

When asked to rate the proposals in order of preference without regard to cost, five members voted Bank Street's the best, four voted for Harvard, and one for MIT.

The committee's report went to Victor Westbrook, an NIE official who had recently taken over as contracting officer for the project. But Justiz, who had taken a special interest in the center from the start, decided to review the recommendation. According to an internal memo by Westbrook, Justiz told him on 19 September that he believed Harvard's was the strongest proposal and that Bank Street's seemed deficient in terms of its staffing levels and costs. Westbrook agreed to review Bank Street's cost figures and, according to his memo, told Justiz that if no irregularities were found, the award should go to Bank Street.

At this point, NIE was running into a severe time constraint: the contract had to be signed by 30 September, the end of the fiscal year. On 28 September, Westbrook again met with Justiz to tell him he had found no irregularities in Bank Street's cost estimates, but Justiz said he

had decided that the award should go to Harvard anyway.

In a lengthy decision memorandum written on the same day, Justiz said, in essence, that he believed Harvard's proposal matched the criteria for the center more closely than Bank Street's did because it entailed more resources and covered a broader range of technologies. He also favored Harvard's conceptual and organizational approach.

Justiz also said he found the committee's technical ratings "extremely close and inconclusive for making a judgment" between the two proposals. However, his memo attempted to make the ratings even closer than they actually were by suggesting that the scores of one reviewer who favored Bank Street should be ignored because he provided little written justification for them. In fact, a reviewer who favored Harvard provided even fewer comments.

Bank Street's protest lambasts Justiz on these grounds and takes issue with most of his more substantive arguments. It also points out that if, like Harvard, Bank Street knew roughly what NIE

expected the center's budget to be, Bank Street's proposal would have entailed more resources. NIE officials claim that Bank Street should have figured out the requirements from the request for proposals.

Bank Street officials say they received several anonymous telephone calls and letters from NIE staff members urging them to protest the award. According to Wilson, Justiz was well aware that his selection of Harvard would draw a protest. But he suggests that Harvard would have had grounds for protesting an award to Bank Street because Bank Street's proposal did not adequately match the criteria.

One ironic footnote to this episode is that Justiz is widely credited with strengthening NIE's peer review system, which had been badly politicized in the first 2 years of the Reagan Administration. "It was a mess, basically, when Justiz was appointed," says Roberta Miller, executive director of the Council of Social Science Associations. "By and large, he has done very well in cleaning it up."—COLIN NORMAN

## EPA Ends Cut and Paste Toxicology

*Pesticide reviewers who leaned too heavily on company assurances and company prose may have missed some health hazards*

"I trust with the submission of this report . . . that we can put the issue of 'cut and paste' behind us," writes John Moore, the new assistant administrator for pesticides and toxic substances at the Environmental Protection Agency (EPA). Thus, in a letter to Representative George Brown, Jr. (D-Calif.), on 5 January, Moore seeks to close the book on a small scandal at EPA that never got much attention but engaged the agency in a prolonged debate with Congress over its scientific credibility.

A subcommittee chaired by Brown\* discovered that EPA staffers were using "cut and paste" methods in writing up their own analyses of toxicological data submitted by pesticide companies. The data are sent to EPA as proof that a chemical proposed for general use will be safe. Brown's committee found evidence that company submissions, which

do not always stress the worst aspects of a chemical, were being cut, reassembled, and filed by EPA staffers as their own independent work. By parroting company verbiage, it was feared, EPA staffers may have been sloppy, missing problems buried in the data but not highlighted in company write-ups.

At the heart of the controversy is the question of whether or not the EPA can be trusted when it declares a chemical safe, especially if the chemical is a pesticide that will be consumed by millions of people as a residue in foods. Many hazardous pesticides are protected by the fact that they have been in use for decades and are allowed on the market by "grandfather" rights, even though they may not meet current safety standards. However, new chemicals are supposed to undergo strict toxicological reviews in EPA's Office of Pesticide Programs (OPP). For several years, OPP has been under pressure to process these new chemical filings more rapidly.

At Brown's insistence, the EPA inves-

tigated the cut and paste allegations. The inquiry was conducted by the Battelle Columbus Laboratories under contract to the very office suspected of malfeasance (OPP), which also had a hand in drafting the final report. It was released on 5 January along with Moore's letter.

The central conclusion is that there was indeed a lot of cutting and pasting, beginning around 1979. Of 578 staff reviews chosen at random, one third contained some unattributed use of company charts and prose. The worry was that this "borrowing" of company verbiage was just the tip of the iceberg. It suggested that reviewers were not doing their job at all.

When Battelle looked closer, it found a tip but no iceberg. It reported that only 29 of the questionable studies reached challengeable conclusions, possibly affecting regulations on 21 chemicals. According to Battelle, five reviews actually failed to report major health effects because they relied on faulty company descriptions of the data. All 21 chemicals in

\*Brown chairs the House agriculture subcommittee on department operations, research, and foreign agriculture, which has responsibility for overseeing EPA's management of pesticides under the Federal Insecticide, Fungicide, and Rodenticide Act.

question are being fully rereviewed, says Moore. He is pleased that the "natural error rate" for serious omissions was just 5 out of 578, or 1 percent.

Referring to a memo written by the chief of the hazard evaluation division, John Melone, Moore gives the view that, "One percent starts to hit the normal human error rate. It doesn't seem outrageous to suggest that a 1 or 2 percent error rate is likely to exist. One needs to be a little nervous that the errors might have been errors of major consequence." (One percent of the several hundred studies done each year is several major mistakes a year.) But there is no plan to conduct a special search for those not already identified.

