Public-Private Partnerships in Biomedical Research: Resolving Conflicts of Interest Arising under the Federal Technology Transfer Act of 1986

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The Federal Technology Transfer Act of 1986 offers private industry the opportunity to enter into cooperative research and development agreements with scientists in federal laboratories and to gain rights in intellectual property resulting from such collaborations. Increased collaboration with private industry, however, expands the potential for conflicts of interest. Resolution of the tensions between the Technology Transfer Act and federal conflict of interest rules is important because federal laboratories, such as the NIH, are experiencing a loss of senior scientists to universities and private industry due to inadequate compensation. These tensions may be resolved by some combination of policies, regulations, and legislation aimed at permitting government scientists to hold certain carefully defined financial interests in inventions resulting from industry collaboration, and to pursue simultaneously other outside activities, such as consulting for different companies.
I. INTRODUCTION

Substantial economic rewards may await companies in the biotechnology industry willing to invest in certain public-private partnerships in research offered by the federal government. Pursuant to legislation enacted during the 1980's — most particularly the Federal Technology Transfer Act of 1986 — private companies that develop biomedical or other biotechnological products and processes may participate in cooperative research with federally-funded laboratories and obtain an assignment of patents or licenses in resulting inventions.

In 1988 and 1989, certain laboratories at the National Institute of Health ("NIH") entered into the first wave of the Cooperative Research and Development Agreements ("CRADAs") authorized by this legislation. As explained more fully below, a CRADA is a contract under which, typically, a company contributes money and expertise to a federal laboratory to augment its ongoing research, in exchange for rights in any resulting inventions. Because of the depth and breadth of research constantly in process at NIH, companies willing to invest in such agreements now have the rare opportunity to gain rights in patentable inventions in the areas of AIDS, cancer, and genetic engineering, to name only a few.

While a CRADA relationship offers the potential for significant rewards to both government and industry, the recent experiences of several biomedical companies with the NIH suggest that establishing such relationships may entangle companies and scientists in an expanded web of potential conflicts of interest. As government employees, NIH scientists find themselves significantly underpaid in comparison to their colleagues who work in private industry and academia. Currently, many NIH scientists choose to supplement their incomes by consulting for private industry. Yet, the network of laws covering conflicts of interest by federal employees may force the government scientist to choose between consulting and establishing a CRADA, not only with the same company, but with companies that are only distantly related through common investors.

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2 See Booth, NIH Scientists Agonize Over Technology Transfer, 243 Sci. 20 (1989). The Booth article reported that about fifty NIH CRADAs had been signed as of January 6, 1989. Id. A recent GAO study indicates that the precise number was 48 as of February, 1989. General Accounting Office, Technology Transfer: Implementation Status of the Federal Technology Transfer Act of 1986 (May 1989). Other agencies that have executed significant numbers of CRADAs include the Department of Agriculture's Agricultural Research Service which has executed 59, National Institute of Standards and Technology which has executed 37, and the Department of the Army which has executed 12. Id.
3 See Fauci, Testimony Before The [Federal] Commission on Executive, Legislative and Judicial Salaries (Nov. 10, 1988). According to Dr. Fauci, Director of the National Institute of Allergy and Infectious Diseases, the average compensation paid to Senior Executive Service physicians is half the average supplemented compensation paid to the chairs of clinical science departments of American medical schools let alone to their counterparts in private industry. Specific examples of recruiting difficulties encountered by NIH are cited in Dr. Fauci's testimony. Id.
Resolving these conflict of interest issues is especially important in the current environment. If the NIH is to maintain its traditional leadership role in scientific research to compete with more attractive job offers from industry and academia, new compensatory mechanisms may be necessary. At the same time, however, the Health and Human Services Office of Inspector General has announced plans to review current NIH policies to determine whether they are sufficient to prevent financial gain by NIH researchers from improperly approving drugs in clinical trials. In addition, only intense objections from industry and academia recently led NIH to withdraw severe proposed conflicts guidelines that would have prohibited researchers who receive federal grants from holding an interest in any company "that would be affected by the outcome of the research." Measures such as these have the potential to chill any interest in cooperative research out of fear of violating conflict of interest laws or guidelines. Accordingly, it is essential to develop new regulations or statutes which deal with the conflict situations that inevitably will arise under the Technology Transfer Act.

This article takes the position that the public-private partnerships envisioned by the Technology Transfer Act represent a congressional choice to permit federal agencies broader latitude in the involvement and compensation of government scientists with private industry than has so far been recognized. This article summarizes current federal law governing the commercialization of federally-funded technology, and offers suggestions for remedying some of the more prominent inconsistencies with the conflict of interest laws. While the article focuses on cooperative research efforts between private industry and NIH laboratories with which the author has had some personal experience, the principles discussed will apply to similar cooperation with other federally-funded laboratories.

