Scientists Seeking "Spy Dust" in Moscow

The four American scientists who went to Moscow on 27 August to look for "spy dust" may have been sent on a mission impossible. They find themselves in a grand mystery play whose technical props could have been invented by Lewis Carroll.

The leader of the U.S. investigators is Ernest McConnell, a toxicologist and pathologist from the National Institute of Environmental Health Sciences, respected in the government for his ability to sort real from artificial hazards in toxic reviews. The other members are Edwin Tinsworth, deputy director of the office of pesticides and toxic substances at EPA; Karen Hammerstrom, a chemical engineer at EPA; and Jeff Lybarger of the Centers for Disease Control (CDC).

Objective number one is to find some spy dust. As one senior CDC official says, "The problem will be to get enough of the stuff to do a dermal absorption test. . . . And if there's no dermal absorption, there's really no hazard to speak of." Finding the stuff will not be easy, however.

The critical ingredient, nitrophenyl pentadienal (NPPD), is not manufactured by any company or academic laboratory in the United States. The early signs are that it is scarce in Moscow as well. Hammerstrom has taken along sterile gauze sealed in glass tubes, with the intention of collecting specimens for later analysis in the United States. Americans in Moscow are being asked to volunteer to have their steering wheels and houses swabbed. But U.S. officials have told the press that the Soviet police may have removed the spy dust from doorknobs just as quickly and surreptitiously as they placed it there. Since the Soviets deny the powder exists, they will not be providing samples for analysis.

Meanwhile, a congressman from Florida, Dan Mica (D), spread the alarm to U.S. territory. Mica called a press conference on 29 August to announce that the Soviets may have dusted American property with NPPD, but he offered no substantiation. He added that the KGB agents who did the dirty work were exposed to the greatest danger from NPPD, an occupational hazard of the spy trade.

As the CDC official put it, it is often the case that the less the hazard, the greater the hullabaloo. The rule may apply to NPPD, for, as McConnell told worried Americans in Moscow, even if the chemical is absorbed through the skin, it is highly reactive and may be transformed into harmless compounds within the body before having a chance to injure human cells.

—ELIOT MARSHALL

Guilty Plea Puts Oraflex Case to Rest

On 21 August, Eli Lilly & Co. wrote to its stockholders to say that it had negotiated an end to a federal investigation that "puts to rest any speculation regarding intentional misconduct by the company" in the marketing of Oraflex, an arthritis medicine suspected of causing liver and kidney failure. The notice came at the end of a 14-month grand jury inquiry requested by the Food and Drug Administration (FDA), the same agency that gave Lilly permission to sell Oraflex in 1982. On the same day that Lilly's letter went out, the U.S. Justice Department released its own memorandum on the case, digging up everything Lilly had put to rest.

The effect of the two statements, together with Lilly's strong emphasis on the fact that it was guilty only of "technical misdemeanors," was to beg a larger question: if Lilly's mistakes were so trivial, why did they produce such anguish? The answer suggested in the Justice Department's brief is that the company slipped up in ways that were neither provably criminal nor acceptable.

According to the Justice Department, Lilly was fully aware of, but delayed telling U.S. authorities about, ten cases in which patients taking Oraflex had suffered fatal or debilitating liver or kidney disease. Because of the delay in 1981 and early 1982, the FDA did not learn of the drug's potentially lethal side effects until after it had approved Oraflex for marketing. The FDA through ignorance also approved a label—the primary medium for warning doctors about side effects—that made no mention of liver or kidney failure.

Lilly must have been aware of the problems by the time its executives held a meeting in Indianapolis on 5 February 1982, Justice says. On that day, Lilly's chief medical officer, chief of pharmaceuticals, and chief international officer discussed a report listing 27 "serious" adverse reactions linked with the drug's use in Britain, including five deaths.

When Lilly officials met with the FDA in June 1982, according to the Justice Department, the company "knew of approximately 50 unpublished liver and kidney reactions that had occurred in the United Kingdom." But Lilly did not tell FDA about any of them and "discussed only those reactions that had been published in the medical literature." Nevertheless, Lilly writes in its letter to stockholders that doctors were not left in the dark because Lilly's sales personnel were told in May 1982 that doctors should be "advised to use a reduced dosage in the elderly and debilitated. . . . "

Oraflex was taken off the market in August 1982, but only after British physicians had written about its problems in medical journals, and after Britain ordered its use suspended. Although Lilly knew of the cases discussed in the journals before the articles were published, it did not report them to the FDA until after publication.

Before Oraflex was discontinued, 26 U.S. patients who had taken it died of liver or kidney disorders and 200 had related but nonfatal problems. The Justice brief says: "While it has not been etablished that the liver and kidney reactions were caused by Oraflex," U.S. physicians "did not have the benefit of a label that warned them that the same reactions observed in their patients had been associated with the use of Oraflex in other [foreign] patients."

Lilly agrees that it violated the letter of the law. And Lilly's former chief medical officer, W.I.H. Shedden, also pleaded no contest. But the company maintains that it acted "promptly" to warn the FDA as soon as it had "the scientific basis to do so." Lilly told stockholders that it pleaded guilty merely "to avoid the time and expense of prolonged litigation."

Whatever the merits of Lilly's legal argument, it will do nothing for the campaign to speed up drug licensing.—ELIOT MARSHALL