

require a survey of several insurance companies. Schnorr said that although NIOSH has the authority to obtain medical insurance files, such a survey would be too time-consuming and expensive.

As a result, NIOSH scientists decided to gather data by interviewing individuals, a method that is common, but raises the possibility of recall bias. In this study, for example, publicity about potential hazards associated with VDT use might cause women who work with VDT's to remember their miscarriages with greater accuracy. Unreported miscarriages among the control group would skew the study results.

NIOSH researchers also had problems finding a suitable control group for the project. They considered workers from a variety of sectors, including the insurance industry, airline reservation offices, and the federal Social Security Administration. They eventually settled on the phone companies because Bell South directory assistance operators use VDT's, while AT&T long distance operators perform similar tasks without computers. The two groups are also similar in socioeconomic class.

NIOSH put the finishing touches to the study design in May 1985, after it had been honed and approved by a group including four nonagency scientists—three epidemiologists specializing in reproductive studies and a stress expert, and two agency scientists—a statistician and a psychologist. The agency decided to focus mainly on whether VDT use is linked to miscarriages and, second, to birth defects in general rather than to a few specific defects. It proposed to interview 2000 VDT users and an equal number of nonusers, which would provide enough data to detect a 50% increase in miscarriages among VDT users. To ensure that both groups are comparable, women would be questioned about stress on the job and their ability to conceive. And, reports of spontaneous abortions would be checked against medical records.

MacMahon and Zierler, however, harshly criticized the study, asserting that because of recall bias, "The likelihood that the study as described will achieve its stated objectives . . . is nil. It is in our view inconceivable that the study would yield results that are definitive, unequivocal, or credible. . . ." They suggested several revisions:

- To minimize the possibility of recall bias, they said that NIOSH should verify unreported miscarriages by examining medical records.

- The questions about stress and fertility should be eliminated because they are "intrusive" or "irrelevant" to whether VDT use is associated with spontaneous abortion.

- The sample size should be enlarged in

order to detect less than a 50% increase in spontaneous abortions.

Drawing upon these comments, Bell South went to OMB, which has the authority under the Paperwork Reduction Act to review the study and approve all federal questionnaires. The company said that even though it supported the concept of a study, the project should be expanded to include women from other industries. The telecommunications industry was being unfairly singled out by NIOSH scientists, it argued. OMB subsequently disapproved the project, an action that is not unusual. Since 1984, for example, it has disapproved five out of 25 surveys proposed by NIOSH.

The budget office now says the study may proceed if NIOSH incorporates many of MacMahon and Zierler's suggestions. It said questions concerning stress and fertility should be eliminated, and that NIOSH should investigate the possibility of unreported miscarriages to minimize recall bias if the study does show a link between miscarriages and VDT use. It did not say, however, that the agency must expand the project to include more telephone operators or workers from other industries.

In an interview, MacMahon expressed satisfaction with OMB's decision. "We got almost everything we wanted," he says. "Our main concern was recall bias. I think the study is now scientifically sound."

NIOSH officials say they will likely go along with the budget office's revisions, although they have expressed concern about OMB's intervention. Schnorr remarks that the changes "reduce our ability to detect" some potential differences between the two groups, but, as a whole, they do not substantially change the study design. The study will take 2 years to complete and cost about \$500,000.

Carl Shy, a professor of epidemiology at the University of North Carolina and an adviser to NIOSH on the study, says that by striking the fertility questions, OMB eliminated the chance to uncover a potential complicating factor in the study results. But, because the questions are not related to the main purpose of the study, he says, they are no great loss. And, in his opinion, a reproductive study that can detect a 50% increase in miscarriages is relatively sensitive.

Bell South spokeswoman Kathleen Hughes said the company had no comment other than to say that "it would continue to participate" in NIOSH's efforts.