Part I of the article details the history and provisions of the Technology Transfer Act and the NIH guidelines currently governing CRADAs. Part II discusses the sometimes contradictory provisions of law on conflicts of interest by federal employees. Assessing these various provisions, this Part argues that the described history of the technology transfer legislation evidences congressional intent to permit government scientists a degree of financial involvement in private companies, through CRADAs, that would be otherwise unlawful. Part III concludes the article with a discussion of several options that federal agencies such as the NIH, or Congress, might follow to achieve the goals of technology transfer, without undermining the letter or spirit of the conflict of interest laws.

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4 33 The Blue Sheet 3 (Jan. 10, 1990).
II. FEDERAL TECHNOLOGY TRANSFER ACT OF 1986

A. Historical Background of Technology Transfer Legislation

In the 1970s, prominent scientists joined with groups of innovative investors to create the first for-profit biotechnology research companies. Such companies were founded on the idea that many products and processes theretofore languishing in the laboratories of scientists might have commercial applications. The most public, but by no means the only such effort, was in the area of recombinant DNA research.\(^6\) In an effort to make commercial use of such research, the companies sought agreements with major universities to share resources, personnel, and technology.

The academic community initially scrutinized such offers with understandable wariness. In accepting the funds and resources of private industry, would universities sacrifice their independence? Would they lose their freedom to pursue avenues of research that are not likely to lead to commercial inventions? Would they become, in effect, mere colonies of the for-profit sector?

The experience of the universities has demonstrated that these concerns were unfounded. Studies have reported that university research faculty who receive a large proportion of their research support from industry, or combine such support with other types of industrial relationships, have significantly more publications and involvement in other professional activities.\(^7\) In addition, the majority of academic scientists operating both with and without significant industry support expressed concern that such support had the potential for shifting too much emphasis to applied research.\(^8\) As one study pointed out, this finding provides evidence that:

> at least at current levels of involvement with industry, faculty remain sensitive to traditional university values and practices. Although not a guarantee against erosion of these values, such faculty attitudes may indicate that they retain a capacity to police their own relationship with industrial sponsors.\(^9\)

The "traditional university values" of NIH scientists should be even more likely to resist erosion because government will always contribute a larger percentage of the total research budget of federal laboratories such as the NIH than will private industry.

In 1980, Congress took its first step to implement a similar program for commercialization of federally-funded technology. The Stevenson-

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\(^6\) See Blumenthal, University-Industry Research Relationships in Biotechnology: Implications for the University, 231 Sci. 1361 (1986).

\(^7\) Id. at 1365; see also Blumenthal, Commercializing University Research, 314 NEW ENG. J. MED. 1621, 1625 (1986); see also Blumenthal, Industrial Support of University Research in Biotechnology, 231 Sci. 242 (1986).

\(^8\) See id. at 1365.

\(^9\) Id.
Wydler Technology Innovation Act of 1980\textsuperscript{10} sought to “improve the economic, environmental, and social well-being of the United States” by, among other things, “stimulating improved utilization of federally funded technology developments by State and local governments and the private sector.”\textsuperscript{11} The Act sought to accomplish this goal by requiring each federal laboratory to establish an Office of Research and Technology Applications to identify and assess each project having potential for successful application in state or local government or private industry.\textsuperscript{12} The Act also created a Center for the Utilization of Federal Technology within the Department of Commerce to serve as a clearinghouse for information on federally-owned or originated technologies having potential commercial application.\textsuperscript{13}

Stevenson-Wydler’s policy of promoting the transfer of federal technology to private industry, state and local governments received a significant boost from amendments to the United States patent laws passed during the same congressional session. Prior to 1980, U.S. companies desiring to use government-funded research to develop new products and processes had to confront what the House committee report described as “a bewildering array of twenty six different sets of agency regulations governing their rights to use such research.”\textsuperscript{14} At that time, the general rule was that rights to inventions developed with federal funds belonged to the federal government. With the Bayh-Dole Patent and Trademark Amendments of 1980 (the “Bayh-Dole Amendments”), Congress amended the patent statute to provide that ownership of patent rights, in substantially all inventions developed in the laboratories of small businesses and nonprofit organizations\textsuperscript{15} through government-funded research, would belong to the private contractor.\textsuperscript{16}

\textsuperscript{12} Pub. L. No. 96-480, § 11 (codified at 15 U.S.C. §§ 3710(b) & (c)) (1982).
\textsuperscript{16} Bayh-Dole Amendments, Pub. L. No. 96-517, § 6(A) (1980) (codified at 35 U.S.C. §§ 201 (a) - (i)) (1982). Regulations implementing this legislation were promulgated on March 18, 1987 (ownership), and on March 12, 1985 (licensing). 37 C.F.R. §§ 401.1 et seq., 404.1 et seq. The original House bill also proposed a uniform patent policy that would have permitted contractors which did not qualify as small businesses or non-profit organizations to obtain an exclusive license to (rather than ownership of) technology developed, but these provisions were deleted in the Senate amendments. See H.R. Rep. No. 1307, Part I, 96th Cong., 2d Sess. 11-22 126 Cong. Rec. 30,560 (1980) (remarks of Rep. Fuqua).
Together, these two pieces of legislation represented a major shift in congressional policy toward the permissible uses of technology conceived or first reduced to practice with federal funds. Under Stevenson-Wydler, the federal government adopted at least a general policy supporting the transfer, where appropriate, of federal technology to private industry and state and local governments which could be anticipated to use it in advancing technological innovation. Under the Bayh-Dole Amendments, this policy began to take shape, as certain elements of the private sector — small businesses and nonprofit organizations — received an extra incentive to apply for government grants or contracts, or otherwise to invest in research also funded in part by the federal government. The incentive, of course, was the possibility of obtaining patent rights to marketable products or processes developed in the course of such research.

