Forecast on Plus Side for R & D Funding in 1983

A new forecast* by Battelle Memorial Institute analysts projects total U.S. expenditures on R & D for 1983 of $83.6 billion, up some 8.2 percent from the estimated $77.3 billion spent in 1982. Adjusted for inflation, the increase would amount to 3.5 percent.

Industry is expected to retain its narrow edge over the federal government as the leading source of R & D funds, although federal funding is seen increasing by a larger percentage. Industry funding is predicted to go up by 7.6 percent to $41.4 billion (49.6 percent of the total); the projected rise in government funding is 8.8 percent to $39.3 billion (47 percent of the total).

Funding for academic science is expected to rise to $9.7 billion in 1983 from $9.3 billion in 1982, giving colleges and universities a slightly smaller share of total R & D funding than they received last year. Industry is expected to provide some $304 million in R & D funding for academic science. This is still a small fraction of the $7.1 billion provided by the federal government, but industry support is seen increasing 10.5 percent compared to 2.7 percent for government. Costs of R & D are projected to rise by 4.5 percent this year, the lowest increase for years.

The forecasters warn that three factors could alter the picture. Inflation could heat up and make the "deflator" figure unrealistically small. Congress and the Administration have not yet thrashed out major appropriations measures for the 1983 fiscal year and the final figures, therefore, remain uncertain. A continuing economic slump could induce industry to cut planned R & D spending.

Battelle has been turning out R & D forecasts since 1960 at its Columbus division and has grown practiced in projecting trends. The analysts think that policies set by the Reagan Administration after it took office will continue to influence R & D spending. They see Administration emphasis on military and space programs likely to particularly benefit aerospace, electronics, and communications industries. Energy R & D, however, is expected to suffer from Administration priorities; the report says, "there is little evidence that energy is perceived as a national problem requiring Federal R & D support." Administration-sponsored tax credits should benefit industry R & D, but the forecasters attach the caveat that poor business and cash-flow conditions could counteract the effect of the credits.

—JOHN WALSH

*Probable Levels of R & D Expenditures in 1983. Report from the Columbus Division of Battelle Memorial Institute.

Genentech Tries Novel Way to Fund Clinical Trials

It has long been conventional wisdom that biotechnology companies will eventually be forced into partnership with large corporations to bring their products to market. The reason is that their limited cash resources will not be able to support the necessary clinical testing and market development—according to one study, it costs $70 million to get a new drug on the market. But Genentech may have found a novel answer to the problem.

The company has raised $55.6 million from wealthy investors to finance clinical trials of human growth hormone and gamma interferon, both of which are being produced by gene-splicing. The novel feature is that the money has been raised by the formation of a partnership, Genentech Clinical Partners, Ltd., which will fund the clinical trials and get a share of the royalties when the drugs are finally marketed.

According to Fred Middleton, vice president for finance and corporate development at Genentech, it is the first time a partnership has been formed specifically to fund clinical trials. One attraction for investors is that it provides a healthy tax shelter—since no profits will be made for the first year or two, the entire investment can be deducted from income.

Investing in an oil and gas partnership would provide a bigger tax write-off, but an investment in a clinical trials partnership should be less risky. The R & D has already been completed, and there is a reasonable chance of generating some income when the drugs reach the market. Although human growth hormone is unlikely to be a big money spinner, gamma interferon has the potential of being a broad antiviral and antitumor drug.

For those reasons, Genentech had little difficulty raising the cash, mostly from individual investors.

—COLIN NORMAN

Potential Conflicts of Interest Detailed at UC

Some 1709 researchers at the University of California received support for their work from nongovernmental sources in the past 6 months, and in 53 cases, the funding involved a potential conflict of interest, according to a report made public by the California Fair Political Practices Commission (CFPPC). None of the potential conflicts was deemed serious enough for the university to disapprove the deal, however.

According to CFPPC rules, a potential conflict of interest arises when a researcher derives support from a company in which he or his immediate family has a financial interest. When that situation occurs, a campus committee must review the arrangements and decide what conditions, if any, should be imposed on acceptance of the support.

The 53 cases reviewed in the CFPPC report involve several instances of researchers receiving support from companies in which they hold stock or from which they receive consulting fees. A few involve the receipt of funds from a nonprofit organization, such as the American Cancer Society, on whose board the researcher serves. The latter cases pose no problems, the report suggests.

The CFPPC, a state agency that oversees regulations governing state employees, adopted rules last spring requiring researchers at the university who receive research funds from nongovernmental sources to disclose their outside financial interests. The rules were vigorously opposed by the university. Pressure for adoption of the rules came chiefly from the California Rural Legal Assistance Council and the Natural Resources Defense Council (NRDC).

NRDC attorney Al Meyerhoff said last week the fact that the university

review committees allowed every project to go ahead suggests "there is at least a hint here of a rubber stamp." The CFPPC report also says that "most of the documentation [concerning the reviews] is so sketchy that it is impossible to determine how substantive the review really was."

