The FDA as purveyor of dangerous drugs

Even aspirin, some scoffers charge, would not be found fit for human consumption if it had to be approved by the present Federal Drug Administration setup. Aside from what this has to say about aspirin, this criticism is primarily directed at the slow-moving bureaucracy of the FDA and at the testing procedures and safety regulations that some (especially drug manufacturers) feel are overly restrictive. But according to the results of an investigation sponsored by Sen. Abe Ribicoff (D–Conn.), just the opposite is true. In fact, says Ribicoff, "The FDA and the companies involved have shown a disregard for public safety which is incompatible with their responsibility to protect and promote public health."

As chairman of the Senate subcommittee on executive reorganization and government research, Ribicoff asked the Government Accounting Office to investigate the FDA's regulation of a number of investigational new drugs (drugs approved for testing but not for public sale) that have been administered in clinical experiments to human subjects. The GAO study, released last week, discusses only 10 of the more than 6,000 such drugs. The results of the study, along with supplemental studies by the subcommittee, says Ribicoff, "strongly suggest that FDA regulation of investigational new drugs has been lax and has not adequately protected the patients who take these drugs."

Specifically, the report found that in eight cases the FDA failed to halt human tests after receiving indications that the drugs were not safe. As a result, more than 2,000 people have been exposed to possibly unsafe drugs.

A typical case was the drug Practolol, sponsored by Ayerst Labs. Evidence of cancer was found in animals given the drug, and on March 11, 1970, the FDA recommended to Ayerst that human testing be discontinued. One month later human testing was still going on and the FDA again advised that it be stopped. No really effective action was taken by the FDA, however, and the testing continued. In January 1971, the FDA tried for a third time to persuade the company to discontinue tests on humans. Ayerst not only refused to comply but even refused to make the findings of the mouse studies (indicating cancerous tumors) available to the doctors who were conducting the human experiments. The doctors thus had no way of evaluating the risks to which their patients were being subjected. Finally, on Aug. 27, 1971, the tests were stopped.

This case is not unique. The GAO found the time lag between discovery of the effects of human and animal tests and reporting them to the FDA ranged from 40 days to 19 months.

Another problem the FDA has had is getting drug companies to do follow-up studies on patients who have used investigational new drugs. E. R. Squibb and Sons, for instance, sponsored a drug called Cinanserin. Human tests were discontinued in August 1969 because of the appearance of tumors in the livers of rats taking the drug. The FDA suggested that Squibb do follow-up studies but Squibb decided not to. Realizing that its lack of follow-up regulations was leaving patients unprotected, the FDA contracted with the National Academy of Sciences for a study of the situation. An NAS committee was formed and its chairman was Lawrence Marks—a Squibb vice president who had participated in the controversy over the follow-ups on Cinanserin. Marks advised an FDA inspector of his position as both chairman of the NAS committee and a representative of Squibb and went on to say he did not feel he should commit the firm to a follow-up procedure until it was standard throughout the industry.

The Ribicoff report states: "It was poor practice for FDA to tolerate a situation where the chairman of a committee established and funded by the FDA for the purpose of recommending follow-up procedures is at the same time personally attempting, on behalf of his firm, to dissuade FDA from requiring follow-up examinations in a particular case."

Reviewing these and other potentially dangerous situations within the FDA, Ribicoff has made several recommendations that would tighten FDA controls of new drug experimentation. Substantial animal testing, he says, should be completed and evaluated before human testing begins. Under current FDA regulations, a drug may be given to humans for up to two weeks after only two weeks of animal studies and prior to full evaluation of those studies. Ribicoff suggests that Congress provide FDA with the resources to hire enough personnel to investigate and evaluate all applications efficiently. He further suggests that any company that fails to perform adequate follow-up studies should be disqualified as a sponsor of any investigational new drugs.

These and other recommendations have been forwarded to FDA Commissioner Alexander M. Schmidt. In what is described by the subcommittee as a "receptive letter," Schmidt responded this week. He stated that the GAO report made some good points and that he would review the matter further.

Defense. At the same time, privately sponsored research was also becoming more concentrated so that by 1970, 100 large companies accounted for 80 percent of the total industrial R&D expenditures.

● Personnel. The total pool of active scientists and engineers grew by 50 percent from 1960 to 1971 and the number of those with doctorates doubled during that period. The effect of more personnel and less money hit university investigators particularly hard, resulting in a net 15 percent drop of funding per individual, in terms of constant dollars, from 1968 to 1972. (Physics and clinical medicine were particularly hard hit, with net individual decreases of 32 percent and 21 percent respectively.) Support for young investigators (those holding a Ph.D. less than seven years) fell the fastest, with the proportion of supported young scientists falling from 65 percent in 1964 to almost 50 percent in 1970.

● Enrollment. Total enrollments in high school science and math courses continued to climb during the 60's at a rate faster than total secondary school enrollment. Physics was the only exception. Undergraduate science enrollment in physics, chemistry and engineering declined in the 1970-71 school year, and graduate science enrollment declined four percent between 1969 and 1970.

The National Science Board interviewed panels of experts in various fields to determine some of the causes and effects of these trends. Causes cited include: economic recession forcing emphasis on quick payoff research, public and political disaffection with the perceived effects of technology on society, lack of understanding of the discovery process and the increasing association of R&D with the Defense Department. All panelists interviewed agreed that decreased funding and the rapid and frequent changes of programs and directions of funding will be detrimental to research. □