Radioactive Waste Backup Threatens Research

With the closing of the Hanford dump, Columbia, Duke, and Harvard are drowning in biomedical garbage

A garbage crisis hit the biomedical research community on 4 October when Dixy Lee Ray, the governor of Washington, closed the only radioactive dump in the country still willing to accept a form of low-level waste known as absorbed liquids. Ray closed the site at Hanford, Washington, in protest against careless practices in packaging and shipping waste, a problem she and other governors have been complaining about for 6 months.

The chief radiation safety officer of Columbia University, Philip Lorio, said, "It's a catastrophe. We don't know what to do. We don't know what's coming up tomorrow. We get all kinds of instructions that change from day to day and are impossible to follow."

Lorio said that haulers are now refusing to collect radioactive trash from Columbia's laboratories; that he had only 2 to 3 weeks' worth of unfilled storage space remaining; and that, if no solution is found within the next month or so, "I'll have to tell the researchers to stop their research." As the backup begins to make itself felt in the laboratory, researchers may continue to work, Lorio conceded, and they may simply begin pouring low-level wastes down the drain. This is not permitted for liquids that are not miscible with water, such as toluene, a commonly used chemical in radiological experiments and a suspected carcinogen. Other low-level radioactive liquids, if they are miscible with water, may be diluted and poured down the drain legally. "We have 300 labs using radioactive materials," Lorio said. "I can't put somebody in each one, standing by the sink to test every sample that goes down the drain." He thought that there had not been any increase in drain dumping, but if the crisis continues, he said, "We're going to get rid of our stuff that way, too. The government's going to force it on us."

Duke University also finds itself in a crisis. The chairman of its radiation safety committee, Henry Kamin, said that the university has no more than 30 days' worth of storage space remaining. The Memorial Sloan-Kettering Cancer Center, according to its radiation safety officer, Jean St. Germain, could last a couple of months, "depending on which priorities give way." She suggested that some research would have to stop, or that desks and chairs would literally be moved to make room for radioactive waste. An official at the New England Nuclear Corporation, a distributor of medical isotopes, estimated that his company could last several months without stopping work, but said that institutions with less storage space might have to shut down. Harvard University has only 2 weeks left before it must begin telling researchers to stop certain kinds of work. Officials at all these institutions agreed that drain-dumping will increase. John Pekin, president of a waste-hauling company called Radiac, said that although "nobody wants to do it," several of his customers have told him that they will begin flushing radioactive liquids into the sewers.

The consensus among university radiation officers is that the problem is a political one created by the accident at Three Mile Island. Most people do not distinguish between low-level wastes of the kind generated at hospitals and research laboratories, which pose negligible health hazards, and high-level wastes of the kind that must be removed from the crippled reactor in Pennsylvania. The public has become more worried about all forms of radiation this year, and radioactive garbage of whatever sort has become a political liability for any official who allows it to be shipped into his jurisdiction.

When the year began, three dumps in the United States were accepting shipments of low-level waste: in Barnwell, South Carolina; in Beatty, Nevada; and in Hanford, Washington. Most of the low-level waste is generated in the eastern part of the country, and most of the East's shipments were going to Barnwell. The governor of South Carolina was thus the first to raise the issue. In the late spring he declared a limit on the amount of waste that would be accepted each year and then, afterward, announced that South Carolina would accept no more scintillation vials or absorbed liquid wastes. The vials are glass tubes containing a liquid compound

NASA—DOE—DOT—DOD—EPA—NIH—NIA—NIAID—NIAMDD—NCI—NTSB—NIGMS—NBS—USGS—WHEW!—OMB—HEW—NSA—NAS—NSF—AAAS—FAA—OSHA—NHLBI—NHI—NINCDS—NINDS—CAB

Crisis in the Alphabet Soup

In Washington, few things proliferate faster than initials. A particularly cumbersome example is the progression of the National Institute of Neurological Diseases and Stroke (NINDS) to the National Institute of Neurological and Communicative Disorders and Stroke (NINCDS). The heart institute has gotten in its licks, too, as it proceeded, organ by organ, from the National Heart Institute (NHI) to the National Heart, Lung, and Blood Institute (NHLBI).

Now, the approval of the new Department of Education has created a new crisis for those—journalists, for example—to whom initials are dear. The Department of Energy has already cornered the market on "DOE". Should the Education Department become DOE2, or possibly DED, as one wag has suggested?

At the same time the Department of Health, Education, and Welfare, having lost Education, is transmogrifying from an easily recognizable—and pronounceable—HEW to DHHS, for Department of Health and Human Services. At first glance, Department of Health and Welfare would seem to be a much simpler and more manageable designation. But perhaps some astute soul in the department noticed that the most tempting abbreviation for this name would be HAW.—J.L.M.