NIOSH official Bierbaum said of the budget office's approval, "This is great. It's too bad [settling on a design] took so long." Schnorr said that agency researchers may be ready to begin the VDT study this fall. ■

MARJORIE SUN

Briefing:

High Court Says No to Administration's Baby Doe Rules

The Supreme Court has finally foiled attempts by the federal government to mandate the type of medical treatment accorded newborns with severe birth defects. In a case decided on 9 June, the court said that the "Baby Doe" guidelines promulgated 2 years ago by the Department of Health and Human Services (HHS) cannot be justified on the basis of the Rehabilitation Act, which forbids discrimination against the handicapped.

The guidelines were struck down by a New York district court in early 1984 after a suit spearheaded by the American Medical Association. An appeals court affirmed the decision, but the government decided to pursue the case to the Supreme Court. Still in place are Baby Doe-type regulations that were passed last year as part of the Child Abuse and Protection Act.

Specifically, the Supreme Court struck down rules which would have required the posting of informational notices in hospitals, expedited access by the federal government to medical records, and ordered expedited compliance actions on the part of state child protective services.

The HHS has tried to assert that the infants in question are protected under the law that says handicapped individuals "otherwise qualified" for services may not be discriminated against. But the court wrote that "the 'otherwise qualified' criterion . . . cannot be meaningfully applied to a medical treatment decision" related to the handicap. It asserted that in cases where treatment has been withheld, the decision has not been based on the handicap but on the wishes of the parents.

The HHS guidelines as originally proposed would have mandated treatment with or without parental consent, but this stance was later reversed to say parental decisions should not be overruled. Since in none of the 49 cases cited by the secretary of HHS was treatment denied in violation of parents' desires, the court points out that the secretary's concerns are largely "theoretical."

Ironically, in view of the philosophy of this Administration, the tartly worded opinion by Justice John Paul Stevens comes across not only as "profamily" but anti-federal intervention. It says "state child protective services agencies are not field offices of the HHS bureaucracy, and they may not be conscripted against their will as the foot soldiers in a federal crusade."

Although the judicial route has now been blocked, disability rights groups have indicated they will continue to fight for more direct federal protection for handicapped infants through new legislation. ■

CONSTANCE HOLDEN

Feynman Issues His Own Shuttle Report, Attacking NASA's Risk Estimates

"When playing Russian roulette, the fact that the first shot got off safely is little comfort for the next," writes Richard Feynman in a scathing commentary he released on the space shuttle disaster.

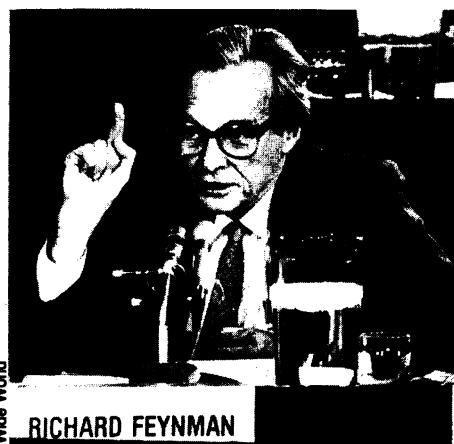
Feynman, a Nobel prizewinning physicist at the California Institute of Technology, was best known—until recently—for the ingenious, cartoon-like diagrams he invented to illustrate the actions of basic particles. Now he is also famous as the independent voice on the Rogers Commission, the presidential team that investigated the shuttle accident. Feynman went his own way from the start. His impromptu experiment with a piece of "O-ring" dunked in ice water, aimed at challenging a witness as the witness spoke, was a memorable point in the hearings.

When it came time to write the conclusions, Feynman decided that his peers had gone mealy-mouthed. He lobbied for an evisceration of the bad logic used by the National Aeronautics and Space Administration (NASA). And he objected to an upbeat comment at the end of the report that "strongly recommended" more federal support for NASA and the space program. He noted that this issue had not been discussed. As a result, it was amended to a mere "urging." Although Feynman is not a dissenter, he wanted to add more definition to the report. So, on 9 June, he held a press conference and released his own "personal observations."

