PMA STATISTICS

1986 THEMES: PRODUCT AND PATENT APPROVALS

WASHINGTON, D.C.—"The approval of four products in a single year signals the movement of medical biotechnology at long last from the laboratory to the treatment center—surely one of the significant events of our time," says Gerald Mossinghoff, president of the Pharmaceutical Manufacturers Association (PMA), headquartered here. The four biotechnology-based therapeutics receiving nods in 1986 from the U.S. Food and Drug Administration (FDA) were:

- Orthoclone OKT3, a monoclonal antibody developed by Ortho Pharmaceutical Corp. (Raritan, NJ) for preventing immune rejection of kidney transplants;
- Intron A alpha interferon, made by Schering-Plough Corp. (Kenilworth, NJ), for treatment of hairy cell leukemia;
- Roferon A alpha interferon, made by Hoffmann-La Roche (Nutley, NJ), for treating hairy cell leukemia; and
- Recombivax HB, a recombinant DNA-based vaccine for preventing hepatitis B, sold by Merck Sharp & Dohme (West Point, PA).

Mossinghoff and colleague William Szkrybalo also report that, broadly defined, 1,232 U.S. biotech patents issued in 1986, up 14 percent over 1985. About half of those were for pharmaceutical and healthcare products, but nearly two-thirds of the patents in this subgroup were awarded to individuals not at U.S. firms, according to an analysis conducted for PMA by OMEC International (Washington, D.C.). Interestingly, it was the established pharmaceutical companies that received the most biotech patents, rather than the genetic engineering upstarts. Among PMA-member firms, Syntex Corp. (Palo Alto, CA) led the pack with 15 patents, Merck (Rahway, NJ) had 13, and Miles Laboratories (Elkhart, IN) and Eli Lilly (Indianapolis, IN) notched 12 apiece. Genentech (South San Francisco, CA), the only purely biotech company among PMA's members, received nine patents last year.

Altogether during 1986, FDA approved 20 new drugs for a wide variety of uses, including treatment of heart disease, arthritis, leprosy, urinary tract infections, bacterial resistance, anxiety, asthma, and psoriasis. Worldwide sales for PMA member firms reached $36.1 billion last year, with U.S. sales accounting for 66 percent of that total. Member companies spent an aggregate $4.6 billion for research, representing a 12 percent increase over 1985.

This evidence of solid growth "should not be taken for granted," Mossinghoff cautions. "The average development time for the 20 new pharmaceuticals approved by the FDA in 1986 was more than 10 years. Review and pre-market approval by the FDA accounted for about 34 months, two months longer than that required for 1985 products." Moreover, three-fourths of the new products were already being used in other countries before FDA approved their use in the United States.

Biotechnology products, however, were substantially more efficient at navigating the FDA maze. Orthoclone OKT3 required 27 months of FDA review; Roferon A, 19.5 months; Intron A, 11 months; and Recombivax HB, only six months.

—Jeffrey L. Fox