Reports of the NIH Panels on

Cooperative Research And Development Agreements

Perspectives, Outlook, and Policy Development

July 21, 1994 and
September 8, 1994

National Institutes of Health

Reports of the NIH Panels on

COOPERATIVE RESEARCH AND DEVELOPMENT AGREEMENTS

Perspectives, Outlook, and Policy Development

July 21, 1994, and September 8, 1994

National Institutes of Health

December 1994

Table of Contents

Overview

The Federal Technology Transfer Act of 1986 (FTTA) authorizes Federal laboratories to enter into cooperative research and development agreements (CRADAs) with private businesses and other entities. Between 1986 and 1993, the National Institutes of Health (NIH) executed a total of 206 CRADAs, most of them with industrial partners. As NIH's experience with CRADAs has grown, several issues of concern have developed, leading the agency to seek advice for the further development of appropriate policy.

On July 21, 1994, NIH convened a panel of experts, including scientists and administrators from Government, industry, and academia, to address three central issues: (1) the scope of research and license rights under a CRADA, (2) fair access to CRADA opportunities, and (3) the so-called reasonable pricing clause. The third issue elicited by far the most discussion, and accordingly, NIH convened a second forum on September 8, 1994, to solicit additional advice and recommendations from primary consumers and other public interest groups. CRADA Forum II focused on the reasonable pricing clause and questions about the appropriate return on the Government's investment in biomedical research: (1) what kind of return is appropriate, (2) how much return is appropriate, and (3) how NIH should balance public payback and new product development.

Because of the overlap in the focus of these two panels, their reports are included in this single document along with supporting documents and background materials that were considered by the panels. These materials will be provided to the Advisory Committee to the Director, NIH, for consideration at its meeting on December 1–2, 1994. NIH will then be in a position to consult

with the Assistant Secretary for Health, Department of Health and Human Services, and other key policymakers to decide what options best promote NIH's dual missions—pursuing new biomedical knowledge and facilitating technology transfer—while maximizing the public investment in biomedical research.

CRADA Forum I

July 21, 1994

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
Bethesda, Maryland 20892

OCT 2 4 1994

Harold Varmus, M.D.
Director
National Institutes of Health
9000 Rockville Pike
Bethesda, MD 20892

Dear Dr. Varmus:

On behalf of the Co-Chair, Dr. Robert Nussenblatt, and the Panel members, I am pleased to transmit to you the final report of the first ad hoc consultant group to the Advisory Committee to the Director, NIH, on "NIH Collaborative Research and Development Agreements (CRADAs): Perspectives, Outlook, and Policy Development".

The Panel's mission was to assess three aspects of present CRADA policies: 1) the scope of the research and license rights under a CRADA; 2) fair access to CRADA opportunities; and 3) reasonable pricing clause. In carrying out its charge, the Panel addressed a number of important questions, including: what are the different types of research collaborations that are conducted under the CRADA mechanisms; should fair access, reasonable pricing, and other administrative policies be differentially applied to the different types of CRADAs; is it appropriate to negotiate licensing terms at the inception of the CRADA, before it is known what technology will be invented and how it can be best licensed to further the public's interest; how should NIH preserve the fundamental nature of the research collaboration, which arise from the knowledge and the relationships of the scientists, while ensuring fair access to CRADA opportunities for U.S. businesses; and should the "reasonable pricing" clause be used by NIH as a mechanism to reflect the public investment in NIH-supported research in the products brought to market through NIH/private sector collaborations.

This Report sets forth the findings and recommendations of the Panel, which are based upon presentations from invited speakers, testimony from public witnesses, and the deliberations of the Panel on July 21, 1994. The Panel trusts that these recommendations will be useful in improving NIH CRADA policies and ensuring that national health goals continue to be enhanced by the research conducted at the NIH.

Sincerely,

Michael M. Gottesman, M.D.
Panel Co-Chair and
Acting Deputy Director for
Intramural Research

CRADA Forum I Panel Members

Chairpersons

Dr. Michael Gottesman
Acting Deputy Director for Intramural Research
Bldg. 1, Room 114
National Institutes of Health
Bethesda, MD 20892

Dr. Robert Nussenblatt
Scientific Director
National Eye Institute
Bldg. 10, Room 10N/202
National Institutes of Health
Bethesda, MD 20892

Members

Mr. Paul Armond
Senior Project Analyst
Pfizer, Inc.
Eastern Point Rd.
Groton, CT 06340

Dr. James Barrett
Chief Executive Officer
Genetic Therapy, Inc.
938 Clopper Rd.
Gaithersburg, MD 20878

Dr. Michael Blaese
Chief, Clinical Gene Therapy Branch
National Center for Human Genome Research
Bldg. 49, Room 2A03
National Institutes of Health
Bethesda, MD 20892

Mr. Steven Carter
Vice President of Research and Development
Bristol Myers Squibb
P.O. Box 4000
Princeton, NJ 08543-4000

Mr. Allan Fox
Fox, Bennett and Turner
750 17th St., NW.
Suite 1100
Washington, DC 20006

Dr. Edwin Gemrich
Senior Contracts Manager
Research Contracts Division
Upjohn Company
7000 Portage Rd.
Kalamazoo, MI 49001

Dr. Brian Mahy
Director, Division of Viral and Rickettsial Disease
Centers for Disease Control and Prevention
Mail A30
Atlanta, GA 30333

Dr. Harry Malech
Deputy Chief
Laboratory of Host Defenses
National Institute of Allergy and Infectious Diseases
Bldg. 10, Room 11N113
National Institutes of Health
Bethesda, MD 20892

Dr. Steven Paul
Vice President for CNS Discovery Research
Eli Lilly and Company
Lilly Corporate Center
Indianapolis, IN 46285

Dr. Dinah Singer
National Cancer Institute
Bldg. 10, Room 4B17
National Institutes of Health
Bethesda, MD 20892

Dr. Alison Taunton-Rigby
President and CEO
Mitotix
One Kendell Square
Bldg. 600
Cambridge, MA 02139

Dr. William Terry
Senior Vice President of the Brigham Medical Center
Brigham and Women's Hospital, Inc.
75 Francis St.
Boston, MA 02115

Ms. Mary Jo Veverka
Deputy Commissioner for Management and Systems
U.S. Food and Drug Administration
Room 14-57
5600 Fishers Ln.
Rockville, MD 20857

NIH Liaison

Ms. Daryl A. (Sandy) Chamblee, J.D.
Acting Deputy Director for Science Policy and Technology Transfer
Bldg. 1, Room 103
National Institutes of Health
Bethesda, MD 20892

Ms. Barbara McGarey, J.D.
Deputy Director
Office of Technology Transfer
National Institutes of Health
6011 Executive Blvd., Suite 325
Rockville, MD 20852

CRADA Forum I: Report of the Panel

Executive Summary

The Federal Technology Transfer Act of 1986 (FTTA) authorizes Federal laboratories to enter into cooperative research and development agreements (CRADAs) with private businesses and other entities. Between 1986 and 1993, the National Institutes of Health (NIH) executed a total of 206 CRADAs, most of them with industrial partners. As NIH's experience with CRADAs has grown, several issues of concern have developed, leading the agency to seek advice for the development of appropriate policy. On July 21, 1994, NIH convened a panel of experts, including scientists and administrators from Government (primarily NIH), industry, and academia, to address three central issues:

1. the scope of research and license rights under a CRADA,
2. fair access to CRADA opportunities, and
3. the so-called "reasonable pricing" clause.

With regard to the first issue, panelists concurred that the agreement (including the research plan) must be drawn as clearly and carefully as possible. Some industry panelists expressed a preference for a broad research plan, while NIH panelists felt that the plan should be narrow enough to protect the scientific freedom of Government investigators. Similarly, some industry panelists felt that the option to negotiate for a license on the resulting technology was insufficient incentive; they would prefer an option on the license itself. Several NIH panelists pointed out the difficulty and risk of negotiating a license before it is known what intellectual property might be developed. The panel did reach consensus on three points: (1) that the scope of the research should be

narrow, although some flexibility was needed on a case-by-case basis; (2) that NIH should not require a commercialization plan at the time the CRADA is negotiated; and (3) that NIH should consider revising its current policy of prohibiting the up-front grant of a license within the CRADA.

The panel also supported the concept of fair access to CRADA opportunities. They concluded that existing Public Health Service (PHS) guidelines ensure reasonable and appropriate access to the overall CRADA process, and that NIH technology transfer personnel conduct a wide range of activities designed to identify CRADA opportunities. One NIH panelist presented the view that there is no legal requirement to ensure equal access for every potential partner to every potential CRADA. However, the panel also recommended that NIH have a rational and defensible basis for the final choice of collaborator or collaborators in any given CRADA.

The reasonable pricing clause proved to be far more contentious. Some panelists from industry opposed its inclusion in any form, claiming that it poses a disincentive to industry. Some NIH investigators reported that potential collaborations are not pursued because industrial collaborators object to the clause. Other panelists pointed out that the clause is neither the best nor the only way to address the pricing of new technology, nor is it necessary to ensure a fair return on the Government's investment in biomedical research. Some public interest groups also opposed the clause because it might delay the availability of new drugs, but one speaker felt that it helped to ensure that new drugs would be available at a fair price. Several panelists pointed out that a number of other protections are already included in technology licenses, while other panelists suggested several additional mechanisms that might be used to ensure that the public investment in the collaborative research was adequately reflected without erecting barriers to collaborative research. The mechanisms suggested included requiring "accessibility plans," removing the clause from some but not all CRADAs, and reserving the clause for unique "breakthrough" drugs for which there is no effective substitute.

Introduction

Both the health of the American people and the competitiveness of U.S. industry can be greatly enhanced if new technologies that are developed in PHS laboratories are commercialized by American companies. To encourage commercialization, the FTTA authorizes Federal laboratories to enter into CRADAs with numerous entities, including private businesses. Under a CRADA, companies may provide funds, personnel, services, and property in support of collaborative research with PHS scientists. Federal laboratories may provide all of these resources except funds, and the Government may also grant to their

collaborators, in advance, intellectual property rights on any invention made by a Federal employee under the terms of the agreement. The FTTA explicitly gives preference to small businesses and to business units located in the United States that agree to manufacture the resulting products substantially in the United States.

Since 1986 through fiscal year (FY) 1993, NIH has executed a total of 206 CRADAs, most of them with industrial partners. These agreements have covered a broad range of research, from the initial application of basic discoveries to advanced clinical trials. In some cases, because of the nature of the research or the intellectual property position of the collaborator, no invention (and hence no new intellectual property) was expected or likely to result from the research. In other cases, new intellectual property was developed during the collaboration. In still others, NIH had extensive intellectual property protection on a technology that was licensed by a CRADA collaborator and further developed under the CRADA.

As the Government's experience with CRADAs has grown, several issues of concern have developed, prompting NIH to seek advice for the development of appropriate policy. On July 21, 1994, NIH convened a panel of experts in a public forum to discuss issues related to CRADAs. The 15-member panel was cochaired by Dr. Michael Gottesman, Acting Deputy Director for Intramural Research, and Dr. Robert Nussenblatt, Scientific Director, National Eye Institute, NIH. Other members of the panel included executives from large and small biotechnology and pharmaceutical companies, PHS scientists, and Government and university administrators. Forum I focused on three central issues:

1. *Scope of research and license rights under a CRADA.* What types of research are conducted under the CRADA mechanism, and how do they differ with regard to the activities and contributions of each party? Should public policy and CRADA contracts reflect these differences? How can the research plan ensure flexibility for following up unexpected results? When is it appropriate to negotiate licensing terms at the inception of the CRADA—that is, before anyone knows what technology might be invented?

2. *Fair access to CRADA opportunities.* How should NIH preserve the fundamental nature of the research collaboration, which arises from the knowledge and relationships of the scientists, while ensuring fair access to CRADA opportunities for U.S. businesses? Does industry have difficulty obtaining information or access to CRADA opportunities?

3. *Reasonable pricing clause.* Given the mandates of NIH to support research and to transfer the results of that research to advance the

public health, should the reasonable pricing clause be used to reflect the public investment in NIH-supported research when products are brought to market through CRADAs? What other mechanisms are available to NIH to achieve this goal?

This report presents the deliberations, findings, and conclusions of the panel with regard to these three issues and the CRADA process in general.

Issue 1: Scope of Research and License Rights under a CRADA

Scope of Research

Panelists concurred that the agreement (including the research plan) must be drawn as clearly and carefully as possible. In particular, the research plan should delineate a finite area of investigation and the precise limits of the collaboration; the research plan should specify exactly what each party will be doing within the collaboration. Some panel members from industry favored more broadly defined research plans in order to maximize the scope of license rights obtained from their investment in the collaboration. NIH panelists felt that the scope should be narrow enough to ensure that the collaboration does not unreasonably limit the ability of NIH investigators to share scientific information, pursue new research directions, or enter into additional CRADAs with other collaborators. In general, NIH prefers applied research rather than basic research as the subject matter for CRADA collaborations. However, one panel member from industry noted that the FTTA contains no such preference and urged that NIH not limit its CRADA collaborations to applied research. Panel members agreed that delineating the scope of the research plan would have to be addressed on a case-by-case basis; that NIH and industry would have to be flexible in negotiating appropriate scope; and that both sides of the collaboration should acknowledge the tension between their respective interests with regard to defining the scope of research.

Scope of License Rights

Consistent with the FTTA, NIH CRADAs provide an option to negotiate an exclusive or nonexclusive license for the commercialization of inventions made by NIH employees in the conduct of the CRADA ("CRADA inventions"). The advantage the company realizes from this provision is that the collaborator can negotiate licenses outside the competitive process that otherwise governs the licensing of Government technology; CRADA license negotiations also tend to

be faster and simpler. Industry panelists expressed concern that an option to *negotiate* for a license is not always sufficient to allow companies to raise necessary capital; they would prefer an option on the license itself.

Several NIH panelists pointed out the difficulty and risk of negotiating the terms of a license, particularly an exclusive license, before it is known what intellectual property (if any) will be developed, and what the best way of commercializing it will be. In addition, certain CRADA inventions, such as research tools, may not be appropriate for exclusive licensing; to grant such a license at the time of the CRADA would frustrate NIH's desire to encourage the wide dissemination of such technologies. Panel members from industry acknowledged these concerns but pointed out that industry faces and resolves similar issues in agreements with universities and other companies, to the extent possible, through thoughtful drafting of each particular agreement. Panelists discussed various ways to address these concerns with the CRADA mechanism, including the following:

- reversion of license rights to NIH if there is lack of commitment or inadequate development of a CRADA invention;
- exemption of research tools from the license option or particular clauses requiring nonexclusive licensing;
- clauses requiring sublicensing in particular circumstances; or
- specification of royalty ranges and caps for particular types of technologies.

Panelists from NIH pointed out that providing an option to a license in the CRADA could also have an adverse effect on small businesses, which would have to demonstrate their ability to develop commercially a wide range of potential inventions. Currently, a prospective CRADA partner need only show itself capable of performing the research delineated in the research plan. If a CRADA invention is made and the collaborator decides to negotiate a license, the collaborator must show at that time its ability and commitment to commercialize the subject technology. Collaborators that are unable or unwilling to commercialize the technologies will not obtain the rights, and NIH will consider the technology available for competitive licensing as part of the general intramural research portfolio. Panel members from industry acknowledged this potential problem for small businesses.

The panel agreed that NIH should not adopt a policy of *requiring* detailed commercialization plans at the time a CRADA is negotiated. However, the panel also agreed that NIH should consider revising its current policy of

prohibiting the up-front grant of an option to a license within the CRADA. The panel did recognize, however, the difficulty of arriving at licensing terms at a stage in which the nature of a potential invention is not clear and the relative contribution of the CRADA partners cannot be fairly evaluated.

Issue 2: Fair Access to CRADA Opportunities

The panel supported the concept of fair access to CRADA opportunities, but it pointed out that the CRADA is not subject to the normal Federal procurement process. Specifically, the FTTA does not require that CRADAs be competed, although it does give "consideration" to small businesses and "preference" to business units that are located in the United States and will substantially manufacture the resulting products domestically. Existing PHS guidelines ensure fair and appropriate access to the overall CRADA *process*, but there is no requirement to ensure equal access for every potential partner to every potential CRADA.

