Government Regulation of the Drug Industry

Part of the reason for the widespread concern about the rapidly increasing costs of medical care is the situation in the drug industry. In mid-July, 1977, the Senate subcommittees on health and scientific research and on antitrust and monopolies held a joint series of hearings to look into the problem.

Part of the difficulty lies in deciding just how profitable is the drug industry. If standard accounting procedures are employed, then the industry's net profit after taxes as a percentage of net stockholders' equity was 18.3% in 1976 as against an average of 13.3% for all manufacturing. The drug industry argues that the figures are deceptive, maintaining that if the considerable funds tied up in research and development were to be counted as an asset on the books rather than as expenditures, the percentage return on stockholders' equity would be considerably lower.

The industry also responds to the government's investigation with a counter-attack of its own. Officials of the drug industry claim that a major reason for the increasing costs of drugs can be laid directly at the feet of the government itself in its demands for additional testing. Frank Markoe, Jr., vice chairman of Warner-Lambert, a company that owns Parke, Davis & Co., said that "the longer period of time now required to take a product from the chemist's bench to the marketplace naturally adds to the overall cost of the company's products." (Reported in Chemical and Engineering News, July 25, 1977, p. 13.)

Extensive Testing

The tests that must be performed for a drug to receive final market approval are extensive. A manufacturer first must submit results from animal tests involving several species that indicate the drug's toxicity and biological effects. From these data judgment is made that the drug has desirable pharmacological effects and that potential risks are within acceptable limits. Then human trials may begin that proceed through three phases: (I) the drug is administered to a small number of healthy volunteers to determine its biological effects and safe dosage range; (II) the drug is administered to patients under carefully controlled conditions that usually require a major medical center to determine its therapeutic efficacy; (III) the drug is distributed to a large number of physicians around the country in order to see how effective and safe it is under ordinary circumstances of clinical practice. After all these stages have been completed, the manufacturer must present reports detailing all these findings in order to obtain final approval. Thus, it may take as long as six years to complete all the testing; then, there is the additional time required for the scientists of the Food and Drug Admin-

istration to assess the information and approve the drug. The agency may request additional information if it is dissatisfied with the way in which some of the tests were performed. (Reported in Newsweek, July 18, 1977, p. 93.)

If it were simply a matter of increasing drug costs, this lengthy testing procedure would not be the receiving the criticisms to which it is now being subjected. Far more significant than merely raising the prices of drugs, critics of this government requirement charge that it is in fact harmful to the health of the American people. Because of these extensive testing requirements, on the average only seventeen new drugs appear on the market each year as compared with three times that number prior to 1962, the year the FDA was empowered to test all drugs for safety and effectiveness. Critics charge that the American public is being denied the benefits of many new drugs because these are kept off the market by the overly elaborate testing requirements. Critics argue that the slightly decreased safety would be far outweighed by the benefits of these drugs.

Under Attack

The FDA has recently come under widespread attack for its Laetrile and saccharine bans, but perhaps the most serious criticism relates to this charge of keeping effective drugs from the American public. The FDA sees itself in a no-win situation. It is criticized for bureaucratic nitpicking, but if it approves a drug that later is seen to produce untoward side effects, then it is seen as yielding to pressure from the drug manufacturers (Newsweek, ibid.).

There appears to be a demonstrable need for the existence of a procedure similar to the FDA's. For example, in 1937 inadequate testing of diethylene glycol, a substance used to dissolve sulfanilamide, led to the deaths of some sixty persons from damage to the kidneys and liver, pulmonary edema, and hemorrhages of the gastrointestinal tract (Drill's Pharmacology in Medicine, Third Edition, p. 227). And in 1962 the nation was made aware of the importance of the FDA when President Kennedy bestowed a national award on Dr. Frances Kelsey, a staff scientist for the FDA, who had withheld approval for use in the United States of thalidomide, a substance which led to the birth of about seven thousand infants with deformed limbs and other organs (Drill's Pharmacology in Medicine, p. 182). Since 1962, however, the prestige of the FDA has gradually waned.

It seems evident that the question of how much regulation is proper does not admit of a simple or easy answer. The issue needs to be reviewed by a panel whose members represent neither the drug industry nor government but who are knowledgeable about the fields of drug research and government regulations, and are concerned for the well-being of the public.