0036-8075/79/1026-0431$00.75/0

(most often toluene) used to "count" radioactive emissions. Absorbed liquids are wastes (including toluene) that have been poured into containers filled with an absorbent such as vermiculite and packed in steel drums. In addition to being slightly radioactive, these liquids pose a problem because they contain highly toxic organic solvents that are difficult to solidify.

When South Carolina rejected these shipments, haulers began taking them to Nevada and Washington. In July, the governors of all three states met in Louisville, Kentucky, and formed an alliance. They jointly wrote to the chairman of the Nuclear Regulatory Commission (NRC) demanding that the NRC take greater responsibility for seeing that the wastes were properly packaged, and threatening, in effect, to go on strike this autumn if the NRC did not respond to their satisfaction. The NRC stepped up its inspection efforts, but apparently failed to satisfy the terms of the summer ultimatum. Some university officials feel the governors are engaging in brinkmanship tactics designed to force the federal government to step in with a broad new plan for low-level waste disposal.

In September, Nevada ceased to accept liquid wastes, and about 1 week later, Washington closed down. According to a spokesman for Governor Ray, the immediate provocation came on 2 and 3 October, when several badly packaged shipments arrived at Hanford. These included an overloaded and poorly maintained truck carrying depleted uranium; three damaged boxes from the Commonwealth Edison nuclear plant in Dresden, Illinois, containing scrap iron and gravel; and a drum from the New England Nuclear Corporation, which had leaked onto the floor of the trailer in which it was hauled. Ray decided to close the site to all shipments until the NRC and the Department of Transportation produce a waste management scheme that satisfies her. In the interim, the governors of Nevada and South Carolina have pledged, as agreed in their pact of last July, not to accept any diverted shipments of wastes originally scheduled to go to Washington.

It is amusing to some antinuclear activists that Dixy Lee Ray should be playing the lead role in this protest, for she was once chairman of the former Atomic Energy Commission and an outspoken proponent of developing nuclear power. But, as the same people point out, next year is an election year for the governor in Washington.

While the moratorium on waste shipments may have created severe problems for Harvard and Duke, other institutions, such as Yale and the National Institutes of Health (NIH), have escaped

FDA Tells Senators of Doctors Who

There are a few rotten apples in every barrel, and Senator Edward M. Kennedy (D-Mass.) recently devoted a morning of hearings to publicizing the cases of rotten clinical investigators the Food and Drug Administration (FDA) has uncovered in the past 2 years.

The hearings were held in connection with proposed FDA regulations on the obligations of the sponsors and monitors of new drug trials with human subjects. At hearings last year by his health and science subcommittee, Kennedy was told of two doctors who had falsified data on new drug testing. Now 29 more are under investigation by the agency, with an eye to disqualification and possible criminal prosecution.

The case histories afforded a glimpse of the precarious and desperate lives some must be leading. One doctor, for example, apparently found himself driven to concoct data at the last minute for studies he never got around to conducting; another was believed by FDA officials to have mugged himself and vandalized his office to cover up for missing records.

Michael Hendsley, of the Office of Scientific Investigations at FDA, emphasized that it was not just private contractors but prestigious academics who had flouted test protocols, falsified data, and submitted phony informed consent documents. "Some people," he said, "regard this as something less than real research."

In the cases cited, no names or places were given, although quite a few of the miscreants seem to have found their way to California. One is "Dr. 31," who was found to have submitted to one drug company sponsor drug testing data identical to those he had submitted to another company. On being confronted by FDA inspectors, he explained that he was such a "compulsive worker" that he had taken the original data with him on a picnic and that they had been lost when the rowboat he was in capsized. He admitted he had falsified the data, but said he had tried to make them as close as possible to those he had lost. This story was disproved when FDA inspectors learned the doctor had tried to get a nurse to state that she had been in the rowboat when the incident occurred. Dr. 31 turned out not to be a doctor at all. An alleged medical graduate from the University of Saigon (which he was not), he had flunked the Massachusetts medical boards ten times before finally getting a license to practice in Ohio. From there he was certified through reciprocal agreement to practice in California, where he worked for 11 years in a Veterans Administration hospital. Hendsley believes that despite Dr. 31's proven fraudulence, he is still practicing in California.

Another case was that of "Dr. 24," a psychiatrist who performed 12 clinical studies of psychoactive drugs for six companies from 1971 to 1978. The suspicions of an FDA official were aroused on a routine data-auditing visit when he found that the doctor's office was empty except for an executive chair. His suspicions were fanned when the psychiatrist brought him a "kindergarten-sized" chair to sit on and then proceeded to turn the thermostat up and down during the visit. It subsequently turned out that most of the patients said to be involved in the study—drawn from the doctor's private practice—were not. Dr. 24's former wife testified at the hearings that he had enlisted her help in creating false data when she was working for him before their marriage. Always too busy to actually do the studies, he opened drug and placebo capsules to determine which was which; he also managed to acquire copies of normal electrocardiograms, which he then arranged to represent pre- and post-study EKG's. The ex-wife, who finally got fed up with the deception and the husband, said the drug companies liked Dr. 24's research "because his dropout