For example, many CRADAs grow out of preexisting relationships and informal exchanges between Government scientists and their colleagues in the private sector. In other cases, the industrial partner may bring to the collaboration a unique resource—in some cases a proprietary drug—or a unique form of expertise. In such cases there may be no need to advertise; there may in fact be no other potential partner. When NIH is actively seeking a partner to advance or exploit its research, on the other hand, then it is both appropriate and advantageous to advertise the cooperative opportunity in order to help find the best partner or partners for each particular case. The panelists agreed that all potential collaborators should have access to CRADA opportunities, in general, and that there must be a rational and defensible basis as well as appropriate documentation for the final choice of collaborator(s) in any given CRADA.

The panel also found that NIH technology transfer personnel are engaged in a wide range of activities designed to identify CRADA opportunities and respond to requests from both private companies and intramural investigators. Opportunities for CRADAs are advertised in appropriate publications. In addition, all of NIH's research activities, research results, and patent applications are available electronically through the Internet system.

Issue 3: Reasonable Pricing Clause

In 1989 PHS, the parent organization of NIH, adopted the following policy statement with respect to the pricing of products developed in part through research at intramural NIH laboratories:

> DHHS has responsibility for funding basic biomedical research, for funding medical treatment through programs such as Medicare and Medicaid, for providing direct medical care, and more generally, for protecting the health and safety of the public. Because of these responsibilities and the public investment in the research that contributes to a product licensed under a CRADA, DHHS has a concern that there be a reasonable relationship between the pricing of a licensed product, the public investment in that product, and the health and safety needs of the public. Accordingly, exclusive commercialization licenses granted for NIH/ADAMHA intellectual property rights may require that this relationship be supported by reasonable evidence.

This statement of PHS policy is contained in Appendix A of the model PHS CRADA. Section 16 of the main body of the model PHS CRADA contains a slight restatement of this policy.[1] If intellectual property is created by PHS employees under a CRADA, and the outside partner exercises its right under the CRADA to negotiate an exclusive license, the pricing provision of the model PHS exclusive license would be applicable. The model PHS exclusive license contains the following pricing provision:

> **DHHS** has responsibility for funding basic biomedical research, for funding medical treatment through programs such as Medicare and Medicaid, for providing direct medical care and, more generally, for protecting the health and safety of the public. Because of these responsibilities, and the public investment in the research that culminated in the **Licensed Patents Rights, PHS** may require **LICENSEE** to submit documentation in confidence showing a reasonable relationship between the pricing of a **Licensed Product,** the public investment in that product and the health and safety needs of the public. This paragraph shall not restrict the right of **LICENSEE** to price a **Licensed Product** or **Licensed Process** so as to obtain a reasonable profit for its sales or use. This Paragraph 5.03 does not permit PHS or any other government agency to set or dictate prices for **Licensed Products** or **Licensed Processes.**

---

[1]"NIH/ADAMHA have a concern that there be a reasonable relationship between the pricing of a licensed product, the public investment in that product, and the health and safety needs of the public. Accordingly, exclusive commercialization licenses granted for NIH/ADAMHA intellectual property rights may require that this relationship be supported by reasonable evidence."

A major factor leading to the adoption of these pricing provisions by the PHS was congressional and public reaction to the launch price of $8,000 to $10,000 per patient per year for azidothymidine (AZT), the drug for acquired immunodeficiency syndrome (AIDS) approved by the Food and Drug Administration in 1987. AZT, the first drug found to hinder replication of human immunodeficiency virus, was marketed by the Burroughs-Wellcome Company and was developed with the involvement of the National Cancer Institute, but not under the provisions of a CRADA. The PHS pricing provisions respond to a concern that, to the extent practicable, medical advances developed in part with public funds be available to the public at reasonable cost.

Panelists' Concerns

One panelist from a pharmaceutical company suggested that pricing might be a reasonable topic of *negotiation* in this sort of very late stage project, in which the Government has already identified a potentially marketable product, but that the clause itself should not be part of most CRADAs. Other panelists from industry were opposed to including the reasonable pricing clause in any form, claiming that it poses a disincentive to industry by its mere presence in the CRADA. Several companies represented on the panel have stated that they will no longer sign any agreements that include a reasonable pricing clause. Other industry panelists stated that the drug development process is inherently risky and that the possibility of Federal review of prices of those few successful products out of the many under test has made potential investors reluctant to invest in pharmaceutical or biotechnology firms. NIH scientists reported that many potential CRADAs are not pursued because potential partners object to this clause.

Public interest groups expressed both support for and opposition to the reasonable pricing clause. One speaker believed that some sort of protection is needed to ensure that new drugs are available at a fair price and that the Government gets a reasonable return on its investment in biomedical research. However, other speakers expressed concern that the clause may backfire if it proves to be an impediment to CRADAs and, indirectly, to the development of important therapeutics. Low prices per se are not the only "interest" of either the Government or the consumer. In many cases, the broader interests of society are best served by ensuring that new and more effective drugs are researched and developed.

Industry panelists noted, and NIH panelists agreed, that the FTTA does not require NIH to address pricing as part of its technology transfer mandate. The FTTA does not address the issue of pricing, and PHS (with NIH as its lead agency for technology transfer activities) is the only Federal biomedical agency

that has addressed the issue in its CRADA policy or model agreement.[2] As a result, panel members from both industry and academia advised that the reasonable pricing clause has become a barrier to technology transfer and that PHS and NIH should consider removing the clause in order to promote the goals of the FTTA and to ensure the development and commercialization of new medical technologies.

A number of additional concerns about the PHS pricing clause were cited, primarily by panelists from industry, including the following:

- *The PHS pricing clause is the wrong way to address the pricing of new technologies.* The cost of new technologies such as new drugs, and of health care generally, is a valid and serious concern but requires a comprehensive approach. However, the issue of how best to develop new products, including drugs, should be segregated from the issues of how to fairly price and pay for these products. This narrow class of research and development agreements—CRADAs and exclusive licenses between NIH and industry—is the wrong place to address pricing, which is a cost and access issue. As a biomedical research agency, NIH is not within its mission or its competence in evaluating or regulating drug prices. Congress, perhaps within the context of the broad, ongoing debate on how to reform the health care system, should carefully weigh these compelling interests and fashion a solution that preserves the incentives for the private sector to develop new technologies while providing mechanisms to ensure that these breakthrough products reach the American public at a reasonable cost.

- *The PHS pricing clause has proven to be a major barrier to some potentially important collaborations.* About 10 firms have indicated an unwillingness to enter into CRADA and licensing agreements with NIH that contain the reasonable pricing clause. This apparent reluctance may also extend back to the informal relationships out of which such agreements normally grow and to materials transfer agreements, which do not normally even involve cooperative research. NIH should do more than eliminate barriers to collaborative research; it should provide more incentives. Already there are important areas of research—such as chemopreventatives, addictive diseases, and antimalaria and antiepilepsy treatments—where industry needs incentives to develop and market drugs arising from new technology development. Industry believes the clause adds to the uncertainty about drug

[2] In addition to PHS, only the U.S. Department of Interior's Bureau of Mines has implemented a pricing clause, which appears to have been explicitly modeled on that of PHS.

development at a time when the pharmaceutical market is changing profoundly. With 1,300 small biotechnology firms now competing to develop and market new drugs, success is increasingly uncertain. The current debate over health care reform also introduces additional uncertainties. Less than one promising drug in a thousand ever gets approved and marketed, and only a third of those ever earn back the company's investment. Under the patent system, it is believed that one result of monopolistic pricing of an individual product in a highly competitive marketplace will be to stimulate new and innovative research on competing products that might be more effective or affordable, or both.

- *The PHS pricing clause is not necessary to ensure a fair return on the Government's investment.* It can be argued that the Government *already* gets a fair return on its investment in the form of new product development, faster product development, and royalties on licenses for drugs and other products that result from Government inventions. In cases of limited Government involvement in product development, the clause should not be triggered. In the kind of early-stage research pursued under many CRADAs, the Government's financial investment and intellectual contribution can be relatively minor in comparison with the involvement of industry in bringing the drug to market. In such cases, the Government's involvement in the research may not warrant subsequent Government scrutiny in pricing.

- *The clause is vague and difficult to enforce.* "Reasonable" does not always mean "cheap" or "inexpensive." In some cases a fair and reasonable price—a price that reflects the size of the company's investment and the risk of the undertaking—may appear very expensive indeed. The FTTA does not expressly authorize the pricing clause or specify any enforcement mechanism. The clause does not specify what standards should be employed to determine whether there is a "reasonable relationship" among the price of a product, the Government's involvement in the product's development, and the health and safety needs of the public. In addition, the clause does not establish any enforcement procedures and sanctions to apply in cases in which a "reasonable relationship" is not established.

Alternatives to the Reasonable Pricing Clause

Panelists from NIH neither agreed nor disagreed with these industry views. Some NIH panelists restated their opinion that there must be a reasonable relationship between the public investment in a product and its price. If NIH

were to remove or revise the clause, it would have to do so in a way that protects the interests of the Government and the people of the United States while promoting the original intent and goals of the FTTA.

Some industry panelists stated that there is no obvious way to modify the reasonable pricing clause itself that would be acceptable to them. However, various panelists cited a number of protections that are already in place and might be strengthened; they also suggested several additional mechanisms that might ensure a reasonable price without erecting new barriers to cooperative research and technology transfer:

- *Modify the Government's exclusive license to ensure reasonable availability.* The Government's exclusive license contains numerous provisions under which a company's exclusive right to practice a Government invention can be modified or terminated if the license does not meet agreed-upon performance standards or milestones or otherwise fails to commercialize the technology expeditiously. These clauses could be modified to allow termination if a company fails to keep a product reasonably available to the intended patient population.

- *Emphasize the use of Government "march-in" rights to protect against abuses.* These provisions allow the Government to practice the invention for its own use or in emergencies. These rights have been used in the past to accomplish the prompt, widespread, and economical dissemination of new vaccines.

- *Require drug companies to use other mechanisms to ensure patient access to drugs.* Several drug companies have already established so-called indigent programs that provide drugs at reduced rates, and sometimes free, to certain patients who cannot afford them. In the past, these programs sometimes have been criticized as public relations efforts that are too small or too limited to have any real effect. The Government could encourage such programs by providing incentives to the companies to expand them and make them more effective. However, academic panelists pointed out that such guaranteed-access initiatives shift costs without controlling prices.

- *Remove the reasonable pricing clause from some but not all CRADA contracts.* Examples include very early stage research and agreements under which drug companies provide proprietary drugs for the use of NIH investigators.

- *Reserve the reasonable pricing clause, or some modification of it, for cases in which there is no effective substitute for the drug in question.*

As noted above, however, high prices for monopolistic products have tended to stimulate research on substitutes, alternatives, and competitors.

General Findings

The mission of NIH is to pursue and apply fundamental knowledge that can improve the health of all Americans. The NIH intramural research program has proved to be a uniquely valuable biomedical resource. Government-industry collaboration is critical for the prompt commercial development of new products arising out of NIH research. The CRADA has proved to be an important and effective mechanism for encouraging such collaboration.

The purpose of the FTTA is to facilitate the transfer of commercially useful technology from the Federal laboratories to the private sector to benefit the American public through such means as the CRADA mechanism. The statute does not require Federal laboratories to consider issues of pricing, and the inclusion of the so-called "reasonable pricing" clause in the model CRADA has generated growing criticism from NIH's industrial collaborators. NIH should seek to provide greater flexibility in negotiating this and other provisions of a CRADA, provided that the broad interests of the government and consumers are still protected. NIH should also seek to simplify, streamline, and expedite the process of negotiating all CRADAs.

CRADA Forum II

September 8, 1994

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
Bethesda, Maryland 20892

Harold Varmus, M.D.
Director
National Institutes of Health
9000 Rockville Pike
Bethesda, MD 20892

Dear Dr. Varmus:

On behalf of the Panel members, I am pleased to transmit to you the final report of the second ad hoc consultant group to the Advisory Committee to the Director, NIH, on "NIH Collaborative Research and Development Agreements (CRADAs): Perspectives, Outlook, and Policy Development".

The Panel's discussion focused only on the third aspect of the July 21 CRADA Forum -- the "reasonable pricing" clause. In particular, its mission was to assess the value of the government's investment in biomedical research and determine what kind of return is appropriate; how much return is appropriate; and how should the NIH balance public payback and new product development. Questions considered by the panel included: is the public investment in products developed through licensing NIH technologies adequately reflected by the payment of royalties and the expeditious development of new products; if additional types of returns are desired, should these be tailored according to the amount of the NIH investment and the stage of the investment in the product development continuum; and if scrutiny of product pricing is appropriate to ensure reflection of the public investment, are NIH licenses the right vehicle in which to require the scrutiny.

This Report sets forth the findings of the Panel, which are based upon presentations from invited speakers, testimony from public witnesses, and the deliberation of the Panel on September 8, 1994. The Panel trusts that these findings will be useful in improving NIH CRADA policies and ensuring that national health goals continue to be enhanced by the research conducted at the NIH.

Sincerely,

Sandy Chamblee

Daryl A. (Sandy) Chamblee, J.D.
Panel Chair and
Acting Deputy Director for
Science Policy and Technology Transfer

CRADA Forum II Panel Members

Chairperson

Ms. Daryl A. (Sandy) Chamblee, J.D.
Acting Deputy Director for Science Policy
and Technology Transfer
Office of the Director
Bldg. 1, Room 103
National Institutes of Health
Bethesda, MD 20892

Members

Ms. Marsha Alvarez
Director
Office of Drug Pricing Program
Health Resources Services Administration
4350 East-West Highway, 10th Floor
Bethesda, MD 20814

Dr. Paul Armond
Senior Project Analyst
Pfizer, Inc.
Easter Point Rd.
Groton, CT 06340

Dr. Peter Arno
Associate Professor
Department of Epidemiology and Social
Medicine
Albert Einstein College of Medicine/
Montefiore Medical Center
111 East 210th St.
Bronx, NY 10467

Mr. David Barr, J.D.
Director, Treatment Education and
Advocacy
Gay Men's Health Crisis
129 West 20th St.
New York, NY 10011

Dr. M. James Barrett
Chief Executive Officer
Genetic Therapy, Inc.
938 Clopper Rd.
Gaithersburg, MD 20878

Mr. Peter F. Carpenter
Public Policy/Public Service Fellow
Mission and Values Institute
1 Larch Drive
Atherton, CA 94027-2125

Mr. William Corr
Deputy Assistant Secretary for Health
U.S. Public Health Service
200 Independence Ave., SW.,
Room 716G
Washington, DC 20201

Ms. Linda Golodner
President
National Consumers' League
815 15th St, NW., Suite 928
Washington, DC 20005

Dr. Charles Grudzinskas
Director
Medications Development Program
National Institute on Drug Abuse
National Institutes of Health
5600 Fisher Lane, Room 11A-55
Rockville, MD 20857

Mr. Jeff Levi
Consultant
7520 12th St., NW.
Washington, DC 20012

Dr. Lance Liotta
Laboratory of Pathology
Division of Cancer Biology, Diagnosis,
and Centers
National Cancer Institute
Bldg. 10, Room 2A33
National Institutes of Health
Bethesda, MD 20892

Ms. Abbey Meyers
President
National Organization for Rare Disorders
P.O. Box 8923
New Fairfield, CT 06812

Dr. Dinah Singer
National Cancer Institute
Bldg. 10, Room 4B17
National Institutes of Health
Bethesda, MD 20892

Dr. William Terry
Senior Vice-President of the Brigham
Medical Center
Brigham and Women's Hospital, Inc.
75 Francis St.
Boston, MA 02115

NIH Liaison

Dr. Thomas Mays
Director, Office of Technology
Development
National Cancer Institute
Bldg. 31, Room 4A51
National Institutes of Health
Bethesda, MD 20892

Ms. Barbara M. McGarey, J.D.
Deputy Director
Office of Technology Transfer
National Institutes of Health
6011 Executive Blvd., Suite 325
Rockville, MD 20852

CRADA Forum II: Report of the Panel

Executive Summary

On July 21, 1994, the National Institutes of Health (NIH) convened a forum to solicit advice and recommendations from the biotechnology and pharmaceutical industries, the academic research community, and the public on issues relating to cooperative research and development agreements (CRADAs). Of the three general questions addressed by CRADA Forum I, the "reasonable pricing" clause elicited the most discussion from industry, NIH scientists, and the public. Accordingly, NIH convened a second forum on September 8, 1994, to solicit additional advice and recommendations from primary consumers and other public interest groups. CRADA Forum II focused on the reasonable pricing clause and on three broader questions about how to repay the Government's investment in biomedical research: (1) what kind of return is appropriate, (2) how much return is appropriate, and (3) how NIH should balance public payback and new product development.