Despite these first steps, in the early 1980s the mechanisms for technology transfer from federal laboratories remained uncertain. Most federal laboratories lacked clear authority to enter into cooperative research projects with private industry.\(^{17}\) In addition, even where federal laboratories were willing to enter into such agreements, neither statute nor regulation defined the rights of the private collaborators in any resulting inventions.\(^{18}\) Recognizing that more work needed to be done, both executive and legislative branches began more vigorously to study ways to improve technology innovation, transfer, and commercialization. In 1983, the White House Science Council Federal Laboratory Review Panel called for greater technology transfer between federal laboratories and the private sector.\(^{19}\) The Panel suggested that the federal government foster strong interactions between its laboratories and industry and users of research in order to "maximize the complementary use of talent and resources... [and] to assure the application of results to broader, practical uses."\(^{20}\) Consequently, the Panel formally recommended that research and development interactions between federal laboratories and industry be greatly increased by more exchange of knowledge and personnel on collaborative projects.\(^{21}\)

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\(^{18}\) The Bayh-Dole Amendments apply only to work performed under a "funding agreement." The patent statute defines such an agreement as "any contract, grant, or cooperative agreement entered into between any federal agency ... and any contractor for the performance of experimental, developmental, or research work funded in whole or in part by the Federal Government." 35 U.S.C. § 201(b)(1984). This language has never been thought to apply to work performed in a laboratory owned and operated by the federal government, such as the laboratories at the NIH. If that were the case, any private company collaborating with an NIH laboratory under a CRADA would automatically be entitled to ownership of any inventions. Given the ownership and licensing options presented in the Technology Transfer Act, it is highly unlikely that Congress intended such a result.


\(^{20}\) \textit{Id.} at 3.

\(^{21}\) \textit{Id.} at 12.
Congress responded to the recommendations of the Panel with the Federal Technology Transfer Act of 1986, which has as its purpose the encouragement of technology transfer between government scientists and private industry.\(^{22}\) The Act is intended to provide federal laboratories with clear authority to enter into cooperative research and development agreements with a wide range of parties, including small "start-up" companies.\(^{23}\)

Recognizing that technology exists in our federal laboratories that is not readily available to private industry, the Act encourages the exchange of commercially valuable information between the public and private sectors by permitting the director of any government-operated federal laboratory to enter into CRADAs with industrial organizations and to negotiate licensing agreements.\(^{24}\) As defined in the Act, a CRADA is a contract in which the federal laboratory and the collaborator agree to share personnel, services, facilities, equipment or other resources toward the conduct of specified research or development efforts consistent with the mission of the laboratory.\(^{25}\) In addition, the non-federal collaborating party may, and usually does, contribute funds to the federal laboratory.

Under a CRADA, a federal laboratory may grant to a collaborating party patent licenses (or assignments or options) in any invention made in whole or in part by a federal employee under the CRADA, subject only to a nonexclusive license retained by the government.\(^{26}\) The lab may also waive any federal ownership rights (again subject to retaining a nonexclusive license), and may permit employees or former employees to participate in efforts to commercialize inventions they made while employees.\(^{27}\)

Of particular significance, the Technology Transfer Act also requires that agencies operating large laboratories\(^{28}\) establish a program of cash awards for employees responsible for commercially valuable inventions and for exemplary activities that result in utilization of science and technology by American industry or business.\(^{29}\) In addition, royalties received by a federal agency for inventions developed under a CRADA or licensed...
by the agency under the patent laws must be shared at a rate of at least fifteen percent with the employee-inventor.\textsuperscript{30}

These provisions of the Technology Transfer Act demonstrate the government's substantial commitment to commercializing technology developed in federal laboratories. More specifically, the latter provisions make plain that Congress affirmatively desired to give federal employees financial incentives to participate in the process: cash awards for encouraging the transfer of technology from federal labs to private industry, and a financial interest in their inventions whenever those inventions are commercialized under a CRADA or otherwise licensed by private industry.

\textit{C. Implementation}

The Technology Transfer Act specifically authorizes each federal agency to issue its own regulations regarding implementation of the statute's provisions.\textsuperscript{31} To date, no agency has promulgated published regulations; however, several agencies, including the NIH, have adopted guidelines for implementing the statute. At the NIH, these guidelines (and the technology transfer program) are the responsibility of the Office of Technology Transfer ("OTT"), formerly the Office of Invention Development ("OID").

Under a typical NIH CRADA, a government scientist collaborates on a specified research project with a company scientist (the "investigators"). The company might also fund one or more research fellows to work with the government's principal investigator on the research project. The company may also contribute other resources, such as additional research scientists, supplies or operating expenses. In exchange for this support and participation, the company obtains rights — typically an exclusive license or an option to an exclusive license — in any invention produced under the collaboration.

