulations on Secrecy in Human Research and Environmental Releases

- Human research can still be conducted in secret today, and under some conditions informed consent in secret research can be waived.

- Events that raise the same concerns as the intentional releases in the Committee's charter could take place in secret today under current environmental laws.

Other Findings

The Committee's complete findings, including findings regarding experiments conducted in conjunction with atmospheric atomic testing and other population exposures, appear in chapter 17 of the Final Report.

KEY RECOMMENDATIONS

Apologies and Compensation

The government should deliver a personal, individualized apology and provide financial compensation to those subjects of human radiation experiments, or their next of kin, in cases where:

- efforts were made by the government to keep information secret from these individuals or their families, or the public, for the purpose of avoiding embarrassment or potential legal liability, and where this secrecy had the effect of denying individuals the opportunity to pursue potential grievances.
- there was no prospect of direct medical benefit to the subjects, or interventions considered controversial at the time were presented as standard practice, and physical injury attributable to the experiment resulted.

Uranium Miners

- The Interagency Working Group, together with Congress, should give serious consideration to amending the provisions of the Radiation Exposure Compensation Act of 1990 relating to uranium miners in order to provide compensation to *all* miners who develop lung cancer after some minimal duration of employment underground (such as one year), without requiring a specific level of exposure. The act should also be reviewed to determine whether the documentation standards for compensation should be liberalized.

Improved Protection for Human Subjects

- The Committee found no differences between human radiation research and other areas of research with respect to human subjects issues, either in the past or the present. In comparison to the practices and policies of the 1940s and 1950s, there have been significant advances in the federal government's system for the protection of the rights and interests of human subjects. But deficiencies remain. Efforts should be undertaken on a national scale to ensure the centrality of ethics in the conduct of scientists whose research involves human subjects.
- One problem in need of immediate attention by the government and the biomedical research community is unrealistic expectations among some patients with serious illnesses about the prospect of direct medical benefit from participating in research. Also, among the consent forms we reviewed, some appear to be overly optimistic in portraying the likely benefits of research, to inadequately explain the impact of research procedures on quality of life and personal finances, and to be incomprehensible to lay people.
- A mechanism should be established to provide for continuing interpretation and application in an open and public forum of ethics rules and principles for the conduct of human subjects research. Three examples of policy issues in need of public resolution that the Advisory Committee confronted in our work are: (1) Clarification of the meaning of minimal risk in research with healthy children; (2) regulations to cover the conduct of research with institutionalized children; and (3) guidelines for research with adults

of questionable competence, particularly for research in which subjects are placed at more than minimal risk but are offered no prospect of direct medical benefit.

Secrecy: Balancing National Security and the Public Trust

Current policies do not adequately safeguard against the recurrence of the kinds of events we studied that fostered distrust. The Advisory Committee concludes that there may be special circumstances in which it may be necessary to conduct human research or intentional releases in secret. However, to the extent that the government conducts such activities with elements of secrecy, special protections of the rights and interests of individuals and the public are needed.

Research involving human subjects. The Advisory Committee recommends the adoption of federal policies requiring:

- the informed consent of all human subjects of classified research. This requirement should not be subject to exemption or waiver.
- that classified research involving human subjects be permitted only after the review and approval of an independent panel of appropriate nongovernmental experts and citizen representatives, all with the necessary security clearances.

Environmental releases. There must be independent review to assure that the action is needed, that risk is minimized, and that records will be kept to assure a proper accounting to the public at the earliest date consistent with legitimate national security concerns. Specifically, the Committee recommends that:

- Secret environmental releases of hazardous substances should be permitted only after the review and approval of an independent panel. This panel should consist of appropriate, nongovernmental experts and citizen representatives, all with the necessary security clearances.
- An appropriate government agency, such as the Environmental Protection Agency, should maintain a program directed at the oversight of classified programs, with suitably cleared personnel.

Other Recommendations

The Committee's complete recommendations, including recommendations regarding experiments conducted in conjunction with atmospheric atomic testing and other population exposures, appear in chapter 18 of the Final Report.

WHAT'S NEXT: THE ADVISORY COMMITTEE'S LEGACY

Interagency Working Group Review

The Interagency Working Group will review our findings and recommendations and determine the next steps to be taken.