The panel concluded that there were both qualitative and quantitative returns on the Government's investment. Among the former are the scientific benefits of public-private collaboration and the development of new medical products; among the latter are royalties paid to NIH and lower prices on new products. The panel reached consensus on the following hierarchy of returns to the public for its investment in biomedical research: (1) fostering scientific discoveries, (2) rapid transfer of these discoveries to the bedside, (3) accessibility of resulting products to patients, and (4) financial returns in the form of royalties.

There has been no decline in the number of NIH CRADAs or technology licenses, but the panel heard anecdotal evidence and the testimony of NIH investigators that some types of collaboration are becoming difficult or impossible to negotiate. Industry panelists reported that their problem with the clause had largely to do with its uncertainty: they were unable to ascertain how or when the Government might intervene in a pricing decision. The panel concluded that the clause is perceived to be a problem and that NIH should do something about this perception.

The panel was not able to agree on a single, specific course of action for NIH. Most of the panelists agreed that, at a minimum, NIH should revise the clause to clarify its meaning and intent. Most of them also agreed that there are at least some types of NIH–private sector collaboration in which the clause is inappropriate and might be removed. Many panelists felt that, instead of the reasonable pricing clause, NIH should require an accessibility plan, just as it now requires a commercialization plan.

Introduction

The Federal Technology Transfer Act of 1986 (FTTA) authorizes Federal laboratories, including NIH, to enter into CRADAs with numerous entities, including private businesses. The purpose of FTTA and CRADAs is to encourage the transfer and commercialization of new technologies that are developed in Government laboratories. Between 1986 and the end of fiscal year (FY) 1993, NIH executed 206 CRADAs, most of them with industrial partners. These agreements have covered a broad range of research, from the initial application of basic discoveries to advanced clinical trials.

In 1989 the Public Health Service (PHS), NIH's parent organization, adopted a policy statement expressing concern that, because of the public investment in the research that leads to a product licensed under a CRADA, there should be "a reasonable relationship between the pricing of a licensed product, the public investment in that product, and the health and safety needs of the public." Exclusive licenses for NIH intellectual property rights may require the company to support this relationship with "reasonable evidence."

A major factor in the adoption of these provisions was the reaction of Congress and the public to the launch price of $8,000 to $10,000 per patient per year for azidothymidine (AZT), a drug for acquired immunodeficiency syndrome (AIDS) developed by the Burroughs-Wellcome Company with substantial NIH involvement, but not under a CRADA. However, NIH investigators

and their industry colleagues have expressed concern that the reasonable pricing clause poses a barrier to expanded research collaboration. This issue elicited the most discussion in the CRADA Forum I, held on July 21, 1994.

Accordingly, NIH convened CRADA Forum II on September 8, 1994, to solicit additional comment, advice, and recommendations from primary health care product consumers and other public interest groups on how best to reflect the public's investment in new health care products arising from NIH research. CRADA Forum II was chaired by Ms. Daryl A. (Sandy) Chamblee, Acting Deputy Director for Science Policy and Technology Transfer, NIH. In addition to NIH researchers and administrators, the 15-member panel included representatives of consumer and health action groups, academic research institutions, and biotechnology and pharmaceutical companies. The panel also included William Corr, Deputy Assistant Secretary for Health.

The question to be addressed by the panel was whether the reasonable pricing clause was an appropriate and effective way to reflect the public's investment in health care products arising from NIH-supported research, and if not, what other mechanisms are available to NIH to achieve this goal. The panel focused on three questions:

1. *What kind of return on the public investment is appropriate?* Is the public investment in products developed through licensing NIH technologies adequately reflected through the payment of royalties and the expeditious development of new products? If not, is it also suitable for NIH to become involved in "downstream" issues of marketing and distribution, such as the pricing of such products? How else could or should the public investment be reflected?

2. *How much return on the public investment is appropriate?* NIH currently obtains a financial payback from licensees for the right to develop Government technology in the form of license execution fees, minimum annual royalties, and royalties on net sales. NIH also ensures expeditious product development through benchmarks and milestone requirements within the license. NIH negotiates this financial and "development" return on a case-by-case basis, taking into account the type of technology, the amount of Government investment (both financial and intellectual), the stage of development of the technology, and the public health benefit or research value of the technology. If additional types of return are desired, should they also be tailored according to the amount of the NIH investment and the stage of the investment in the product development continuum? As with royalties and development benchmarks, should NIH negotiate for additional

types of payback on a case-by-case (or categorical) basis, using the above criteria?

3. *How should NIH balance public payback and new product development?* If scrutiny of product pricing is appropriate to ensure reflection of the public investment, are NIH licenses the right vehicle through which to require the scrutiny? If not, how and by whom should this be accomplished? If assumed by NIH, will this role conflict with the NIH technology transfer mission and hamper new product development? Is decreased new product development acceptable in return for having NIH play a role in the "downstream" marketing and distribution of the product? If not, how can NIH become involved without negatively affecting new product development?

The remainder of this report focuses on panelists' discussion of these three issues.

Appropriate Types of Return

As NIH Director Harold Varmus pointed out in his charge to the panel, the question of whether the Government should expect a return involves the proper role and true goal of Government in funding biomedical research. It became clear from subsequent discussion that there are indeed multiple returns on the Government's investment. For example, a panelist from an academic research institution suggested that, since the mission of NIH is to generate new biomedical knowledge and transfer it for commercial development, the proper return on the Government's investment may be the amount of information generated and transferred. Similarly, one of the NIH participants described the "returns" from a CRADA, the most important of which were the special expertise that the industry partner brings to a project and the greater speed with which the results of NIH research are developed. Some consumer panelists, however, felt that these benefits are fruitless if patients do not have access to the resulting drugs and treatments.

Another important qualitative return is the new product development that is achieved through the commercialization of new technologies arising from NIH research. This return was particularly important to several panelists and public speakers addressing new AIDS treatments and drugs for so-called orphan diseases. One consumer panelist felt that the pharmaceutical industry was also failing to address the need for new treatments for addiction and genetic diseases. In fields where significant disincentives to new product development already exist, companies might be hesitant to develop new products.

Finally, two types of return on the Government's investment are clearly quantitative: direct returns in the form of royalties paid to NIH, and indirect returns in the form of lower prices for consumers and for Federal health programs. Consumer panelists were particularly forceful in insisting that the Government's investment must be returned not only in new knowledge and new drugs but also in affordable drugs. Several panelists pointed out that the issue is prices, not the industry's development costs, and that "reasonable price" is too often misunderstood to mean "lowest possible price." One panelist added that both royalties and access programs are forms of cost shifting. However, a consensus emerged that the true issue may be *accessibility* rather than prices per se. Some panelists suggested that other mechanisms might be available, but it remains unclear whether they would be more effective than the reasonable pricing clause in ensuring accessibility.

Mechanisms currently used by PHS to ensure accessibility include competitive licensing, development of therapeutic analogs, and discounts for Federal agencies, as well as so-called indigent programs. One industry panelist described five different programs through which his pharmaceutical firm makes a wide range of drugs available to patients who could not otherwise afford them. Most of these programs rely on individual physicians, but some are conducted in cooperation with community health centers or State health programs. Panelists from consumer groups pointed out that many of these programs can be hard to identify and use, because they impose stringent eligibility standards or paperwork requirements that tend to work against the patients who need them most.

In the end, the panel concurred in the following hierarchy of returns on the public's investment in biomedical research, from most to least important:

1. fostering scientific discoveries,
2. rapid transfer of discoveries to the bedside,
3. accessibility of resulting products to patients, and
4. royalties.

Appropriate Amount of Return

NIH typically receives five kinds of financial payback for the technologies it licenses: *execution fees* at the time the license is signed, *minimum annual royalties* regardless of sales, *benchmark royalties* when important development milestones are reached, *patent costs* for which the licensee reimburses NIH, and *earned royalties* as a percentage of sales. There is a lag of approximately 5 to 7 years between granting a license and receiving earned royalties, but NIH technologies have already earned a total of $73 million in royalties since 1986.

Most of this amount has come from a small number of technologies, including the AIDS test kit, a hepatitis vaccine, and an innovative centrifuge, that have generated from $500,000 to several million dollars apiece. CRADA licenses represent only 2 percent of all NIH licenses, and relatively few CRADAs result in licensable technologies.

To expedite the commercialization of NIH technology, an NIH license includes benchmarks and development milestones. The negotiations reflect the maturity of the technology and the degree of investment and risk for both NIH and its partner. For example, the license for a research reagent might have lower execution fees but earned royalties of 15 to 30 percent of sales, while the license for an early-stage therapeutic that requires considerable additional research and development by the company might have higher execution fees and minimum annual royalties but earned royalties of only 3 to 8 percent. Similarly, a smaller biotechnology company with low capitalization might prefer to pay higher royalties on sales in exchange for lower execution fees. There was no indepth discussion from panel members on whether the present royalties rates are too high or too low. But one industry panelist commented that, when NIH has assumed most of the risk and done most of the work, in addition to royalties NIH also might reasonably raise the issue of the pricing of the resulting product.

The panel concluded, however, that the question of royalties is less important than the issue of new product development and accessibility. NIH already uses several mechanisms to ensure the accessibility of new drugs, including competitive licensing and the development of therapeutic analogs. One NIH participant suggested that instead of a reasonable pricing clause the CRADA contract include a reasonable access clause. Just as the company must provide a commercialization plan, so it would be required to provide an accessibility plan detailing the mechanisms and milestones it would use to ensure that the drug would be available to Government agencies and needy patients. Three additional mechanisms were suggested by some panel members: (1) providing up to 25 percent of the drug free of charge, (2) deeper discounts to Medicaid and Medicare, and (3) an indigent- or compassionate-access program with generous eligibility criteria, less paperwork, and prompt approval, possibly administered by an independent organization with consumer representation. One industry panelist's response to this discussion, however, was that it is unreasonable to expect the industry to substantially shoulder the burden of accessibility for everyone who may need the drug.

Several academic and industry participants on the panel favored the idea of an accessibility plan as an alternative to the reasonable pricing clause, subject to further definition. Consumer representatives on the panel were also supportive, but they cautioned that price would remain a central question in accessibility

because of the great number of people who pay for drugs out of pocket, and because the cost of free drugs and Government discounts will be shifted to paying customers.

Balancing Public Payback and New Product Development

The central question here was whether the reasonable pricing clause has a negative effect on cooperative research and whether that effect can be ameliorated by modifying the clause. There has been no decline in the number of new CRADAs since 1990, according to NIH administrators, although there may be a change in the growth rate or in the mix of CRADA types. In fact, from FY 1990 through FY 1993 the number of new CRADAs executed each year was 32, 26, 30, and 41, respectively. One industry panelist felt that there should be far more CRADAs than are currently negotiated, given the budget and personnel of NIH, but NIH panelists pointed out that NIH represents a diverse universe of science and scientists, little of which is appropriate for CRADAs.

In addition, anecdotal evidence and the testimony of NIH investigators indicate that many research collaborations are becoming difficult or impossible to negotiate. For example, the panel heard testimony from one NIH investigator that he has been unable to obtain access to a company's proprietary compound to use in his research on the development of more effective, less toxic antiepilepsy drugs. Although the company had patent protection, it wished to enter into a CRADA rather than a materials transfer agreement, to ensure that it could obtain licensing rights to everything that NIH may "serendipitously" discover, such as a new use for the material. As a result, a potential collaborator, who had already synthesized several promising compounds, was unwilling to provide them to NIH, hobbling its research and possibly delaying the development of much-needed drugs. However, it is uncertain that these problems can be attributed to the reasonable pricing clause.

Furthermore, reasonable pricing may be only part of the problem. Industry participants reported that the degree of uncertainty is the real problem, and that uncertainty can also arise from delay in negotiating the agreements and from ambiguity about a potential collaborator's rights to the resulting intellectual property. While the pricing clause may not be an absolute barrier to CRADAs, it is a real concern to industry, and as one industry panelist pointed out, the perception that it is a problem is itself a problem.

Overall, on various occasions panel members mentioned that there exists a gap in data and statistics that might be helpful in determining the future of the reasonable pricing clause, including information on the effect of the clause on

collaboration; clear and explicit definitions for key concepts such as "reasonable price," "risk," "accessibility," and "eligibility;" and clear and detailed development of potential alternatives. However, the panel concurred that while these measures may be helpful or desirable, such data would be extremely difficult, and even impossible, to collect in some cases.

There was also concern among the panelists that NIH has no mission, authority, or expertise to set drug prices. There was little enthusiasm for adding that responsibility to NIH's mission or for developing the necessary regulatory bureaucracy at NIH. Furthermore, doing so would raise a conflict of interest with NIH's statutory responsibility to foster collaboration with the private sector. Panelists suggested that this responsibility might better be placed in the Health Care Financing Administration or some other agency that already has a large staff of economists and accountants. Some panelists also noted that the issue of drug pricing might more properly be debated by Congress, where the prices of *all* drugs (especially those supported by the public) can be addressed, rather than by NIH, where only products developed from NIH intramural research are affected.

Questions About the Clause Itself

Panelists representing consumer groups pointed out that the language of the reasonable pricing clause forbids PHS to set or control prices. They therefore questioned whether the clause is an enforceable mechanism or merely a "concern" on the part of NIH and PHS. Some academic and industry panelists countered that the present clause is so rigid and ambiguous that it may be inconsistent with the FTTA and may even interfere with technology transfer.

Consumer panelists also expressed concern that pharmaceutical companies were objecting to the reasonable pricing clause—although it has never been enforced and may in fact be unenforceable—because it might be used to force them to open their books and justify how they set prices. Panelists from academic research institutions suggested that this question reflected a broadly held but generally unspoken opinion that pharmaceutical companies do not price drugs fairly, that in fact they make too much money and drive up the cost of health care. Other panelists countered that it was reasonable for companies not to want the Government or anyone else involved in sensitive pricing decisions, adding that even the companies do not know what a reasonable price will be at the time they negotiate a CRADA.

The panel appeared to agree that the reasonable pricing clause has introduced uncertainty into at least some CRADAs, and that the level of uncertainty is a real and valid concern for industry. One consumer panelist ventured the

opinion that the problem may be the ambiguity of the clause and not necessarily the clause itself. Therefore, if the reasonable pricing clause remains part of CRADA negotiations, this uncertainty must be reduced through clarification of the CRADA's language and intent. In addition, the panel agreed that the task of determining and enforcing a reasonable price is not within the capacity of NIH and should rest elsewhere.

Options for NIH Action

As a means of eliciting consensus and structuring recommendations from the panel, the chair suggested nine options for further action by NIH and asked for the panel's response to them as a guide in setting future policy. These options and the panel's responses are summarized below.

1. *Maintain the status quo.* There was no defense of the reasonable pricing clause as it currently stands. At the very least, its language and intent should be clarified.

2. *Revise the clause.* There was a clear consensus that the concept of "reasonable pricing" must be defined more clearly and explicitly. This action is desirable whether the clause is retained in the language of the agreement itself or as a philosophy in the NIH policy statement on CRADAs (see option 5). Panelists representing consumer interests also wanted a clearer sense of how the clause would be enforced and how noncompliance would be addressed. Some panelists added that the policy should become more flexible as well as less ambiguous; another suggested that NIH's industrial partners might be willing to pay significantly higher royalties in exchange for reducing the ambiguity of the clause.

