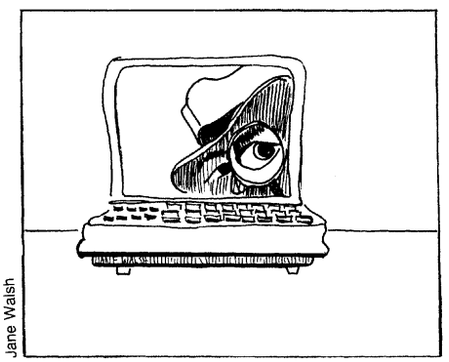
Auditors Scour Labs in Search of Waste

With an eye to $52 billion in U.S. property, federal auditors are checking equipment at university labs in an unprecedented effort to root out extravagance and misuse

Teams of federal investigators are beginning to scour labs across the country in search of waste, fraud, and abuse. The unprecedented audit, covering federal property in the hands of contractors or grantees and including a fair amount of scientific equipment, has resulted in moans from university administrators and complaints from scientists who feel auditors may not appreciate the utility of a particular device.

The wide-ranging inquiry is being performed under charter from the President's Council on Integrity and Efficiency, and covers programs administered by some ten federal agencies. A preliminary survey by the council in 1981 found that contractors and grantees had purchased equipment worth more than $52 billion, a significant part of it unnecessary or extravagant.



Jane Walsh

"Nobody's saying there's anything criminal going on," says William Bonsteel of the Office of Management and Budget (OMB), "but maybe some groups get four machines when they really need only one."

The interagency audit, the first of its kind, began in mid-June and should be finished by November. Armed with computer printouts of equipment purchased on federal contracts and grants, auditors sweep through labs, checking serial numbers and asking questions about how certain equipment is used. Cases of severe abuse may end in disciplinary action. More importantly, the audit is expected to result in a tightening of procurement policy for federal agencies. Said the council in its preliminary report, issued in December 1981: "Significant problems exist in the acquisition of Government property and related areas of accountability and use. . . . The objective of the audit would be to determine if adequate agency systems and internal controls are in place to ensure that only authorized and needed property is acquired. . . ."

About 15 sites will be visited by some 40 federal auditors during the summer and fall, including the universities of Washington, Wisconsin, Pittsburgh, Minnesota, and Stanford University. Also on the hit list are defense contractors, federal labs, and national research centers administered by federal agencies. Although the mandate of the council covers all federal property, the audit is focusing on common items purchased by grantees and contractors, such as computers and computer terminals.

As word of the impending audit spread among university administrators around the country, questions were raised about its legality. OMB circular A-88 holds that a university has to face only one wide-ranging federal audit, performed by a leading agency on campus. At the University of Wisconsin, for instance, the lead agency for routine audits is the Department of Health and Human Services. Some university administrators thus wondered whether the interagency audit would be illegally duplicative. The question was reluctantly put to rest by the National Association of College and University Business Officers. "We checked into it," says Milton Goldberg, executive director of the association's council on governmental relations, "and it turned out they [the Council on Integrity and Efficiency] are operating on a separate charter from the President, so the audit is O.K."

Some administrators are worried about the disruption of research and possible lack of expertise among auditors. At the University of Washington at Seattle, the regular audits on campus are performed by the Office of Naval Research. Now, with the interagency task force on its way, administrators are awaiting two independent top-to-bottom federal examinations of procurement procedures in the same month. "It's quite disruptive," says Walter Triebel, head of the university's office of government fiscal relations. "They've agreed not to step on each others' toes, but we're worried. You've got to hope and pray that when you get new auditors they're professional and know what they're doing. Sometimes you get them green and they start making all kinds of stupid mistakes and the faculty and staff get quite upset."

In defense of the audit, program officials at OMB point to some of the waste uncovered, mostly at industrial labs, during the preliminary survey.

- A contractor with 2000 employees had 1055 computer terminals, the vast majority unused. One employee had three terminals, two in his office and one at home.
- A contractor had 156 lawn mowers, 29 unused and still in shipping containers more than a year after purchase.
- A contractor in southern Ohio (where heavy snowfall is rare) purchased two snowmobiles, which went unused.
- A contractor bought a 75-millimeter Zenza Bronica camera for $5671, an elaborate professional device used only by plant guards to take pictures of accidents around a plant.
- A contractor paid $11.6 million to lease computers, some $3 million more than it would have cost to buy them outright.

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- A contractor bought 16 professional movie projectors with sound. Over the course of 2 years, the projectors were used a total of nine times.
- A contractor had several large shops with $1.9 million worth of machine tools, 445 of them, most of which went unused.
- A contractor purchased a refrigerator and a microwave oven, used solely to store and heat the lunch of a guard in a small gatehouse.