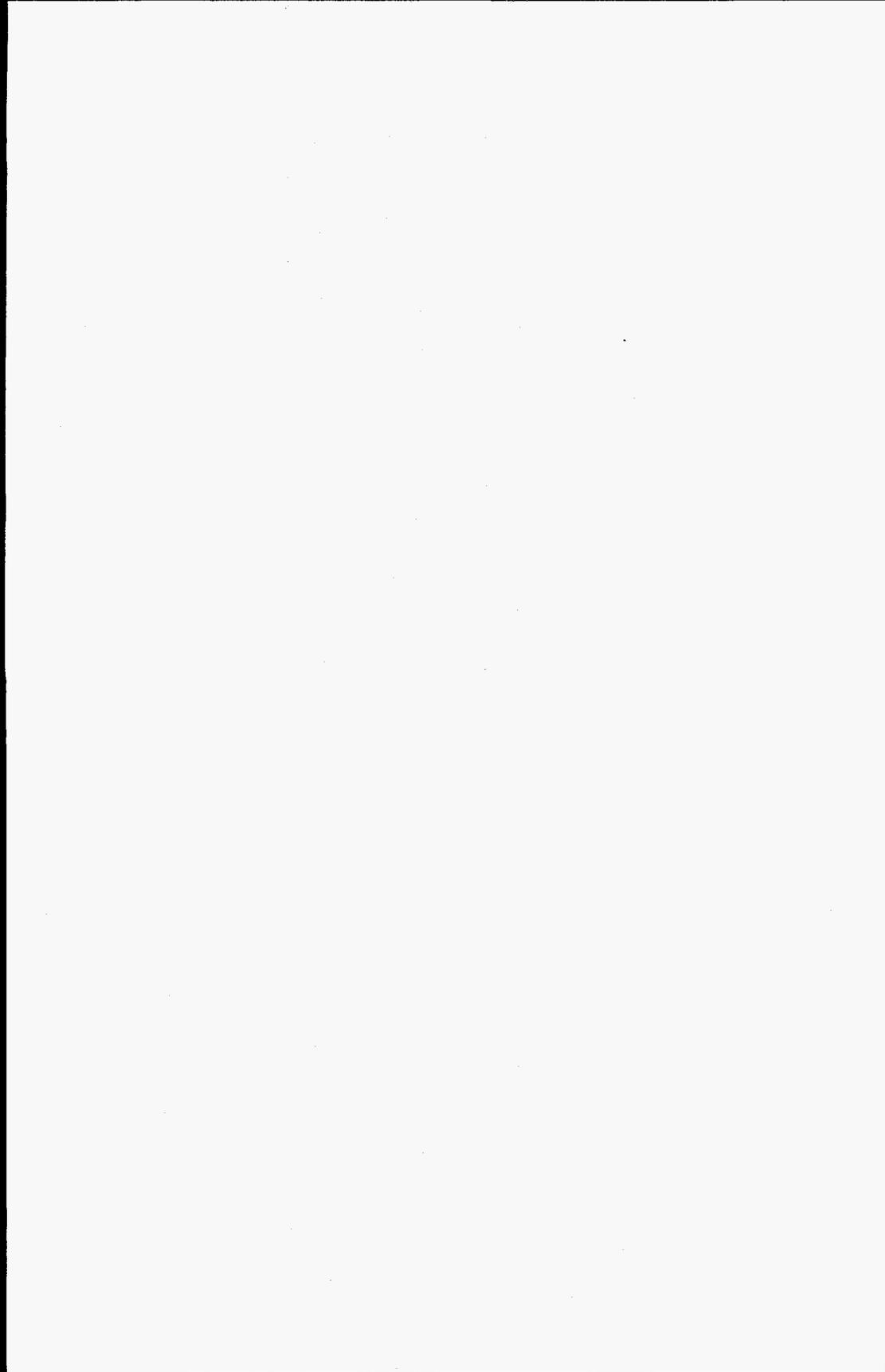
Continued Public Right To Know

The complete records assembled by the Committee are available to the public through the National Archives. Citizens wishing to know about experiments in which they, or family members, may have taken part, will have continued access to the Committee's database of 4,000 experiments, as well as the hundreds of thousands of further documents assembled by the Committee. The Final Report contains "A Citizen's Guide to the Nation's Archives: Where the Records Are and How to Find Them." This guide explains how to find federal records, how to obtain information and services from the member agencies of the Interagency Working Group and the Nuclear Regulatory Commission, how to locate personal medical records, and how to use the Advisory Committee's collection.