3. *Remove the clause selectively, on the basis of CRADA type.* There was also a consensus that the reasonable pricing clause is inappropriate and counterproductive in some categories of NIH-private sector collaboration. Relatively few CRADAs result in new intellectual property, so including the clause in all CRADAs may be inappropriate. Several panelists recommended that NIH determine the appropriateness of the clause on the basis of the amount of risk incurred to date by NIH in the project.

4. *Eliminate the clause from the CRADA, but retain it in exclusive licenses.* As it currently stands, the clause does not pertain to the CRADA itself but rather serves to alert the industrial partner that the clause will appear in any exclusive license that follows from the

CRADA. Panelists from NIH certainly supported the idea of not worrying about pricing until the drug is shown to be effective in patients. But while there was some agreement on this option, there was no consensus, in part because it leaves unresolved the questions of definition, applicability, and enforcement that are addressed by the preceding options.

5. *Eliminate the clause from both the CRADA and the exclusive license, but retain it as a statement of philosophy in NIH policy.* One panelist from NIH suggested that reasonable pricing is a philosophy that should never have become a policy. The solution would be to remove the clause from the body of the model CRADA contract but retain it as a statement of philosophy in appendix A of the contract, the "NIH Policy Statement on CRADAs and Intellectual Property Licensing." There was no consensus on this option: panelists representing consumer interests expressed reluctance to do without any protection in these agreements, while others felt that statements of philosophy had no place in negotiating licenses or contracts.

6. *Eliminate the clause altogether and rely on other provisions of the exclusive license agreement.* In addition to the reasonable pricing clause, all NIH exclusive licenses allow the Government to modify or terminate the license if the licensee fails to reasonably satisfy unmet health and safety needs, or keep the licensed product reasonably available to the public after commercial use commences. Thus the reasonable pricing clause may not add substantively to the power NIH already exercises over its exclusive licenses. These provisions raise their own questions of definition and enforcement, however, and panelists representing consumer groups were reluctant to remove the clause entirely. One said that the taxpayers need to know that the Government is watching out for them; another said NIH and PHS have a social responsibility to create a certain level of accountability in the pharmaceutical industry. These panelists favored keeping a specific pricing clause.

7. *Eliminate the clause but add new, explicit grounds for termination based on lack of access and/or excessive prices.* This option would address some of the drawbacks of option 6, but the panel did not address it directly.

8. *Eliminate the clause from the model agreement, but negotiate it on a case-by-case basis.* One of the panelists described the mixed success that his pharmaceutical company has had in trying to negotiate a CRADA without the clause. This option represents a variation on

option 3, in which the reasonable pricing clause is included as an exception rather than the rule.

9. *Eliminate the clause, but require an accessibility plan.* There was general but qualified consensus on the desirability of requiring an accessibility plan as part of a CRADA or exclusive license contract. Several panelists said that such a plan should be required regardless of what NIH decides to do about the reasonable pricing clause. Another panelist suggested that licensees be given the option of accepting the reasonable pricing clause or coming up with an accessibility plan. However, this option raises many of the same questions as the reasonable pricing clause, namely, What would an accessibility plan look like, which CRADAs would be required to have one, who would review it, and who would enforce it? In addition, would such an administrative process further hinder the already slow process of negotiating and executing CRADAs. As with reasonable pricing, panelists agreed that NIH should not administer accessibility; one panelist suggested establishing an independent, third-party "full-access fund" to receive royalty-like payments from drug companies, determine eligibility, and make payments. Eligibility and paperwork were cited as particularly difficult issues, and some panelists from consumer groups were reluctant to move to an accessibility clause, even for a trial period, without retaining the reasonable pricing clause as a fallback.

Findings and Conclusions

The panel concluded that, while there is as yet no proof, there is at least a perception that the reasonable pricing clause is an impediment to achieving NIH's mission under the FTTA, namely, promoting cooperative research and facilitating the transfer of technology to the private sector. They also reached general agreement that NIH should do something to address this perception. However, they could not agree on a single, specific course of action. The foregoing discussion suggests that there was greatest support for some combination of options 2, 3, and 9—that is, clarify the clause and consider removing it on the basis of CRADA or in exchange for an accessibility clause—but this support was never unqualified.

Appendix A

CRADA Forum I Background Information

CRADA Forum I Agenda

Bethesda Holiday Inn
8120 Wisconsin Avenue
Bethesda, MD 20814

July 21, 1994

7:30–8:30	Registration
8:30–8:45	Charge to the Panel Dr. Harold Varmus, Director, NIH
8:45–9:00	Program Overview Ms. Daryl A. (Sandy) Chamblee, OD, NIH
9:00–9:30	CRADA Primer and Overview Dr. Dinah Singer, NCI
9:30–10:45	Case Study #1: Basic/Preclinical CRADA 15 min. NIH (Ms. MaryAnn Guerra, NHLBI) 15 min. Industry (Mr. Larry Stambaugh, Syntello) 45 min. Panel Discussion
10:45–11:00	Break
11:00–12:15	Case Study #2: Clinical/Sole Source CRADA 15 min. NIH (Dr. Mitchell Max, NIDR) 15 min. Industry (Ms. M. Dianne DeFuria, Bristol-Myers Squibb) 45 min. Panel Discussion
12:15–1:30	Lunch

1:30–2:45	Case Study #3: Government Developed/Owned Technology 15 min. NIH (Dr. Thomas Mays, NCI) 15 min. Industry (Ms. Lisa Raines, Genzyme, Inc.) 45 min. Panel discussion
2:45–3:00	Break
3:00–3:30	Congressional Views
3:30–5:00	Public Comment Period
5:00–6:00	Dinner
6:00–8:00	Panel Writing Session

CRADA Forum I Mandate

The Federal Technology Transfer Act of 1986 (FTTA) and subsequent executive order 12591 (April 10, 1987) were developed in recognition that U.S. industrial competitiveness can be greatly enhanced if technology developed in Federal laboratories is commercialized by American industry. To stimulate technology transfer, the FTTA authorizes Federal laboratories to enter into cooperative research and development agreements (CRADAs) with industry (and others) and provides incentives to both the Federal scientists and collaborating companies to do so. CRADAs provide an opportunity for NIH scientists to join with their private colleagues in the joint pursuit of common research goals. Since 1986, NIH has conducted cooperative biomedical research, primarily with industrial partners, under 206 CRADAs. As the Government's experience with CRADAs has grown, several issues of concern have developed, prompting NIH to seek advice and develop appropriate policy.

The NIH Director is convening the Forum on CRADAs to solicit advice and recommendations from the biotechnology and pharmaceutical industries, the research community, and the public on issues relating to cooperative research and development agreements. The Forum will focus its deliberations on the following issues:

- *Scope of the research and license rights under a CRADA.* What are the different types of research collaborations that are typically conducted under the CRADA mechanism? Are these types of collaborations fundamentally different from each other with regard to the activities undertaken and each party's contributions? If so, is it appropriate to develop specific public policy tailored to these different types of collaborations? Should fair access, reasonable pricing, and other administrative policies be differentially applied to CRADAs, and if so, to which types of CRADAs should these policies be applied? How can a CRADA research plan be drafted to ensure maximum flexibility for the scientists in following up on unanticipated research results while satisfying the parties' requirements for specificity and precise definition of the licensing rights governed by the CRADA? Is it appropriate to negotiate licensing terms at the inception of the CRADA, before it is known what technology will be invented and how it can be best licensed to further the public's interest? If so, in what circumstances is this appropriate? What terms can reasonably be negotiated in advance?

- *Fair access to CRADA opportunities.* How should NIH preserve the fundamental nature of the research collaboration, which arises from the knowledge and relationships of the scientists, while ensuring fair access to CRADA opportunities for U.S. businesses? Does industry have difficulty in obtaining information or access to CRADA opportunities? Is the current policy on fair access adequate?

- *Reasonable pricing clause.* Given the mandates of NIH to support research and to transfer the results of that research to advance the public health, should the "reasonable pricing" clause be used by NIH as a mechanism to reflect the public investment in NIH-supported research in the products brought to market through NIH/private sector collaborations? Does the clause strike the appropriate balance between these dual mandates? What other mechanisms are available to NIH to achieve this goal?

NIH CRADA FORUM I
July 21, 1994

CRADA Forum I
Case Studies

- Basic/Preclinical CRADA
- Clinical/Sole Source CRADA
- Government Developed/Owned Technology

CRADA Case Study 1: Basic/Preclinical CRADA

Scientists in the Laboratory of Sexually Transmitted Diseases (LSTD) at the National Microbe Institute (NMI) carry out both basic and clinical research aimed at the control and prevention of sexually-transmitted diseases. Specific projects typically underway in the laboratory include basic studies of microbial physiology and antigenic structure, the development of rapid diagnostic kits for identification of various pathogens, and collaborative clinical trials evaluating experimental drugs and vaccines. Clinical trials done collaboratively with other laboratories and Divisions within the NMI utilize clinical trial sites both within NMI's intramural program, as well as with Principal Investigators supported by NMI's extramural program. In this latter case, a network of vaccine centers have been established through both contract and cooperative agreement grant support at non-Federal research institutions. Each of these centers offers expertise in the development, production and evaluation of putative vaccines.

During the last two decades, Dr. Jenny Drake, LSTD, has been actively involved in the identification and characterization of antigenic structures expressed by the gram-negative bacteria, Bruscida bugdalia. Work in her laboratory has been funded primarily through the NMI's intramural research budget and has amounted to over 15 million dollars. A significant advance that has resulted from this effort is the identification of key antigenic determinants on one of the major membrane proteins of B. bugdalia. The LSTD believes that one or several of these determinants will be an excellent candidate as a primary target antigen for the development of a vaccine against this sexually-transmitted disease. Due to the potential impact that such a vaccine could have on the public's welfare, NMI has sought to protect new discoveries in relation to these antigens by submitting several patent applications. The scope of the claims contained in these applications are broad and may cover a number of "fields of use" for these molecules.

Recently, as a first step towards the development of a vaccine against B. Bugdalia utilizing one of these antigenic determinants, the LSTD began vaccine formulation studies in an animal model developed in their laboratory. From these early studies it became clear that additional technology would need to be developed or acquired by the laboratory to incorporate into the putative vaccine additional elements to ensure that the candidate antigenic determinants would adequately "trigger" the immune system and protect the initial site of attack by the B. Bugdalia microbe. The LSTD did not have the expertise to develop such vaccine delivery technology. Dr. Drake contacted a colleague at a company which she knew, through a former consulting relationship, had the requisite expertise. Dr. Drake also consulted with the MNI Technology Transfer Office (TTO) for assistance in identifying possible collaborators to develop this

vaccine.

With the help of the TTO, the NMI advertised an opportunity to collaborate in a CRADA with the LSTD for the development of a vaccine against B. Bugdalia. This advertisement was made in a major monthly publication dedicated to biotechnology. It required potential collaborators to submit capability statements identifying specific company expertise and resources available for the development of such a vaccine. Many proposals were received and several companies were selected since each not only met capability requirements but had unique proprietary technology that appeared to fulfill the "triggering" element. The company with which Dr. Drake had formerly consulted was among those selected. The NMI Technology Assessment Board, in concert with the TTO and the LSTD, decided that by collaborating with four of these companies all known targeting mechanisms to date would be evaluated in this system.

In light of the LSTD's desire to evaluate these candidate antigens in each of the known proprietary technologies, the NMI began negotiations for the establishment of four different CRADAs with each of the four identified collaborators for this project. Each collaborator would contribute its own proprietary technology and expertise to the project. It was apparent that negotiations for the establishment of these CRADAs would be on even ground given that both the U.S. Government and the collaborators were coming to the collaboration with equally strong patent positions with regard to each of their proprietary technologies.

Negotiations began regarding the CRADA agreements and the disposition of patent rights developed prior to the execution of the CRADA. In order for any of the companies to market a vaccine based on LSTD's technology, licensing issues for these background patents needed to be resolved. Two of the four companies voiced their desire to obtain exclusive licenses to the patents for all fields of use. Because the NIH Office of Technology Transfer (OTT) determined that exclusivity to the background patents was not required for this technology to be further developed and commercialized, OTT negotiated and executed non-exclusive rights to each of the known antigens to the four potential CRADA collaborators. OTT reasoned that non-exclusive licensing was necessary to develop all possible forms of the vaccine and the addition of each company's proprietary delivery system would provide sufficient exclusivity to allow further incentives for development and commercialization.

Concurrent with the disposition of background patent rights, the parties began negotiating the CRADA. The companies were concerned that the research plan of the CRADA be as broad as possible, to provide flexibility in following up on un-

anticipated results of the research, perhaps adding their own new proprietary technology or expanding the research to other antigens discovered jointly or by the LSTD. Because the research plan sets forth the research that will be carried out and delineates the scope of licensing rights promised to the collaborator, it was important to the collaborators that all the research being carried out as well as that which might be anticipated be described in the research plan. The LSTD, however, was concerned that an overly broad research plan, encompassing more than what was actually planned to be conducted under the CRADA, would unnecessarily tie up the work of the lab and preclude other collaborators from seeking and obtaining CRADAs with Dr. Drake or her colleagues in the lab. The LSTD was particularly careful not to promise overlapping rights to additional antigens that the laboratory may discover, and accordingly insisted on a specific and well-drafted research plan.

One of the collaborators was also concerned that the terms of the exclusive license to be granted under the CRADA were not defined. Indeed, the CRADA did not even grant a license at all, but instead provided only an option to negotiate an exclusive or non-exclusive license. The collaborator requested that fields of use, benchmarks, royalty rates, and other licensing terms be set forth in the CRADA to provide certainty for the company. The LSTD responded that the PHS policy was not to negotiate licensing terms at the negotiation of the CRADA, since it was unknown at that time what the invention will be and therefore difficult to determine appropriate terms. The LSTD pointed out that the option to negotiate a license provided a key benefit to the company- exemption from the competitive licensing process which governs all other licensing of government intellectual property.

Finally, all the collaborators voiced their objection to the inclusion in the Public Health Service (PHS) Model CRADA and Model Licensing Agreement of a reasonable pricing clause. Because it was anticipated that new intellectual property rights would be developed under these CRADAs, the collaborators expected to negotiate exclusive licenses to CRADA inventions and did not believe it was reasonable or appropriate for the PHS to become involved in this aspect of the commercial development of a future vaccine candidate. The companies believed that while PHS had engaged in substantial development with regard to the microbial structure and antigenic structure, the government's financial involvement to date would be dwarfed by the millions of dollars in development, FDA approval, and commercialization costs which the companies would be expending to bring a vaccine to the marketplace. They also argued that the reasonable pricing clause was unnecessary where the government was sharing its basic technology with several partners and thus could anticipate that

competing products would reach the marketplace.

The LSTD pointed out that the reasonable pricing language contained in the CRADA was limited to new inventions that would arise out of the CRADA, and in no way encumbered the companies' current proprietary technology. Through the reasonable pricing clause, they argued, the PHS was attempting to sensitize companies to the concern of the government that products developed through collaboration with the government not be inaccessible to the public once they reach the market. They pointed out that the clause was not a price setting clause but required only a reasonable relationship between the pricing of a licensed product, the public investment in that product, and the health and safety needs of the public. They also expressed their concern that a vaccine be widely available to the public to ensure the maximum effectiveness in eliminating sexually transmitted diseases.

The LSTD was able to successfully negotiate and execute 3 of the four CRADAs with inclusion of the reasonable pricing clause and a specific research plan. The fourth company, a small biotech company largely dependent on venture capital, was not able to convince key investors that the government, through the reasonable pricing clause would not attempt to control the price of a vaccine product developed under the collaboration. As a result, the fourth company is not actively developing a vaccine with their delivery system, but continues seeking other sources of useful antigens for further evaluation.

Issues to Address

* Where both the Government and the Collaborator bring significant intellectual property contributions to the collaboration, and it is anticipated that new intellectual property will be further developed, how should the CRADA be used to reflect and protect the public interest in the product eventually developed through the CRADA? How should the public interest be defined?

