Federal Budget for FY 1986 to Cut Millions from FDA, NIH, and Medicare

FDA Approves 30 New Drugs in 1985 Including Four Diagnostic Agents

The US Food and Drug Administration (FDA) announced that in 1985 the agency approved 30 new drugs, the largest number "since legislation in 1962 required drugs to be reviewed for effectiveness as well as general safety," according to Otis R. Bowen, MD, secretary of the US Department of Health and Human Services (HHS).

Four diagnostic agents are on the list, including one radiopharmaceutical—indium-111 oxyquinoline (Amersham Corp.), which was approved last December (see *Newsline:* Feb. 1985, p. 122; June 1985, p. 555; Dec. 1985, p. 1359; Feb. 1986, p. 170).

The other newly approved diagnostics include iopamidol (Isovue™, Squibb), and two radiocontrast agents, ioxaglate meglumine/ioxaglate sodium (Hexabrix™, Mallinckrodt) and iohexol (Omnipaque™, Sterling-Winthrop).

Budget Cuts Could Delay Reviews

Manufacturers of medical products in the United States have expressed concern, however, over the slashed budgets resulting from the Balanced Budget and Emergency Deficit Control Act of 1985 (P.L. 99-177), commonly known as the Gramm-Rudman-Hollings bill. Passed by Congress at the end of 1985, the bill legislates budget cuts designed to eliminate the federal deficit within five years.

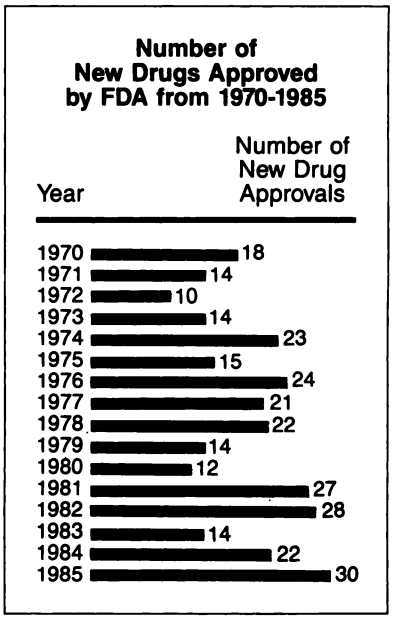
The White House Office of Management and Budget (OMB) recently published its Sequestration Report for Fiscal Year 1986 (see *Federal Register,* Jan. 15, 1986, pp. 1918-2236), which outlined the amount of money taken out of each part of the federal budget to bring the federal deficit down to $171.9 billion in 1986. (The target deficits for the following years are $144 billion in 1987, $108 billion in 1988, $72 billion in 1989, $36 billion in 1990, and zero in 1991.)

The Health Industry Manufacturers Association (HIMA), which represents more than 300 manufacturers of medical devices and diagnostic products, issued a statement on the impact of the balanced budget act on the FDA, which is subject to a $15.9 million decrease in its $368.8 million budget.

"There's really only one place where the FDA's $15.9 million can be taken—out of its workforce," said Frank E. Samuel, Jr., president of HIMA. "And, contrary to popular impression, fewer people doesn't mean reduced regulations. It means more regulatory delay. It means less surveillance of quack devices. It means slower technologic innovation. It means reduced international competitiveness at a time when our nation's trade deficit is increasing," added Mr. Samuel.

Mr. Samuel also noted that reducing the FDA's capacity to review new products "damages the economy and undermines public health." Based in Washington, DC, HIMA has a membership that produces 90% of the diagnostics and medical equipment made in the United States, according to the association.

The OMB report also includes the following reductions: $112 million in the $2.6 billion budget for the National Institutes of Health (NIH);



$377.7 million in the $2.1 billion budget for the Health Care Financing Administration (HCFA), which controls Medicare and Medicaid; $21.9 million in the $511.5 million budget for general science and research activities of the Department of Energy (DOE); $61.4 million in the $1.4 billion budget for the DOE's uranium supply and enrichment activities; $13.9 million in the $324.6 million budget for the DOE's nuclear waste disposal fund; $13.5 million in the $313.5 million budget for the Nuclear Regulatory Commission (NRC); $103.9 million in the $787.7 million budget for medical care in the Veterans Administration (VA); $6.5 million in the $152.4 million budget for VA medical and prosthetic research; and $1.7 million in the $40.8 million budget for the VA's medical administration and miscellaneous operating expenses.