

study. "We have done well" in developing a basic understanding of the biological processes that lead to cancer, and in providing better care for patients, he adds.

At the Weiss hearing, National Institutes of Health director Bernadine Healy picked up on that theme, describing the "superb basic research" on breast cancer funded by NIH. Healy pointed out that funding for breast cancer research since 1985 has been growing faster than the total NCI budget. Much of that research, she said, focuses on genes that appear to affect the rate of cancer development—the *p53* tumor suppressor gene, which is often defective in cancer patients and a genetic abnormality on chromosome 17 associated with family clusters of breast cancer at an early age (see *Science*, 9 August, p. 612). Healy went on to mention potential new drugs such as taxol, a potent extract from the bark of a rare Pacific yew, which she called "the most exciting drug to come along in the last 15 years." She said it will be tested on breast cancer patients. NCI is also about to launch a 16,000-member clinical trial of the drug Tamoxifen, an estrogen suppressor, in the hope that women who have already had cancer in one breast can avoid it in the second. Although none of the basic research has yet put a dent in the mortality statistics, there have been significant changes in cancer therapy.

One big improvement, GAO says, has been the medical community's effort to scale back the severity of surgery used to remove tumors, and a new attempt to give patients control over their own therapy. For example, the use of radical or Halsted mastectomies—commonplace in the 1950s—was "not present" in the hospital charts from the 1990s the GAO sampled, indicating they are rarely used now. Surgeons are likely to use more limited "lumpectomies" and, in recent years, combinations of surgery plus some form of chemo- or hormone therapy. The report concludes that "breast cancer patients are treated better than they were, but it is not clear that they are treated more effectively." The GAO concludes that the quality of life for cancer patients has improved because "the management of the disease has improved."

There's even more uncertainty about why the incidence of the disease is rising. The statistics are alarming: A U.S. woman's chances of becoming a breast cancer patient are now double what they were in 1940. Or, as patient rights advocate Ruth Spear said at the hearing: "It is inconceivable to me that my daughters should have a higher risk of developing breast cancer than their grandmothers." (Yet, at the same time, their chances of dying of heart disease have declined.) One reason for the increase in breast cancer risk, Healy said, is the improved

screening, which detects slow-growing tumors at an early stage. But she added that "some of the increase cannot be explained."

This led several witnesses to argue that the government should shift the emphasis of funding for breast cancer research toward prevention. Devra Davis, scholar in residence at the National Academy of Sciences, noted that only 30% of breast cancer cases are now linked to identifiable causes. And most of these have to do with diet or genes. "Clearly there are environmental factors, broadly conceived, that are involved" in triggering the disease, Davis said. She cited two recent studies, one from Israel and the other from Vermont, suggesting that women with breast cancer may have been exposed to more toxic chemicals than cancer-free controls. Davis' general message was that more funding should go to finding potential carcinogens in the environment.

The commanding general in the War on

Cancer, NCI director Samuel Broder, agreed with the logic but said the agency has already completed or is planning "well-designed studies" on the chemical 2,4-D, on potent amines, and on polycyclic hydrocarbons. And Healy reminded the audience that she is organizing a large (140,000 strong) study of women's health that will examine the effects of diet, artificial hormones, and vitamins on cancer, heart disease, osteoporosis, and stroke. The "enormity of the breast cancer problem," Healy said, was one of the things that prompted her to ask for the study.

While NIH is gearing up for a more vigorous attack on breast cancer, there are still no magic bullets in sight. As the GAO's Silberman put it, "Nowhere in the pipeline is there any drug that is going to transform the situation dramatically." The same, unfortunately, is true for most other common cancers 20 years after the government declared war on the disease. ■ ELIOT MARSHALL

## Canadian Biotech Regs Under Fire

For years Canadian industry has complained that regulations governing the introduction of new biotechnology products are cumbersome. Indeed, some critics charge that Canadian regulations are a decade behind those in the United States—and that Canadian industry suffers as a result. Another example of special pleading by a regulated industry? Not according to a government report issued last month by the National Biotechnology Advisory Committee (NBAC), which reports directly to the minister of science. It concludes that current delays and regulatory uncertainties are discouraging new research and investments in commercial facilities, driving up the costs of innovation, and undermining public confidence in biotechnology.

Take pharmaceuticals. Due to a lack of expertise and staff reductions at the federal ministry that is responsible for biopharmaceuticals, approvals are slow: They can take from 1 to 3 years. According to the report, Health and Welfare Canada should give "urgent priority to increasing the number of professionals and technical personnel committed to assessing new biopharmaceuticals," and regulations should be "harmonized" with those of other countries.

One way to shortcut the approval process, the report says, is to cut out duplication of clinical trials that have already been held in the United States. "Standardize and simplify those regulations pertaining to the licensing of product, so you don't have to repeat again

all of the clinical studies, at least for Canada and the U.S.," says NBAC chairperson William Cochrane, an Alberta-based venture capital consultant who spent 11 years as the chief executive officer of the large Toronto-based biotech firm Connaught Labs.

The report also complains that regulations governing the 100 or so field tests of genetically altered plants conducted in Canada since 1988 are antiquated and confusing, while in other areas regulations are nonexistent. Genetically altered microbes for bioremediation, for instance, fall outside existing legislation, which means that companies are unwilling to get into this business because businesses are unwilling to invest in an uncertain regulatory environment. Environment Canada has authority to regulate such organisms under the 1988 Canadian Environmental Protection Act, but it is still developing the rules.

In spite of the report's tone, all is not lost for Canadian biotech, says Terry Walker, special adviser for biotechnology regulations in the federal ministry of Industry, Science, and Technology Canada. Walker argues that the process of implementing and streamlining regulations is already under way, including consultations with corresponding U.S. departments, between Canadian levels of government, and between departments. Adds William Winegard, Canada's minister for science: "We have the brains, now let's get rid of the barriers." ■ DOUGLAS POWELL

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\* "A National Biotechnology Business Strategy: Capturing Competitive Advantage for Canada," released November 25, 1991.