

apy. The letter described the greatest problem arising from such requirements revolved around the use of strontium-89 chloride, used for severe pain from widespread bone metastases of cancer. Because the isotope is so potent and long-lived, the letter states, only physicians who understand basic radiation science and low-level radioactive waste disposal should administer this drug; otherwise, mistakes, not hard to make, could threaten the patient and the public. The NRC's requirement guidelines allow training courses that take as little as nine days—while the board examination in nuclear medicine calls for two years residency. The NRC's guidelines thus interfere with the general definition of what it means to be a nuclear medicine physician.

Dr. Reba told *Newsline* that one way of defining a nuclear medicine physician is by describing what a nuclear medicine physician does—which is where the Manpower Survey comes in useful again. The answer incorporates, for example, “how many studies are done and how long it takes to complete a study from the beginning—from meeting with the patient, performing the study, analyzing the study, talking to the physician, and issuing a report,” he said. With such numbers in hand, “It’s simple arithmetic to determine how many physicians it takes to perform nuclear medicine studies.” Hard numbers like these might be the first step in convincing the powers that be just what the future workforce in the field will need.

Lantz Miller

News Analysis

NOT NUCLEAR MEDICINE: THE GOVERNMENT'S RADIOBIOLOGICAL AND OTHER EXPERIMENTS

**News media have new
heyday with old hat;
scientific questions
glossed over**

IN A REVERSAL FROM EARLIER departmental policy, Energy Secretary Hazel O’Leary announced in December that the DOE would investigate the propriety and legality of a random set of scientific studies from the 1940’s to the 1970’s united only because the agency or its predecessor partly sponsored them and they dealt with radiation. Although the public and media reacted with shock, as if the experiments had been top secret files just now opened, the studies had long been publicly accessible; the new elements this time were the DOE’s new attitudes and the revelation of subject names. What may concern nuclear medicine practitioners is how this research—lit in a harsh light—has been haphazardly lumped into their field.

Media outcry about such experiments dates at least to 1974, when *Mother Jones* magazine brought to light a series of studies at Oak Ridge National

Laboratory that tested whole-body radiation as therapy for leukemia, resulting, the article complained, in no benefit to the subjects. In 1984, Richard Ottinger, chairman of the House Subcommittee on Energy Conservation and Power, requested information from the DOE on human radiation-test subjects in projects funded by the department and its predecessors. With this information, Ottinger’s successor on the committee, Edward Markey, devised a report, “American Nuclear Guinea Pigs: Three Decades of Radiation Experimentation on U.S. Citizens.” The DOE responded in 1987 with a letter countering Markey’s alarmism and concern for harmful effects and concluding there was no need for compensating or following-up the subjects.

Nuclear War, Nuclear Medicine

Now in what some observers see as a shift in attitudes between the Reagan-Bush and Clinton administrations, Sec. O’Leary has said there is a need to consider follow-up and compensation. But such a strategic shift may also be partly a privilege of the “post-Cold War” era. Perceiving a lessened nuclear threat after the Soviet Union’s demise, many members of the federal government, like O’Leary and President Clinton himself, are promoting the image of greater openness with the pub-

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lic and divulging some Cold War secrets, including unannounced nuclear explosions and experiments on humans in connection with the weapons development programs. But, in the media's reportage, any experiment from the nuclear era using radiation on humans and sponsored to any degree by the department comes in the grabbag of shocking revelations that includes nuclear explosions. Thus, by misuse of the term "nuclear medicine," the practice is tacitly associated with mushroom clouds.

