NIMH Review of Fraud Charge Moves Slowly

Allegations made at the end of 1983 about research on the use of drugs in the mentally retarded have yet to be sustained or put to rest

THE National Institute of Mental Health (NIMH) is currently engaged in an extremely protracted investigation of alleged research fraud by one of its former grantees. The inquiry, apparently the first case of its kind for the agency, has been dragging on for almost 2½ years.

The investigation centers around the research activities of Steven E. Breuning, a 34-year-old psychologist who has made major contributions to the literature on the use of psychoactive drugs with institutionalized mentally retarded populations.

Concerns about Breuning's research were first brought to the attention of NIMH in December 1983 by two former colleagues, Robert Sprague of the University of Illinois and Thomas Gualtieri of the University of North Carolina. Sprague and Gualtieri, who have both collaborated with Breuning, have reported what they believe to be discrepancies in Breuning's work and claim that some of the research on which his scientific reports are based was not, in fact, conducted.

In the absence of a final report from NIMH, a cloud continues to hang over Breuning's work. At the request of NIMH officials, the University of Pittsburgh, where Breuning worked from 1981 until 1984, has conducted two investigations. The results have been submitted to NIMH but have not been made public. NIMH itself had an investigator, former National Institutes of Health official James Schriver, looking into the matter for several months. Then, in 1985, NIMH formed a panel of outside reviewers, headed by psychiatrist Arnold J. Friedhoff of the New York University School of Medicine. The Friedhoff panel has completed its inquiry into the case and has forwarded its conclusions to the institute.

Breuning's scientific work is of considerable significance in his field because, according to Sprague, only a handful of researchers worldwide are involved in looking at the effect of psychoactive drugs on the mental health and behavior of the retarded.

Such drugs are employed with 30 to 50% of institutionalized mentally retarded, who suffer from very high rates of emotional, behavioral, and brain disorders. Neuroleptic or antipsychotic drugs, sometimes called the major tranquilizers, are those most commonly used to modify behavior in patients who are aggressive, hyperactive, self-destructive, or who won't comply with treatment. Stimulant drugs are also used with hyperactive patients, particularly children.

Breuning argues that neuroleptics, which can produce lingering ill effects—namely tardive dyskinesia, a Parkinson-like disorder that affects motor control—are overused. He contends that stimulant drugs are often more effective, a claim that appears to be backed up by his research.

Gualtieri and others have also been concerned about the excessive and inappropriate use of neuroleptics. But Breuning, coeditor (with Alan Poling of Western Michigan University) of a widely used 1982 book, *Drugs and the Mentally Retarded*, takes a more extreme stance than does Gualtieri.

NIMH says draft report is written but must be reviewed.

Breuning got a doctorate in psychology from the Illinois Insitute of Technology in 1977, and was employed for a year at the Oakdale (Illinois) Regional Center for Developmental Disabilities, later moving to the Coldwater Regional Center in Michigan. In 1979, while Breuning was working at Coldwater, Sprague took him on as an on-site investigator for an NIMH-funded study of neuroleptics he was conducting. Breuning has also collaborated with Gualtieri, and the two have published one study of tardive dyskinesia in patients at North Carolina and at Coldwater [*Psychopharmacology Bulletin*, vol. 18, No. 1 (1982)].

In January of 1981 Breuning was appointed director of the John Merck program at Pittsburgh's Western Psychiatric Institute and Clinic. There he continued to write up the results of Coldwater research and obtained his own NIMH grant to study the effects of stimulant medication on the retarded. He left Pittsburgh in April 1984 and took his present post as director of clinical services at the Polk Center in Pennsylvania's Department of Public Welfare.

Sprague continued to work with Breuning after the latter moved to Pittsburgh. In late 1983, Sprague says he began to develop suspicions about the authenticity of Breuning's research when Breuning reported what struck him as impossibly high reliability ratings with the use of a tardive dyskinesia rating scale. Sprague decided to review Breuning's published work as well as his progress report on his NIMH grant, noting various details that he found inconsistent or improbable.

In late 1983, Breuning sent Sprague the abstract of a paper he planned to present with Gualtieri at the December 1983 meeting of the American College of Neuropsychopharmacology. The abstract described a follow-up to the study in which patients in North Carolina and Coldwater had been monitored for tardive dyskinesia after their withdrawal from neuroleptics. The abstract reported on a further 2 years of monitoring 45 of the 57 Coldwater patients. Sprague took this opportunity to call Neal Davidson, Coldwater's director of psychology, to see what he knew of the study. He learned that Davidson had never heard of it. Davidson later told *Science* that he was not aware that Breuning had conducted any research whatsoever with human subjects at Coldwater, where he held a clinical position.

Breuning, in a letter to Sprague, acknowledged that he hadn't been able to locate much of the old Coldwater data. "Following a review of the data on [45 of the] clients and phone calls to Neal [Davidson] and others it is clear that there are major problems and that these data are not usable," he wrote. He agreed that since all the raw data were "not presently available . . . the data should not be presented at ACNP."

In December 1983 Sprague, following discussions with Breuning and Gualtieri, wrote up his criticisms in detail and submitted them to his own department head and to NIMH, which forwarded them to Pittsburgh. Sprague claimed to find inconsistent or improbable data relating to numbers of subjects in the experiments, time spans covered, and research methods used, as well as apparent gaps in the records at Coldwater.