—COLIN NORMAN

Judge Orders Regulation of Ethylene Oxide

A federal judge has rebuked the Reagan Administration for delaying new regulations to limit occupational exposure to ethylene oxide, a carcinogenic chemical. In a decision on 5 January, Judge Barrington Parker said that the delay resulted from "a clear error of judgment" and ordered the Occupational Safety and Health Administration (OSHA) to write by 25 January a tighter standard for ethylene oxide exposure.

The substance, a colorless gas, is used widely as a fumigant, sterilant, and pesticide and as an intermediate in the manufacture of such products as textiles, detergents, and bottles. The primary beneficiaries of a tougher regulation will be hospital workers, who are frequently exposed in the course of sterilizing medical instruments.

The judge noted that the government was aware of "solid and certain" evidence showing that workers are subjected to grave health risks from exposure well below the current federal limit of 50 parts per million. Two studies in Sweden, published in 1979, showed excess leukemia among factory workers exposed to between 10 and 30 parts per million. Other studies in humans showed mutagenic effects and excess miscarriages, and several animal studies showed excess mortality and abdominal cancer.

In 1981, the Nader-affiliated Health Research Group and a national labor union sued OSHA, citing this evidence and seeking an immediate reduction of the standard to 1 part per million. OSHA was persuaded by the American Hospital Association, the Ethylene Oxide Industry Council, and the Health Industry Manufacturers Association not to act promptly, and proposed instead to consider a tighter limit through its normal, drawn-out procedure for rule-making, with a final decision in 1984.

The judge called this "the least responsive course short of inaction," and noted that the government was unable to cite any scientific evidence that favored a delay. Documents made public in court indicated that OSHA's scientific advisers had in fact recommended swift action, but that they were overruled by higher officials, including Thorne Auchter, the agency's director. The agency also claimed that it should defer to the Environmental Protection Agency, which had regulated the substance as a pesticide. "The Court is unpersuaded," said Judge Parker.

—R. JEFFREY SMITH

Reagan Reluctantly Approves Fallout Study

An effort in Congress to compensate citizens in Utah and Nevada who contracted cancer as a result of atmospheric nuclear testing in the 1950's and 1960's has moved slightly ahead. On 4 January, President Reagan signed into law a bill that directs the government to study the issue more carefully and to prepare a report that could serve as a model for determining how much compensation each victim should get. Until now, uncertainty and disagreement on this topic has delayed any congressional action.

According to several sources, Reagan approved the requirement only because it was attached to a bill that he liked—the 1982 Orphan Drug Act, designed to promote the development of therapies for rare diseases—and because it was sponsored by a conservative Senator whom he likes—Orrin Hatch, a Republican from Utah. The Defense Department (DOD), the Energy Department (DOE), and the Office of Management and Budget (OMB) each expressed objections to the provision. The Justice Department counseled Reagan to veto the bill outright.

None of the agencies objected to the first portion of the provision, which orders the Department of Health and Human Services (HHS) to develop better estimates of the radiation doses to human thyroids from the fallout, and to relate these doses to a probable incidence of cancer in a report to Congress at the end of the year. An aide to Hatch says that the only opposition to this order came from the medical community, which has exposed the thyroids of roughly 10 million Americans to radiation in the course of certain therapeutic and diagnostic procedures. The aide says that several physicians telephoned to ask, "why are you picking on our isotope [iodine-131]? Why not strontium or cesium [which are not used in medical practice]?" Thyroid cancer is thought to be one of the most likely outcomes of high fallout exposure.

The second portion of the provision orders HHS to prepare statistical tables that indicate the likelihood of contracting any cancer after exposure to specific doses of ionizing radiation. It specifies that the tables are to include doses over a broad range, from 1 millirad to more than 1000 rads, and are to account for varying exposures among men and women at different ages. There is some doubt that this can really be accomplished, given a continuing scientific controversy over the effects of extremely low radiation doses. Consequently, the bill asks HHS to include its own assessment of the "credibility, validity, and degree of certainty associated with such tables."

Perhaps the most controversial aspect of the provision is a requirement that the data be presented "in such a manner and with the information necessary to determine the probability of causation of any individual who has or has had a radiation related cancer and has received any given dose." DOE and DOD fear that this provision will permit soldiers, veterans, and nuclear industry workers to sue their employers or the government. Similarly, OMB fears that judicial acceptance of the HHS numbers could make the federal government liable for billions of dollars in damages for radiation-induced cancers. Justice Department officials complained that, at the least, it would undercut its defense of the government in ongoing court trials.

The tables will probably be prepared by the Bureau of Radiological Health in the Food and Drug Administration. Congress said that the tables must be ready within a year.

—R. JEFFREY SMITH