"Energy Secretary Hazel O'Leary has unmasked previously secret government reports of up to 800 nuclear medicine experiments during the 1940's and 1950's," reported the January 3, 1994, *USA Today*, ignoring the facts that the experiments were not all related to "nuclear medicine" and had been publicly accessible. The front-page article proceeded to call subjects "unwilling victims," and the only experiments it mentioned were those involving the injection of plutonium. A guest article in the January 14, 1994, *New York Times*, by Gregg Herken, PhD, chairman of space history at the Smithsonian's National Air and Space Museum, and James David, demonstrated a historical linkage of these experiments to Dr. Joseph G. Hamilton, who was researching the use of radioactive aerosols as a form of weaponry. In discussing experiments involving the release of enormous amounts of radiation into the atmosphere, a December 17, 1993, *Times* report stated, "For all its dangers, such research clearly advanced nuclear medicine."

The final incriminating link in the media's recent grilling of "nuclear medicine" has been the comparison of the research to the work of Nazi doctors (indeed, Dr. Herken and Mr. David's article was titled, "Doctors of Death"). In describing the experiments on human subjects, Ms. O'Leary told *Newsweek*, "The only thing I could think of was Nazi Germany" ("America's Nuclear Secrets," December 27, 1993). Such a specter hovered over the revelation of the mineral absorption studies on mentally retarded students at Fernald State School (Waltham, MA), and studies of the effects of radiation on the testicles of prison inmates in Oregon and Washington. In 1950, the director of the Atomic Energy Commission even received a memo from one of the agency's researchers, warning, "If this [radiation research] is to be done in humans I feel that those concerned in the Atomic Energy Commission would be subject to considerable criticism, as admittedly this would have a little of the Buchenwald effect." The news media have quoted and dedicated entire articles to this memo as seemingly telltale of the government's own

awareness of its dubious operations. A December 28, 1993, *New York Times* report about the memo emphasized the warning out of context, so that it appeared only that the AEC was getting an internal caution which it promptly ignored.

But a more careful scrutiny of this memo and its circumstance reveals as much about the news media and their eagerness to overlook historical or scientific fact for a good story. The famous memo happened to have been penned by no other than Dr. Hamilton. A reading of the entire memo reveals not so much a moral concern that experiments like his own might have a "little of the Buchenwald touch," but that the experiments which he is adamantly pushing throughout the letter just might be seen that way by critics. The eeriness thus arises not merely from the fact that the agency was warned of the experiments' "Buchenwald touch," but because the researcher admitted this while pushing the experiments. "Hamilton was described as an internal dissenter in one piece, when he was concerned about public relations and not ethical aspects," said Dr. Herken.

Story First, Reality Second

Furthermore, in the December 28 *Times* story, the researcher appeared to be advocating the use of primates instead of humans. But in fact, the researcher went on to say, "There is much to recommend the use of adult males past the age of 50 in good physical status... the picture as I see it is to ascertain the disabling range and factors which might influence it." This was the same researcher who, according to Dr. Herken and Mr. David, two years later wrote that he was still "most desirous that the [radiological warfare] program continue to develop as rapidly as possible." In the news media's eagerness to find an early hero against the government's radiobiological experiments, they landed upon anything but. Such a willingness to paint a particular tableau may make colorful art but may help muddy the picture when it comes to scientific and legal investigations—yet has also typified the news media's handling of precarious scientific matters in this situation, beyond lumping it all under the false rubric of "nuclear medicine."

The current revival of interest in the government's radiobiological experiments began with a series of articles last November in the *Albuquerque Tribune*, which reputedly turned Sec. O'Leary's attention to the matter. Unlike previous investigations of the experiments, the *Tribune's* report told the stories—revealing the identities—of five of the 18 subjects in the plutonium studies. These human-interest stories of various patients in the

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1940's who were unwittingly subjected to radiation studies created such a stir that the *Tribune* reprinted them in a 48-page tabloid-sized format. As a whole, though, despite the gargantuan effort behind it, it is an unwieldy, meandering read; what the series lacks in analysis it makes up for in bulk—but the unclarity of this enormous volume of material, and the juxtaposition of certain pieces of information, strangely lends itself to particular interpretations of the patients' medical histories.