Initially, the first NIH CRADAs often were drafted by counsel for the proposed collaborator, and then revised by the parties in negotiation. In April 1989, OTT (then OID) adopted for use by the NIH and the Alcohol, Drug Abuse and Mental Health Administration ("ADAMHA") a model CRADA which, while still subject to negotiation, set forth the basic legal framework for the collaboration. The role of the collaborating investigators is to draft a research plan which defines the scope of the collaboration. This is an important step because the description of the scope of the collaboration could be regarded as limiting the scope of inventions as to which the private collaborator is entitled to licensing rights. A clear description also facilitates management oversight at NIH and at the collaborating company.

\textsuperscript{31} Id. at § 3710a(c).
Once the CRADA and research plan have been reduced to writing, the
NIH investigator must complete a CRADA Clearance Form and submit
it with the proposed agreement to his or her laboratory chief. At the NIH,
the CRADA must first be approved by both the lab chief and the Scientific
Director of the lab's research institute.\textsuperscript{32} The CRADA next must be cleared
by the OTT and the NIH legal counsel.\textsuperscript{33}

Approval by the OTT, the NIH legal counsel, the lab chief, and the
Scientific Director is all that is required if the CRADA does not address
the possibility of an exclusive license. Virtually all CRADAs contemplate
exclusive licensing and, therefore, must also be forwarded to the CRADA
Subcommittee of the NIH/ADAMHA Patient Policy Board for review.
Currently, the CRADA Subcommittee is appointed by the Chairman of
the Patent Policy Board and consists of senior scientists and administra-
tors (of different NIH/ADAMHA institutes and from the Director's office),
as well as legal counsel. Following CRADA subcommittee review, the
Chairman of the Patent Policy Board gives approval on behalf of the NIH
Director. The CRADA may be signed by the institute director and re-
turned to the collaborator for its signature once any required changes
have been made. The CRADA Subcommittee must transmit a written
explanation of changes or disapproval to the director of the laboratory
concerned.\textsuperscript{34}

III. LIMITATIONS ON TECHNOLOGY TRANSFER:
FEDERAL CONFLICT OF INTEREST LAWS

The described provisions of the Technology Transfer Act, while clear
enough on their face, nevertheless present interesting problems in stat-
tutory construction. Although legislative history suggests that Congress
did not intend the Act to change existing conflict of interest laws,\textsuperscript{35} ex-
perience with those laws reveals an indisputable conflict with the Tech-
nology Transfer Act.

\textsuperscript{32} The NIH currently has sixteen such institutes, centers, or divisions, such as
the National Cancer Institute and the National Center for Human Genetic
Research.

\textsuperscript{33} Legal counsel to NIH is provided through Attorney Advisors assigned by the
Office of General Counsel of the Department of Health and Human Services. This
office has developed its own list of provisions that a CRADA should contain,
including the specific contributions of each party, rights upon termination, and
a specific disputes resolution clause.

\textsuperscript{34} 15 U.S.C. § 3710a(c)(5). Under the terms of the Technology Transfer Act,
any disapproval or modification by the Agency director (or his or her designee)
must be accomplished within 30 days. \textit{Id}. The NIH treats this 30-day period as
beginning with the date of CRADA Subcommittee approval.

Cong. & Admin. News 3452 (Technology Transfer Act "make[s] no changes in
the conflict of interesting laws affecting federal employees or former federal em-
ployees"). The passage goes on to discuss former employees, suggesting that Con-
gress's focus was on those conflict of interest laws that preclude lobbying or
otherwise representing a party before any agency with respect to any matter on
which the employee worked while at NIH. \textit{See} 18 U.S.C. § 207; 45 C.F.R. § 73.735-
1401.
The activities of employees of the NIH are regulated by statutes which are applicable to all federal employees, regulations which are applicable to all HHS personnel, and internal guidelines that are issued by the NIH itself. The provisions impose both civil and criminal penalties on “public officials” who violate them. The NIH Manual also “states the policies and guidelines which govern outside work and activities requiring approval above the level of the BID Director.” These provisions are inapplicable to work performed pursuant to a CRADA because such work is, by definition, part of the employee’s “official duties” and hence, not “outside work.” However, as discussed later, the Manual is applicable to scientists who consult for private industry and, therefore, may have an impact on such a scientist’s freedom to enter into a CRADA. The discussion below summarizes these provisions and the limitations they place on NIH scientists engaged in CRADAs with private industry.

A. Criminal Statutes

Chapter 11 of Title 18 of the U.S. Code makes felonies of Bribery, Graft, and Conflicts of Interest. While the provisions of this chapter defining traditional bribery offenses are unlikely to be a source of concern to scientists or industry, other more general conflict of interest provisions do raise such concerns.