Supplemental volumes to the Final Report contain supporting documents and background material as well as an exhaustive index to sources and documentation. These volumes should prove useful to citizens, scholars, and others interested in pursuing the many dimensions of this history that we could not fully explore.

*Advisory Committee on Human
Radiation Experiments*

GUIDE TO THE REPORT



The Final Report is written in an easily accessible style, but it is of necessity long. This guide provides a roadmap and capsule descriptions of each section of the report.

Preface

The Preface explains why the Committee was created, the President's charge, and the Committee's approach.

Introduction: The Atomic Century

The Introduction describes the intersection of several developments: the birth and remarkable growth of radiation science; the parallel changes in medicine and medical research; and the intersection of these changes with government programs that called on medical researchers to play important new roles beyond that involved in the traditional doctor-patient relationship. The Introduction concludes with a section titled "The Basics of Radiation Science" for the lay reader.

Part I. Ethics of Human Subjects Research: A Historical Perspective

Chapter 1. Government Standards for Human Experiments: The 1940s and 1950s

In chapter 1 we report what we have been able to reconstruct about government rules and policies in the 1940s and 1950s regarding human experiments. We focus primarily on the Atomic Energy Commission and the Department of Defense, because their history with respect to human subjects research policy is less well known than that of the Department of Health, Education and Welfare (now the Department of Health and

Human Services). Drawing on records that were previously obscure, or only recently declassified, we reveal the perhaps surprising finding that officials and experts in the highest reaches of the AEC and DOD discussed requirements for human experiments in the first years of the Cold War. We also briefly discuss the research policies of DHEW and the Veterans Administration during these years.

Chapter 2. Postwar Professional Standards and Practices for Human Experiments

In chapter 2 we turn from a consideration of government standards to an exploration of the norms and practices of physicians and medical scientists who conducted research with human subjects during this period. We include here an analysis of the significance of the Nuremberg Code, which arose out of the international war crimes trial of German physicians in 1947. Using the results of our Ethics Oral History Project, and other sources, we also examine how scientists of the time viewed their moral responsibilities to human subjects as well as how this translated into the manner in which they conducted their research. Of particular interest are the differences in professional norms and practices between research in which patients are used as subjects and research involving so-called healthy volunteers.

Chapter 3. Government Standards for Human Experiments: The 1960s and 1970s

In chapter 3 we return to the question of government standards, focusing now on the 1960s and 1970s. In the first part of this chapter, we review the well-documented developments that influenced and led up to two landmark events in the history

of government policy on research involving human subjects: the promulgation by DHEW of comprehensive regulations for oversight of human subjects research and passage by Congress of the National Research Act. In the latter part of the chapter we review developments and policies governing human research in agencies other than DHEW, a history that has received comparatively little scholarly attention. We also discuss scandals in human research conducted by the DOD and the CIA that came to light in the 1970s and that influenced subsequent agency policies.

Chapter 4. Ethics Standards in Retrospect

With the historical context established in chapters 1 through 3, we turn in chapter 4 to the core of our charge. Here we put forward and defend three kinds of ethical standards for evaluating human radiation experiments conducted from 1944 to 1974. These are (1) basic ethical principles that are widely accepted and generally regarded as so fundamental as to be applicable to the past as well as the present; (2) the policies of government departments and agencies at the time; and (3) rules of professional ethics that were widely accepted at the time. We embed these standards in a moral framework intended to clarify and facilitate the difficult task of making judgments about the past.

Part II. Case Studies

Chapter 5. Experiments with Plutonium, Uranium, and Polonium

In chapter 5, we look at the Manhattan Project plutonium-injection experiments and related experimentation. Sick patients were used in sometimes secret experimentation to develop data needed to protect the health and safety of nuclear weapons workers. The experiments raise questions of the use of sick patients for purposes that are not of benefit to them, the role of national security in permitting conduct that might not otherwise be justified, and the use of secrecy for the purpose of protecting the government from embarrassment and potential liability.

