

went to a great deal of trouble to talk directly to a range of different scientists," says Carole Jordan of the University of Oxford, president of the Royal Astronomical Society. Now researchers can only wait and see how the new minister responds.

Nobody expects Hunt to abandon the white paper's central goals, given the political momentum that has built up behind Waldegrave's reforms. The major question, however, is whether he will have sufficient time to devote to science policy. Waldegrave himself was only a part-time science minis-

ter—he also had responsibility for the civil service—and Hunt will have even less time to devote to science policy. In addition to the science and civil-service portfolios, he has been given a new post as cabinet "chief of staff," acting as Major's right hand and chairing six key cabinet committees.

At best, notes Oxford's Anderson, that position could give Hunt a unique opportunity to direct science policy across the whole of government, maybe allowing him to press other ministers to address the failings of U.K. industry when it comes to picking up on re-

search results from academia. Certainly, Hunt argues that his chief-of-staff role will strengthen research policymaking: "My new responsibilities place the cabinet minister in charge of science at the heart of government," he told *Science*. The downside, however, caution some scientists, is that science could fall off the bottom of Hunt's priority list—just as many researchers are looking for a steady ministerial hand to ensure that the reforms ushered in by last year's white paper do not threaten basic science.

—Peter Aldhous

GOVERNMENT-INDUSTRY COLLABORATION

NIH Panel Rejects Pricing Clause

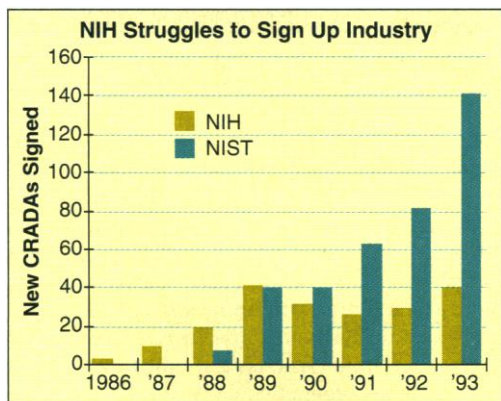
In 1989, the National Institutes of Health (NIH) got caught in the public outcry over the price that Burroughs Wellcome Co. was charging for the anti-AIDS drug AZT. NIH scientists had collaborated with the company in developing the drug, and members of Congress wanted to know why Burroughs Wellcome was able to charge patients more than \$2000 for a year's supply. As a direct result of that flap, NIH adopted rules that prohibit its scientists from entering into any research collaboration with a private company unless the company promises that the price of any product from the collaboration reflects the government's role in developing it.

In theory, the idea seems perfectly reasonable. But last week an NIH advisory panel heard a chorus of complaints from industry and NIH scientists—many of them members of the panel itself—that this so-called "reasonable pricing" policy has been at best misguided. They charged that it has hampered potential collaborations between industrial and federal scientists and led to NIH racking up one of the worst records of any federal lab in fulfilling Congress's aim of commercializing government-funded research.

After listening to these complaints for the best part of a day, the panel's recommendation to NIH was no surprise: Abandon all attempts to influence drug pricing. Its report will go to NIH Director Harold Varmus, who is expected to consider changes in NIH's policies later this year.

Created by a 1986 technology transfer law, Cooperative Research and Development Agreements (CRADAs) are the primary vehicle that establishes collaborations between federal researchers and industry. They are fueling the technology-transfer boom at federal research agencies such as the Department of Energy and the National Institute of Standards and Technology. But among all the research agencies, only NIH has insisted on inserting a reasonable-pricing clause in most of its CRADAs.

NIH's clause innocuously calls for a "reasonable relationship"—supported by "reasonable evidence"—between the price of a product of NIH-industry collaboration and the public investment in that work. But biotech and pharmaceutical companies have refused to enter into CRADAs with NIH because



Stalled. Although NIH does five times the in-house research, it lags far behind the National Institute of Standards and Technology in generating cooperative research agreements (CRADAs) with industry.

they fear Congress may use the clause to investigate their pricing policies, to demand access to their financial records, and maybe even to set the price of new drugs. Such fears may not be entirely unfounded: Last year Representative Ron Wyden (D-OR) introduced a bill that would have effectively set the price of CRADA-developed drugs, and he and others have proposed similar legislation as part of health-care reform packages.

NIH scientists have felt the chill. Mitchell Max, head of the clinical trials unit at NIH's National Institute of Dental Research, testified last week that some companies withhold experimental drugs from NIH researchers who want to use them as research tools for fear that any formal government tie could come back to haunt them when the drug is ready for market. "It's having a crippling effect on my research and that of others at NIH," Max said. "I and others will leave [NIH]

if we can't get the drugs to do our work."

Although most panel members and those who testified last week favor scrapping the pricing clause entirely, some felt there was room for compromise. Suggestions included:

- Deleting the pricing clause in the case of CRADAs for investigational drugs used as research tools when the company already has a solid patent position on the drug and the total NIH contribution to the project is less than \$1 million;

- Exempting CRADAs in which NIH makes an "insignificant" contribution to a product's development costs; and

- Requiring companies to provide "reasonable access" to the drug for those who cannot otherwise afford it.

But industry representatives weren't looking for compromises. They argued that, even if the government has the right to control price or access, NIH—as a research agency with virtually no regulatory functions—is the wrong agency to play that role. Restrictions on basic research, argued Alison Taunton-Rigby, chief executive officer of the Boston-based biotech company Mitotix, "should not be used to compensate for deficiencies in the health-care system." A spokesperson for Wyden told the panel that "my boss agrees that NIH is not the right place to do this," but he added that Wyden believes the federal share in fostering some government-industry collaborations is large enough to warrant lower prices—and that the rules must be spelled out somewhere.

Even if the controversy over the pricing clause is resolved, companies thinking about entering into a CRADA will still have plenty to complain about. A preliminary agreement between an NIH scientist and a company requires six additional layers of review, a process that can take more than a year. In addition, the agency also restricts both the research scope of a CRADA collaboration and the intellectual property rights it is willing to extend to the company. These policies, says the Biotechnology Industry Organization, "undercut the incentive of companies to enter into CRADAs."

—Christopher Anderson