One criminal statute presents some danger of liability primarily in connection with the CRADA approval process. Under this provision, it is unlawful to give or receive any compensation for services rendered or to be rendered by an officer or employee of the United States in relation to any matter in which the United States has a direct and substantial interest. This provision would prohibit an NIH scientist from receiving anything of value for serving as a consultant or otherwise lobbying on behalf of a particular applicant for a CRADA. The penalty is an unspecified fine and/or up to two years in prison.

36 The statute defines “public official” to mean, among other things, “an officer or employee or person acting for or on behalf of the United States, or any department, agency or branch of Government thereof . . . in any official function, under or by authority of any such department, agency, or branch of government.” 18 U.S.C. § 201(a)(1). This definition obviously includes any scientist employed by the NIH.
38 Id. at § 2300-735-4(A) at 1.
39 See id. at § 2300-735-4(D)(1)(a) at 8; 15 U.S.C. § 3710a(a) (CRADA represents work “on behalf of” the sponsoring federal agency).
40 18 U.S.C. § 210(a), (b).
A related statute prohibits a government officer or employee from participating "personally and substantially" in, among other things, a "contract" or "other particular matter" in which the employee has a financial interest.\(^4\) The penalty is a fine not to exceed $10,000 and/or up to two years in prison.

Finally, it is clear that a private company may not circumvent any of the above provisions by offering a gift or salary "bonus" to the scientist for his or her additional value to the company. Government employees may not accept anything of value "for or because of any official act performed or to be performed," and the salary of a United States employee may be paid only by the United States.\(^4\)

B. HHS Regulations and NIH Rules

The HHS regulations add some specificity to these criminal provisions. For example, an HHS employee may not solicit or accept anything of monetary value from a person the employee knows or should know has sought or is seeking a contract, or a business or financial relation with the employee's "principal operating component" (i.e., an NIH institute or laboratory).\(^4\) The employee also may not participate personally and substantially as a government employee in any matter in which he or she has a financial interest.\(^4\) Violation of any HHS conflict of interest regulation may result, in addition to the criminal penalties described above, in administrative discipline, including admonishment, written reprimand, reassignment, suspension, demotion, and removal.\(^4\)

An additional regulatory provision and other related NIH Manual provisions should be noted primarily in relation to the NIH scientist's consulting role. The Manual permits employees to enter into consulting agreements with private concerns under certain conditions. The conditions include accepting no more than $25,000 annually, with no more than $12,500 from any individual company.\(^7\) NIH also prohibits scientists from consulting for the same company with which they are collaborating under a CRADA. This NIH policy is based on a regulation prohibiting consulting for companies "with which the official duties of the employee are directly related, or indirectly related if the indirect relationship is significant enough to cause the existence of conflict or apparent conflict of interest."\(^4\)

\(^{42}\) 18 U.S.C. § 208(a).
\(^{43}\) 18 U.S.C. §§ 201(c)(1), 209.
\(^{44}\) 45 C.F.R. § 73.735-501.
\(^{45}\) 45 C.F.R. § 73.735-801. This provision also applies to the other persons identified in 18 U.S.C. § 208(a).
\(^{46}\) 45 C.F.R. § 73.735.1201.
\(^{47}\) Manual, § 2300-735-4 at 12.
\(^{48}\) 45 C.F.R. § 73.735-704(a)(1) (emphasis added).
In addition, NIH employees must obtain approval of the proposed activity prior to entering into any consulting arrangement and must avoid any outside activity that would result in a conflict of interest, affect NIH's appearance of objectivity in the eyes of the biomedical community, or interfere with an employee's regularly assigned duty. As a consultant, an NIH scientist may provide a company with the benefit only of his or her "general knowledge and expertise." Information "concerning the employee's ongoing NIH research" may not be provided under a consulting agreement unless the information is also made available to the public on a nonexclusive basis. This situation is different under a CRADA, which by statute calls for the sharing of the scientist's research information with the company, and typically, by agreement, places certain confidentiality obligations on the scientist.

C. Tensions Between Technology Transfer and Conflict of Interest Laws

The provisions described will affect NIH scientists who are involved in CRADAs with private industry in two ways. One category of effects is represented by certain clear rules that, if followed, should not be cause for concern. A second category, however, is rife with potential for conflict.

1. Clear Rules

Under the plain language of the current law, no NIH scientist may accept anything of value as payment for helping a company obtain or negotiate the terms of a CRADA or as a reward or gratuity for participating in research under a CRADA. Similarly, a scientist must take care not to negotiate or arrange for future employment with any company with which he or she has a CRADA relationship. These restrictions apply despite the absence of any intentional violation on the part of the scientist as any violation (intentional or not) could result in criminal prosecution or administrative sanction.

These provisions do not appear to prohibit contributions of funds, personnel services, equipment, or other resources to the scientist's lab for research under a CRADA by a company in which the affected NIH scientist does not own any interest. Such items, if offered and accepted under a CRADA without corrupt intent, obviously are "provided by law for the..."
proper discharge of official duty” through the Technology Transfer Act. The only potential limitation might arise if such contributions were so tangential to the research that acceptance might present the appearance of a conflict of interest.