Chapter 6. The AEC Program of Radioisotope Distribution

In contrast to the plutonium injections, the vast majority of human radiation experiments were not conducted in secret. Indeed, the use of radioisotopes in biomedical research was publicly and actively promoted by the Atomic Energy Commission. Among the several thousand experiments about which little information is currently available, most fall into this category. The Committee adopted a two-pronged strategy to study this phenomenon. In chapter 6, we describe the system the AEC developed for the distribution of isotopes to be used in human research. This system was the primary provider of the source material for human experimentation in the postwar period. In studying the operation of the radioisotope distribution system, and the related "human use" committees at local institutions, we sought to learn the ground rules that governed the conduct of the majority of human radiation experiments, most of which have received little or no public attention. Also

in this chapter we review how research with radioisotopes has contributed to advances in medicine.

Chapter 7. Nontherapeutic Research on Children

The Committee then selected for particular consideration, in chapter 7, radioisotope research that used children as subjects. We determined to focus on children for several reasons. First, at low levels of radiation exposure, children are at greater risk of harm than adults. Second, children were the most appropriate group in which to pursue the Committee's mandate with respect to notification of former subjects for medical reasons. They are the group most likely to have been harmed by their participation in research, and they are more likely than other former subjects still to be alive. Third, when the Committee considered how best to study subject populations that were most likely to be exploited because of their relative dependency or powerlessness, children were the only subjects who could readily be identified in the meager documentation available. By contrast, characteristics such as gender, ethnicity, and social class were rarely noted in research reports of the day.

Chapter 8. Total-Body Irradiation: Problems When Research and Treatment are Intertwined

Moving from case studies focused on the injection or ingestion of radioisotopes, chapter 8 shifts to experimentation in which sick patients were subjected to externally administered total-body irradiation (TBI). The Committee discovered that the highly publicized TBI experiments conducted at the University of Cincinnati were only the last of a series in which the government sought to use data from patients undergoing TBI treatment to gain information for nuclear weapons development and use.

This experimentation spanned the period from World War II to the early 1970s, during which the ethics of experimentation became increasingly subject to public debate and government regulation. In contrast with the experiments that flowed from the AEC's radioisotope program, the use of external radiation such as TBI did not in its earlier years involve a government requirement of prior review for risk. The TBI experimentation raises basic questions about the responsibility of the government when it seeks to gather research data in conjunction with medical interventions of debatable benefit to sick patients.

Chapter 9. Prisoners: A Captive Research Population

In chapter 9 we examine experimentation on healthy subjects, specifically prisoners, for the purpose of learning the effects of external irradiation on the testes, such as might be experienced by astronauts in space. The prisoner experiments were studied because they received significant public attention and because a literally captive population was chosen to bear risks to which no other group of experimental subjects had been exposed or has been exposed since. This research took place during a period in which the once commonly accepted practice of nontherapeutic experimentation on prisoners was increasingly subject to public criticism and moral outrage.

Chapter 10. Atomic Veterans: Human Experimentation in Connection with Bomb Tests

Chapter 10 also explores research involving healthy subjects: human experimentation conducted in connection with atomic bomb tests. More than 200,000 service personnel--now known as atomic veterans--participated at atomic bomb test sites,

mostly for training and test-management purposes. A small number also were used as subjects of experimentation. The Committee heard from many atomic veterans and their family members who were concerned about both the long-term health effects of these exposures and the government's conduct. In seeking to reconstruct the story of human experimentation in connection with bomb tests, we found need and opportunity to examine the meaning of human experimentation in an occupational setting where risk is the norm.

Chapter 11. Intentional Releases: Lifting the Veil of Secrecy

In chapter 11 we address the thirteen intentional releases of radiation into the environment specified in the Committee's charter, as well as additional releases identified during the life of the Committee. In contrast with biomedical experimentation, individuals and communities were not typically the subject of study in these intentional releases. The secret releases were to test intelligence equipment, the potential of radiological warfare, and the mechanism of the atomic bomb. While the risk posed by intentional releases was relatively small, the releases often took place in secret and remained secret for years.

