Political Fallout: A National Bioethics Board?

Biomedicine has been shaken in recent months by a series of "seismic ethical events," says Gary Ellis, director of the human subjects protection office at the National Institutes of Health (NIH). One was the announcement last October that biologists at George Washington University were ready to clone a human embryo. But that was a mere foreshock of the jolt felt in December, triggered by news reports of unknowing people exposed to radiation during a series of experiments (see main story). And now there may be an aftershock: Government science officials are talking about creating a new, national bioethics review board.

The move began last week, after the president issued an executive order establishing an outside panel to guide a federal investigation of the radiation research. The panel will include 15 people and will be chaired by Ruth Faden, director of the Law, Ethics, and Health Program at Johns Hopkins University. This panel, the executive order says, will "determine the ethical and scientific standards" to be used in judging the radiation research, which began in the 1940s. The investigative group itself will be an interagency team that will comb through government files reaching back to the early days of the atomic era, checking on experiments between 1946 and 1974. It will also randomly sample studies conducted after 1974, when the government first issued regulations on human subject research.

Some officials would like the investigations to go even further. They hope the White House will charter a national bioethics committee to look at issues other than radiation exposure. There have been several such panels in the past. The most recent, called the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research, expired when its charter ran out in 1983. Now public health leaders such as D.A. Henderson, deputy assistant secretary for health science at the Department of Health and Human Services (HHS), and M.R.C. Greenwood of the President's Office of Science and Technology Policy (OSTP), think it's time to try again. Greenwood says it would make sense to set the panel up as an adjunct to the new Science and Technology Council in the White House.

The powers and jurisdiction of such a panel have not yet been defined. If it were modeled on the previous commission, it would examine issues at the cutting edge of research and clinical practice—such as the patenting of genes—and make policy recommendations; agencies would be free to take or leave the advice. Nor is it clear how close the plan is to reality. It appears to have the backing of top research officials at HHS, the Department of Energy, and the White House, and some support in Congress. But it remains to be seen whether the president, after asking federal agencies to cut their staffs and outside consultants, wants to create yet another advisory panel.

–Eliot Marshall

and feces for some time—a complicated prospect. Team leader Robert Harris had decided that such experiments would best succeed if the subjects were in a confined location and under medical supervision. The Fernald children met those criteria. The experiment suggested that oatmeal did indeed flush calcium from the system, but at a slow rate that would only affect children with very low-calcium diets.

Only "a tiny, tiny amount" of radioactive calcium was used, says Constantine Maletskos, a member of the team. According to MIT Radiation Protection Office director Francis Masse, the dose was 4 to 11 millirems above background. (Typical background levels are about 300 millirems.) By comparison, a typical treatment for hyperthyroidism involves hitting the thyroid with a drink that delivers about 10 million millirems. "They would have had more if they had flown to Denver for a while," Maletskos says, where they would have been exposed to that high-altitude city's greater number of cosmic rays.

Although the doses of radiation were small, the consent for the experiment would not have met today's standards. "In those days doctors were the kings of their facilities," says Maletskos. "They were in charge of their patients. [The Fernald supervisors] told us they had consent, and it would never have occurred to us to question them." Maletskos says he was horrified to learn on 26 December in a story from *The Boston Globe* that the consent forms sent to the parents by the school had neglected to mention "radioactivity." The school merely asked parents about participating in nutritional experiments. But even if the forms had mentioned radioactivity, there are doubts consent could ever be properly obtained from retarded subjects or their parents. Indeed, today the whole issue of informed consent by the mentally impaired is regarded as so blurred that experimenters believe they should not be used as a study population.

Similar questions of consent dog some of the cases mentioned in the Markey Report. An example is the injection of radioactive uranium-235 into at least 11 comatose, terminal cancer patients between 1953 and 1957 by William Sweet of Massachusetts General Hospital, in Boston, and his associates. The procedures were done as part of the development of what is called "neutron-capture therapy." Neutron-capture therapy takes advantage of the fact that tumors absorb more of certain isotopes than healthy tissues do. After placing those isotopes in the body, doctors bombard the patients with neutrons, which split the isotopes, releasing radiation that kills surrounding cancer cells.

In the 1950s, this idea was little more than plausible-sounding speculation. No one knew which isotope would best be absorbed by tumors. Sweet decided to find out. After obtaining permission for the injections from the patients' families, he carried out the study. The results were disappointing. Uranium, it seemed, was not absorbed in sufficient quantities by the tumor to make the therapy practical; in current attempts at neutron-capture therapy, boron is used.

Even at the time this work could have aroused qualms. In 1953, the year Sweet began his experiments, the British Medical Council campaigned against the use of comatose subjects in research. And as far back as 1948, the Federation of American Societies of Experimental Biology expressed concern that experimenting on the "hopelessly incurable" would "corrupt" the doctor-patient relationship, because it could make their rapid deaths desirable if an autopsy was needed. Nowadays, research with no potential for direct benefit to the terminally ill subject is generally avoided.

Yet these matters of consent and safety frequently fall into gray areas, as researchers acknowledge. People with AIDS, for instance, clamor to be experimented on with medications whose effects are so poorly understood that neither physician nor patient can give consent truly informed by knowledge of risks and benefits. "Who knows what people will think of that in the future?" Stannard says. "We should be humble and wonder what we now are doing that will horrify our descendants." Unlike radioactive decay rates, the rate of change in morality standards has never been accurately measured.

–Charles C. Mann

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