2. Potential for Conflict

a. “Financial Interests”

The CRADA provisions of the Technology Transfer Act do, however, present several other potential tensions with the conflict of interest laws. For example, under the conflict of interest laws, NIH scientists must avoid financial interests in any “matter” or “contract” in which the employee is involved “personally and substantially.” This language would seem to preclude a scientist from deriving any financial benefit from work performed under a CRADA. Yet, the Technology Transfer Act specifically calls for cash awards to federal employees who contribute to technology commercialization, and more importantly, requires that agencies share royalties from commercialized inventions with the inventor-employee. Since most CRADAs provide for assignment of patent ownership or licensing rights in inventions to the collaborating company, an NIH scientist receiving such royalties from an invention developed under his or her CRADA obviously will have a financial interest that otherwise would be prohibited by the conflict of interest laws.

In September, 1988, the United States Office of Government Ethics issued an advisory opinion that royalty sharing under the Technology Transfer Act does not give an employee a personal “financial interest” to which the conflict of interest laws are applicable. While this definitional dance clearly was intended by Congress, it does not alter the reality that royalty sharing and other financial rewards are in fact financial interests that could encourage scientists to focus on commercialization to the detriment of their other official duties or to favor companies with which a CRADA relationship exists.

b. Consultant - CRADA Issues

A related problem involving consultants has already arisen. The author has assisted companies wishing to establish CRADAs with NIH scientists who have existing consulting relationships with the company or with a related entity. For example, an NIH scientist had a consulting relation-

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58 45 C.F.R. § 73.735-701(b)(1).
59 18 U.S.C. § 208(a); 45 C.F.R. § 73.735-801(a).
ship with a health care venture capital fund and with one of its portfolio companies. At the time of the CRADA proposal, the portfolio company had re-financed and was less than half owned by the fund. In addition, only two of the fund’s directors continued to sit on the seven-person board of the company.

In the course of the scientist’s consulting relationship with the company, the parties determined that it would be to their mutual benefit to propose a CRADA related to the scientist’s existing work at NIH. The terms of the proposed CRADA provided that the CRADA would supersede the existing company consulting agreement, but not the agreement with the fund. Although the CRADA ultimately was approved, the scientist was required to resign from his consulting position with the fund, as well as with the company. Thus, the scientist was required to sacrifice a source of personal income in order to secure the advantages of a favorable research collaboration for his laboratory. Despite their obvious innocence, these events aroused sufficient notoriety to lead the NIH to sponsor a conflicts of interest retreat in December, 1988.

These events illustrate several of the tensions that exist between the Technology Transfer Act and the conflict of interest laws:

i. “Financial Interest”. First, a consulting relationship provides a scientist with financial remuneration. If the parties to a consulting agreement propose a CRADA, those consulting fees could be considered compensation for obtaining the scientist’s cooperation in preparing and proposing the CRADA. Since the CRADA represents the personal and substantial involvement of the scientist in a “particular matter,” consulting fees paid even prior to proposal and adoption of the CRADA could be construed to represent a prohibited “financial interest” in the business of the company.

Thus, any time a company and one of its consulting scientists decide to replace their consulting relationship with a CRADA, an issue will arise concerning the presence of a conflict of interest. In the absence of an NIH policy or HHS regulation, this issue will be resolved on an ad hoc and potentially arbitrary basis by one or more of the numerous NIH officials who have the opportunity to review the CRADA.

ii. Related Companies. Second, where one or more biotechnology companies has received its initial funding through a single venture capital fund or other large investor, a scientist with a CRADA with one company could be prohibited from consulting for the fund or another company under the HHS regulation which would prohibit consulting for organizations with which the official duties of the scientist (i.e., the CRADA) are sufficiently related to cause the appearance of a conflict.62 In the absence of a policy or regulation, identifying the point where such a relationship becomes too indirect to create even the appearance of conflict is determined on a case-by-case basis.

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62 45 C.F.R. § 73.735-704(a)(1).
IV. Options for Resolution of Tensions

The Technology Transfer Act instructs each agency which implements CRADA or licensing authority to review its employee standards of conduct to ensure that they adequately establish guidelines for situations likely to arise. If unable to resolve potential conflicts within the existing statutory framework, the agency is instructed to propose necessary changes to the appropriate congressional committee. This final section suggests certain options for resolving some of the tensions described above. These options may be considered by the NIH as either changes in policy or regulation, or as proposed legislation.

As may be seen from the above discussion of tensions, the Technology Transfer Act embodies a substantially revised congressional attitude toward the participation of government scientists in the commercial endeavors of private industry. Certain personal financial interests that are clearly prohibited by existing conflict of interest laws are encouraged, and even mandated, under the Technology Transfer Act.

It is apparent then that some revision in current conflict of interest statutes, HHS regulations, or NIH policy, is required. The federal conflict of interest provisions applicable to HHS employees is “[t]o assure that the business of [HHS] is conducted effectively, objectively, and without improper influence or the appearance of improper influence ... [by assuring that employees avoid] conflicts of private interests with public responsibilities.”

