Executive Summary

For the past 15 years, federal technology transfer has received bipartisan interest, as policymakers sought to enhance the availability of federally supported research for further development by industry. Through the 1980s, Congress enacted a series of laws that encourage commercial development of federally funded research at both universities and federal laboratories. Such laws (chiefly the Bayh-Dole Act of 1980, Stevenson-Wydler Act of 1980, and Federal Technology Transfer Act of 1986; Public Laws 96-517, 96-480, and 99-502, respectively) were not aimed specifically at genome, or even biomedical, research. However, such research and the commercial biotechnology enterprises that surround them clearly have benefited. The success of the biotechnology sector owes much to federal technology transfer and intellectual property policies.

As a commercial enterprise, biotechnology represents billions of dollars of investment, and the engine that drives most investment is intellectual property protection of a venture's research. OTA has consistently reported to Congress that intellectual property protection has played, and continues to play, a critical role in U.S. preeminence in commercial biotechnology. By the late 1960s, advances in biological and genetic technologies had begun to unlock the mysteries of human disease, and in the United States, progress in the biomedical field derived largely from federally funded research. In the 1980s, judicial and legislative policies expressly encouraged moving results from federally supported biomedical research to the marketplace.

Intellectual property and technology transfer continue to play an important role in biotechnology research and development (R&D). The National Institutes of Health's (NIH) 1991 filing of patent applications on thousands of human DNA sequences was

justified, in part, as a means for the federal government to ensure that the public's investment in biomedical research—in this case at a federal laboratory—was optimized through patents that would be attractive to investment by industrial partners.

Such federal-private sector partnerships were made possible under technology transfer legislation enacted in the 1980s. Today, a system of laws, regulations, and policies exists to transfer the fruits of publicly funded research—through grants or contracts at academic research institutions or federal laboratories—to industry. With respect to research conducted under the auspices of the Human Genome Project, the technology transfer policies and practices of NIH and the U.S. Department of Energy (DOE) are key. Additionally, laws and policies outside the scope of legislation designed specifically to facilitate technology transfer also affect federal technology transfer. Indirect forces that affect patent position can influence technology transfer—e.g., licensing and patenting practices in the private sector frequently fall under antitrust scrutiny.

The bulk of technology transfer for life sciences research occurs via the rich academic biomedical infrastructure that is unique to the United States. Universities and research institutions benefit from the level of support provided by the government's sponsorship of basic biomedical science. In return, public investment and technology transfer policies encourage commercial development and have helped make the United States the world's leader in biotechnological development. Both the research base and the progress of dedicated biotechnology companies (DBCs) trace their roots to the growth in federal support of biomedical research since the early 1970s. In fact, the United States is one of few countries with a developed network of university technology transfer offices for DBCs to utilize. Moreover, the initial appearance of DBCs was confined largely to the United States, based in part on the availability of publicly funded biomedical research at universities.

According to a 1993 survey of the Association of University Technology Managers, revenue to U.S. universities from technology licensing agreements grows by 25 percent annually, and in 1992, nearly 1,500 patents were issued to colleges and universities—four times the number issued in 1982. Currently, technology transfer at most institutions is integral to the university's structure and mission, though most do not yet generate income sufficient to support their technology transfer operations.

Cooperative Research and Development Agreements (CRADAs) are one high-profile instrument by which federal laboratories enter into partnerships with the private sector to develop research results into commercial products. With respect to NIH, OTA found that NIH has made extensive use of its authority to enter into CRADAs. However, measuring returns from NIH CRADAs—at least by income—is difficult: Some of NIH's potentially lucrative CRADAs involve therapeutic agents that have not completed the eight to ten years of clinical trials required for market approval by the Food and Drug Administration. Viewed from the private sector, participants at a 1994 OTA workshop who were drawn from a broad spectrum of biotechnology and genome research companies reported some frustration with NIH's CRADA review process, but were supportive of CRADAs per se.

Technology transfer at DOE centers on the national laboratories, and biomedical-related CRADAs reflect DOE-funded research in drug development, diagnostics, therapeutics, and technologies for rapid DNA sequencing. Life science applications are a minority of DOE CRADAs, because most of DOE's technology transfer focuses on its historical role in nuclear weapons and energy research. OTA found that, in general, representatives of national laboratories and company respondents to an OTA survey agree that DOE's CRADA formation process is micromanaged—sometimes to a debilitating degree—by DOE headquarters.

OTA data reveal that CRADAs at NIH and DOE have been a source of negligible income to the agencies. For biotechnology companies responding to the OTA survey, approximately 1.9 percent ($31 million) of gross revenues (e.g., in-

come from goods and services, plus royalty income) associated with all R&D over five years resulted from R&D performed under CRADAs. Likewise, neither NIH nor DOE have realized significant financial return in the form of royalties on CRADA inventions. CRADAs seem most useful for both federal researchers and the partnering company as a mechanism to share resources—i.e., despite the lack of economic payoff to date, CRADAs afford qualitative benefits to all parties.

Data from OTA surveys of selected biotechnology companies and of university technology transfer offices highlight the relative success of implementation of federal technology transfer laws at universities conducting life sciences research supported by NIH and DOE (in comparison with actual technology transfer efforts undertaken by NIH and DOE themselves). Two factors help explain this differential: universities have more experience in transferring technology to industry and the scale of extramural research support at universities is larger than intramural research funding in the case of NIH; DOE spends a substantial component of its human genome research budget intramurally at national laboratories.

Companies report that biomedical CRADAs are useful for sharing basic research resources—especially the materials and equipment available in federal facilities and the expertise of federal personnel. Conversely, companies have provided materials, equipment, expertise, as well as funding for research or the patent application process or compensation for federal researchers. Of companies surveyed by OTA, a minority (13 percent) felt the risks and expenses of CRADAs exceed the benefits.

Insofar as patents and publications are viewed as a positive benchmark for federal researchers, the benefit of CRADAs to federal researchers was further quantitatively documented by OTA's examination of patenting and publishing of NIH intramural scientists involved in CRADAs compared to non-CRADA NIH researchers. NIH CRADA researchers obtain more than five times as many patents as non-CRADA scientists. The impact of patents from NIH CRADA researchers versus non-CRADA NIH patentholders also differed: Patents from CRADA scientists are more frequently cited. As measured by publications, CRADA scientists at NIH publish twice as many papers as non-CRADA researchers, though each group publishes equally in influential journals.

Overall then, federal technology transfer related to life sciences research has proved to be beneficial financially to universities and companies, but the principal benefit thus far to industry, academia, and federal laboratories centers on non-income measures. In the context of the Human Genome Project, this effort was launched and is still largely supported by public funding. Nevertheless, private sector interest and investment in genome research has escalated over the past two years, as its federal funders intended. Whether financially measurable benefits exceed qualitative benefits of federal technology laws and policies from the Human Genome Project remains to be seen. There is little question, however, that public, private, and academic partnerships will prove important for the commercialization of genome research.