To prevent a recurrence, the EPA circulated a memo in October 1982 forbidding the use of unattributed quotes in reviews. Moore has announced a number of other changes. Most important, the chiefs of review sections will no longer be asked to take on special assignments that could distract them from supervising the reviewers. This should strengthen the "second line of defense," Moore says. Melone plans to devise a standard format for submission of company data and for staff reviews.

Like many housecleaning inquiries, this one began as a collaboration between a gadfly on EPA's staff and an investigator on Capitol Hill. The gadfly is Adrian Gross, a toxicologist in OPP who has advised congressmen, journalists, and even prosecutors on how to spot sloppy toxicology. The investigator was Charles Benbrook, formerly an aide to Representative Brown, now executive director of the Board on Agriculture at the National Academy of Sciences. Gross was the first to publicize the cut and paste problem.

The inquiry began in earnest in November 1982 when Gross reported that a staffer had cut and pasted a review of a herbicide called Harvade, neglecting to cite evidence of carcinogenicity. Harvade is manufactured by the Uniroyal Company. EPA had proposed granting "tolerances," or permission to have the chemical appear as a residue on crops, in this case on cotton and potatoes. Melone agreed to take a "second look," but claimed that the plagiarism was "an isolated problem that was dealt with last February." The head of the pesticide office said that this was "not a common practice among reviewers and has ended." The man who held Moore's position at the time, John Todhunter, took a swat at the gadfly, saying that Gross "seemed to delight in finding problems and criticizing people."

The matter finally went before an independent review group that the EPA consults on pesticide matters, the Scientific Advisory Panel. Gross presented his arguments, as did industry spokesmen and other EPA staffers. After mulling it over, the panel sided with Gross. In June 1983 it announced that some rat brain tumors were worrisome and that "the preponderance of evidence suggests that Harvade is a carcinogen of low potency." The safe exposure level proposed by EPA, according to the panel, "does not seem to be justified on the basis of the data." In August, the EPA decided to grant a tolerance for Harvade on cotton but to deny one for potatoes. In issuing the denial, however, OPP left the door open, indicating that the agency might reverse itself on potatoes if the company submitted favorable metabolism studies.

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**"EPA reviews of pesticide studies are too regularly flawed scientifically. . . . Is it any wonder that the general public is confused?"**

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Meanwhile, a case not picked up in the Battelle inquiry has caused a stir in OPP. In March 1983, Gross found that a fungicide made by Ciba-Geigy (metalaxyl) and sold in the United States as Ridomil was the subject of a cut and paste review. Based on this review, the EPA concluded that metalaxyl presented no carcinogenic threat. In January 1983 the EPA granted tolerances for residues in a variety of foods, including avocados, beef, cucumbers, eggs, grain, pork, melons, milk, onions, peanuts, chicken, potatoes, beans, lamb, squash, and tomatoes. Metalaxyl, it appears, will be a widely used product. A systemic fungicide, the chemical is taken up by the roots and spread through the entire plant. It cannot be removed by washing. All pending actions on metalaxyl, and on two analog compounds manufactured by other companies, have been held up since last spring.

In summarizing the toxicology reports in 1982, the EPA reviewer accepted Ciba-Geigy's view that the slight increase in rat thyroid tumors among test animals was not significant. But he asked that mouse carcinogenicity data be submitted as well. Benbrook learned last summer that EPA granted the tolerances before the mouse data were reviewed, and that some Greek scientists had de-

cided that, based on their own research, metalaxyl was carcinogenic. Ciba-Geigy says the Greek study appears to have been badly designed, and, in any case, the Greeks are not willing to share their data unless paid a very large fee. Ciba-Geigy points out that the World Health Organization, Canada, and other reviewing agencies have cleared metalaxyl for use in 40 countries.

Under pressure to come up with a fresh and truly independent analysis, the EPA produced a review in August 1983 that called metalaxyl carcinogenic and found that the worst-case risk after a lifetime of exposure would be 76 cancer cases per 1000 people—a very high risk. Ciba-Geigy objected. Company officials took their complaints to top OPP officials and met to review the data in two private sessions. On reflection, the agency agreed that the numbers were misconstrued. In order to resolve the issue, the company sent tissue slides from the rat study to an independent group of pathologists for rereading. These consultants and other academic toxicologists agreed with Ciba-Geigy that there was no significant indication of a carcinogenic effect in the rat or mouse data. Moore says the EPA may be satisfied with these results, and may soon move forward as originally planned. He is waiting for final approval from EPA's carcinogen assessment group. However, the agency still has not committed itself to this position in writing, no doubt out of fear that a new and unexpected problem may come to light. Given the record, that is a reasonable fear.

Benbrook thinks that metalaxyl may prove *not* to be a threat to public health. But he says his confidence in the EPA's willingness and ability to catch such threats has not been strengthened by the metalaxyl story. In a 6 January letter to Moore (penned by Benbrook), Representative Brown writes: "I do not wish to be overly critical" but "EPA reviews of pesticide studies are too regularly flawed scientifically. . . . Is it any wonder that the general public is confused. . . . when expert scientific opinion within EPA routinely swings up or down by two or three orders of magnitude?"

Benbrook acknowledges that his second-guessing of the EPA has contributed to the pandemonium, but argues that good work can withstand this kind of challenge. He adds that other congressional committees, including one headed by Representative James Scheuer (D-N.Y.), are taking an interest in the subject. If anything, the scrutiny is likely to become more intense.

—ELIOT MARSHALL