* How can a CRADA research plan be drafted to ensure maximum flexibility for the scientists in following up on unanticipated research results while satisfying the partys' requirements for specificity and precise definition of the licensing rights governed by the CRADA?

* Is it appropriate to negotiate licensing terms at the inception of the CRADA, before it is known what technology will be invented and how it can be best

licensed to further the public's interest? If so, in what circumstances is this appropriate? What terms can reasonably be negotiated in advance?

* Is the reasonable pricing clause an appropriate provision to include in a CRADA to reflect the government's concern that products arising out of a CRADA collaboration be accessible to the public when they reach the market? If not, what other provisions can the parties negotiate to ensure accessibility?

NIH CRADA FORUM
JULY 21, 1994

CRADA Case Study 2: Clinical/Sole Source CRADA

A laboratory in the Neurobiology and Analgesic Branch (NAB) of the National Institute of Pain Research (NIPR) is involved in characterization of peripheral and central neural structures and neurotransmitters involved in pain processing. Both basic and clinical research at NIPR focuses on the development of novel methods for measuring pain and sensory function in humans, as well as application of these approaches to improve treatment.

Several decades of animal studies by a number of laboratories, including NAB, have suggested the neurotransmitter Amine Q, found in spinal cord sensory neurons and specific sites within the central nervous system, is involved in generating pain perception. According to the NAB's hypothesis, the excitation by Amine Q leads to changes in CNS neurons manifested as a progressively increased perception of pain. This mechanism is thought to underlie chronic pain in various neuropathies, arthritis, or trauma. There had been no opportunity to test this hypothesis in humans; a number of Amine Q antagonists had been shown to relieve pain in animals, but all were quite toxic. This situation changed when Eastern Pharmaceuticals, Inc. (EP) developed compound Z, which demonstrated promise in initial human toxicity studies. Other companies were working on related compounds, but were 12-18 months behind.

After NAB scientists read a 1992 report of compound Z's analgesic action in Nature, they realized that this was an ideal opportunity to test their hypothesis in humans. They wrote to the company to propose doing the first Phase 2 human pain studies, suggesting a number of research designs that could shed light on the mode of action of compound Z in various forms of chronic pain. The studies were to include unique methods for examining sensory processing in humans that the NAB lab had developed. NAB scientists did not publicly advertise the availability of this research collaboration or contact any of the other companies working on related compounds. NAB received a quick response from Dr. Ian Jones, an Associate Director for Clinical Research at EP, indicating an interest in collaborating with the NAB scientists. Within two months, the respective research teams had agreed on an initial group of protocols. The estimated cost to perform the research would be about $80,000, a bit more than half of which EP agreed to defray. Dr. Jones indicated in early conversations that his colleagues at EP were reluctant to collaborate with a U.S. Government lab, predicting that "the delays and paperwork will kill you." It was their opinion that any number of commercial laboratories or universities could more expeditiously satisfy EP's commercial needs in demonstrating clinical safety and efficacy of compound Z to the FDA. Despite their misgivings, Dr. Jones wished to pursue a collaboration with the NAB.

The research protocol was quickly approved by the NAB's clinical research IRB, in preparation to execute a CRADA formalizing the

collaboration. EP already owned or had filed patents for the use of compound Z in acute and chronic pain, neurological and psychiatric disorders, and indications for diseases involving various other organ systems. In view of this, both NAB and EP agreed that any findings regarding treatment of pain or other neurological symptoms in the proposed studies would probably not constitute new intellectual property. In light of the possible discovery of some totally unexpected effect of compound Z, EP included provisions in the proposed CRADA that addressed licensing rights to any intellectual property that resulted from the studies.

However, in reviewing the Public Health Service (PHS) Model CRADA and Model Licensing Agreement supplied by the NAB Technology Development Coordinator, Dr. Jones registered immediate displeasure at the inclusion of a reasonable pricing clause in both agreements. It was EP's position that because they had shouldered the risk of developing compound Z from basic research to clinical studies, and the NAB was only now entering the picture with a desire to evaluate this compound for its own research purposes, there was no justification for the U.S. Government to impose the clause. NAB was quick to point out that the reasonable pricing language contained in the CRADA was limited to new inventions that arose out of NAB's clinical evaluation of compound Z. Through the reasonable pricing clause, NAB argued, the PHS was attempting to sensitize companies to the concern of the government that products developed through collaboration with the government not be inaccessible to the public once they reach the market. Moreover, NAB was willing to grant an option to an Exclusive Licensing Agreement that afforded FP with exclusive rights to any such inventions. This option meant that EP would be exempt from the usual competitive government licensing process.

EP refused to agree to the fair pricing clause, pointing out that a lower price for one indication would drive down the price for all of the indications that they had already patented. Further, EP argued that the drug was their discovery and they didn't need NAB collaboration to get FDA approval. EP sought approval of a new Model CRADA format for collaborations such as this, in which the reasonable pricing language was deleted, based on the company's sole development and proprietary patent position in the area of the proposed research and the unlikelihood that the collaboration would generate new intellectual property. EP also argued that the government's concern about accessibility of a product developed with government assistance could be addressed through means other than pricing constraints and, in any event, that the public investment in this particular collaboration was minimal and did not warrant interference in the market forces governing product development.

Although the PHS agreed to consider these arguments, such a new Model CRADA had not yet been developed and in the interest of moving forward with the research EP finally agreed with NAB's suggestion that EP agree to accept nonexclusive licensing for the serendipitous discoveries which might arise under the CRADA. Although the research began, the discussions and approval process took almost 7 months, and EP's competitors were now close behind. Dr. Jones, the government's strongest supporter in the negotiations, now agreed with his colleagues that he would never attempt another CRADA with PHS.

Issues to Address

- Where a company brings a patented or patent pending compound into a CRADA collaboration and the nature of the research is such that the discovery of new intellectual property is unlikely, how should PHS address reasonable pricing? Should the reasonable pricing clause be deleted under these particular circumstances?

* If one of the objectives of the pricing clause is to ensure that the public investment in the development of a product is considered in the collaborators' pricing decisions, are there approaches other than the pricing clause that would be more productive?

* Does this situation deter companies from entering into CRADAs with the PHS? If so, does the resulting inability of PHS scientists to obtain access to promising new compounds for research constitute a disadvantage to the public in that such compounds may be delayed in reaching the marketplace or may reach the marketplace without the benefit of the scientific expertise of PHS scientists? Will the ability of PHS to attract the best clinical scientists be hampered because of the diminished accessibility to promising new compounds by its laboratories?

* If a company is the sole source of a compound or material to which PHS scientists seek access for government research purposes, how should the government address "fair access" concerns?

NIH CRADA FORUM
July 21, 1994

CRADA Case Study 3: Government Developed/Owned Technology

A botanist, working under contract for the National Institute of Cellular Regulation (NICR), collected leaves in the rain forests of Motribo from plants identified to have healing properties. Upon her return, a colleague at NICR isolated an agent from the leaves, compound Q, that was shown to be active as an anti-growth factor in a variety of tissue culture cells. Upon thorough analysis it was found that compound Q had been identified over twenty years previously and patented for another use. All valid patents on Q had expired.

Chemists at the NICR analyzed compound Q and found it to be too complex to make synthetically, thus requiring supplies of the natural (leaf) product as the sole source of compound Q. Unfortunately, political complications between Motribo and the current Presidential administration precluded any possibility of obtaining quantities of natural product sufficient to do extensive studies.

Notwithstanding the limited source, given the promising nature of compound Q NICR decided to experiment with the small quantity isolated from the original natural product sampling of leaf. NICR conducted appropriate preclinical studies that indicated that compound Q had little toxicity. As a result, NICR submitted an Investigational New Drug (IND) application to the FDA, and filed a patent application with the PTO on a new method of use for compound Q. Unbeknown to NICR, a foreign pharmaceutical corporation had also filed an application with the PTO for a similar method of use for compound Q. Very expensive interference proceedings between NICR and the foreign firm seemed imminent.

Following the filing of the IND with the FDA, NICR clinical studies revealed compound Q as a very active anti-tumor agent in several kinds of cancers. These promising findings left NICR in need of an industrial collaborator to assist in the further development of compound Q for broad use in cancer therapy. One of NICR's main concerns at this time was the ethical dilemma of not having sufficient quantities of the compound Q-containing natural product for future studies, as well as for public use thereafter.

NICR advertised the opportunity for a CRADA in the Federal Register and received ten proposals from both large and small biotechnology companies, as well as several foreign industrial entities. Following a careful review by an ad-hoc committee, Large Pharmaceuticals Inc. (LPI), a company based in Paris, France, was selected as the CRADA collaborator. LPI was chosen based on their demonstrated ability to obtain compound Q from other sources, their financial resources and expertise adequate to fully develop and market compound Q. Also in their favor was their willingness to begin immediate negotiations for the exclusive licensure of the patent application currently in

interference proceedings in the PTO and, under this licensing agreement, paying for all costs related to the continued prosecution and defense of this patent application.

NICR began CRADA negotiations with LPI, and negotiations were undertaken separately to address the licensing of the "background" patent filed before the collaboration was initiated. Although LPI argued that licensing rights to the background patent should be provided through the CRADA because such rights were necessary to the continuing commercial development of compound Q, NICR pointed out that the statutory and regulatory authority governing the licensing of existing government intellectual property requires a competitive licensing process for the licensing of government owned intellectual property, unless such intellectual property is developed under a CRADA. The CRADA is the only mechanism through which the government can promise intellectual property rights in advance. The intellectual property covered under the background patent, having been developed prior to the CRADA collaboration, cannot be considered a CRADA invention falling within the scope of PHS authority to license non-competitively.

Additional problems arose in the CRADA negotiations due to the presence of a provision in the CRADA stating that the reasonable pricing clause would be a part of any exclusive license agreement negotiated under the CRADA. LPI argued that the government's investment in the original research and development of compound Q would be adequately reflected in the royalty payments expected to be negotiated under the exclusive license. LPI expected that the royalty negotiated by the government would reflect the government's development efforts to date and the potential value of compound Q as a therapeutic agent. Although NICR convinced LPI of the importance of public accessibility to any product developed from compound Q, LPI felt the clause was ambiguous and predicted that it would have a difficult time convincing potential investors that the clause did not mean that the government would someday attempt to set the price of compound Q.

Finally, fair access to this CRADA collaboration became an issue. At the time NICR chose LPI as its collaborator, a Freedom of Information (FOIA) request was received by NICR for all documents relating to the development of compound Q. This request had come from legal counsel retained by a small, domestic biotechnology company (SC) who believed that NICR's procedures for identifying and selecting a CRADA collaborator were counter to the edicts and legislative intent of the FTTA. Their chief proposition was that NICR had failed to give preference to small, domestic businesses in their selection process as required under Federal Statute. To rebut this claim NICR explained that the requirement that the collaborator have the ability to make GMP product precluded many

small biotechnology companies from competing successfully. SC counter-argued that when the proposed project reached the point where GMP production would be required, they would either contract out this activity, or build their own facility with new-found capital generated via introduction of a new stock offering.

After several months of negotiation and clearance through the bureaucracy of LPI and the PHS, a CRADA was executed. LPI successfully competed for an exclusive license to the background patent and the parties compromised on the reasonable pricing clause by inserting a statement reciting that the clause did not give authority to the PHS to set the price of compound Q. Having voiced its concern over the selection of LPI but failing to move NICR to abort the intended collaboration, SC wrote its Congressional representatives and focused on seeking other CRADA opportunities.

Issues to Address

* What constitutes fair access to CRADA opportunities? Do companies perceive a problem with access to collaboration opportunities? Although the FTTA states a preference for small business and domestic manufacture, there is no requirement that individual CRADA opportunities be advertised. How should the small business preference be weighed in choosing a CRADA collaborator who can most effectively bring a product to the bedside? Should the PHS require the public advertisement of all CRADA opportunities, or establish more definitive guidelines governing access to CRADA opportunities?

* How should the reasonable pricing clause be handled in this situation? If the clause is not imposed, what alternatives can be negotiated between the parties to address government concerns of reasonable pricing and accessibility to products developed in part by the government? Should there be a threshold level of government development (such as pre-existing intellectual property) to "activate" fair pricing and accessibility concerns? How could this threshold be determined and measured effectively? Should alternative access programs be explored?

* Are companies deterred from entering into CRADAs due to the inability of the PHS to bring background patent

rights into the CRADA for licensing. What detriment to companies, if any, occurs by requiring companies to compete for background patent rights?

NIH CRADA FORUM
July 21, 1994

CRADA Forum I Invited Speakers

July 21, 1994

NIH Speakers

Ms. Daryl A. (Sandy) Chamblee, J.D.
Acting Deputy Director for Science Policy
and Technology Transfer
Bldg. 1, Room 103
National Institutes of Health
Bethesda, MD 20892

Dr. Dinah Singer
National Cancer Institute
Bldg. 10, Room 4B17
National Institutes of Health
Bethesda, MD 20892

Dr. Harold Varmus
Director
Bldg. 1, Room 126
National Institutes of Health
Bethesda, MD 20892

Case Studies Speakers

Ms. M. Dianne DeFuria
Senior Director of Biotechnology
Bristol-Myers Squibb
Route 206
Provinceline Road
Princeton, NJ 08543

Ms. MaryAnn Guerra
Executive Officer
National Heart, Lung and Blood Institute
Bldg. 31, Room 5A48
National Institutes of Health
Bethesda, MD 20892

Dr. Mitchell Max
Chief, Clinical Trials Unit
NAB, National Institute of Dental
Research
National Institutes of Health
Bethesda, MD 20892

Dr. Thomas Mays
Director, Office of Technology
Development
Bldg. 31, Room 4A51
National Cancer Institute
National Institutes of Health
Bethesda, MD 20892

Ms. Lisa Raines
Vice President of Government Relations
Genzyme, Inc.
1020 19th St., NW., Suite 500
Washington, DC 20036

Mr. Larry Stambaugh
President/CEO
General Biometrics/Syntello
4350 Executive Dr., Suite 310
San Diego, CA 92121

Congressional Speaker

Mr. David Schulke
Chief Health Policy Advisor
The Honorable Ron Wyden
U.S. House of Representatives
1111 Longworth House Office Building
Washington, DC 20515

CRADA Forum I Public Testimonies

July 21, 1994

Mr. Raymond Frisco, J.D.
Lawyer
Washington, DC

Mr. Lowell Harmison
Former Deputy Secretary
Office of the Assistant Secretary for Health
Washington, DC

Mr. Max Hensley, J.D.
Lawyer
Gillette Sciences
San Francisco, CA

Mr. John Kleimer
Vice President
Americans for Medical Progress
Washington, DC

Mr. Jamie Love
Director
Taxpayer Assets Project
Washington, DC

Mr. Chuck Ludlam
Vice President for Government Relations
Biotechnology Industry Organization (BIO)
Washington, DC

Mr. Lou Schuster
Chairman
Suburban Maryland High Technology Council
Rockville, MD

Mr. Peter Staley
Co-Chair
Public/Private Subcommittee of the National Task Force on AIDS Drug Development
Washington, DC

CRADA Forum I
Prepared Public Statements

July 21, 1994

- Eric Brewster (Regeneron Pharmaceuticals, Inc.)
- John Clymer (Americans for Medical Progress, Inc.)
- Raymond S. Fersko (Gordon Altman Butowsky Weitzen Shalov & Wein)
- Chuck Ludlam (Biotechnology Industry Organization)
- Peter Staley (National Task Force on AIDS Drug Development)

REGENERON REGENERON PHARMACEUTICALS, INC.
777 OLD SAW MILL RIVER ROAD
TARRYTOWN, NY 10591-6707
914-347-7000
FAX 914-347-2113
E-mail eric.brewster@regpha.com

ERIC S. BREWSTER
TECHNOLOGY TRANSFER ADMINISTRATOR

July 19,1994

Harold Safferstein, Ph.D.
Technology Transfer Branch
Nation Institute of Allergy and Infectious Diseases
National Institutes of Health
Building 31, Room 7A-32
9000 Rockville Pike
Bethesda, MD 20892

Dear Dr. Safferstein:

My name is Eric Brewster, and I am the Technology Transfer Administrator for Regeneron Pharmaceuticals, Inc. of Tarrytown, New York. I am writing to explain Regeneron's strong opposition to the "reasonable pricing" clause now required in all NIH/private sector agreements.

