

on large, complex systems. Thousands of possible sequences of reactor failures were assessed by computer for their probability and for their ultimate effects stated in terms of radioactivity released, casualties caused, and property damaged.

A major focus of the study was the much discussed loss-of-coolant accident or LOCA. A LOCA begins with a sudden break in a main pipe carrying cooling water to a reactor's hot core of uranium fuel. Critics of the AEC have contended that the commission has never adequately tested the backup safety systems—especially the emergency cooling systems of power plants—to ensure that a LOCA would not lead to melting of a reactor core, penetration of the massive containment dome surrounding the reactor, and dispersion of lethal fission products over a wide area.

The Rasmussen study found that, as the hypothetical severity of such an accident increased, its probability de-

creased. At one extreme, the annual chance of a core meltdown could reach 1 in 17,000 but would involve no more than one death and \$100,000 in property damage beyond the nuclear plant site (the reactor itself might be a multimillion dollar loss and casualties could occur to workers on the site). At the other extreme—the “bottom line,” as Rasmussen put it—would be a core meltdown, followed by failure of all backup safety systems: all during the worst possible weather conditions. This, Rasmussen said, could lead to some 2300 fatalities, \$6 billion in property damage, and the permanent contamination of 31 square miles of land around the reactor. But this accident's probability is rated at only 1 in 10 million.

The study has its limitations, as Ray and Rasmussen readily acknowledged. It applies only to present designs of light water reactors and not to other elements of the nuclear fuel cycle. It does not take into account the possi-

bility of sabotage, although Rasmussen said a saboteur could not cause an accident more severe than the ones considered in the study. The possibilities of human error in operating a nuclear plant were factored into the calculations, but the possible presence of fundamental design errors in safety systems could not be predicted, Rasmussen said.

He nonetheless declared the study to be “the most careful and definitive assessment” of risks associated with nuclear plants that had ever been done, and Ray agreed. Early next year, after reviewers' comments have been studied, the commission will issue a final report representing “the definitive position of the AEC,” she said. The report avoids directly answering a central policy question—how safe is safe enough? But Ray left the clear impression that accident probabilities put forward in the Rasmussen report mean that nuclear power is indeed safe enough.

—ROBERT GILLETTE

Dalkon Shield Affair: A Bad Lesson in Science and Decision-Making

Months of confusion and doubt about the Dalkon shield intrauterine device (IUD) are winding down to an unsettling end. Throughout a summer of uncertainty about the safety of the shield, people were anticipating a full-dress public hearing on the evidence. That hearing, which drew about 200 persons, was held during the third week of August at Food and Drug Administration (FDA) headquarters in the Parklawn building in Rockville, Maryland. By the conclusion, a special FDA panel was persuaded that sales of the shield continue to be temporarily suspended. From information gathered since the voluntary suspension of sales and distribution by the manufacturer in late June, the FDA disclosed at the recent hearings that the original number of serious problems presumably associated with the shield had about doubled, the total now being 11 deaths and 209 infected abortions.

But ambiguities still color a respecta-

ble scientific appraisal of the safety of the shield by the Center for Disease Control in Atlanta, in spite of the panel's action. Whether the shield is any worse than other devices has yet to be firmly established. Further clouding the issue is the indisputable fact that both the pill and pregnancy are more dangerous than IUD's in general, including the Dalkon shield. Unsubstantiated doubts and rumors guided public officials and other influential people who made public statements during recent months about the shield, producing a fragmented, often contradictory running commentary in the press.

Between the morning news and the usual string of local advertisements, radio stations early this summer were broadcasting a public service announcement of sorts, a recall for Planned Parenthood patients. The family planning organization whose nationwide clinics provide women with various types of contraceptives was asking that

all its patients who had been fitted with the Dalkon shield turn themselves in for a checkup, and possibly a new contraceptive.

On 23 May, on the orders of Dr. Celso-Ramon Garcia, then chairman of its national medical committee, all Planned Parenthood centers stopped prescribing the shield. On 29 May, after a full meeting of that committee in Washington, D.C., the antishield directive was reissued with a recall clause. It said not only that no new shields should be inserted but that women wearing them should be advised to have them removed because of a “serious risk to their health in the event that they should become pregnant with the IUD in place and choose to continue that pregnancy.”

The Planned Parenthood recall was apparently inspired by a “Dear Doctor” letter that A. H. Robins Company of Richmond, Virginia, had sent to some 120,000 physicians. That letter, dated 8 May, was not mailed until the middle of the month and not announced publicly until the end of the month. As far back as last February, Robins officially acknowledged reports that its product might be hazardous. Specifically, the company's advisory panel on family planning and birth control met to discuss reports that there was an unusually high incidence of midtrimester

septic abortion among women who became pregnant with the shield in place. Such abortions, which occur because of a serious bacterial infection in the uterus, are extremely rare, whether the pregnant woman has an IUD in place or not, so when evidence came to light showing that since 1970 there had been 36 such cases in shield wearers, Robins and their advisers were concerned. The FDA was kept informed by Robins of these cases implicating the shield from the beginning.