Proceeding patient-by-patient, the stories erratically interweave case histories with details about the Atomic Energy Commission and the nuclear weapons program, its scientists and bureaucrats, and the physicians who administered the plutonium and cared for the patients. The tales are of grueling bouts and lifelong fights with ill-health, all the more poignant because the patients were subjected to tests they could not possibly have understood—as plutonium itself was so poorly understood—even if they had been informed. Desperate to discover the element's health effects on plutonium workers in the Cold War's early days, the AEC and its associated scientists, instead of conducting the studies on those "in the know" about plutonium, opted to inject the classified substance into terminally ill patients without (by orders of top-secret investigation) telling them what was happening. The logic was that these patients would be dead before they could develop tumors from the radiation; the irony was that many of the patients lived for decades, and whatever had caused their "terminal" illnesses could never definitively be distinguished from plutonium's effects in follow-up studies. Paradoxically, making sense of these limited, small-sample studies demanded a record of plutonium excretion studies and toxicology—which didn't exist. It is this very lack of clarity about plutonium that makes the *Tribune's* long, garbled lists of illnesses so poignant and seemingly attributable to a menacing government.

Eda Schultz Carlton, for example, whose records of rash, slight hepatitis, and hypoproteinemia hinted of only marginal terminal condition, was recuperating on a high-protein diet at Strong Memorial Hospital (Rochester, NY), when she was injected with 0.30 μCi of ^{239}Pu on November 27, 1945. The patient lived for almost forty more years, with continued poor nutrition, weight fluctuations, gastrointestinal problems, vertigo, and many other health problems. She developed a chronic fear of cancer. In the 1970's, she was told of the experiment and eventually became convinced it was the cause of a cancer she never got. But the *Tribune's* detailed page-and-a-half excerpt from 30 years

of her medical records, presented in the context of the gruesome experiment, cannot help giving the impression that the plutonium caused a lot of problems. (Considering plutonium's effects on the immune system are so poorly understood, the data have not been very helpful to researchers, either.)

A similar scenario holds with Elmer Allen, a railroad porter who developed bone cancer and thus had to have a leg amputated. While at the hospital, the plutonium research team injected his calf with 0.096 μCi of ^{238}Pu on July 18, 1947. But again, the article's mass of subsequent medical history on Mr. Allen tacitly implicated the experiment in his troubles through guilt by association (whether or not the writer intended this): his alcoholism, his paranoid schizophrenia, even his sense of life wasted without a leg all appear exacerbated if not brought on by his use as a guinea pig. Fred Sours, a small-town New York politician, was admitted to Strong for generalized dermatitis and weakness, but after injection with 0.386 μCi of ^{239}Pu on April 3, 1946 and death 1.25 years later, autopsy showed he also had chronic passive congestion of liver and spleen, muscular atrophy, dilation of the heart, hypertrophy, bronchitis, and bronchopneumonia. In the article, these facts are followed by a brief discussion of health physicists' disagreements over plutonium's acute effects, ending with one health physicist insisting that such injections could cause serious damage.

Such tacit predetermination of scientific matters underlies the whole *Tribune* series and surfaces in more than incriminating case histories. The imagery is often loaded: "The old woman carried within her arthritic bones a silvery metal... that powers nuclear bombs.... A metal that draws scientists like honey." One of these sweet-talking scientists even "boasted that LSD could halt cancer growth." The speculative and often indeterminate nature of some science and medicine becomes an enemy of the people when there is a patient who "purportedly" had bone cancer and thus had a leg amputated. But this same indeterminacy becomes a friend of the people when one health physicist speculates that an 85-year-old woman's bones developed holes not from osteoporosis but from radiation injected 40 years before. The article depends upon the hedges of science when they benefit a certain preconceived notion but upon none of the doubts when they hurt it. Even the article's premise about the particular ways that plutonium is bad for health depends partly upon the research it is condemning on moral and scientific grounds. Thus the whole series undermines its mission by begging the question of how we can know the dangers of plutonium to

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humans unless it has been studied in humans. It covers up this obfuscation with sheer bombardment of medical detail. It compensates for keen moral inquiry into what scientists should do when encountering a Pandora's box like plutonium—cold war or no—by substituting the bathos of sad lives that only engenders moral outrage. To search out enemies called “scientists”, whose “legacy is in the thin black bylines in scientific journals devoted to the budding field of nuclear medicine,” the series uses the tool of the “enemies” own—hunches about plutonium's dangers. In sum, to make a stirring story, it has defined its own terms and reality and muddied the issue.