Regeneron was founded in 1988 to develop biotechnology-based products to treat neurological diseases and conditions for which no cures exist. Regeneron is engaged in the discovery and development of neurotrophic factors, which are naturally occurring proteins that promote the proliferation, survival, differentiation, and function of cells of the nervous system. These neurotrophic factors may have the potential to be used as drugs to treat a wide variety of neurological conditions, including motor neuron diseases such as amyotrophic lateral sclerosis (ALS, commonly known as Lou Gehrig's disease), diseases of the peripheral nervous system (such as diabetic neuropathy), and diseases of the central nervous system (such as Parkinson's disease and Alzheimer's disease).

Regeneron, like other biotechnology-based companies, has established its own research and development staff and facilities for the discovery, characterization, and development of new technologies.

In addition to the technology developed by our own scientists, Regeneron has gained access, through cooperative arrangements with corporate partners and researchers at major medical, academic, government, and commercial institutions, to technology that has had a positive impact on both basic research and the drug development process. Regeneron has a limited number of sponsored research agreements with academic laboratories focused on novel neurotrophic factors and their use and has entered into licensing agreements for specific technology for commercial development from a small number of academic institutions and corporations. We have collaborative development agreements with larger corporations to conduct basic research and commercialize specific compounds. Most frequently, we enter into research collaboration agreements with academicians who require Regeneron's scientific know how and materials (which have great value, and which are provided without financial charge) for their research projects, the majority of which are federally funded. In return for providing materials and scientific help, we seek to license rights in any inventions which are generated. Regeneron currently has agreements of this type with 372 investigators all over the world. Regeneron provides proprietary substances to these investigators with an aggregate value in the millions of dollars. You can see that the technology transfer process goes in both directions—we transfer technology into federally funded labs at at least the same rate that we hope to transfer it out.

Regeneron has provided proprietary material, free of charge, to over 180 academic, government, and commercial institutions through collaboration agreements. These collaborations provide scientists with research material and technology not available commercially and permit Regeneron to license potential technology which may result from these collaborative studies. These agreements provide Regeneron with resources far beyond our current capabilities. Without such agreements, the company would likely not have been founded, would not be as far along as we are in our development efforts, and certainly would not have been able to obtain financial backing from risk-oriented investors.

About the only type of technology transfer or collaboration arrangement that we do not participate in is CRADAs with NIH intramural scientists.

Alone among the Federal agencies with technology transfer programs, NIH has, as a matter of administrative discretion, included in its technology transfer agreements certain terms which permit NIH to specify or regulate the price for any product which is developed from the transferred technology. The NIH price review process is undermining technology transfer for one simple reason: there is no way for a private firm to evaluate the impact of the drug pricing clauses on the potential for commercial development of a product. As a result, an increasing number of biotechnology and pharmaceutical companies, particularly large companies which have ample resources and scientific capacity to fund their own research and develop their own technology, now refuse to enter into CRADAs with NIH, and they refuse to enter into joint ventures with other companies that have entered into CRADAs.

Regeneron has in the past year, however, entered into two collaborations with NIH intramural scientists using collaboration agreements other than a CRADA. I would like to describe one of these collaborations in detail.

Scientists at Regeneron and Dr. Igor Klatzo of the National Institute for Neurological Disorders and Stroke (NINDS/NIH), one of the world's leading researchers in the area of cardiac arrest cerebral ischemia, decided to enter into a collaborative study on the effects of one of Regeneron's proprietary materials on cerebral ischemia in rats. Unlike our agreements with researchers at academic institutions, this collaboration was formalized using an agreement which does not grant Regeneron the first option to license any technology developed as a result of the collaboration. We entered into this agreement because we believe that although a great deal of important knowledge will be gained through this collaboration, no new patentable technology will result from it.

To date, Regeneron has already provided Dr. Klatzo with know how, assistance, and proprietary materials valued at over $300,000. In light of some particularly exciting recent results obtained during this collaboration, which is now only seven months old, additional experiments have been planned. In order for Dr. Klatzo to carry out these experiments, he will be provided with additional materials valued at over $1.2 million! Clearly, research of this type could not be undertaken without the assistance of the biotechnology and pharmaceutical industry.

I bring up this example because, like Regeneron, many private companies are declining to enter into CRADAs with the NIH. As a result, NIH researchers are being cut off from resources (know how, materials, and, in effect, support) that would be available to them at academic institutions outside the NIH (since the pricing clause now applies only to CRADAs relating to the intramural (Bethesda) and not the extramural (university and foundation) research programs funded

by NIH). In addition to threatening the NIH's position as one of the world's foremost biomedical research institutions, this will ultimately be a loss for science, the biotechnology industry, and the American public.

The issue is not whether private companies are willing to share the economic benefits of transferred technology with the government. We are willing to pay reasonable fees and royalties. A private company can take these potential future royalty payments into account as it develops a product. This is standard practice when one private company licenses technology from another. Royalty requirements work because firms can reasonably predict what they will cost and how they will affect their potential for commercial success with the product.

Many independent studies have found that the NIH discretionary price review process is crippling the technology transfer process at NIH.

- The NIH insistence on price controls has "nearly ruined the system," said Dr. Steven Paul, the former scientific director of the National Institute of Mental Health and a creator of the NIH technology transfer program. Cited by Dr. Robert Goldberg in "Race Against the Cure: The Health Hazards of Pharmaceutical Price Controls," Policy Review, Spring 1994 (number 68), pg. 34.

- The HHS Inspector General noted that the controversy at NIH over CRADA pricing threatens support for the program (Office of Inspector General, Dept. of HHS, Technology Transfer and the Public Interest: Cooperative Research and Development Agreements at NIH (OEI- 92-01100) (Nov. 93)). This report finds that the use of an arbitrary "reasonable price clause" is undermining the transfer of NIH patents to private companies. Many private biomedical research companies now refuse to participate in CRADAs. This fact undermines the rationale for appropriating so many billions of dollars to fund this basic research. The impact of these price controls has been startling. 1993 was the worst year for new CRADAs in the history of the program. In 1992, 47 new CRADAs were reached and in 1993 this declined to 26 new CRADAs. Moreover, most of these new CRADAs do not involve drug development, a trend that results from the application of the pricing clause.

- Dr. Bruce Chabner, Director of the National Cancer Institutes (NCI) Division of Cancer Treatment, in testimony at a congressional hearing last year discussed specific instances in which companies have discontinued projects or suspended CRADA negotiations because of concerns raised by the "reasonable pricing clause." Chabner noted that "Other companies have simply refused to become involved with the NCI in early drug development . . . . NCI has no doubt that companies will not accept the risks of investing large sums in the development of a government product if their freedom to realize a profit is restricted. These companies are not willing to put their corporate fate in the hands of a government-appointed committee of experts. There are less risky ways for companies to make a profit." Testimony of Dr. Bruce Chabner, Director of the Division of Cancer Treatment, National Center Institute, before the House Subcommittee on Regulation, Business Opportunities and Energy of the House Committee on Small Business (Jan. 25, 1993).

- The Committee to Study Medication Development at the National Institute on Drug Abuse states that the "reasonable-pricing clause required in (DHHS CRADAs) in the last year has been identified by NIDA as a major deterrent to attracting private-sector partnerships. . . " The Committee "recommends a change in the reasonable pricing provisions of DHHS

CRADAs so that licensees or manufacturers of medications know explicitly the ultimate pricing or pricing structure for their potential therapeutic agent." It found that the number of CRADAs established by NIH had dropped from 126 in 1992 to about 26 in 1993. Development of Anti-Addiction Medications: Issues for the Government and Private Sector, Institutes of Medicine, 1994.

- A recent article cites NIH officials attributing the price control clause for the precipitous decline in CRADAs. "Many pharmaceutical companies are reconsidering CRADAs, and NIH officials say four of the largest -- Pfizer, Abbott Laboratories, Merck and the Upjohn Co. -- have told NIH that they plan to forego new CRADAs unless the pricing clause is removed." Christopher Anderson, "Rocky Road for Federal Research Inc.", Science, 497 (October 22, 1993).

- The Cancer Letter has recently published a draft "Action Plan on Breast Cancer" developed from a recent NIH conference convened by Secretary Donna Shalala which recommends "increase(d) efforts to speed the translation of basic research into clinical applications" and "review of the reasonable pricing clause in relation to CRADAs, as they impact on the flow of industrial funds into clinical research and, thus, affect collaborations." Cancer Letter, March 25, 1994.

The NIH discretionary price control clause in CRADAs is undermining the transfer of this government developed technology.

No one in the biotechnology industry is arguing that private biopharmaceutical companies should be permitted to charge unreasonable prices for their products. The industry, as a whole, does not charge unreasonable prices for its products now, which is demonstrated by the fact that the prices for biotechnology products tend to be higher, not lower, outside the U.S.

Instead of attempting to set or regulate prices, NIH should aggressively license its technology in exchange for upfront cash payments and/or royalties on sales. The amounts of these payments or royalties should be determined by negotiation between the parties and could vary, based on (among other things) the stage at which the technology is transferred. Innovative payment and royalty agreements could be developed. These royalty payments could be made into a biomedical research trust to fund more basic research.

The worst possible scenario is for the government to continue its basic research and then refuse to license its technology on terms that will ensure that it will be commercialized. Everyone loses with this approach, including taxpayers who fund the research, citizens who might benefit from the products, firms which could hire employees and pay taxes, and the United States for decreased competitiveness.

In conclusion, the "reasonable pricing" clause of the NIH CRADA impedes the establishment of scientific collaborations between intramural NIH researchers and industry, inhibits the transfer and development of technology that would ultimately benefit the public, does not necessarily reflect the public investment in NIH-supported research (or, more accurately, underestimates the private investment in intramural NIH research), may ultimately undermine the NIH's position as a leading biomedical research institution, and essentially blocks, rather than furthers, the intent of the Federal Technology Transfer Act of 1986 (FTTA).

Thank you for the opportunity to share these views with Dr. Varmus and the NIH CRADA Forum Panel.

Very truly yours,

Eric S. Brewster
Technology Transfer Administrator

cc: Sen. Alfonse D'Amato
Sen. Daniel P. Moynihan

Americans for Medical Progress, Inc.

STATEMENT OF JOHN M. CLYMER
VICE PRESIDENT
AMERICANS FOR MEDICAL PROGRESS
at
NATIONAL INSTITUTES OF HEALTH
COOPERATIVE RESEARCH AND DEVELOPMENT
AGREEMENTS FORUM
July 21, 1994

My name is John Clymer. I am Vice President of Americans for Medical Progress (AMP). AMP is a non-profit, non-partisan educational organization. We protect and promote the interests of our country's biomedical research community.

Thank you for the opportunity to share with you our views on technology transfer.

The Congressional intent of current technology transfer policy was to encourage commercialization of technologies discovered in federally-funded laboratories. Congress has viewed technology transfer programs as mechanisms to spur economic activity and to improve the well-being of citizens through, say, enhanced medical care.

Programs to transfer biomedical technology from government-funded labs to private industry which, in turn, develops new cures and treatments and brings them to market, have been quite successful.

Now, however, NIH's addition of a "reasonable price" clause to its cooperative research and development agreements threatens to hinder the development of life saving medical innovations.

The "reasonable price" clause is counter-productive. It drives medical research companies away from technology transfer. Representatives of several major drug development companies told me their firms will not enter into any new NIH CRADAs until the "reasonable price" clause is dropped.

One told me, "This reasonable pricing clause is straining a lot more relationships between NIH and industry than just those in the CRADA area. There's a fear on the part of companies that doing anything with NIH may result in getting caught up in this type of a pricing clause."

A U.S. International Trade Commission report states that, "the enactment of cost-containment programs, price controls, or both on a national level often results in decreased

Crystal Square Three • 1735 Jefferson Davis Highway • Suite 907 • Arlington, VA 22202-3401 • Tel 703.412.1111 • Fax 703.412.1116

levels of R&D spending. Several countries that have implemented such programs have seen their pharmaceutical industries weaken or shift outside their borders."

Reduced technology transfer hurts all parties -- NIH, academic institutions which receive NIH funds, research companies and, most important, patients.

For NIH to do excellent basic research, then have it go un- or under-utilized is inefficient and contrary to Congressional intent.

Moreover, many companies won't enter cooperative R&D agreements with NIH-funded university labs because they don't want to get entangled in price controls. This deprives some of our country's most productive medical research institutions of crucial sources of research funds.

But it's patients waiting and praying for life-saving and extending therapies for deadly diseases who suffer most. Many of the companies who shun NIH CRADAs are among those most capable of developing and manufacturing new drugs.

The "reasonable price" clause threatens future medical progress. A recent Congressional Research Service study found that, "Since NIH has chosen to utilize the fair pricing clause, fewer firms are interested in cooperative work with the laboratory."

The report warned, "The implications may be significant, not just for the companies involved, but for the development of new biotechnology drugs to meet the health, public welfare, and economic growth needs of this Nation."

NIH does not have the expertise to determine the "reasonableness" of prices. NIH do not have an office dedicated to the administration of this policy nor does it have relevant experience.

NIH is alone among federal research agencies in its inclusion of a "reasonable price" clause in its CRADAs. They serve the public through policies that provide for rapid, effective development of new technologies to improve human health.

Americans for Medical Progress supports system changes to reduce medical inflation. But price controls such as the "reasonable price" clause will exacerbate health care costs by delaying or preventing the introduction of cost-saving medical innovations.

AMP believes funds from products based on NIH research should be reinvested in biomedical research. One way to achieve this would be for royalties paid by companies for NIH technologies to be earmarked for additional NIH research, rather than going to the Treasury as general revenues.

I urge you to consider the adverse impact of the "reasonable price" clause on technology transfer and, more important, our country's medical progress. That, after all, is the goal we share

Thank you for your attention.

GORDON ALTMAN BUTOWSKY WEITZEN SHALOV & WEIN
114 WEST 47TH STREET
NEW YORK, N.Y. 10036-1510

MARJORIE SYBUL ADAMS
THEODORE ALYMAN
JORDAN L. BLEZNICK
DAVID M. BUTOWSKY, P.C.
RONALD M. FEIMAN
JEFFREY M. GUSSOFF
STEPHEN A. HELMAN
RICHARD M. HERVEY
PAUL RICHARD KARAN
IRVING H. PICARD
BONNIE D. PODOLSKY

ELLIS L. REEMER
MICHAEL B. REUBEN
DOUGLAS S. RICH
VICTOR J. ROCCO
KEITH L. SCHAITKIN
BARRY D. SHALOV
STUART M. STRAUSS
BRUCE J. WEIN
MARC WEITZEN
LAWRENCE J. ZWEIFACH

REBECCA A. BERLOW
DAVID M. BRENSILBER
DENNIS M. BRESNAN
JUNE H. BRETTLER
JEFFREY P. BURNS*
ANDREW H. CHARLES
M. JEAN CONNOLLY
ISAIAH D. COOPER
CLIFFORD S. DICKSON
DANIEL A. ETNA
KIM B. FIELDS
DEBORAH A. GARFIELD
JEFFREY S. GERON
KAREN B. GOLDFARB
HILLEL Y. GOLDSTEIN
VIRGINIA J. HARNISCH

JON D. KAPLON
STACY L. KATZ
JONATHAN KLEIN
NANCY D. LIEBERMAN
LAWRENCE A. LONDON
FELICIA A. MENNIN
CARIN F. MUHLBAUM
LOUISA S. RUFFINE
HOLLY G. RUSSELL
BRUCE D. SHAPIRO
LYLLIAN S. SIMINS
LISA A. STANCATI
CLAIRE R. TELECKI
JUDSON K. VICKERS
ISAAC M. ZUCKER

*ADMITTED IN OHIO ONLY

WRITER'S DIRECT DIAL NUMBER
(212) 626- 0822

TELEPHONE (212) 626-0800
TELECOPIER (212) 626-0799

RAYMOND S. FERSKO
C. LEONARD GORDON
DENNIS H. GREENWALD
JAVIER HERNANDEZ
COUNSEL

July 18, 1994

Dr. Hank T. Safferstein
Cooperative Venture Manager
Technology Transfer Branch
National Institutes of Allergy and
Infectious Diseases
National Institutes of Health
Building 31, Room 7A-32
9000 Rockville Pike
Bethesda, MD 20892

Re: Forum on Collaborative Research and Development
Agreements Meeting July 21, 1994

Dear Dr. Safferstein:

I am writing in response to the Notice that appeared in the *Federal Register* of July 8, 1994, concerning the above-referenced Forum.