There is undoubtedly a potential for uncovering waste and abuse in the purchase of scientific equipment. Yet some

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scientists who have already been subject to the audit say zealous and inexperienced auditors may not be painting a fair portrait. At the University of Wisconsin at Madison, one indignant scientist said the audit team seemed preoccupied with equipment such as minicomputers and kept asking naïve questions about why they were needed. There were no scientists on the team, and answers provided seemed to go over the heads of the auditors. The scientist also complained that audits seemed to be held when the principal investigator was absent, a situation in which the person responsible for the equipment is not in a position to defend or explain apparent discrepancies.—WILLIAM J. BROAD

FDA to Reexamine Bendectin Data

The Food and Drug Administration (FDA) has decided to take another look at all studies to date that might bear on the question of whether Bendectin causes birth defects. Bendectin is the only drug specifically approved for nausea and vomiting of pregnancy and it is taken by about 25 percent of all pregnant women in this country.

The FDA last looked at Bendectin studies in September of 1980 at which time its panel of experts examined data from animal studies and 13 epidemiological studies and concluded that there is no demonstrated relation between the drug and birth defects. However, it is impossible to prove that any drug is harmless. The panel recognized a "residual uncertainty" about Bendectin's safety during pregnancy (*Science*, 31 October 1980, p. 518).

Despite the FDA's conclusions, a growing number of parents are convinced that Bendectin caused birth defects in their children. More than 100 lawsuits have been filed against Merrell-Dow, Bendectin's manufacturer, although the plaintiffs lost in the one case that did go to trial. Recently, public attention has been focused again on Bendectin as a result of newspaper stories indicating that there is new evidence which shows a strong link between Bendectin and birth defects.

The FDA's decision to reexamine all the Bendectin data was prompted by a meeting on 8 April between FDA commissioner Arthur Hull Hayes, Surgeon General C. Everett Koop, Representative Doug Walgren (D–Pa.), and Harry Meyer, director of the National Center for Drugs and Biologics.

Susan McFalls, a member of Walgren's staff, says the congressman is concerned by some new data that he believes may implicate Bendectin in birth defects. There is a rat study showing that Bendectin may cause diaphragmatic hernias, a potentially fatal defect in which the stomach and other organs get into the lung cavity through a hole in the diaphragm. There is a monkey study showing that Bendectin may cause ventricular septal defect, a hole between the chambers of the heart. And there is evidence from a new in vitro test for teratogens that Bendectin may cause birth defects. "We have been concerned for some time because we have seen both these defects [diaphragmatic hernias and ventricular septal defects] in reports from physicians and patients," McFalls says.

Ann Wilk, a reviewing pharmacologist at the FDA, notes the very preliminary nature of the new Bendectin studies. The rat study, done by Reimer Roll of Bundesgesundheitsamt in West Berlin, is still unpublished and the FDA has only a summary statement and reams of raw data which the agency is now having translated into English. Roll apparently sees a slight incidence of diaphragmatic hernias at very high doses of Bendectin with no dose-response effect. But, says Wilk, the FDA cannot yet say anything about his methods. In the meantime, Roll is repeating his study and the FDA is repeating it "with some modifications," according to Wilk.

The monkey study, conducted by Andrew Hendrickx of the Primate Research Center at the University of California at Davis, also is unpublished except in abstract form. Hendrickx, however, notified the FDA of his results in May of 1981. He gave 12 cynomolgus monkeys 10 to 20 times the normal human dose of Bendectin throughout the major period when organs are developing. Two of the monkeys aborted their fetuses. He then examined seven of the remaining fetuses about 2 months prior to term. In four of the seven, he saw an intraventricular septal defect, but it is not clear what this finding means because fetal monkeys normally have a hole in the septum earlier during development. When Hendrickx examined the three monkey babies that were carried to full-term, he found that they were completely normal. Wilk asks of the septal holes that Hendrickx found in the four fetuses, "Was this a delay in development or would it persist until birth?"

Merrell-Dow is now funding Hendrickx in a much larger study, which will take 2½ years and will be double-blind. There will be four groups of monkeys, 20 pregnancies in each group, and three doses of Bendectin.

In the meantime, another small-scale monkey study, involving nine animals and conducted by Harold McClure of Yerkes Primate Research Center, showed no effect of Bendectin on rhesus monkey fetuses.

After hearing of these animal studies, the FDA requested that researchers conducting epidemiological studies, including Boston University's Drug Epidemiology Unit and the Centers for Disease Control, look for an association between Bendectin and heart defects or diaphragmatic hernias. In these studies none has been found as yet.

The in vitro study that McFalls referred to was conducted by John Hassell of the National Institute of Dental Research. He added Bendectin to cultured cells that normally would develop into cells resembling cartilage. The added Bendectin prevented this development. Hassell and Wilk concur that it is difficult to evaluate this study because no in vitro test has yet been validated—it has not been shown that these tests can reliably distinguish known teratogens from substances known not to harm fetuses.

At the present time, the FDA is considering a labeling change for Bendectin to reflect the possibility that the recent animal studies may turn out to demonstrate teratogenicity. Bendectin's label now says there is no evidence of teratogenicity in animal tests. But the agency scientists feel that, in the final analysis, their best data will be from continued epidemiological monitoring of Bendectin. And, as yet, there is no persuasive evidence from human studies that the drug causes birth defects.—GINA KOLATA

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