Study Says U.S. Drug Firms Falling Behind

But Academy study contrasts with earlier findings by OTA that the drug industry is healthy

The health of the U.S. pharmaceutical industry has slipped dramatically in the face of increasingly robust foreign competition, especially from Japan, according to a new study by the National Academy of Engineering. The study, *The Competitive Status of the U.S. Pharmaceutical Industry*, attributes much of the industry's weakening to growing problems in innovation.*

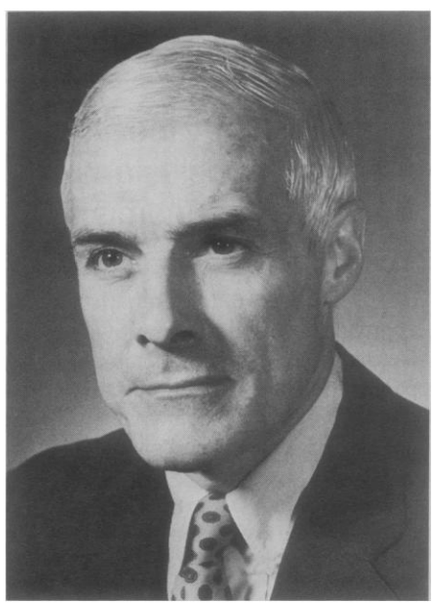
Compared to foreign competitors, the report says, the American industry has grown much less rapidly in terms of R & D expenditures and the number of drugs tested. There is "a clear relative deterioration" in the U.S. drug industry's research efforts, the study says. It goes on to suggest ways to combat the relative decline of the industry and, among them, endorses a controversial proposal that would extend the life of drug patents in the United States. The drug industry is likely to use the study to bolster its case for patent restoration legislation that Congress is now considering.

But the study's description of domestic ailments in U.S. innovation for the drug industry contrasts markedly with an analysis by Congress' Office of Technology Assessment (OTA). "The work done on this subject at OTA would support neither the Academy study's premises nor conclusions about innovation," says Donna L. Valtri, an economist and assistant project director of the 1981 OTA report. The OTA findings, in fact, are not discussed in the Academy study.

Charles Edwards, chairman of the panel and president of Scripps Clinic and Research Foundation, said in an interview that the OTA report was "overly optimistic in its analysis. Ours was more realistic." The panel, he said, did discuss the OTA report. For a fuller discussion of innovation, "perhaps our report might have been better if it had included it," remarked Edwards, who is also a former commissioner of the Food and Drug Administration (FDA).

The report is one of a series of studies being conducted by the Academy concerning the impact of technology and its effect on productivity and trade. Other reports have examined the auto and machine tool industries.

The Academy study looked at several factors to measure innovation that in almost every case showed a relative decline. But OTA says that by looking at another set of factors U.S. innovation has been steady, if not growing, for several years. There is "a lack of consensus among experts about how to measure innovation," Valtri testified at a congressional hearing last February. To complicate matters, it is difficult to weigh the importance of an individual factor, she said.



Panel chairman Charles Edwards

The Academy report endorses the controversial proposal to extend patent life for drugs

The Academy study, for example, argues that relative innovation is declining, relying heavily on calculations of percentages and ratios such as the U.S. share of R & D expenditures worldwide. The Academy study notes that the average annual growth of R & D money spent during 1973 to 1979 by drug companies located in the United States was only about 1 percent. During the same period, growth in R & D spending by the United Kingdom was 13 percent; Germany, 8 percent, and Japan, 8 percent. But if the base figures are examined, the picture is less alarming, Valtri points out, noting that real expenditures in the United States were enormous. While firms in the United States spent $1.2 billion for R & D in 1978, industry in the United Kingdom allocated $332 million, in Germany $750 million, and in Japan $641 million.

The Academy report also compares the number of applications for investigational new drugs that are filed with the FDA to the number of U.S. patent registrations. An increase in the ratio could be interpreted as an encouraging sign of growing innovation. But the ratio has declined since 1969. The study says that while the number of patents filed has risen, drug firms have become much more selective about the drugs they will develop because premarket testing has become so costly. Thus the companies are not filing applications for investigational new drugs at the same rate as they are for patents.

But Valtri suggests that the smaller ratio may not necessarily indicate a drop in innovation. She speculates that the number of patents filed may have increased for reasons not directly related to the development of new drugs. She explains that firms are now much more protective about their products and will file several patents for different aspects or characteristics of the same basic product or process.

According to the Academy study, American firms have also slipped in their share of patents filed with the U.S. Patent and Trademark Office compared with foreign companies—from 65 to 50 percent during the 1970's. But the meaning of this drop, in terms of U.S. competitiveness, is unclear, given that the closest contender to the domestic industry, West Germany, accounted for only 12 percent of the patents registered here in 1979. Furthermore, the actual number of patents filed has roughly doubled since 1963 to around 2000 in 1979. The Academy report says that the number of patents held by foreign companies quadrupled during the same period. That may again look distressing, but Valtri remarks that "it's much more difficult to double a large number than to quadruple a small number."