Captive Women and Innocent Children

The *Tribune* series, although bypassing an opportunity to illuminate scientific vagueness and moral hinterlands that the Cold Warriors had to trample through, only sired an even less scientifically literate progeny. Any experiment connecting the government and radiation became an item. The story of the whole-body radiation treatments on leukemia patients resurfaced, along with the other studies in the Markey report, like those on prison inmates' testicles. The DOE set up an 800 number in December, and within two weeks was receiving 500 calls per hour. Callers—many veterans—told of army doctors sticking radioactive capsules up their noses or of how a sudden drop of a mysterious canister on a ship's floor left the entire crew bedridden. By the end of December, the Defense Department (DOD) and the National Aeronautics and Space Administration (NASA) began investigating their files, and the Department of Veterans Affairs (DVA) began poring through their hospital files for questionable human studies. A poignant case that came to light by the end of the year concerned the radiotracer mineral absorption studies at the Fernald State School. The story, broken by the *Boston Globe* December 26, invoked the image of mentally retarded boys mercilessly subjected to dangerous radiation and so incensed the public that Sen. Edward Kennedy (D-MA) and Rep. Edward Markey (D-MA) began hearings on the matter in mid-January.

But according to those who have investigated the experiment, it was hardly comparable to the grisly plutonium research. Francis X. Masse, director of radiation safety at Massachusetts Institute of Technology, which partly sponsored the research, said “Objectivity has gone out the window.” He described how, in the 1940's, many Fernald students were showing up iron-deficient, and there was concern that the school's high-grain, cereal-based diet could be blocking iron uptake,

since grains are known to affect mineral absorption. Using a radioactive isotope of iron from the MIT cyclotron, researchers added trace amounts to seven meals over eight to nine months to see how much iron was taken into the blood; they were thus able to determine whether the students needed iron supplements, and whether these should be taken before, during, or after the meal. “The exposure of students ranged from 170-340 mrem, most in between,” Mr. Masse said. “Today's studies which allow [radiation] on minors allow 500 mrem.”

The calcium studies at the Fernald School in the 1950's used ^{45}Ca , which is used to this day in osteoporosis studies, and gave no more than 8 mrem total dose per student. Both the iron and calcium studies were published in the general literature. “Nothing is hidden,” Mr. Masse said. “The kids are identified,” as are their weights and doses. “Ten thousand kids were at risk at the Fernald School” because of the school's diet, and the authorities “were able to adjust for it by studying a couple of kids,” Mr. Masse said. “No one was hurt. It would have been criminal *not* to [test them]—it would have been malpractice.”

But much of the current furor over this case has arisen over whether the subjects received informed consent. Indeed, by one student's report, the authorities had lured boys to join the experiment by saying they would be members of a “science club,” without telling exactly what the research entailed. But the record on consent in this case remains unclear. “Consent at the time was typically oral,” Mr. Masse said. “Consent in this case was the Fernald School. The correspondence shows clearly the use of radioactive materials. Whether or not this was passed on to the parents and students is not clear. In those days, use of radioactivity was widely heralded; they didn't have radioactivity paranoia.”

Similarly, a set of Vanderbilt University studies on pregnant women in the late 1940's, which the *Times* reported as studies “to determine the effect of radioactive iron on fetal development,” were also misrepresented. Roscoe R. Robinson, MD, vice chancellor for health affairs at Vanderbilt University Medical Center (VUMC, Nashville, TN), described in VUMC's *Reporter* how the experiments had actually sought to evaluate the intestinal absorption of iron during pregnancy (iron-deficient anemia was a serious problem in the 1940's) and thus to help understand the cause and treatment of iron deficiency. The original studies, Dr. Robinson states, were not funded by the federal government, nor were they conducted on poor women, but on all classes. Fur-

thermore, one of the original investigators asserts that the subjects received verbal consent—though Dr. Robsinson also concurs that a similar study would not be conducted on healthy pregnant women today.

