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**EXCLUSIVE AGREEMENTS BETWEEN FEDERAL  
AGENCIES AND BRISTOL-MYERS SQUIBB CO. FOR  
DRUG DEVELOPMENT: IS THE PUBLIC INTEREST  
PROTECTED?**

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**HEARING**

BEFORE THE

SUBCOMMITTEE ON REGULATION, BUSINESS  
OPPORTUNITIES, AND ENERGY

OF THE

COMMITTEE ON SMALL BUSINESS  
HOUSE OF REPRESENTATIVES

ONE HUNDRED SECOND CONGRESS

FIRST SESSION

WASHINGTON, DC, JULY 29, 1991

Printed for the use of the Committee on Small Business

**Serial No. 102-35**



**STATEMENT OF JAMES P. LOVE  
Director, Taxpayer Assets Project  
Center for Study of Responsive Law**

before the

**Subcommittee on Regulation, Business  
Opportunities, and Energy**

of the

**Committee on Small Business**

**United States House of Representatives**

on

**The National Cancer Institute's  
Cooperative Research and Development Agreement (CRADA)  
with Bristol-Myers Squibb  
for the development of the drug taxol**

**July 29, 1991**

determinations.

Before analyzing the BMS/NCI CRADA agreement, it is useful to review other earlier cases involving publicly developed drugs.

### Cisplatin

Cisplatin, marketed by Bristol-Myers Squibb under the brand name Platinol, is a drug widely used for a number of forms of cancer, including testicular, ovarian, and bladder cancer. Cisplatin was developed from NIH-funded research at Michigan State University. In 1977, Michigan State University granted Bristol-Myers a five-year exclusive contract to manufacture cisplatin. When the initial contract had expired in 1983 cisplatin had become the largest selling cancer drug in the United States. 1983 sales were estimated at \$65 million.

Under the terms of the existing laws and regulations, the federal government had the right to decide if the patent could be extended on an exclusive basis, or if it would have to be licensed on a non-exclusive basis.<sup>2</sup>

The proposed extension of the cisplatin patent was seven years. Michigan State University, and its licensing agent, Research Corporation, had received millions of dollars in royalties from Bristol-Myers and wanted to renew the exclusive licensing agreement. At least five companies wrote to the Department of Health and Human Services (HHS) opposing the renewal of the Bristol-Myers exclusive license.

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<sup>2</sup>See the notices in the *Federal Register*, Volume 48, Number 25, page 5313, on February 4, 1983 and in the *Federal Register*, Volume 48, Number 223, page 53177, on November 25, 1983.

Among the issues HHS considered in the renewal of the cisplatin license was the amount of money that license holders would spend on future cisplatin research. The new firms hoping to manufacture cisplatin argued that non-exclusive licensing would lead to competition, which would drive down the drug's price. In response to concerns that a more competitive market structure would lead to less investment in cisplatin research, one of the smaller firms made a novel, thoughtful suggestion. Andrulis Research Corporation suggested that the license agreements require each manufacturer of cisplatin to contribute a share of its revenue into a research fund that would be managed by NCI or a private foundation. Had this proposal been followed, the government could have specified any amount that it wanted be spent on research. The federal government could also have managed the research program itself, and ensured that research findings were made public.

HHS, upon the advice of NCI, rejected the Andrulis proposal, and renewed the Bristol-Myers exclusive license. In return, Bristol-Myers agreed to spend a reported \$35 million in future cisplatin research, including research on head and neck, cervical, prostate, malignant lymphoma, bone and soft tissue sarcoma, upper gastrointestinal, lung and esophageal cancers. The trade press also reported that Bristol-Myers agreed to lower its price for Platinol by 30 percent.

Bristol-Myers was required to provide regular "Platinol Research and Development Program Status Reports," to the NCI Cancer Therapy Evaluation Program (CTEP).

According to the "Platinol Research and Development Program Status Report for

the Period of 30 June 1985 to 15 February 1986," dated April 1, 1986, which was submitted to Dr. Robert E. Wittes, then the Associate Director of CTEP, Bristol-Myers spent \$1.338 million on cisplatin research in 1984, and \$3.47 million in 1985.

In 1988 Bristol Myers notified Dr. Robert E. Windom of HHS that it had received a new extension of the Bristol-Myers exclusive licenses for the life of the patent. Several companies objected to this five-year extension of the cisplatin license. Michigan State University's licensing agent told HHS that it was required to approve the extension, without further conditions, on the basis of President Reagan's December 22, 1987 Executive Order. The Executive Order, Number 12618, removed restrictions on non-profit patent rights that were marketed prior to the 1984 amendments to the University and Small Business Patent Act.<sup>3</sup>

Among the many lessons of the cisplatin license renewal is that the federal government was able to obtain substantial concessions from Bristol-Myers, including a 30 percent decrease in the price of the drug. Based upon Bristol-Myer's annual revenues from cisplatin in 1983, the research commitment seemed like an easy burden to bear, particularly since it could be spread out over several years.

I find the Andrulis Research Corporation proposal, that a part of the royalty be set aside for research to be a compelling solution to a potential problem that increased market competition causes. Indeed, I find it hard to understand how NIH justified its 1983 decision to extend the Bristol-Myers license, in the face of evidence that several firms were willing entrants into the cisplatin market. I can only infer from this and

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<sup>3</sup>Public Law No. 98-620.

subsequent actions that NIH is indifferent to the impact of market structures on drug prices.

## AZT

The story of AZT is often told, and it is worth repeating here. As the members of this Subcommittee know, AZT was developed through federally-funded research, and NCI scientists were first to discover the effectiveness of AZT on the AIDS virus.<sup>4</sup> After NCI had established AZT as a promising AIDS treatment, Burroughs Wellcome agreed to sponsor clinical tests of its own and to file IND and NDA applications with the FDA.

In July 1985, the FDA designated AZT as an orphan drug for the treatment of AIDS. In March 1987, the FDA approved the Burroughs Wellcome NDA for AZT. Based upon the earlier FDA designation of AZT as an orphan drug, Burroughs Wellcome was given seven years of exclusive rights to market AZT in the United States for the purpose of treating AIDS.

Burroughs Wellcome's initial prices for AZT shocked many. The per-patient cost for an annual supply were \$7,000 to \$10,000. Most of this cost was paid by Medicaid. In the storm of controversy caused by the high price of AZT, the scientists at NCI claimed to be surprised. For example, in a story in the *Washington Post*, NCI's Dr. Samuel Broder was quoted as saying "We didn't pick up fast enough on the cost issue. . . the

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<sup>4</sup>See for example, the Prepared Statement of Robert E. Windom, MD, Assistant Secretary for Health, included in U.S. House of Representatives, Committee on Energy and Commerce, Subcommittee on Health and the Environment, *AIDS Issues, (Part 1)*, Hearings. March 10, April 27, and September 22, 1987.