

“Ethical Harm” and the

During the 1940s researchers in the United States injected plutonium into eighteen hospital patients without their informed consent. Reports of this research in the scientific literature and investigations during the following decades did not raise public concern, but in 1993 a series of news articles identified five of the patients and drew more attention to the plutonium injections. DOE Secretary O’Leary publicly questioned the ethics of the research. Subsequent news articles described additional studies that had exposed human subjects to radiation without their informed consent. Public concern mounted, Congress held hearings, and President Clinton appointed an Advisory Committee on Human Radiation Experiments.

The Advisory Committee’s assignment was to determine the ethical and scientific standards for the human radiation experiments and to evaluate whether the experiments met those standards. After reviewing a mass of information, conducting hearings, and deliberating at monthly meetings for a year and a half, the Advisory Committee issued its Final Report in October 1995. We review this report and the issues it attempts to resolve below; the human research with plutonium is described in “The Human Plutonium Injection Experiments” in this volume.

As first recounted in the news, the plutonium injections seemed disturbingly similar to the experiments for which several Nazi doctors were imprisoned or executed after trials at Nuremberg. The scientists in the United States had opportunistically used hospital patients as unwitting subjects in non therapeutic studies of exposure to radiation. Although the researchers expected the patients to die soon of their existing

illnesses, some survived for decades after the plutonium injections. Their survival intensified questions about the effects of the experiments.

Clarification of the news was soon forthcoming. Radiation scientists familiar with the plutonium research pointed out that the patients received very small amounts of radiation considered unlikely to cause injury or illness. Furthermore, the purpose of the research was not to determine the effects of exposure to plutonium, but its pathway through the body. Comparison of the amount of injected plutonium with the amount of plutonium excreted by the patients enabled the researchers to develop a model for estimating occupational and accidental exposures of atomic weapons workers from their excretion. In its investigation, the Advisory Committee found no evidence that the plutonium injections injured anyone. Also, the Committee agreed with the scientists that the plutonium injections “produced results that continue to benefit workers in the nuclear industry today.”

The Committee confirmed, however, that the patients “were not told that they were to be used in experiments for which there was no expectation they would benefit medically, and, as a consequence, it is unlikely they consented to this use of their person.” The failure to inform the patients might be attributed to the difficulty of discussing a substance whose very existence was classified, and to the customs of medical research at the time. The Committee determined that “it was not uncommon in the 1940s for physicians to use patients as subjects in experiments without their knowledge or consent” even when the research held no prospect of benefiting the patients.

Thus, some have argued, the plutonium injectees suffered only “ethical harm”—an unexceptional invasion of their rights without practical consequences. By contrast, the moral transgressions of the Nazi doctors involved unspeakable acts of maiming and murder.

The Advisory Committee confronted several difficult issues in evaluating experiments that did not cause physical harm or deviate from common practice. The problem of “retrospective moral judgment” was especially challenging: could the Committee apply current ethical standards to research conducted a half-century ago, or should the ethical evaluation be limited to the standards and values of that time? The Committee also considered whether the families of the patients (now all dead) should be compensated for “ethical harm” and if so, by what measure. Perhaps most important, the Committee drew lessons for the future from its review of the plutonium research.

Judging the past

Federal regulations now require informed consent for most experiments with human subjects. At the time of the plutonium injections, however, there were no regulation or professional standards that required the consent of hospital patients to participate in research. On what basis, then, could the plutonium injections be criticized?

From the outset of its deliberations, the Committee attempted to avoid judging the past by today’s standards. The Committee concluded that in addition to government rules and professional standards, which are applied only prospectively, there are also “basic ethical principles” that are not limited by

Plutonium Injection Experiments

Michael S. Yesley, J. D.

Office of Laboratory Counsel—General Law, Los Alamos National Laboratory

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Informed consent

The principal of respect for a competent individual's right of self-determination serves both practical and idealistic goals. The idealistic goal appears to predominate: respect for the individual is a fundamental, virtually unquestioned value in western society. But informed consent serves practical goals as well, including the encouragement of rational decision-making, enhancement of the physician-patient relationship, and reduction of unfavorable public reaction. Clearly, obtaining informed consent to the plutonium injections would have served the last goal well and avoided the subsequent outcry.

Although informed consent was not obtained in either the Nazi medical experiments or the plutonium injection experiments, significant distinctions can be drawn. Hospital patients are a vulnerable population, but they do not endure the inhumane, sharply reduced circumstances of the concentration camp victims. Competent hospital patients retain the ability to give informed consent, but voluntariness was impossible in the concentration camps. Also, there was a substantial difference between the drastic experimental procedures of the Nazis and the injections of tracer amounts of plutonium. Exposure to radiation above certain levels will have severe consequences, but the Advisory Committee found no evidence that the low doses of the hospital patients caused harm.

Still, the low risk of the plutonium injections and the important national security interests served by the research did not justify the failure to obtain informed consent. If the eighteen hospital patients had been asked, most of them—or others in their place—would probably have consented to the plutonium injections. They would have been told the research posed little risk to them and was important to assure the safety of workers involved in protecting national security. During the post-war period when the plutonium research was conducted, the patients' response to this patriotic appeal would likely have been positive. Although they would have based their decisions to participate in the research on limited knowledge, their

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consent would have been recognized in later years. Their story in the 1990s would not have been about exploitation, but about their contribution to this country's efforts to become a nuclear power.