In a telephone interview with *Science*, Breuning said that he did indeed conduct the research that has been questioned. Asked if he had acknowledged any irregularities in his research he said no—not any in his published work. With regard to the study

described in the 1983 abstract that was never presented, Breuning said some of the raw data were several years old and had been destroyed to protect patient confidentiality. In a second conversation, he added: "I'm not sure if data [are] lost that means there's a problem with the abstract." He referred further questions to his lawyer, Thomas E. Coval, who, when contacted, declined to comment.

Breuning resigned from Pittsburgh in April 1984 while the university's first investigation was under way. Pittsburgh officials will not comment on the inquiry, which was confined to the tardive dyskinesia studies that were conducted before Breuning came there. But according to Schriver's report, the inquiry did confirm that raw data from Coldwater were unavailable.

Pittsburgh informed NIMH in the summer of 1984 that it had no grounds to take action against Breuning for any work he performed there, according to a letter to Sprague from NIMH acting director Larry B. Silver. However, Silver wrote, "because several issues remain unanswered . . . the NIMH will conduct a comprehensive investigation of the allegations" against Breuning. It was at that point that Lorraine Torres, an NIMH official in charge of the case, asked Schriver to begin an investigation.

Then in January 1985, reportedly under considerable prodding from Schriver, Pittsburgh officials began their second investigation, which this time included a look at Breuning's work at the university's Western Psychiatric Institute and Clinic. The results were delivered in mid-1985 to Friedhoff's panel, which the NIMH appointed in early 1985. Schriver parted company with Torres on the conduct of the matter and left the case in that summer.

Friedhoff, whose panel has interviewed the various principals—some of them several times—will not comment on the case. The few outsiders who know about the Breuning affair are puzzled by the slow pace of the investigation. Sprague finds it "reprehensible" that the government is pursuing its responsibilities "with such glacier-like speed." Breuning himself says that although "certain people have heard only one side of the story" he doesn't feel handicapped by the delay since there are "no major problems" to be revealed.

Torres says that a "very big" draft report has been submitted to NIMH but it will be months before the results are made public. First, Breuning has to review it and his comments must be considered by the panel. Then, the heads of NIMH and its parent agency, the Alcohol, Drug Abuse, and Mental Health Administration, have to review the final version. ■ CONSTANCE HOLDEN

Senator Blasts Administration's Reinterpretation of ABM Treaty

A Democratic senator has blasted the Reagan Administration's assertion that space-based missile defenses can be developed and tested without contravening the 1972 Antiballistic Missile (ABM) Treaty. Senator Carl Levin (D–MI) announced on 1 December that his own review of the classified negotiating record leads to the inescapable conclusion that the treaty forbids such development and testing. Moreover, Levin argues that his restrictive interpretation of the treaty is shared by virtually everybody who was involved in the negotiations.

Exactly what is permitted under the ABM Treaty emerged as a central factor in the Reykjavik summit meeting between President Reagan and Soviet leader Mikhail Gorbachev (*Science*, 31 October, p. 533). Gorbachev sought to confine the U.S. Strategic Defense Initiative (SDI) to the laboratory—a restriction that would have gone well beyond the treaty—while Reagan insisted that the program not be held back.

Senator Levin: *The State Department's review of the record was "fatally flawed."*

Disputes over the interpretation of the treaty have not been limited to the summit. In fact, a debate has been raging in the United States for the past year. Until recently, it was generally accepted that the treaty permits research, development, and testing only of ABM systems that would be deployed in fixed positions on land, and that it limits work on "exotic" space-based systems to research. The dispute essentially revolved around what types of research on exotics are permitted.

Last October, however, the State Department's legal counsel, Abraham Sofaer, came up with a new interpretation. A review of the negotiating record, he said, indicates that the treaty places no limits on development and testing of systems that were not "current" in 1972, when the pact was signed. This new interpretation would permit all work on SDI to proceed to the point of actual deployment.

The State Department's new interpretation sparked a storm of protest, and earlier this year the Administration announced that it would abide by a more restrictive reading of the treaty that prohibits testing of anything more than subcomponents of SDI systems. However, the Administration said it reserves the right to switch to Sofaer's more liberal interpretation at any time.

Several members of Congress sought access to the classified negotiating record to check Sofaer's conclusion. After a lengthy tussle, the State Department agreed to provide the record to members of the Senate Armed Services Committee. Levin is the first to announce his findings.

He argues that the process used by Sofaer to review the record was "fatally flawed." Levin accuses Sofaer of being selective in his use of quotes from 1972 Senate hearings on the treaty, and he complains that Sofaer failed to interview officials involved in the negotiations to ascertain their understanding of what the pact actually limits. Levin says his own review of the record and interviews with the negotiators supports a restrictive interpretation of the treaty: it permits research, development, and testing of fixed land-based systems, but places sharp limits on development and testing of space-based systems.

Levin's interpretation was supported by two people involved in the negotiations—Albert Carnesale, currently a professor of government at Harvard, and Sidney Graybeal, now vice president of System Planning Corporation—at a AAAS symposium on arms control on 4 December. They noted that there was no disagreement in 1972 on what the treaty meant, and Graybeal pointed out that one negative vote in the Senate was cast by former Senator James Buckley precisely because the pact restricted development of exotic systems.

Levin has called for a new, independent review of the treaty. The State Department has declined, however. In a statement issued on 1 December, it defended Sofaer's interpretation and said "an outside study of the ABM Treaty is unnecessary." ■

COLIN NORMAN