represented on the Joint Commission; each group nominated its own candidates. They managed to reach unanimous conclusions in the report, but this unanimity is not present in the constituencies that nominated them. There is one general exception. Everyone seems to agree that the nation needs a comprehensive and systematic program to detect unexpected reactions to prescription drugs. That need was brought home again last month.

By coincidence, the same week this report was being released, an apt illustration of the problem it addresses came to light. On 16 January, the FDA decided in an emergency move to pull a drug called Selacryn (generic name: ticrynafen) off the market because it is unsafe. Only 8 months earlier, in May 1979, the FDA had given its approval to the manufacturer, Smithkline & French, to put Selacryn on the market. The company moved aggressively to advertise its product, which is designed to control high blood pressure and fluid retention, because of millions of potential users. During its brief moment in the sun, Selacryn may have been taken by 250,000 American sufferers of hypertension. By mid-January, the FDA and the company had tabulated some unexpected associated casualties: 52 cases of liver damage, including 30 cases of jaundice, and five deaths. It is not clear how many of the deaths were directly caused by the drug.

The FDA and company officials are reluctant to discuss details at present because an investigation is now in progress. The responsible FDA official, Judith Jones, director of the division of drug experience, says that Selacryn appears to have produced bad effects once in every 1000 to 5000 users. She does not think that a more elaborate postmarketing surveillance program would have identified the problem much sooner.

Sidney Wolfe, director of the Health Research Group (a Ralph Nader satellite), thinks that the Selacryn case illustrates the inadequacy of FDA's premarketing as well as postmarketing efforts. Wolfe says the official data he has seen suggest that the drug was tested according to common procedures on only 533 people before it was released. He thinks this was not a large enough population to ensure the safety of the enormous population of potential users. Yet he also says the case is "a good example of how, despite all the handicaps the FDA has, once they got wind of trouble, they moved reasonably quickly."

Wolfe places the burden on the company, for he thinks it should have sent a "red flag alert" to the FDA no later than November 1979 warning that the drug was producing serious reactions. He claims to have spoken with a physician who gave the company strong evidence of trouble in mid-September, and he points out that the company's *routine* quarterly report on Selacryn filed in November mentioned 12 cases of liver damage and 40 cases of renal failure. The law stipulates that a manufacturer must pass along to the FDA within 15 working days any report of unexpected side effects. The alert, it appears, was not raised clearly until December.

A spokesman for Smithkline & French said, "We believe we acted responsibly." He cited an FDA press release given out in January praising the company for its cooperation.

The FDA has several methods, none highly developed, for catching problems after a drug has gone to market. Most of its information comes from the drug companies. They are required by law to report on adverse effects for the first several years after a new drug has been released for general use. Under a separate program, called "spontaneous reporting," physicians are asked to alert the FDA of any problems they encounter with newly released drugs. The FDA receives about 10,000 reports a year from the companies and about 2000 a year from physicians. In addition, the agency has recently commissioned a number of larger than usual studies of drug use through its own contracting authority and through its ability to pressure the drug companies to do safety related research.

The FDA follows these reports as best it can. It tries to sift out the critical warning signs and pass the information along to physicians, but it cannot always stay

Army to Lose Overseas Labs

A government plan to reduce the number of Americans that it employs overseas has landed with disproportionate effect on the tropical disease research programs conducted by the Army and Navy.

Just at a time when a new American military presence overseas has become a distinct possibility, the Office of Management and Budget (OMB) has directed the Walter Reed Army Institute of Research to close down or contract out the work of its six overseas medical research laboratories and the Navy to cut loose its laboratories in Cairo and Manila.

The Walter Reed Army Institute of Research, which has a long tradition of tropical disease research, is somewhat distressed at the prospect of being shorn of its overseas laboratories. The OMB's action will severely limit the military's ability to control infectious diseases and will make it hard to recruit tropical disease specialists in the future, the institute believes.

The military medical laboratories have made important contributions to tropical disease research, many of which have benefitted the host country as well. The laboratories also have a significant diplomatic dimension. The Navy's medical unit in Cairo was the only American presence in Egypt during the critical period before the Yom Kippur war when official relations were severed; the Army's research unit in Bangkok has played a similar role.

The OMB's aim in closing the laboratories is not money: Since most of the work is to be contracted out, savings will be small. The purpose is the high bureaucratic objective of reducing the number of government employees abroad.

The overall goal is to reduce by 5 percent the 11,000 government employees overseas. The Department of Defense was assigned to cut 300 people. About 120 of these cuts were allocated to the military medical laboratories, a distribution which has the evident appearance of being made according to bureaucratic clout rather than merit.

The 5 percent reduction was ordered by the White House primarily because of a belief that there was a duplication of function among the many government agencies with people overseas. It is generally conceded that the military medical laboratories do not duplicate anyone else's work. Nevertheless, to fulfill the bureaucratic form of the President's original intention, though not its substance, the Army and Navy must hand over their overseas medical research laboratories to contractors.—N.W.

0036-8075/80/0222-0854$00.50/0