

Washington Post
10-15-71

Flu Vaccine Data Altered, Hill Is Told

By Morton Mintz
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An obscure federal health agency used "dubious techniques" to test the influenza vaccine relied on by millions of Americans, and then "tampered" with the test results, two investigators charge in a report made public yesterday on Capitol Hill.

They also accused the agency, the Division of Biological Standards of the National Institutes of Health, of having ignored scientific data in its own files that materials capable of causing cancer in hamsters were found in a cold vaccine administered to all Army personnel in the late 1950s and early 1960s.

In addition, the investigators said DBS disregarded evidence that could have prevented the use of contaminated Salk polio vaccine which led, in 1955, to the paralysis of 150 persons. More than 18 million people received injections of the flu vaccine in each of the last three years.

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Flu Vaccine Test Tampering Charged on Hill

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The investigators are Dr. J. Anthony Morris, a DBS virologist, and James S. Turner, author of "The Chemical Feast" and a former associate of Ralph Nader.

They made their charges in a 24-page single-spaced memo delivered to Dr. Robert Q. Marston, director of the NIH, on Sept. 27.

On the same day, joined by University of Maryland microbiologist B. G. Young and Lederle Laboratories virologist J. E. Whitman Jr., they gave a copy of the memo to Sen. Abraham A. Ribicoff (D-Conn.).

The memo "raises serious questions of the utmost importance to the public health," the four scientists told Ribicoff, chairman of the Senate Subcommittee on Executive Reorganization and Government Research.

In a speech prepared for delivery today, Ribicoff said he has asked Elliot L. Richardson, Secretary of Health, Education, and Welfare, to investigate the charges against DBS and to make a full report to the subcommittee.

Ribicoff said that, at his request, the General Accounting Office will review the regulatory responsibilities of DBS.

Richardson had no immediate comment. Dr. Roderick Murray, director of DBS, was reported en route to Geneva. His agency provides the licenses without which no vaccine can be distributed in interstate commerce. Last year 19 vaccines were being sold in the United States.

"Incredibly," Ribicoff said, DBS says it has "no legal authority to test vaccines for effectiveness in actually preventing diseases," meaning "that no federal agency tests vaccines to see if they work."

In a statement last night, Dr. Marston of the NIH expressed "every confidence in the scientific integrity and dedication" of Murray and his staff.

At the same time, Marston disclosed that in August he had directed an NIH unit to study the "organization, management and personnel practices" of DBS; that he initiated "an in-house review" of the "as yet unsubstantiated allegations" made by Morris and Turner immediately on receiving them, and that he also has asked the DBS Board of Scientific Counselors, "augmented by selected experts," to review the charges.

Ribicoff also disclosed that the GAO will review the role

of the Food and Drug Administration and the Public Health Service in the use of isoniazid, a drug prescribed for an estimated 750,000 Americans to treat and prevent tuberculosis.

The senator recalled that, under a PHS program, 2,300 persons who work on Capitol Hill started a year-long program of isoniazid treatment after TB was found in six Hill employees, that several users developed hepatitis, and that two among them, both newsmen, died last November.

The flu vaccine, which first came into prominent use in 1967, has been "overrated as to its benefits," Dr. Morris of DBS said in a phone interview.

In children it often induces fever, in some pregnant women it can endanger the fetus, and in all users there is a risk that vaccine "literally loaded with extraneous bacteria" will be injected, he told a reporter.

Moreover, Morris said, it is "impossible" to test the product, known as bivalent influenza virus vaccine, for potency.

He and Morris cited this sworn statement by the DBS's Dr. Alexi Shelokov: "For many years I have not taken influenza vaccine myself; I

have not been impressed with its potency." Shelokov was responsible for insuring the potency of the flu vaccine from 1963 until 1969, and was certifying it to be potent during that time.

Shelokov's successor, Dr. Nicola Tauraso, said recently, "I think for the first time in many years... since 1968 we have been able to insure that the public gets potent vaccine consistently."

He was relying on the so-called CCA test. Its validity was challenged 11 years ago by a famed DBS researcher, Dr. Bernice E. Eddy. Her supervisor, Dr. Joseph Smadel, blocked publication of her paper, the investigators charged yesterday. Since then, they said, DBS has relied on the Pharmaceutical Manufacturers Association "to set the standards (inaccurately) for influenza virus vaccine potency."

In 1966 and 1967, the Morris-Turner memo said, DBS released at least three lots of flu vaccine even though one of its scientists, Dr. Casper Hiatt, had put a "hold" order on them because the manufacturers had not presented evidence that they were free of contamination by trace metals. There are eight manufacturers of the vaccine.

Turning to Salk polio vaccine, the memo said that in

1954 and 1955 Dr. Eddy discovered that live virus capable of causing paralysis was present in several lots. DBS leadership knew of this, but released the lots anyway, with 150 cases of paralytic polio following.

In the late 1950s, DBS developed the cold vaccine. In 1960, Dr. Eddy discovered that it could cause cancer in hamsters.

"DBS responded to her discovery by denying her permission to attend certain professional meetings and to publish other papers," Ribicoff says in the speech prepared for the Senate.

"She was deprived of most of her testing animals and most of her testing facilities," he said. "Finally, on March 8, 1961, she was relieved of her job and reassigned."

DBS continued to release the vaccine as late as Sept. 16, 1963, but finally, Ribicoff said, decided that Dr. Eddy had been "right after all." The cold vaccine is no longer available.

Many cancer specialists hold that a chemical that is definitely and reliably cancer-producing in one or two species of animals is very likely to be similarly active in other species, including humans.

"Something is seriously

wrong in DBS," Ribicoff said. "The cause of the problem may lie in the division's dual role as both developer and regulator of vaccines."

The complaint was reminiscent of those made about the Atomic Energy Commission (fostering atomic energy and regulating it) and the CIA (gathering intelligence and engaging in operations).