Thousands of women, many of them understandably frightened by the headlines and radio reports, wondered what to do. Should she or shouldn't she have her Dalkon shield removed? Nobody really knew for sure.

Planned Parenthood, obviously, thought she should. The FDA was more restrained. It began gathering data to decide what action, if any, should be taken in light of the reports that the shield might be hazardous, but made no statement at that time about what women wearing the shield should do. Two of its relevant advisory committees were scheduled to meet early in June, and the agency decided to keep still until then. After those meetings the committees each went along with the idea of suspending new shield insertions, although their convictions on the subject were less than firm. In each case, a decision to recommend that policy was reportedly reached by a margin of only one vote. A couple of weeks later, Louis Hellman, deputy undersecretary for population affairs of the Department of Health, Education, and Welfare (HEW), came out with a position closer to that of Planned Parenthood. At a 2 July press conference, Hellman declared that he had ordered all federally funded birth control clinics to stop prescribing the Dalkon shield and, although he did not urge a recall, he did suggest that physicians remove the controversial IUD from any patient who happened to come in for a routine checkup.

By that time, A. H. Robins had already agreed to suspend sales pending further inquiry. A press release dated 28 June announced the suspension, but emphasized that neither the company nor the FDA was recommending that women wearing the IUD successfully



Dalkon shield

have it removed. It also said that about 2.2 million shields "have been in use in the United States" since they were first marketed in 1970 and added, lest its stockholders panic, that "discontinuing sale of the Dalkon shield would not adversely affect its 1974 estimated earnings by more than 2 cents per share." (Robins' main business is making drugs.) The accurate estimate of shields in use is a debatable point, ranging from the FDA's guess of 1.3 million to Robins' figure of 2.2 million.

On 12 July, FDA Commissioner Alexander Schmidt issued a "clarifying" statement that said the agency was going to hold full-dress hearings in August and in the meantime was not advising a patient recall. The real problem, Schmidt said, appeared to be limited to those few cases in which the shield wearer becomes pregnant with the device in place. If that happens, physicians were advised to remove the IUD and then either offer their patients a therapeutic abortion or else monitor the pregnancy very carefully for signs of infection, which can develop and spread with considerable speed. (In one reported case, the woman was dead within 31 hours of the appearance of symptoms.)

Later, Hellman told *Science* that he "regretted" his statement and really agreed with Schmidt all along. Garcia, too, said that if he had it to do over again, he would not have urged Planned Parenthood to recall its shield wearers in such haste.

Although it now appears that their actions may have been right, it seems that at the time, a number of actions were taken on the basis of precious little information.

Officials were strongly influenced by the survey made by researchers at the Center for Disease Control (CDC). The study, headed by Henry Kahn, now of Emory University in Atlanta, was intended to assess the safety of IUD's in general and was not intended to make comparative evaluations of one design versus another; hence, many problems arose in interpreting its results for the Dalkon inquiry. Kahn, in his opening remarks at the FDA hearing, said of the mail survey to some 34,000 physicians, half of whom responded, "We've raised questions but have not answered

them all." He also acknowledged the survey data was of little value in making judgments about the Dalkon shield in comparison with other devices such as the Lippes Loop and the new Copper 7.

Several witnesses at the hearing agreed with him on that and some of them were sharply critical of the CDC survey, Daniel G. Seigel of the National Institute of Child Health and Human Development (NICHD) and Irving Kessler of Johns Hopkins among them. Included in their list of objections were the fact that the response to the survey questionnaire was only 50 percent and that it covered too short a time to be meaningful. Doctors were asked to report on hospitalizations and deaths among IUD wearers for only a 6-month period and some critics felt that, because duration of use is an important factor in a woman's physiological reaction to an IUD, 6 months is too short a study period. Kessler called the CDC survey a "quick and dirty look" at the problem of IUD safety and called for a thorough, epidemiologically and statistically sophisticated analysis of the situation. Seigel said that NICHD already has plans for such a study. Meanwhile, in May the FDA contracted Batelle's Pacific Northwest Laboratories to update the official FDA report on IUD's, last done 6 years ago.

Until these studies are completed, which could be as long as 2 years from now, FDA's official advisers and everyone else are left with second-rate data. It is regrettable, to say the least, that this is the case. After the experience with oral contraceptives and the difficulties authorities encountered in coming up with reliable information about the number of women using various types of pills, for how long and with what effects, it seems incredible that the same situation prevails with respect to IUD's. But there it is.