0036-8075/79/1026-0432$00.50/0

the crisis through good fortune of one kind or another. Yale, for example, has made a storage area in a large unused building that once housed an electron accelerator. It has lots of space. NIH luckily has a waste disposal agreement with a division of Todd Shipyards of Galveston, Texas. This company, unlike those serving many of the eastern universities, disposes of liquids simply by burning or evaporating them. This process releases small amounts of radioactivity into the atmosphere. Todd sends only the residual solid material to the dump and, as a result has no difficulty persuading Nevada to accept its shipments. The director of this operation, Charles Hathaway, said recently that he expects the ban on the shipment of liquids into the dumps to become permanent. His business is growing rapidly.

Radiation safety officials at Harvard, Columbia, Yale, and other institutions said they, too, would like to burn the toluene taken from their laboratories, but that public sentiment would not allow it. Jacob Shapiro of Harvard claimed that the amount of radiation released by burning liquid wastes would be so insignificant that a person could stand near the exhaust stack and breathe the fumes continuously without violating the minimum exposure standards set by the NRC.

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George Holeman of Yale was envious of the University of Illinois at Urbana-Champaign, which has burned radioactive wastes for 2 years.

Be that as it may, none of the institutions in the Northeast is planning to do likewise. They may search for new ways to solidify waste, or they may simply try to hire companies like Todd Shipyards to do this work for them. It will be expensive. Even without the shift to solidification, the cost of disposing of wastes in the Northeast has at least doubled this year because of the lengthened shipping distances.

Suddenly low-level wastes have become an important problem. About this, nearly everyone agrees. And nearly every participant in the waste-making and waste-shipping enterprise is quick to point out that the responsibility for cleaning up the mess lies somewhere else.—ELIOT MARSHALL

Fake Data in Clinical Drug Trials

rate was so low." She concluded, "It seems to me that what happened was fairly blatant and fairly obvious. I don't see why no questions were asked."

Other cases cited included that of an investigator who removed the labels saying "not for human use" from an intravenous feeding solution and administered it to human subjects.

Most of the examples described at the hearings reflected poorly on the sponsoring companies, which were supposed to monitor the trials, rather than on the FDA. There was one case, however, of a prominent physician who managed to string the FDA along for close to a decade. This man had achieved a close relationship with FDA's Division of Neuropharmacology and was able to get investigational new drug (IND) permits that made him both sponsor and investigator. The FDA continued to trust him throughout the late 1960's and early 1970's despite the fact that he failed to submit progress reports, maintain his records properly, respond to inquiries, or follow protocols. When one drug he was working with was discovered to have life-threatening side effects, he was directed to limit its administration to "hardship cases," a stricture he ignored. When he could no longer ignore the annoyance of the FDA, he flew to Washington in a private plane and treated the members of the Neuropharmacology Division to a catered lunch. On being told that his IND would have to be lifted, he threatened to protest by landing a helicopter with most of the prominent people in his practice on the building where the FDA offices are located. "We are close to getting rid of him," testified Hendsley.

One private research company, Bio/Basics International Corp. of New York, also found itself under the gun at hearings. Last year the FDA developed doubts about data from studies on an analgesic, suprofen, conducted by Bio/Basics for Ortho Pharmaceutical. Subsequently, the FDA found eight of nine suprofen studies monitored by Bio/Basics to be deficient. In one study, FDA suspicions were aroused by the lack of placebo responders (normally the rate is at least 15 percent). On the night before the inspectors were to visit the doctor's office, the office was vandalized and records dumped into a whirlpool bath. Afterwards, a fire of mysterious origin broke out near the records room. Finally, on the night before the second try at inspection, the doctor was mugged in his office—struck on the head by a paperweight that was later found to bear only his fingerprints. When FDA officials contacted the patients in his study, it turned out that consent forms had been faked and the patients did not know anything about the study.

The president of Bio/Basics strenuously defended his company's integrity at the hearings, and claimed it was being smeared by vague innuendos that might well put the company out of business. Kennedy was not sympathetic.

The members of the subcommittee, including Howard Metzenbaum (D-Ohio) and Richard Schweiker (R-Pa.), professed themselves "shocked" and "deeply disturbed" at the evidence. Kennedy himself used the hearings as a forum to repeatedly stress the need for companies to have access to source data—that is, patient records—so they could be compared with reports submitted by investigators. He says this provision is essential for monitoring of studies and should be included in the FDA's clinical investigation regulations proposed 2 years ago, which have yet to be finalized.

Kennedy had kind words for the FDA and for the "vast majority" of clinical investigators. But, in reference to the cases described at the hearing, "there is the nagging question of whether we are looking at the iceberg or the tip of the iceberg."—CONSTANCE HOLDEN