sired, Fultz claimed. The backlog of untended reactor problems is "large and growing." Fultz noted that by the end of 1985, inspectors had produced a list of 198 recommendations, some dating back to the 1970s, none of them settled. In November 1986, an in-house safety committee expressed its concern about the backlog, indicating, Fultz said, a possible "trend toward a gradual deterioration of safety. . . . "

Yet another study of these reactors came out on 27 January. It was performed by an independent consultant, Gordon Thompson of the Institute for Resource and Security Studies, for the Natural Resources Defense Council (NRDC). NRDC, an environmental group, has sued DOE over management of the L reactor at Savannah River. Thompson did not have access to the data given to the GAO and Academy investigators. But, like them, he zeroed in on the emergency cooling system as a weak point. The cooling system in these plants, he writes, is "somewhat primitive" and not flexible enough to deal with all possible accident conditions. Furthermore, he finds that "no firm analytic basis has been available on which to determine [the cooling system's] effectiveness."

Thompson also finds it "disappointing" that no up-to-date risk analysis will be ready before 1988. In view of the antique systems used to suppress radiation leaks, he finds it hard to credit DOE's official view that a worst possible accident would release less than 1% of the radioactive core. Even harder to understand, Thompson says, is the assumption that the worst possible accident would cause no more than 3% of the fuel to melt. Thompson notes that many commercial operators, whose plants have better safety systems, concede that accidents could cause a 100% core melt.

Outsiders often see safety issues differently from DOE staffers. This is not surprising. People in one part of an agency are generally sympathetic to programs run by colleagues elsewhere in an agency. For this reason some members of Congress argue that safety and environmental programs at DOE should be given independent status.

In the hearings before Glenn's committee on governmental affairs, DOE officials testified about more than a score of actions they have already taken to counter the criticism that the agency has been lax in controlling pollution and reactor hazards. Mary Walker, assistant secretary for environment, safety, and health, suggested that the controversy has grown more intense precisely because DOE has aired its problems in public. Secretary Herrington, she said, has brought in a new era of safety consciousness. Recently, her office was given independent authority to shut down any facility found not to meet DOE's new, more demanding standards.

Glenn appeared skeptical, saying that reforms of this kind should not depend on the commitment of individuals, but should rest on institutional change. He thinks it is necessary to end the conflict inherent in DOE's role as a manager and self-regulator of nuclear projects.

Glenn plans to introduce a bill this spring that would end DOE's power to manage defense sites without outside review. According to congressional staffers, the bill would strip away DOE's authority over environmental issues, bring in an outside board to monitor reactor safety, and end DOE's strict controls on access to employee health records. It would also remove existing epidemiological research programs on the effects of radiation. The programs might be shifted to the Department of Health and Human Services.

Separate legislation aimed at bringing outside scrutiny to DOE activities has been proposed in the House of Representatives by Ron Wyden (D–OR) and Mike Synar (D–OK). ■ **ELIOT MARSHALL**

OTA: Property Right, Donor Consent Factors Cloud "Gifts" of Human Tissue

Twenty years ago, the thought of a patient claiming rights to a drug derived from his cancerous tumor would have seemed remote to researchers. But for scientists developing new diagnostic tools and drugs through biotechnology the prospect of losing part of the financial rewards of that work is no longer inconceivable. At the same time there is growing concern about the rights of people who donate raw tissue and cell material for research. Must researchers disclose to tissue donors that subsequent research could lead to a commercial product? And should companies and institutions share any resulting profits with tissue donors or their heirs?

The Office of Technology Assessment (OTA) suggests that there is now a need for Congress to take stock of these issues and other matters involving technological advances in biological research and its application in health care. Until recently, exchanges of human tissues have not been of much concern. They generally have occurred free-of-charge in a cooperative spirit. But in *Ownership of Human Tissues and Cells*,* the first of a series of reports entitled *New Developments in Biotechnology*, OTA foresees a more complicated world for research that is dependent on human tissue specimens.

The production of diagnostic tools and new drugs from the use of cell fusion, cloning, and recombinant DNA techniques, says OTA, raises a series of fundamental policy and ethical questions. In particular, should the federal government permit commercial trade in human cell lines, and should physicians and researchers be compelled to disclose potential research and commercial interests to patients and research subjects?

Federal and state agencies often require that patients or other donors be told that tissues may be used for research. But the rules do not always apply. And, disclosure requirements usually stop short of telling these donors that their cells or body parts have potential commercial value.

The legal basis for donors to claim a property right to a cell line or even to a drug that may eventually be developed from donated human tissue is murky, according to OTA. "The law of property was not written with this kind of thing in mind," says Barbara Miskin, an attorney with Hogan and Hartson of Washington, D.C., and former deputy director of the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research.

Amid this legal quagmire, many researchers, universities, and companies have begun to strengthen their disclosure procedures. Cetus Corporation of Emeryville, California, for example, requires institutions supplying cell lines or human tissues to demonstrate that the material was obtained through informed consent and that they have a clear title. At Centocor Inc., of Malvern, Pennsylvania, donors are offered a one-time advance payment or a royalty on any product that results from the donation of cells or tissues.

Despite efforts to secure releases and improve record-keeping, there are no assurances at this point that researchers and institutions are free from future claims. Nor is it certain that the existing system of free donation of human biological materials will continue. Ultimately, says OTA, the resolution of these issues may depend on how Congress chooses to regulate the procurement and the distribution of human tissues and cells. ■ **MARK CRAWFORD**

*Copies of *New Developments in Biotechnology: Ownership of Human Tissues and Cells* (OTA-BA-337) may be obtained from the U.S. Government Printing Office.