Feynman objects most strongly to NASA's way of calculating risks. Data collected since the early days of the space program, including records used by NASA's range safety officer, Louis Ullian, show that about one in every 25 solid rocket boosters has failed. About 2900 have been launched, with 121 losses. Feynman says it is reasonable to adjust the anticipated crash rate a bit lower (to 1 in 50) to take account of today's better technology. He would even permit a little more tinkering with the numbers (to 1 in 100), to take credit for exceptionally high standards of part selection and inspection. In this way, the Challenger accident, the first

solid rocket failure in 25 shuttle launches (with two boosters each), fits perfectly into Feynman's adjusted rate of one crash per 50 to 100 rocket firings.

But Feynman was stunned to learn that NASA rejects the historical data and claims the actual risk of a crash is only 1 in 100,000. This is the official figure as published in "Space Shuttle Data for Planetary Mission RTG Safety Analysis" on 15 February 1985. It means NASA thinks it could launch the shuttle, as is, every day for the next 280 years and expect not one equipment-based disaster. Feynman searched for the origin of this optimism and found that it was "engineering judgment," pure and simple. Feynman concluded that NASA, "for whatever purpose . . . exaggerates the reliability of its product to the point of fantasy."



NASA "exaggerates the reliability of its product to the point of fantasy."

It is not really as bad as that, according to Milton Silveira, NASA's chief engineer in Washington. "We don't use that number as a management tool," he said in a telephone interview. "We know that the probability of failure is always sitting there, and we are always looking for it and trying to prevent it." The 1 in 100,000 figure was hatched for the Department of Energy (DOE), he says, for use in a risk analysis DOE puts together on radioactive hazards on some devices carried aboard the shuttle. These are plutonium-driven power units for deep space probes, such as Galileo and Ulysses. To reassure the public, the government must certify that the shuttle can take off from Cape Canaveral without dumping plutonium on the beaches and orange groves of Florida.

DOE and General Electric, supplier of the power units, write up a detailed risk analysis before launch. They are accustomed to expressing risk in statistical terms. NASA is not, but it must help them prepare the analysis. To speak in DOE's language, NASA translates its "engineering judgment"

into numbers. How does it do this? One NASA official said, "They get all the top engineers together down at Marshall Space Flight Center and ask them to give their best judgment of the reliability of all the components involved." The engineers' adjectival descriptions are then converted to numbers. For example, Silveira says, "frequent" equals 1 in 100; "reasonably probable" equals 1 in 1000; "occasional" equals 1 in 10,000; and "remote" equals 1 in 100,000.

When all the judgments were summed up and averaged, the risk of a shuttle booster explosion was found to be 1 in 100,000. That number was then handed over to DOE for further processing. To no one's surprise, the overall risk of a plutonium disaster was found to be terribly, almost inexpressibly low. That is, 1 in 10,000,000, give or take a syllable.

"The process," says one consultant who clashed with NASA, "is positively medieval." He thinks Feynman hit the nail exactly on the head. There are ways of taking experience into account while totting up the statistics, he added, but "once you divorce it from a scientific process, you make it susceptible to the whims of political necessity." Unless the risk estimates are based on some actual performance data, he says, "it's all tomfoolery." He also complained that NASA, because of its low opinion of the usefulness of such data, has been unwilling to pay for their collection.

Silveira says he views the entire field of statistical risk analysis with suspicion, precisely because he knows how much tomfoolery goes on. "I had some experience in this earlier," he says. "You tell me what you want to prove [with numbers] and I'll prove it." He learned his lesson with the Apollo program when the statisticians announced that there was less than a 1 in 20 chance of getting a man on the moon. After the moon landing, "We threw away all that data," and have not used the approach since.

NASA does give DOE the numbers it insists upon having, but pays little attention to them itself. Instead, NASA relies on its own system of component analysis, which is designed to keep track of all critical parts in the system and to isolate and fix every problem as it arises. Thus, in Silveira's view, the shuttle is always approaching infallibility. Historical rocket booster data are essentially irrelevant. The agency relies on experienced judgment, not the numbers game, in deciding where the risks lie. The reason for the Challenger disaster, in his view, is that those responsible for exercising their judgment on booster problems failed to do so. They "were operating outside the system" and let the situation get out of hand. ■

ELIOT MARSHALL