June 2003

TECHNOLOGY TRANSFER

NIH-Private Sector Partnership in the Development of Taxol

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Highlights

Highlights of GAO-03-829, a report to the Honorable Ron Wyden, U.S. Senate

Why GAO Did This Study

The transfer of technology from government-funded medical research laboratories to the private sector aims to have new pharmaceuticals brought to market more efficiently than would be possible for a federal agency acting alone. Much of the pharmaceutical-related technology transfer originates with research funded by the National Institutes of Health (NIH). GAO was asked to examine the legal and financial issues involved in technology transfer as illustrated by the research, development, and commercialization of Taxol. Taxol was developed through a cooperative research and development agreement (CRADA) between NIH and the Bristol-Myers Squibb Company (BMS) and by 2001 had become the best-selling cancer drug in history.

Specifically, GAO examined (1) how the technology transfer partnership affected the research and development of Taxol, (2) what NIH's financial investment was in Taxol-related research, and what the financial outcomes were of the technology transfer process related to Taxol, and (3) what factors influenced how NIH exercised its authority in Taxol-related technology transfer activities. GAO reviewed relevant materials and statutes governing technology transfer, reviewed the patent history of Taxol, interviewed NIH and BMS officials, and reviewed data on NIH's financial investment and drug pricing policies.

www.gao.gov/cgi-bin/getrpt?GAO-03-829.

To view the full product, including the scope and methodology, click on the link above. For more information, contact Marcia Crosse at (202) 512-7119.

What GAO Found

The 1991 NIH-BMS CRADA was one of the first CRADAs to result in a major breakthrough drug. NIH's partnership with BMS provided the company with the research results that enabled Taxol to be commercialized quickly and made available as a treatment for cancer patients. Prior to the CRADA and during the first 2 years of the agreement, NIH conducted most of the clinical trials associated with the drug. The results of these trials were critical for BMS to secure FDA's approval in 1992 to market Taxol for the treatment of advanced ovarian cancer. As agreed in the CRADA, BMS supplied the drug to NIH researchers to overcome previous shortages. The additional supplies from BMS allowed NIH to increase the number of patients enrolled in NIH clinical trials for this drug from 500 patients by 1989 to nearly 29,000 patients over the course of the CRADA.

NIH made substantial investments in research related to Taxol, but its financial benefits from the collaboration with BMS have not been great in comparison to BMS's revenue from the drug. NIH estimates that it spent $183 million on all Taxol-related research from 1977 through the end of the CRADA's term in 1997. For one portion of its spending, NIH estimates that it spent $96 million to conduct clinical trials supporting the CRADA; this was offset by a $16 million payment from BMS. In addition, BMS supplied Taxol to NIH, the value of which GAO estimates to be $92 million. NIH spent an additional $301 million on Taxol-related research from 1998 through 2002, some of which was for cancer research, making NIH's total Taxol-related spending $484 million through 2002. BMS's sales of Taxol totaled over $9 billion from 1993 through 2002. BMS agreed to pay NIH royalties at a rate equal to 0.5 percent of worldwide sales of Taxol as part of a 1996 agreement to license three NIH Taxol-related inventions developed during the CRADA. Royalty payments to NIH have totaled $35 million. The federal government has been a major payer for Taxol, primarily through Medicare. For example, Medicare payments for Taxol totaled $687 million from 1994 through 1999.

Several factors affected NIH's exercise of its broad authority in negotiating its Taxol-related technology transfer activities. First, NIH did not have a patent on Taxol and thus could not grant an exclusive patent license to a CRADA partner. Second, in NIH's evaluation, it was limited by a shortage of available, qualified alternative CRADA partners. Finally, the negotiation of royalties for NIH's Taxol-related inventions was affected by multiple considerations, including the priorities that both NIH and BMS assigned to different factors in the setting of royalties. These factors include the stage of development, the potential market value of the license, and the contribution to public health of making the product available.

In commenting on a draft of this report, NIH provided additional information about its expenditures and the contributions of BMS, which GAO incorporated, and also discussed its evaluation of whether BMS's pricing of Taxol was reasonable.