The Academy study caps its argument

**The Competitive Status of the U.S. Pharmaceutical Industry: The Influences of Technology in Determining International Industrial Competitive Advantage* (National Academy Press, Washington, D.C., 1983).

that U.S. innovation in the drug industry is lagging by noting that the number of new and distinct drugs which have been selected for clinical trials has dropped from 72 percent during the late 1960's to 56 percent a decade later. In the same category, companies abroad increased their share from 28 to 44 percent. According to the 1981 OTA report, however, counting only new chemical entities "fails to reflect innovations resulting from new formulations, new combinations of active ingredients, or new uses for existing drugs." But including all types of drugs approved by the FDA for use in clinical trials, the figures indicate that "innovation over the last decade was stable for several years with steady increases in more recent years," Valtri testified in February.

The Academy report says that Japan in particular has been aggressive in the international pharmaceutical industry. Historically Japan has not been a significant force in the world market because "Japanese-owned firms were not at all successful at innovation," it says. Several factors, however, have reportedly spurred innovation in Japan. Private industry has poured millions of dollars into R & D. In addition, the Japanese government has targeted the drug industry for international expansion. Its national health insurance program favors innovative drugs and provides lower prices for more established drugs. It revised its patent policy to also protect products, not only processes. It has also denied many foreign companies adequate patent protection, instituted non-tariff trade barriers, and promoted generous pricing policies with its domestic firms. The results have been "quite dramatic," the report claims.

But the data supporting that conclusion are not clear-cut. The study refers to the fact that Japanese R & D expenditures have zoomed from only $27 million in 1964 to $641 million in 1978. But the United States spent almost twice as much as Japan in 1978. The report says that in 1981, Japanese firms "ranked first in terms of major new drugs introduced into world markets." While Japan unveiled 17 major drug products, the United States only introduced 12. But the measure used to define a major new drug is not stated in the report. The figures were quoted from an article in *Scrip*, a newsletter covering the drug industry, which did not explain exactly what standard was used, according to the Academy study's principal author and researcher, Lacy Glenn Thomas, an associate professor at Columbia's Graduate School of Business. "The figures give you a qualitative sense of what's happening," he said.

The report goes on to note that the Japanese accounted for 16 percent of the U.S. patents issued last year for pharmaceutical and medicinal products. The United States, although the study does not say so explicitly, accounted for 62 percent.

The Japanese gains are cause for concern, according to the report. If the Japanese vigorously continue to expand their market and R & D expenditures, "reversal of any Japanese gains will be exceptionally difficult." The Academy panel, however, did not report the same apprehension about the growing West German drug industry. Compared to Japan, it has shown about the same rate of growth in R & D money in 1978, and filed for a greater percentage of U.S. patents.

OTA's report "would support neither the Academy study's premises nor conclusions about innovation," says an OTA economist.

The Academy report suggests that, in the face of growing foreign competition and a decline in U.S. innovation, domestic companies will confront a further drop in sales and exports. It recommends several options to bolster the domestic industry.

- The federal government should authorize the export of drugs that are not FDA-approved if a foreign nation has sanctioned their use. This recommendation has been discussed in Washington for years, but has never achieved much momentum because critics charge that such an action would pose ethical problems. One panel member, Philip Lee, a professor of social medicine at the University of California at San Francisco, did dissent to the recommendation.
- Foreign trade barriers such as pricing and regulation should be investigated to determine a U.S. response. The report does not elaborate what actions the federal government might take.
- Congress should pass legislation that extends patent protection of drugs and allows greater tax credits for research.

The pharmaceutical industry is delighted with the recommended changes. The Pharmaceutical Manufacturers Association has already cited the Academy report as further endorsement of patent extension. Indeed, industry was heavily represented on the Academy panel. Seven of the 12 panel members have strong, if not direct, affiliations with drug companies. The committee included William Hubbard, Jr., president of Upjohn; Robert Wood, chairman of the board of Eli Lilly; Lewis Sarett, retired vice president of Merck & Company; Peter Hutt, former FDA general counsel and a partner at Covington and Burling, which represents many drug firms; Kent Blair, a vice president of a securities firm and a former executive at Merck; William Wardell, director of the Center for the Study of Drug Development at the University of Rochester, which is supported largely by industry; and Alejandro Zaffaroni, president of the drug company Alza Corporation. The panel relied considerably on data from industry sources.

Other members were Philip Lee of the University of California; Arthur Sackler, a physician and publisher of Medical Tribune Newspapers; and Paul Wehrle, professor of pediatrics at the University of Southern California. The only economist on the committee was Albert Williams, director of the Health Sciences Program at the Rand Corporation.

Panel chairman Edwards acknowledged that there was essentially "nothing in the report that hasn't been said before." But "it's a good report because it highlights problems in the industry." One limitation of the study, he noted, is that it does not discuss the potential impact of genetic engineering on the drug industry. "The report isn't as current as it could be," Edwards said. Research for the report began 3 years ago and was written basically a year ago.

Thomas concedes that if more data could have been collected, he would have included more current information, especially concerning Japan. He says he also would have liked to examine foreign industrial policy in greater depth in areas such as patent policy and tax law. More data would have also helped to confirm the U.S. trends, he noted.

The report stresses that foreign competition is coming up fast from the rear. But the observation that U.S. innovation has actually increased in and of itself is not given much attention. Without a broader discussion of other ways to measure innovation, such as OTA's methods, and without more data on foreign companies, it is difficult to determine the full implications of increased competition from abroad.—**MARJORIE SUN**