My comments are specifically relevant to circumstances arising from background patent licensing and the licensing of cooperative research developments.

I am writing in my own capacity as a legal counselor and advisor in technology transfer issues. I have been negotiating these issues with PHS and the component institutes

of the NIH since the inception of the Federal Technology Transfer Act. I believe that the concerns which I express here are of increasing importance to present and future CRADA participants. These concerns must be addressed, if the CRADA concept is to survive and be successful.

As a CRADA partner, the Government has a duty as a matter of law to deal fairly with its CRADA partners. The Ad hoc Group of Consultants should make policy recommendations to safeguard CRADA partners from breaches of this duty.

We are in an embryonic period of technology transfer, when the Government is undertaking transactions that might otherwise occur solely in by the commercial sector. As a matter of law, the Government must be held to the same standards as private parties when it engages in commercial transactions, unless there is a statute of regulation to the contrary. *See, e.g., Travelers Indemnitee Company v. First National State Bank of New Jersey*, 328 F. Supp. 208 (D.N.J. 1971); *Molton, Allen & Williams, Inc. v. Harris*, 613 F.2d 1176 (D.C. Cir. 1980).

In particular, when a CRADA partner is granted rights in a given patent or patent application, the Government should not engage in conduct that might diminish the value of the rights granted to the CRADA partner. To do so is wasteful of the taxpayers' investment and undercuts an industry that relies on a consistent valuation of Government technology in gauging the commitment of its own resources to the CRADA.

No patent or patent application which is made available to an industry CRADA partner should be compromised by action taken pursuant to another CRADA. When NIH licenses patent document to one CRADA partner, and another CRADA partner has a patent which is alleged to dominate, the strength of the former document must not be compromised. By the same token, where a Government licensed application is involved or may become involved in an opposition or an interference proceeding, the Government must not engage in conduct that diminishes the value of the rights it has licensed. This means, for example, that the Government must enforce its patent application at all stages of prosecution and after the grant of a patent, and that no institute can enter into a CRADA or license or any other relationship that has the effect of diminishing the value of background rights licensed under another CRADA.

If Company A is relying on background rights for a CRADA with NIH and Company B has a patent that is alleged to dominate over the patent application licensed to Company A, then NIH is in breach of its common law duties of fair dealing to Company A if it enters into an agreement with Company B that in any way reduces the value of the right licensed to Company A. For example, if NIH is opposing Company B's patent alleged to dominate over the application of NIH licensed to Company A, NIH cannot grant rights to Company B in the patent application licensed to Company A without safeguarding the rights of Company A. NIH must begin to make commercial decisions which may result in a reduced quantity of transactions, but an enhanced quality of its transactions.

There has been discussion about decentralizing technology transfer by having each institute administer its own technology transfer. I caution that there must be a centralized system that tracks all of the NIH component institutes CRADAS, so that no CRADAS are entered into that have the potential to compromise in any fashion technology that the Government has already licensed to another CRADA partner. This requires an ability to have available an institutional knowledge of all aspects and nuances of relevant CRADAS that can be drawn upon before entering into new CRADAS. In point of fact, NIH does not possess such an ability even now.

Thank you for the opportunity to present these views. I believe the CRADA program has great potential, but the foregoing concerns must be dealt with so that the Government's partners can rely upon the Government as a viable partner in this important work.

My kindest regards,

Cordially,

Raymond S. Fersko

RSF:sb

BIOTECHNOLOGY INDUSTRY ORGANIZATION

STATEMENT OF CHUCK LUDLAM VICE PRESIDENT FOR GOVERNMENT RELATIONS BIOTECHNOLOGY INDUSTRY ORGANIZATION AT THE NATIONAL INSTITUTES OF HEALTH CRADA FORUM JULY 21, 1994

My name is Chuck Ludlam and I am Vice President for Government Relations of the Biotechnology Industry Organization (BIO).

BIO represents over 500 companies and other organizations, including virtually every company with which NIH has CRADAs.

BIO representatives have testified at two recent Congressional hearings on technology transfer issues and will testify soon at another. We have a 60 member Technology Transfer Task Force at BIO working on these issues.

We appreciate the scheduling of this Forum and the opportunity to present our views.

There is overwhelming support for technology transfer in the Congress. It is rightly viewed as a fundamental policy to enhance our nation's competitiveness. The NIH technology transfer program is vital to the health of millions of individuals who are suffering from diseases for which there are no effective treatments or cures.

I would like to make four points.

First, BIO believes that NIH has no legal authority for its "reasonable price" clause and that it undermines the effectiveness of the NIH technology transfer program.

In terms of legal authority we believe that NIH has no more authority to impose a pricing clause on licensees than FDA would have to add pricing to "safety" and "efficacy" as a regulatory requirement.

In terms of the impact of the clause I have personally heard from dozens of companies which would not even consider a CRADA with NIH. Many of them are reluctant to say this publicly.

Their reason for their refusing to participate is clear. With the pricing clause they are not able to make any determination of the likelihood that they will be able to generate a reasonable rate of return on their considerable research and development investment.

They are perfectly willing to pay reasonable fees and royalties, but they must reserve their right in a free enterprise economy to set a price for their products. This price will, of course, be dependent on the health care marketplace.

Let me cite one example of the impact of this policy.

I am aware of one company which was negotiating a joint venture with another company which had been awarded a one million dollar grant from the Department of Energy (DOE). DOE is an agency which has never imposed a "reasonable price" clause in its grants or licenses. This particular grant included no such clause. However, the investors in the company negotiating the joint venture insisted that the company with the grant renounce the grant to avoid any possibility of "contamination" of the joint venture project and it offered to pay, and did pay, the DOE grantee one million dollars to make up for the renounced grant.

In short, the concern over the NIH "reasonable price" clause is now undermining relationships between other agencies of the government and private companies. It is certainly undermining the effectiveness of the NIH technology transfer program.

Because the "reasonable price" clause is undermining the effectiveness of the NIH technology transfer process, it may ultimately undermine the rationale for appropriations for NIH research.

The interests of the government are fully satisfied if the CRADA partners of NIH agree to pay appropriate fees and royalties on any commercial product which is developed from the agreement and if the whole program stimulates research into cures and therapies for deadly and costly diseases, employment and economic growth and the competitiveness of U.S. firms.

Most important, because this clause is undermining the technology transfer process it is fundamentally inconsistent with the interests of the patients who wait for cures and therapies. They are the ones who die and feel pain as a result of this policy. For them this is not a question of statutes, law, or economics.

Second, let me comment on the political context in which this issue is being considered.

We cannot ignore the fact that drug prices are controversial and the current "reasonable price" clause included in NIH CRADAs is a political statement as much as a regulatory requirement. Drug prices are the subject of heated debate in the Congress as part of the health care reform debate.

Let me be more specific. Legislation has been introduced which would, in effect, require the government to set prices for drugs which are utilized by Medicare beneficiaries if the "Federal government had a substantial role in the research and development of the drug." The prices would be set by subtracting a "rebate" from the manufacturer's sales price and requiring that it be paid to the government.

If enacted into law this bill would be the first legislative requirement for the government control of the prices of licensed technology.

Ominously, the bill makes no distinction between direct and indirect government roles in the research and development of the drug. It would require the setting of prices for drugs developed under licensing agreements pursuant to both the NIH intramural and extramural programs.

It would require this price setting even though the manufacturer is paying a royalty to the government agency or academic institution from which the technology was licensed.

The term "substantial" is, of course, not defined.

If a company refuses to abide by the price set by the government it would be blacklisted from all sales under the Medicare program.

The bill would only apply to drugs sold to Medicare beneficiaries, not to drugs sold to non-Medicare beneficiaries. We believe, however, that once Medicare has set a price that this price would, in effect, set the ceiling for the price of the drug no matter what market is involved.

This proposal may well be offered as an amendment to the health care reform legislation in the next few weeks.

Let me be clear. If this NIH Forum reaffirms the current NIH "reasonable price" clause it will, in effect, invite Congress to institutionalize the pricing clause and apply this requirement to both the NIH intramural and extramural programs.

It is time for NIH to stand up and say that this policy has been tried and has proved to be counter-productive. This is NIH's issue, not just BIO's.

Third, let me comment on the relationship between NIH technology transfer policies and those of other government agencies with CRADAs.

NIH is the only agency involved in biomedical research with includes the "reasonable price" clause in CRADAs.

We believe it is particularly strange that this clause is included in CRADAs from the NIH Human Genome Project but not in CRADAs from the Department of Energy genome program.

The clause is not included in the CRADAs of the Walter Reed Hospital or the many other government agencies involved in biomedical research.

If there exists a rationale for including the pricing clause in NIH CRADAs, there is no reason why such a clause should not also be included in the CRADAs of other agencies.

If the clause can apply to medicines, it can also apply to flat panel screens.

In fact, if pricing clauses are included in licenses where companies pay royalties to the government, it would seem to make even more sense for grantees of the government to sign such clauses.

This would potentially affect grantees of the National Science Foundation, grantees of the NIST Advanced Technology Program, SBIR award recipients, and numerous other government grant programs.

In short, the issue here goes way beyond NIH. The issue here is generic to every government technology transfer program. If the government develops technology and transfers it to company or provides a grant, the company is able to develop a product and generates sales, and a controversy arises over the price of this product, calls will come for the government to regulate the prices of the licensees or grantees. Other technology transfer and grant programs are just a headline away from calls for price controls.

NIH shares its statutory mandate for CRADAs with that of other agencies and it is, therefore, incumbent on it to coordinate its policy with that of other agencies with CRADAs. There should be a heavy presumption against NIH adopting any policy which is fundamentally inconsistent with that of the other CRADA agencies. The fact that no other agency has engaged in this form of price control substantiates our view that NIH has no legal authority for this policy.

The NIH "reasonable price" policy will undermine the effectiveness of every government technology transfer policy -- or grant program -- to which it would be applied. NIH bears a heavy responsibility for setting, or confirming at this Forum, any policy and precedent which would undermine the effectiveness of the CRADA programs of other agencies.

Finally, it may be tempting for NIH in its current review of CRADAs to decide to

limit its pricing clauses only to very late stage development agreements, where a drug is essentially ready to be marketed to the public. This would severely limit the application of the clause. In most cases the private industry licensee must invest substantial sums, a multiple of the amount invested by NIH, in the development of a drug, taken through clinical trials, approved by the FDA, and sold to the public.

Such a restriction would ensure that NIH would have the greatest difficulty in licensing products which could quickly provide medical benefits to patients. Barriers and disincentives for technology transfer in these cases would be not just be unwise, it would be tragic.

In addition, if NIH restricts its use of the pricing clause to these rare cases, it will still have a chilling effect on the whole technology transfer program. Every licensee would be concerned that any research it undertakes with the NIH would eventually, as it focuses more and more on a specific product, come under the pricing clause. Companies often enter into a series of CRADAs, each with its own specification of the work, and they would be reluctant to enter into the first CRADA for fear that the second or third or fourth would contain the pricing clause.

The issue here is one of law, policy and principle. Pricing of medicines is for the health care market to determine, not the NIH. This is neither the agency's mandate or responsibility. Its responsibility is to conduct the best possible basic research and to transfer its technology in a manner that will ensure that it will reach the bedside of patients. This is what the American people and the Congress expect and deserve.

To conclude, the simple, practical, fair and legal approach to this issue is for NIH to aggressively license its technology in exchange for reasonable fees and royalties. This will fully reimburse the government for its expenditures and revitalize the NIH CRADA program.

Again, we applaud the NIH for undertaking this review of the CRADA program and appreciate the opportunity to present the views of the biotechnology industry at this Forum.

I ask that a copy of testimony presented on behalf of BIO to the Joint Economic Committee be printed in the hearing record. This testimony presents a complete statement of BIO's views on the NIH CRADA program.

Thank you again for this opportunity to testify. I am happy to answer your questions.

BIO

BIOTECHNOLOGY INDUSTRY ORGANIZATION

BIO POSITION PAPER FOR NIH FORUM ON CRADAS July 21, 1994

The following Position Paper is submitted by the Biotechnology Industry Organization at the July 21 NIH CRADA Forum. It covers a range of issues impacting the effectiveness of the NIH technology transfer process.

Introduction

The mission of the National Institutes of Health (NIH) is to conduct biomedical research in an effort to improve the health and quality of life of the American people. The authority granted to NIH to enter into Cooperative Research and Development Agreements (CRADAs) has and will continue to support and facilitate NIH's research mandate. CRADAs also offer the public a vital chance to accelerate the transition of discoveries into health care products. NIH's administration of its CRADA authority is problematic, however, and BIO offers the following comments in the spirit of collaboration and in the best interests of the United States public.

(1) Applicability of CRADAs to Diverse Research Projects

NIH appears to have taken in inappropriately conservative view of the kinds of projects that it will approve for CRADAs. The NIH Director should encourage NIH scientists to enter into CRADAs when this will facilitate their research and the transfer of research discoveries into practical uses. NIH also directly benefits from CRADAs by accessing external research expertise, proprietary research materials, and funding for post-doctoral staff, equipment and travel.

Pursuant to Section 301(a) of the Public Health Service Act, agencies of the Public Health Service, such as NIH, are authorized to

conduct...and encourage, cooperate with and render assistance to other appropriate public authorities, scientific institutions and scientists in the conduct of, and promote the coordination of, research, investigations, experiments, demonstrations, and studies

relating to the causes, diagnosis, treatment, control, and prevention of physical and mental diseases and impairments of man...

In pursuit of this solemn mission, NIH supports a broad spectrum of research approaches, spanning from basic laboratory research to clinical research.

The Federal Technology Transfer Act (FTTA) defines a CRADA as "any agreement between one or more Federal laboratories and...non-Federal parties...toward the conduct of specified research or development efforts which are consistent with the missions of the laboratory." The legislative history and implementation of the FTTA by various agencies show no indication that it was the intention of Congress to limit CRADAs only to research that reflects "practical technology" rather than generally to encourage collaboration with industry in mission-appropriate research. In other words, Congress broadly defined the categories of collaboration (e.g., research or development) that are to be encouraged, rather than any particular kind of projects (basic or applied). BIO notes that the PHS Act, which defines NIH's mission, explicitly also encourages cooperation, encouragement and assistance.

In recent internal debates at NIH, the propriety of CRADA projects such as those involving gene therapy have been questioned because they encompass very basic scientific objectives. However, because NIH policies reserve the right to publish the results of any CRADA project, CRADAs on mission-appropriate projects, such as involve gene therapy, should not be viewed as a threat to the integrity or mission of NIH. NIH has and should assure the public that access to NIH is fair and that NIH laboratories have not become captives of industry. NIH should refrain from attempting to make subjective decisions about which projects are basic vs. applied and encourage all investigators to consider CRADAs as the FTTA contemplates.

(2) Staffing for the CRADA and Technology Transfer Programs

Most Federal laboratories have established industrial liaison offices and more significantly have allocated at least one full time professional staff person to coordinate the development of a CRADA program. A successful program requires outreach to industry, training of NIH staff and scientists and a commitment to continuous program improvement. Surprisingly, NIH has not filled a CRADA position at the Office of Technology Transfer (OTT). This function should not continue to be a side job for senior OTT staff. Reasonable assistance to companies and the acceptance of CRADAs on the part of intramural scientists requires a "champion" on the central-NIH staff. The consequences of inadequate staffing in technology transfer matters recently were highlighted at a hearing of the House Small Business Committee. Adequate staffing of the CRADA program is necessary for it to be successful.