Chapter 12. Observational Data Gathering

The final case study, in chapter 12, looks at two groups that were put at risk by nuclear weapons development and testing programs and as a consequence became the subjects of observational research: workers who mined uranium for the Atomic Energy Commission in the western United States from the 1940s to 1960s and residents of the Marshall Islands, whose Pacific homeland was irradiated as a consequence of a hydrogen bomb test in 1954. While these observational studies do not fit the

classic definition of an experiment, in which the investigator controls the variable under study (in this case radiation exposure), they are instances of research involving human subjects. The Committee elected to examine the experiences of the uranium miners and the Marshallese because they raise important issues in the ethics of human research not illustrated in the previous case studies and because numerous public witnesses impressed on the Committee the significance of the lessons to be learned from their histories.

Chapter 13. Secrecy, Human Radiation Experiments, and Intentional Releases

Part II concludes with an exploration of an important theme common to many of the case studies--openness and secrecy in the government's conduct concerning human radiation research and intentional releases. In chapter 13 we step back and look at what rules governed what the public was told about the topics under the Committee's purview, whether these rules were publicly known, and whether they were followed.

Part III. Contemporary Projects

Chapter 14. Current Federal Policies Governing Human Subjects Research

Chapter 14 reviews the current regulatory structure for human subjects research conducted or supported by federal departments and agencies, a structure that has been in place since 1991. This "Common Rule" has its roots in the human subject protection regulations promulgated by DHEW in 1974. The historical developments behind these regulations are described in chapter 3. Following a summary of the essential features of

the Common Rule, chapter 14 discusses several subjects of particular relevance to the Advisory Committee's work, such as special review processes for ionizing radiation research, protection for human subjects in classified research, and audit procedures of institutions performing human subjects research.

Chapter 15. Research Proposal Review Project

Chapter 15 describes the Research Proposal Review Project (RPRP), the Advisory Committee's examination of documents from research projects conducted at institutions throughout the country, including both radiation and nonradiation proposals. Documents utilized in the RPRP were those available to the local institutional review boards (IRBs) at the institutions where the research was conducted. The goals of the RPRP were to gain an understanding of the ethics of radiation research as compared with nonradiation research; how well research proposals address central ethical considerations such as risk, voluntariness, and subject selection; and whether informed consent procedures seem to be appropriate.

Chapter 16. Subject Interview Study

The RPRP discussed in chapter 15 reviewed documents prepared by investigators and institutions and submitted in IRB applications. This study was complemented by a nationwide effort to learn about research from the perspective of patients themselves, including those who were and were not research subjects. The Subject Interview Study (SIS), described in chapter 16, was conducted through interviews with nearly 1,900 patients throughout the country. The SIS aimed to learn the perspectives of former, current, and prospective research subjects by asking about their attitudes and beliefs regarding the

endeavor of human subject research generally and their participation specifically.

Discussion of Part III

The RPRP tried to understand the experience of human subjects research from the standpoint of the local oversight process, while the SIS tried to understand it from the standpoint of the participant. Although the two studies related to different research projects and different groups of patients and subjects, some common tensions in the human research experience emerge in both projects, and they are described in the "Discussion" section of part III. For example, it has long been recognized that the physician who engages in research with patient-subjects assumes two roles that could conflict: that of the caregiver and that of the researcher. The goals inherent in each role are different: direct benefit of the individual patient in the first case and the acquisition of general medical knowledge in the second case. The interviews with SIS participants suggest that at least some patient-subjects are not aware of this distinction or of the potential for conflict. In our review of documents in the RPRP we found that the written information provided to potential patient-subjects sometimes obscured, rather than highlighted, the differences between research and medical care and thus likely contributed to the potential for patients to confuse the two.

Part IV. Coming to Terms with the Past, Looking Ahead to the Future: Findings and Recommendations

Chapter 17. Findings

In chapter 17, our findings are presented in two parts, first for the period 1944 through 1974 and then for the contemporary period. These parts, in turn, are divided into findings regarding biomedical experiments and those regarding population exposures.