Ethical evaluation

In the absence of informed consent, however, the Advisory Committee concluded that the plutonium experiment was unethical. Using patients as means to the ends of the researchers and deceiving the patients about the nature of the procedures violated basic moral principles without justification. The needless failure to obtain informed consent, not the research methodology, drew the Committee's condemnation. "Only extraordinary circumstances can justify deception and the use of people as mere means by government officials and physicians in the conduct of research in the conduct of research involving human subjects. . . . [W]e see no reason that the laudable goals of the research could not have been pursued in a morally acceptable fashion."

Furthermore, the Committee was dismayed that the government kept the identity of the plutonium subjects secret for many years, not for national security purposes, but apparently out of concern for public relations and legal liability. The Committee concluded that the secrecy deprived the subjects and their families of any opportunity to pursue grievances based on the plutonium research.

Distinguishing actions and actors

Although the Committee condemned the failure to obtain informed consent, it did not severely censure the well-in-

tioned researchers who had followed the customary practices of the time. The Committee distinguished between the wrongfulness of actions and the blameworthiness of the actors: “Even when wrong was done, it does not follow that anyone should be blamed for the wrong.” Although a wrongful act should be condemned, the individual who committed the act might be excused for “culturally induced moral ignorance” that the actor could not reasonably be expected to remedy, or because the details of applying a principle evolved subsequently.

The Committee concluded, somewhat opaquely, that “government officials and investigators are blameworthy for not having had policies and practices in place to protect the rights and interests of human subjects” in nontherapeutic research. But “to the extent the research was thought to pose little or no risk, government officials and biomedical professionals are less blameworthy”.

Compensation and other remedies

The Advisory Committee was not specifically asked to make recommendations about compensation, but this topic was unavoidable. It received much attention at the Committee’s meetings, particularly in testimony by individuals who were exposed to radiation in occupational, environmental, and research settings. Those exposed persons face many legal obstacles to securing compensation, including government immunity, the difficulty of proving that illness or death was caused by radiation exposure, and, for those who were not physically harmed, the absence of a legal remedy solely for an infringement of rights.

The Committee adopted a position that distinguishes ethics from law, holding that “people who were used as research subjects without their consent were

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In addition, the Committee found that the government’s self-protective policy of secrecy for many years following the plutonium research had denied subjects and their families the opportunity to pursue potential grievances, thereby compounding the original wrong in a manner that could have had material effect. Accordingly, the Committee recommended that financial compensation be provided to the families of the plutonium research subjects—a remedy that may require legislation.

wronged even if they were not harmed”. However, the Committee also concluded that financial compensation is not an appropriate remedy in the absence of material harm—a result that reintroduces the legal standard. In such cases, the government should apologize to those who were wronged.

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Lessons for the future

What lessons can be gained from the human radiation experiments? Members of the Advisory Committee believe their assignment offered a valuable opportunity not only to redress past wrongs, but also improve existing mechanisms for the protection of human research subjects.

In particular, the current informed consent requirements were found ineffective. Jay Katz, a member of the Advisory Committee who has long been concerned with this issue, saw problems in three-quarters of the current protocols for greater-than-minimal-risk studies reviewed by the Committee. Although local committees (Institutional Review Boards, or IRBs) had approved the informed consent forms in these studies, the forms failed to distinguish the research goals of the studies and their consequences for the subjects. Instead, a mass of unnecessary detail obscured the significance of participating in the research.

There were even indications of a problem uncovered more than two decades ago: the Committee’s interviews with many subjects revealed they did not know they were participating in research, although they had signed informed consent statements. The legal niceties of the consent process had been observed and the signed forms pro-

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duced. But the research subjects were still treated as a means to the scientists' ends, not as informed participants in the research.

To improve subject protection in the future, the Committee recommended that IRBs (1) focus on more-than-minimal-risk experiments; (2) assure that consent forms clearly distinguish research from treatment, identify the sponsors and purposes of the research, and specify the financial implications of participating or not participating in

the research; and (3) assure that participation in research does not diminish the subjects' opportunity for medical benefits that would be available to nonparticipants.

"Ethical harm"

The effects of the plutonium injections were not as damaging to the subjects as the early news stories painted, nor were they so inconsequential as many scientists, then and now, believe. Our society demands that human subjects of experimentation not be treated merely as means to the researchers' end. In retrospect, the greatest harm of the plutonium injections may be the erosion of public trust in the institutions of science and government for having appropriated decisions that belong to individuals. ■

Further Reading

Advisory Committee on Human Radiation Experiments. 1995. *Final Report*. U.S. Government Printing Office (October 1995).



Michael S. Yesley came to Los Alamos as a staff attorney in 1989 and has provided legal advice to Laboratory management on protection of human research subjects, information practices, taxation, and environmental litigation. Most recently Michael has been working on preventive law and legal information projects, intended to make legal considerations and materials more accessible to Laboratory employees. Michael was the staff director of the National Commission for the Protection of Human Subjects from 1974 to 1978, whose reports were implemented in the federal regulations that now govern human experimentation. Following the National Commission post, Michael has practiced law and has held several positions on bioethics committees, among them Chairman of the Institutional Review Board at RAND, and coordinator of the DOE program on the Ethical, Legal and Social Implications of the Human Genome Project (ELSI). As co-ordinator of the ELSI, he compiled a basic ELSI source, a bibliography, and has spoken on ELSI issues at numerous meetings in the United States and abroad. Michael is a member of the Human Genome Organization (HUGO), the American Society of Law, Medicine and Ethics, and the Bioethics Committee of St. Vincent Hospital in Santa Fe. From October 1994 to February 1995 Michael directed the Laboratory's Human Studies Project Team. He earned a B.A. in philosophy in 1960 and a law degree in 1963 from Harvard University.