

NEWS BRIEFS

Two Biopharmaceuticals Approved in Japan

Centocor, Inc., a biopharmaceutical company based in Malvern, PA, announced on January 28, 1986, that its monoclonal antibody tests for ovarian cancer and hepatitis B have been approved by the Japanese Ministry of Health and Welfare.

CA 125, a blood test for ovarian cancer, is the only monoclonal antibody-based *in vitro* assay which reacts specifically with circulating antigens expressed by ovarian tumors, according to Centocor. (CA 125 is currently available in the United States for investigational purposes only.)

Hepatitis B, an *in vitro* radioimmunoassay used primarily in the screening of blood banks and for diagnosis of hepatitis, was developed in collaboration with Centocor at the Massachusetts General Hospital in Boston, and was the first monoclonal antibody-based hepatitis test approved by the US Food and Drug Administration, according to the company. ■

Report Published on Immunotherapy Market

From 1985 to 1990, the market for monoclonal antibody products in immunotherapy is expected to grow from \$5 million to \$225 million, according to a recently published report by Frost & Sullivan, Inc., an international market research firm.

The monoclonal antibody products covered in the projection include agents with radiotherapeutic and chemotherapeutic components. The market for all immunotherapy products, including pharmaceuticals and lymphokines, is expected to grow from \$797.7 million to \$1.5 billion in the next four years.

Pharmaceuticals today account for 86.7% of sales in immunotherapy products, and are expected to drop to 63.7% in 1990 as monoclonal antibodies and lymphokines gain in market share, according to the report.

The 208-page report, which also covers therapeutic apheresis (extracorporeal purification of blood), gamma globulins, and bone marrow transplantation, is available for \$1,850.

[For more information, contact: Frost & Sullivan, Inc. 106 Fulton St., New York, NY 10038 (212) 233-1080; or Frost & Sullivan, Ltd., 104-112 Marylebone La., London W1M 5FU (01) 935-4433.] ■

ProPAC Issues Report on NMR Reimbursement

The Prospective Payment Assessment Commission (ProPAC) met on March 6 to finalize its annual report to the secretary of the US Department of Health and Human Services (HHS). Recommendations for reimbursement of nuclear magnetic resonance (NMR) procedures were a main item on the agenda.

ProPAC recommended that an additional payment, or "add-on," for NMR procedures to compensate for capital costs of the equipment be instituted for a period of three years, and adjusted as necessary if and when capital payment policies under the Prospective Payment System (PPS) change.

The recommended add-on in fiscal year 1987 for institutions which have their own NMR unit is \$124 per scan. For hospitals that refer patients to other institutions for NMR scans, or that do not receive capital reimbursement under PPS, the recommended add-on is \$282.

For fiscal years 1988 and 1989, the

add-on amounts for all hospitals should be recalculated to reflect any change in the average cost of an "efficiently produced scan," according to the report. ProPAC defines an efficient unit as any machine that produces 55 scans per week.

ProPAC was established in 1983 to make recommendations to the HHS secretary on various aspects of Medicare's diagnosis-related groups (DRGs) payment program for hospital services. The main responsibilities of the advisory group include advising HHS on the appropriate annual percentage change for DRG payments and on the need for changes in the DRG classification system. ProPAC also collects and evaluates data on medical practices, patterns, and technology, and reports its activities to Congress. The 15-member commission includes one member of The Society of Nuclear Medicine, Barbara J. McNeil, MD, PhD, professor of radiology at Harvard University Medical School. ■

Senate Hearings on FDA User Fee

The Senate Labor and Human Resources Committee has scheduled hearings for June 6 on the possible implementation of a user fee for new drug applications (NDAs). Last year the US Food and Drug Administration (FDA) proposed that fees be charged to parties filing NDAs (see *Federal Register*, Aug. 6, 1985, pp. 31726-31732), but the proposal was prohibited by the Congress.

The Reagan Administration, however, is in the process of developing a similar proposal, which is expected to channel funds derived from the user fee through the FDA to speed up the approval process. ■