We begin our presentation of findings for the period 1944 through 1974 with a summation of what we have learned about human radiation experiments: their number and purpose, the likelihood that they produced harm, and how human radiation experimentation contributed to advances in medicine. We then summarize what we have found concerning the nature of federal rules and policies governing research involving human subjects during this period, and the implementation of these rules in the conduct of human radiation experiments. Findings about the nature and implementation of federal rules cover issues of consent, risk, the selection of subjects, and the role of national security considerations.

Our findings about government rules are followed by a finding on the norms and practices of physicians and other biomedical scientists for the use of human subjects. We then turn to the Committee's finding on the evaluation of past experiments, in which we summarize the moral framework adopted by the Committee for this purpose. Next, we present our findings for experiments conducted in conjunction with atmospheric atomic testing, intentional releases, and other

population exposures. The remaining findings for the historical period address issues of government secrecy and record keeping.

Our findings for the contemporary period summarize what we have learned about the rules and practices that currently govern the conduct of radiation research involving human subjects, as well as human research generally, and about the status of government regulations regarding intentional releases.

Chapter 18. Recommendations

Chapter 18 presents the Committee's recommendations to the Human Radiation Interagency Working Group and to the American people. The Committee's inquiry focused on research conducted by the government to serve the public good--the promotion and protection of national security and the advancement of science and medicine. The pursuit of these ends--today, as well as yesterday--inevitably means that some individuals are put at risk for the benefit of the greater good. The past shows us that research can bear fruits of incalculable value. Unfortunately, however, the government's conduct with respect to some research performed in the past has left a legacy of distrust. Actions must be taken to ensure that, in the future, the ends of national security and the advancement of medicine will proceed only through means that safeguard the dignity, health, and safety of the individuals and groups who may be put at risk in the process.

Many of our recommendations are directed not to the past but toward the future. The Committee calls for changes in the current federal system for the protection of the rights and interests of human subjects. These include changes in institutional review boards; in the interpretation of ethics rules and

policies; in the conduct of research involving military personnel as subjects; in oversight, accountability, and sanctions for ethics violations; and in compensation for research injuries. Unlike the 1944-1974 period, in which the Committee focused primarily on research that offered subjects no prospect of medical benefit, our recommendations for the future emphasize protections for patients who are subjects of therapeutic research, as many of the contemporary issues involving research with human subjects occur in this setting. We also call for the adoption of special protections for the conduct of human research or environmental releases in secret, protections that are not currently in place.

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 come to increasingly value the ethics of research involving human subjects as central to the scientific enterprise. We harbor no illusions about the Pollyanna-ish quality of a recommendation for professional education in research ethics; we call for much more. We ask that the biomedical research community, together with the government, cause a transformation in commitment to the ethics of human research. We recognize and celebrate the progress that has occurred in the past fifty years. We recognize and honor the commitment to research ethics that currently exists among many biomedical scientists and many institutional review boards. But more needs to be done. The scientists of the future must have a clear understanding of their duties to human subjects and a clear expectation that the leaders of their fields value good ethics as much as they do good science. At stake is not only the well-being of future subjects, but also, at least in part, the future of biomedical science. To the extent that that future depends on public support, it requires the public's trust.

There can be no better guarantor of that trust than the ethics of the research community.

Finally, our examination of the history of the past half century has helped us understand that the revision of regulations that govern human research, the creation of new oversight mechanisms, and even a scrupulous professional ethics are necessary, but are not sufficient, means to needed reform. Of at least equal import is the development of a more common understanding *among the public* of research involving human subjects, its purposes, and its limitations. Furthermore, if the conduct of the government and of the professional community is to be improved, that conduct must be available for scrutiny by the American people so that they can make more informed decisions about the protection and promotion of their own health and that of the members of their family. It is toward that end that we close our report with recommendations for continued openness in government and in biomedical research. It is also toward that end that this report is dedicated. Some of what is regrettable about the past happened, at least in part, because we as citizens let it happen. Let the lessons of history remind us all that the best safeguard for the future is an informed and active citizenry.

Advisory Committee on Human Radiation Experiments

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Executive Director

Jeffrey Kahn
Associate Director

Anna Mastroianni
Associate Director

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Director of Communications
Counselor to the Committee

Sarah Flynn
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