The financial incentive provisions of the Technology Transfer Act suggest that, at least in part, a CRADA represents a confluence, not a conflict, of private interests with public responsibilities. The Office of Government Ethics’ decision that royalty-sharing with a CRADA scientist is not a prohibited financial interest illustrates that the government shares this view. As long as new regulations or policies appear unlikely to “improperly influence” the course of NIH research, or otherwise to interfere with the “efficiency” and “objectivity” of NIH, they will satisfy the conflict of interest laws. Where an accommodation cannot be reached under existing law, the NIH and HHS have a statutory and moral obligation to recommend appropriate amendments to the Congress.

The following paragraphs briefly suggest options for resolving some of the most prominent of these tensions between the Technology Transfer Act and the conflict of interest laws.

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65 45 C.F.R. § 73.735-101.
A. Redefinition of Prohibited “Financial Interest”

Under current law, an NIH scientist may not receive cash or property or hold stock or other “financial interests” that would result from a “particular matter” in which the scientist is engaged. Since the Technology Transfer Act requires that a scientist participating in a CRADA receive a portion of the royalties on any resulting invention, it is clear that such royalties cannot be a prohibited financial interest. This result is mandated by statute and has been accomplished by the Office of Government Ethics ruling.

However, the principle recognized by this Technology Transfer Act provision is that federal law no longer prohibits all “financial interests” in the fruits of private industry collaboration. Given this fact, it seems appropriate for the NIH (by policy) or HHS (by regulation) to promulgate a narrower definition of “financial interest” for purposes of inventions resulting from a CRADA. Such a definition could permit any such interest that is less likely than royalty-sharing to interfere with the purposes of the NIH by placing undue pressure on scientists to point their research in commercial directions.

In determining whether a particular financial interest is more or less likely than royalty-sharing to entice an NIH scientist away from his or her fundamental mission of research, it may be useful to construct a hierarchy of effects that various such interests are likely to have on scientists. At one extreme there would be an interest that depends upon the profitability of the collaborating company. This category would include, among other things, stock or stock options. Incentives such as these seem most likely to lead a scientist to channel his or her research in a direction favored by the company.

At the other extreme would be financial interests that have little or no dependence upon the profitability of collaborating companies. This category would include interests such as a fixed bonus to be awarded to a collaborating scientist. Such a bonus would be least dependent on the profitability of the private company if it were administered by the NIH out of a pooled account established by all companies collaborating with a particular laboratory or institute. Even if the supplement were paid directly by the collaborating company, the scientist’s interest would solely depend on the continued existence of the company, not on its greater or lesser profitability.

Royalty-sharing falls somewhere between these two extremes, but it falls closer to the top, i.e., to the profitability-dependent end of the hierarchy. Royalty payments typically are a percentage of gross sales of a product and, therefore, the amount varies in proportion to how much profit the particular invention generates for the company. On the other hand, royalty payments, like salary supplementation, will cease altogether only if the company fails or stops making the product.

What is clear from this discussion is that a supplemental salary is less likely than royalty-sharing to induce a scientist to direct his or her re-
search in favor of a collaborating company. As noted above, a federal statute prohibits the payment of a government salary by a private company. However, given the royalty-sharing provision and underlying policy of the Technology Transfer Act, the NIH might lawfully be permitted without legislative action to establish a pool of funds from collaborating companies and use it to supplement the salaries of scientists participating in a CRADA. This approach has been used for years by many major universities to supplement the income of physicians and scientists. Even if such a program were not permissible without legislation, the NIH would clearly be within its authority under the Technology Transfer Act to propose such legislation to Congress.66

B. Consultant-CRADA Issues

The issues presented by an NIH scientist who, in the course of a consulting arrangement, seeks to begin developing a CRADA proposal with the private company, are somewhat more complex. This creates issues concerning both financial interests and the sharing of information.

1. “Financial Interests”

When an industry consultant and his or her company develop a CRADA proposal, the issue presented is the extent to which consulting fees might be viewed as a prohibited “financial interest” under the conflict of interest laws. Perhaps the easiest solution, and one that probably could be accomplished by NIH policy or HHS regulation, is a redefinition of “financial interest” to exclude consulting fees paid prior to implementation of the CRADA.

Another solution would be to retain the current conflict of interest rule prohibiting an NIH scientist from discussing non-public ongoing research in the course of industry consultation. Application of this rule would require a scientist to terminate his or her consulting agreement at the moment a decision is made to pursue a CRADA proposal. This solution has the twin advantages of not disrupting existing NIH policy and of being self-policing. Since NIH scientists currently are trusted not to divulge information on ongoing research during a consulting relationship, there is no apparent reason why they should not be trusted to exercise the same good judgment prior to beginning CRADA negotiations.

The least desirable solution would be for NIH to impose a waiting period after a consulting agreement before the consulting scientist could work with the same company under a CRADA. This solution is least desirable because it would postpone valuable research collaboration for any scientist who, ironically, has determined to sacrifice the personal financial benefit of a consulting fee in favor of the NIH/public benefit of a CRADA.