No one knows for sure how many women have been fitted with IUD's, let alone how many with each type. Lacking these totals, the essential question of whether one device is indeed more hazardous than another remains unanswered. Planned Parenthood, which has been inserting first Loops and now shields for years, has little data of its own to contribute. Manufacturers have data on distribution—Robins, for example, knows it has shipped about 2.2 million shields from its plant—but little on actual use. And even FDA's most recent efforts to gather new data on

the subject leave something to be desired. In its July Drug Letter, the agency asked physicians to drop it a line about any problem IUD cases they came across. The FDA listed certain kinds of information it was seeking but several important questions, including those about the patient's age and whether or not she had had a child, were conspicuous by their absence. Both of the latter two factors are thought to be particularly significant in assessing the shield which, more than other devices, has been inserted in young, highly fertile women who have not had any children.

In deciding to maintain the status quo

temporary suspension of June, the panel of outside advisers only echoed the now familiar disclaimer that has plagued the "investigation" of the Dalkon from the beginning, that there is simply not enough evidence to convict or acquit the shield. The group recommended that still another committee be formed to study the problem. What this one can do in the next 2 to 4 weeks that the other panels could not do is anybody's guess.

The continuing limbo must be a disappointment to commissioner Schmidt who had been promising a definitive decision soon after the 21 August hearing. Schmidt's final verdict will probably

come by the end of next week, but there is no reason to think this will be the last we hear of the Dalkon shield. As far as the 1.3 million to 2.2 million women already wearing the shield are concerned, the FDA emphasized that shields being worn without complications should not be removed. Nonetheless, with the bad publicity the shield has already received, it is difficult to imagine those women will be comforted by the FDA assurance.

—BARBARA J. CULLITON and
DEBRA S. KNOPMAN

Knopman will be a senior at Wellesley College this fall.

Fermi National Accelerator Lab: Making the Users More at Home

During the protracted bargaining that resulted in the construction of the Fermi National Accelerator Laboratory (FNAL) near Batavia, Illinois, agreement had to be reached not only on the difficult issues of how much the big machine would cost, where it should be located, and how powerful it would be but also on how to guarantee a "national" character for the facility.

The Atomic Energy Commission (AEC), which pays the bills at Batavia, was committed to the principle that the lab not be monopolized by researchers from any particular institution or region and went some way toward forestalling the problem by bestowing the contract for operating the facility on the Universities Research Associates, Inc. (URA), a consortium of research universities now numbering 52. So far, the new lab's director, Robert R. Wilson, and his staff have fashioned a management system designed to provide fair access and also to avoid other pitfalls found in other big accelerator labs.

To provide formal representation for visiting experimenters (for whom the lab after all is intended), an FNAL User's Organization was formed that now has about 1000 on its mailing list. The user's group deals on most matters with the lab management, but there is also an arrangement under which rep-

resentatives of the user's group meet regularly with the URA board of trustees without top lab managers being present.

Batavia is really in its first summer of operation with a full complement of university researchers and their families in residence, and many of the issues raised by the user's group relate to problems of setting up housekeeping for longer or shorter periods at Batavia.

Batavia's overseers were aware that the new lab's location on the farthest fringes of Chicago's commuting suburbs might not be regarded as a garden spot by physicists and their families, more accustomed as they are to summering on the coasts rather than simmering in a converted cornfield.

Housing was a problem because what was available on the private market tended to be distant or expensive and provision for on-site housing ran into an AEC policy of avoiding competition with private enterprise. Now, after a long period of negotiation, a compromise seems to have been reached which permits the use of some original farmhouses that were moved from locations around the lab's site to the village of Weston and the reconversion to living units of some small houses in an ill-starred subdivision the government took over as part of the 6800-acre site. Units

for about 80 families and accommodations for some 100 single people are in the process of being converted for use.

URA has financed the construction of a swimming pool, and Wilson, with characteristic resourcefulness, negotiated the building of a couple of tennis courts at a cut rate by a contractor whose equipment was on the scene to build a road. A variety of activities are available, from a film series to a riding club, and a survey of wives was conducted this summer, in part to see what else can be done.

On the job, visiting researchers still complain about such things as the food in the cafeteria and the lack of transportation to and from the lab. The lab's 24-hour research day makes it more difficult to assure creature comforts, but the visitors, who make allowance for the fact that this is still a breaking-in period for the lab, seem to feel in general that the management is trying to respond to suggestions.

A more serious complaint comes from some experimenters who say that supporting services available at other accelerator facilities to groups actually "on the floor" running experiments are not available to the same extent at Batavia. As one senior researcher said, "It can be frustrating, you just can't find people to do things."

The same man questioned whether the lab management was putting the emphasis on the right support groups but attributed the problem primarily to budget restraints, saying "they're trying to do experiments on a scale not matched by funding."

A crucial matter at Batavia, obviously, is the choice of the research