The Evolving Culture of Ethics

But the Administration's response to the swelling of reports on human radiation experiments may only strengthen the notion that researching with faintly radioactive tracers is synonymous with deliberate atmospheric diffusion of highly radioactive gases. The White House has formed a task force, the Human Radiation Interagency Working Group, to oversee the retrieval and inventory of records from 1944-1974 in every agency involved in the issue (DOE, DOD, DVA, NASA, the Department of Health and Human Services, and the Central Intelligence Agency). A January 19, 1994, directive from Secretary to the Cabinet Christine A. Varney requires the relevant agencies to sample records for further investigation and for making records public—including declassifying and redacting for the privacy of research subjects. But the directive lumps together any experiment involving human radiation and specified mammoth experiments like “two radiation warfare field experiments,” or “six tests... of radiation warfare ballistic dispersal devices.”

Certainly, much of the current drama over this random group of experiments likely arises from the fact that since the 1940's, *formalizing* informed consent has been a new development. Although most scientists acted humanely before this development, most perhaps relied too heavily upon their own instincts about what was good for the subject. As individual rights have spread to more and more groups in this country in this century, research ethics have shifted so that subjects' rights are primary. Yet, just as someone today may look back with shock at how women did not get to vote even through World War I, research practice of 50 years ago may appear a little primitive. “Informed consent was not formalized by the government until 1964, through the Declaration of Helsinki,” said Mr. Masse. “1968 was the first time granting agencies required an institution to get [informed consent]. By 1971-72, research institutions started seeing that studies got consent.” Virtually all the studies in the current uproar were done by 1974.

Richard C. Reba, MD, SNM president and pro-

fessor of radiology at the University of Chicago, said that even after 1950, “research ethics shouldn't have been any different” than today. “All reasonable people are opposed to doing anything on a patient—whether normal treatment or diagnosis or experimental—without explaining to the patient what we're doing.” As to the current protest that many of the experiments did not benefit the patient, Dr. Reba noted that “Frequently, what is done on the patient in research doesn't benefit the patient.” Nonetheless, “We clarify that with research there may be no direct benefit to the patient but to society. Research is done to find new information. A therapeutic trial may have direct benefit. But in diagnostic or radiobiological trials, there may not be [such benefits].”

As to whether the controversy is going to lead to even tighter research ethics, Robert Wood, Director, Medical Applications and Biophysical Research Division of the DOE's Office of Health and Environmental Research, said, “I don't see that this latest hoo-hah will have much affect on what we've been doing.” He averred that the government's Assurance Process for making sure that human research is carried out in all government-funded labs—including following strict informed-consent guidelines—is about as extensive as can be. But one effect of the uproar may be to “make people more cautious” about being research subjects, Dr. Reba said. “People may refuse because it's an unknown, uncertain thing.... Until things are straightened out, they may say, ‘I don't want to do it.’ There may be some who would have volunteered—even if [the research] is not radioactive—who would not now. I know physicians have reduced the number of tests ordered.”

In the face of the media's confusion of many experiments of 50 years ago with the modern practice of nuclear medicine, Dr. Reba enjoins “all nuclear medicine physicians, radiologists, and scientists to take measures to teach their technicians and workers to clarify that this is not clinical nuclear medicine—and spread the message to the general public. I don't know how to, in a formal way: if anyone does have an idea, let me know. We have to spread the word.” Considering how far the word about an odd melange of dubious and legitimate experiments has spread, physicians have sizable pedagogic chore ahead in distinguishing radiobiology and other types of science from nuclear medicine for the whole public.

Lantz Miller