2. Related Companies

It is NIH policy to prohibit scientists from consulting for a private company while simultaneously working with that company under a CRADA because such work, by definition, is "directly related" to the scientist's "official duties." In addition, any consultation for the same company, even in an area outside the scope of the CRADA, is considered to be a sufficiently "significant" indirect relationship to cause the appearance of a conflict.

However, this reasoning is not persuasive as applied to a scientist who consults for a venture capital fund that provided the initial financing for a company with which the scientist wishes to establish a CRADA ("Company A"). The reasoning is still less compelling if the same scientist wishes to consult instead for a different company initially financed by the fund ("Company B"). In neither case does the scientist's consulting have any "direct" relationship to his or her official duties. The only question is whether there is an "indirect" relationship significant enough to create an apparent conflict.

Neither the NIH Manual nor HHS regulations define what is meant by the "appearance" of a conflict of interest. In the absence of any such direct authority, the closest analogous principles of law would seem to be those requiring a judge to recuse himself or herself from hearing a case that would create the appearance of impropriety. The classic formulation of this standard calls for disqualification where the judge's impartiality might reasonably be questioned.67

The test of reasonableness is whether an objective, disinterested observer, fully informed of all the facts, would entertain significant doubt that justice would be served absent recusal.68 Adapting this standard to the situation at hand, the question would be whether a reasonable, informed observer would entertain a significant concern that an NIH scientist would be tempted by a consulting fee to alter the direction of research under a CRADA with Company A, in order to benefit the entity paying the fee (the fund or Company B), in a manner inconsistent with his or her official duties.

The answer to this question will depend on the specific factual situation. Thus, a comprehensive statement of general principles for purposes of NIH policy or HHS regulations might be difficult to formulate. However, certain basic principles should not be hard to articulate.

It seems clear that an appearance of conflict could reasonably be found only if the directors of the fund were in a position to set the scientific policies of the company with the CRADA (Company A). This is so because unless the fund had this sort of control, the company's scientific interests would be likely to diverge from those of the fund. The NIH scientist thus

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68 E.g., Pepsico, Inc. v. McMillan, 764 F.2d 458, 460 (7th Cir. 1985).
could not focus his or her work in a direction desired by the fund. In this typical situation then, the fund's interest in the direction of research under a CRADA is sufficiently remote that an informed observer could not reasonably entertain significant concern that payment of a consulting fee by the fund would tempt a scientist to move that research in a direction chosen by the fund.

There is still less appearance of conflict where the NIH scientist wishes to consult for Company B while participating in a CRADA with Company A. Again, as long as Company B is not in a position to control the scientific interests of the company with the CRADA (either directly, or by virtue of being itself controlled by the fund), a consulting fee from Company B does not present any reasonable appearance of a conflict of interest with the official duties of the scientists under the CRADA.

In formulating CRADA regulations or policy then, HHS or NIH could reasonably adopt a standard that permits a scientist with a CRADA with Company A to consult simultaneously for the venture capital fund that provided its initial financing, unless the fund exercises control over the scientific activities of the company. In the case of consulting for Company B, such consulting should be permitted unless the fund controls both entities. An appropriate and easily enforced standard for control would be to hold a majority of Company A's stock or a majority of the seats on its board of directors.

V. CONCLUSION

Like universities in the 1970s, federal laboratories such as the NIH now face the daunting but important challenge of cooperating with private industry to bring the wealth of their scientific knowledge and experience into the stream of commerce. The task is daunting because it requires a careful balancing of potential competing interests: the scientist's need for freedom to pursue new directions; the government's need to assure the public benefit of inventions derived from public funds; and industry's need to assure a reasonable return on its investments by protecting its trade secrets and proprietary information from its competitors. The task is made more daunting by the restrictions placed on financial compensation of NIH scientists, as compared with their counterparts in academia and private industry. Yet, meeting the challenge is important because such a sharing of knowledge and resources presents tremendous potential for rapidly reducing scientific advances from laboratory experiments to products and processes that will aid in the treatment of disease.

The CRADA process begun by the Technology Transfer Act creates the framework for such developments. Important cooperative efforts are already under way at the NIH. But much remains to be done, specifically in the area of conflicts of interest. The NIH should begin by adopting policies and working with HHS officials to develop regulations that give full range to the employee financial incentives already authorized by the Technology Transfer Act, while protecting the legitimate interest of academic freedom and assuring a public benefit from public funds.
Redefining prohibited "financial interests" to exclude certain rewards resulting from CRADA research is one possible beginning that might be accomplished without legislative action. Other financial incentive programs that present less of a risk of conflict of interest than the royalty-sharing and reward provisions of the Technology Transfer Act might also be permissible by NIH policy or HHS regulation. In addition, a set of rules covering typical situations where CRADAs and consulting agreements might be thought to overlap would be beneficial. Of course, any such plans, even ambitious ones, could be proposed to Congress with the NIH's endorsement.

Armed with the mandate given it by the Technology Transfer Act, the NIH should begin collaborating with industry not only to develop new biotechnology, but to develop new policies that will encourage more scientific cooperation by easing the tensions between the technology transfer and conflict of interest laws. Ultimately, the beneficiaries of both forms of collaboration will be those whose illnesses are cured by the resulting inventions.