Additionally, NIH reorganized the Office of Technology Transfer last October and established a number of managerial, administrative and support positions. Still vacant are positions for the OTT Director, Division Director for Technology Transfer, Chiefs of two technology transfer teams, several legal assistants and a Division Director for Administration. NIH's seeming inability to recruit and fill these positions has limited its ability to transfer technology , resulted in professional staff handling secretarial duties and interfered with timely

communications and decisions. Giving OTT the staff tools that it needs to perform its vital public health mission should become a clear priority for the NIH Director.

(3) Delay and Inconsistency in the CRADA Process:

Negotiation of licensing agreements between private companies is complicated and it is no less complicated when the government is a party. Both parties to an agreement need to be flexible, good listeners, and responsive to the special circumstances of the agreement. Many companies find that negotiating a CRADA with the government is a frustrating and lengthy process. This drives up the expense, delays research and provides a disincentive to begin the negotiations. Government technology transfer agents need to be well trained and given the discretion to negotiate a reasonable agreement without undue bureaucratic delay. These agents need to have the discretion to tailor license terms to the specific requirements of the license.

Simply put, the CRADA approval takes too long.

A key factor that seems to contribute to the delays is undue bureaucracy, with no fewer than six (6) levels of review and approval. This seems to lead to an unwillingness to make decision at all levels, a lack of authority to make decisions at the decentralized level, and a "second guessing" of those few decisions actually made at different levels.

There is a disconnect between CRADAs and licensing.

The corporate world perceives the CRADA process to include any technology that results from collaborations. For the NIH, these processes are completely separate. Collaborators are asked to accept the risk, should inventions result, that a license would in fact be guaranteed, as authorized by the FTTA, and the time delay that negotiating and executing suck an agreement would entail.

There is a lack of consistent policies on acceptable terms and lack of standards.

Because each Institute negotiates all the terms (research as well as business and legal terms) of its CRADAs separately, there are often significant differences between what is acceptable in one Institute, as compared to another, or even as compared to general NIH policies. Some Institutes insist on more restrictive language than that which would be acceptable to NIH as a whole. Some Institutes agree to language that is contrary to NIH policies, requiring a renegotiation and repeat of the minimum of six levels of review and approval.

There is a lack of familiarity with business management, operations, and finance.

Most Institute technology transfer personnel have transferred into the positions from administrative or research positions. These individuals often lack sufficient specific business/technology transfer experience. In addition, it seems to lead to a cautious attitude toward for-profit businesses by these government administrators

One reasonable solution to these issues is to have centralized CRADA and concomitant

License negotiation. Dealing with one party, sufficiently trained and adequately supported, would solve the coordination problems and go a long way toward reducing bureaucratic delays.

However, BIO recognizes that each Institute has its own unique research mission. Therefore, we recommend that each Institute maintain its responsibility for negotiating the specific areas of scientific areas of scientific collaboration appropriate to its authorized mission. We suggest that the CRADA subcommittee be abolished, in favor of greater Institute control over their own research missions, and in favor of a more generalized NIH technology transfer policy committee. a centralized office should be established to negotiate all business and legal issues and terms of the CRADA document itself, with staff uniquely well trained in these matters.

If a centralized office is not possible, we recommend a team approach to CRADA negotiation, with greater involvement of the licensing specialists from the Office of Technology Transfer, and dedicated staff form the Office of General Counsel at the earliest stage of discussions with the corporate collaborator. This team should have the authority to approve CRADAs. Member of this team should be known to the potential collaborates.

At a minimum, we recommend that consistent cross-Institute policies and procedures be established, that Institute staff be rigorously and routinely trained and retrained in those policies and procedures, that there be established a dedicated, centralized CRADA support staff, perhaps within the OTT. Hopefully, greater understanding of corporate motivations may reduce the confrontational attitude prevalent among some at the NIH, and generate an attitude of mutual cooperation.

(4) Enforcement of Patent Rights

In virtually all cases the transfer agreement involves the licensing of a patent or patent application. Patent issues are quite complex. It is common for patents to conflict with one another, and there can be complicated negotiations and litigation among various patent owners. It is critical for one to enforce ones patent vigorously in every forum. Patents which are not well defended can be devalued or even made worthless. In most cases it is the licensee which has the greater interest in enforcing the patent. The government is not experienced in, or funded for, this specialty and should rely on licensees to handle any challenges to the patent.

In theory, each institute relies on the NIH Office of Technology Transfer (OTT) to manage virtually every aspect of the institutes patent portfolio. Thus, OTT is expected to act rather like an in-house corporate counsel on behalf of the institute, interacting with selected outside counsel on diverse issues such as when to file an application, whom to name as inventor(s), what to claim, and how to handle relations with licensees. Even when the institute can afford a patent liaison to interface with OTT, however, the press of work and critical understaffing at OTT means it cannot maintain consistent communications with the institute or act as if it lacks a clear mandate from the institute or even know what the latter wants. Conversely, institute personnel tend to perceive that they, rather than OTT, must make all decisions about a given case. The result is general confusion and sometimes open antagonism between OTT and the "client"institutes, a fact that is communicated to outsiders in the form of

mixed signals and indecisiveness. The NIH Director should articulate the authority delegated to the OTT and ensure that the institutes cooperate.

Thus, NIH gives the general impression that it is unable either to prosecute and enforce its patents effectively or to delegate such functions to its licensees. The aforementioned absence of an effective management structure for technology transfer is exacerbated by wholly inadequate levels of funding and staffing for OTT operations. The simple task of reaching the appropriate person at OTT can become a difficult task for institute personnel and outsiders alike, for example. As a consequence, both morale and the availability of trained advisors at OTT have worsened steadily in recent years.

Finally, OTT's ability to deal productively with the private sector is undercut by the fact that the final word on patent enforcement as well as numerous contractual issues comes not from the NIH General Counsel's Office but rather from the U.S. Department of Justice. In particular, key individuals of Justice have made no secret of their hostility toward the notion that the U.S. government should ever be a party, even indirectly, to an effort to enforce any government-owned patent. The division of authority with Justice adds yet another delay to decision-making at NIH and, in addition, makes it nearly impossible for NIH to "grant to [a] licensee..the right of enforcement" pursuant to 35 USC §207 (a)(2). --

(5) Scope of Work Limitations

Scientific research is a process typified by serendipity. One discovery can lead to another, surprises are common, and dead ends can be very instructive. If NIH overly restricts the scope of the work to be conducted under a CRADA, the flexibility of the scientists to pursue interesting leads is limited and the attractiveness of the research project to the company is diminished. Similarly, if NIH limits the scope of the license so that serendipitous discoveries are not covered, it may leave a licensee unprotected when it achieves a medical advance. The agreements need to include both directly and indirectly related discoveries that are made in the course of the collaboration. Restricting the scope of the technology covered by the license ignores the nature of the scientific discovery process and is unreasonable, given the public interest in expeditious product development.

In the past year or two, NIH appears to have adopted a policy of trying to restrict both the scope of CRADAs that it will enter into and the rights it is willing to transfer exclusively with respect to technology developed under a CRADA. For example, when a company proposes a work plan with several related approaches to a particular problem, NIH may restrict the plan to one approach. If an invention arising under the CRADA has several related uses, NIH may attempt to restrict exclusive rights to only the particular use for which work was done under the CRADA. This policy undercuts the incentive of companies to enter into CRADAs, does not fully recognize the serendipitous nature of scientific research, and is counter to the policies embodied in the Technology Transfer Act of 1986.

We recognize the need for NIH to avoid CRADAs that may unfairly or unwisely tie up the work of an entire laboratory. However, this does not mean that a broad work plan is automatically to be rejected. Such a work plan should be permitted, once an NIH researcher

or group of researchers decide they would like to collaborate with a company in a broad area and that company brings to the collaboration meaningful scientific and other resources consistent with the proposed work plan. Similarly, unrealistic attempts to narrow a broad work plan to eliminate reasonably foreseeable secondary areas and aspects of the work that are directly related to the primary efforts is an unrealistic view of the nature of science and business. Since the technology rights available for licensing exclusively under a CRADA are defined by the work plan, such unrealistic boundaries create major concerns and provide major disincentives to a company for entering into a CRADA. A company simply cannot allow itself to be placed in a situation where its work may have enabled a broad new area of technology, yet be entitled to exclusive rights for only to part of that technology. this places it in the position of having enabled its competitors.

An overly restrictive work plan also ignores the serendipitous nature of science. Unexpected discoveries are common, and scientists are trained to pursue interesting leads, often shifting course quickly from an original research plan. if NIH overly restricts the scope of the work to be conducted under a CRADA, the flexibility of the scientists to pursue interesting leads is limited, and the attractiveness of the research project to the company is diminished. therefore, there needs to be some degree of flexibility in the work plan, which is accomplished by having a plan that is reasonably broad in scope and flexible in the description of the project.

Similarly, if the CRADA results in an invention, there needs to be reasonable breadth and flexibility with respect to the technology to be licensed exclusively to the collaborator. Unreasonable restrictions on the c\scope of the field or fields of the licensed technology or artificial divisions within a particular field unfairly limits the returns that the collaborator reasonable expects and significantly undercuts incentives to enter into future CRADAs. While it may be inappropriate to license a field of use to a company that is not in that field ar has no immediate plans to enter it, it is also inappropriate to deny the reasonable and logical implications of the specific research and discovery. Also, if NIH limits the scope of license so that serendipitous discoveries are not covered, it may leave licensee unprotected when it achieves a medical advance. The agreements need to include both directly and indirectly related discoveries that are made in the course of the collaboration. Again, a company should not be put into a position of funding and participating in research, the technological results of which can then be licensed to a competitor.

The goal of the 1986 Act is to encourage transfer of technology from government laboratories to the private sector. We believe that meeting this goal requires an overriding philosophy of taking all reasonable steps to facilitate broad technology transfer. Consistent with the reasonable protection of the public interest and the fair implementation of a technology transfer program, NIH should "err" on the side of broad rather than narrow technology transfer policies and activities.

(6) Observance of Duty of Fair Dealing

In some cases, an NIH scientist or one or more institutes are working with more than one company at a time on a given or related subject. It is critical for NIH to protect the intellectual property licensed to each of its licensees and to ensure that NIH does not engage in any conduct

which reduces the value of the rights it grants to its CRADA partners. NIH must not enter into CRADAs that have the potential to compromise any of the technology that it has licensed either by way of background rights or in any other manner.

(7) Negotiation of Licensing Terms

NIH is reluctant to negotiate and agree to a license upfront for whatever technology might be developed under a CRADA. Under current CRADA guidelines, the commercial collaborator has only an option to negotiate a license to develop the inventions of the joint research project, in contrast to a license to develop and commercialize the invention. The absence of a licensing obligation from NIH regardless of the performance of the commercial collaborator under the original CRADA, or its capabilities or commitment to commercialize the invention, adds an unacceptable level of risk to the original financial investment for the commercial collaborator. Steps should be taken to protect the interest of both parties.

Specifically, NIH should develop criteria defining an acceptable commercial partner. During the original CRADA negotiation the commercial collaborator would be given the opportunity to provide acceptable evidence of its experience, capability, and commitment to commercialize the expected inventions to meet the criteria established by NIH. Based on the information presented by the partner, NIH would certify the acceptability of the partner for purposes of a subsequent licensing agreement.

During the original CRADA negotiation both parties will agree on basic terms of the agreement to develop and commercialize the invention. These terms will include the degree of exclusivity of the license and the range of royalties and fees. This will at least provide a cap on the license cost to the company. With this information available at the outset, the company will decide whether there is sufficient upside to justify its investment. At the same time the company would be protected against a new entity coming in to buy a successful project and outbidding the original sponsor that took all the risk. In short, CRADA partners should have vested license rights at the outset in all fields of use to whatever inventions are made under a CRADA.

(8) Reasonable Price Clause

BIO's position on the "reasonable price" clause is covered in BIO's written submission to the NIH Forum.

INTELLECTUAL PROPERTY AND FAIR PRICING CLAUSES IN AGREEMENTS BETWEEN THE FEDERAL GOVERNMENT AND PRIVATE INDUSTRY RELATING TO RESEARCH ON PHARMACEUTICAL PRODUCTS FOR SERIOUS OR LIFE-THREATENING DISEASE

The Pulbic/Private Issues Subcommittee of the National Task Force on AIDS Drug Development has identified two barriers that may prevent the rapid development and evaluation of treatments for HIV/AIDS: 1) the National Institutes of Health (NIH) has declined to include clauses granting exclusive patent licenses for inventions made during research conducted under cooperative research and development agreements (CRADAs) and other research agreements with the pharmaceutical industry, and 2) the NIH began in 1989 to insist on the inclusion of so-called "fair price" or "reasonable price" clauses in CRADAs and other research agreements with the pharmaceutical industry.

The Subcommitee believes that these two policies have resulted in a stifling of collaboration between the federal government and the pharmaceutical industry, and could prevent the rapid development of treatments for HIV/AIDS. The lack of appropriate intellectual property clauses and the inclusion of fair pricing clauses represent administrative decisions that are not required by congressional enactment. The Subcommittee recommends that appropriate intellectual property clauses should be included in, and pricing clauses should be excluded from, CRADAs and other collaborative agreements relating to pharmaceutical products (including drugs, biologics, and medical devices) for serious or life-threatening diseases (an established category of products for which the FDA considers treatment INDs under 21 C.F.R. §312.34 and accelerated approval of NDAs under 21 C.F.R. subpart H).

The Subcommittee recognizes the issue of pharmaceutical prices as it relates to access to health care, but believes that any response to this issue should be comprehensive. By targeting only those pharmaceuticals resulting from collaboration between industry and government, the NIH has inadvertently stifled such collaboration.

As an alternative to fair pricing clauses, the payment of royalties to a government agency which develops and transfers a technology to a private firm for commercialization might be considered. This would serve to compensate for the public investment in a marketed product, provide additional revenues for government research, and provide a special incentive for government agencies to enter into collaborative agreements.

Appendix B

CRADA Forum II Background Information

CRADA Forum II Agenda

Bethesda Marriott
5151 Pooks Hill Road
Bethesda, MD 20814

September 8, 1994

7:30–8:30	Registration
8:30–8:45	Charge to the Panel Dr. Harold Varmus, Director, NIH
8:45–9:15	Overview of CRADAs and NIH Licensing Program Ms. Barbara McGarey, OTT, NIH
9:15–9:45	History and Effect of the "Reasonable Pricing" Clause Dr. Thomas Mays, NCI, NIH
9:45–10:45	***Panel Discussion*** Paying Back the Public Investment: What Kind of Return Is Appropriate?
	Comments from the Floor
10:45–11:00	Break
11:00–12:30	***Panel Discussion*** Paying Back the Public Investment: How Much Return Is Appropriate?
	Comments from the Floor
12:30–1:30	Lunch

1:30–2:45	***Panel Discussion*** Paying Back the Public Investment: Balancing Public Payback and New Product Development Comments from the Floor
2:45–3:45	Additional Public Comment Period
3:45–4:00	Break
4:00–5:30	Panel Writing Session

CRADA Forum II Mandate

The Federal Technology Transfer Act of 1986 (FTTA) and subsequent executive order 12591 (April 10, 1987) were developed in recognition that U.S. industrial competitiveness can be greatly enhanced if technology developed in Federal laboratories is commercialized by American industry. To stimulate technology transfer, the FTTA authorizes Federal laboratories to enter into cooperative research and development agreements (CRADAs) with industry (and others) and provides incentives to both the Federal scientists and collaborating companies to do so. CRADAs provide an opportunity for NIH scientists to join with their private colleagues in the joint pursuit of common research goals. Since 1986, NIH has conducted cooperative biomedical research, primarily with industrial partners, under 206 CRADAs. As the Government's experience with CRADAs has grown, several issues of concern have developed, prompting NIH to seek advice and develop appropriate policy.

The NIH Director convened a Forum on July 21 to solicit advice and recommendations from the biotechnology and pharmaceutical industries, the research community, and the public on issues relating to cooperative research and development agreements. The Forum focused its deliberations on scope of the research and license rights under a CRADA, fair access to collaborative research opportunities, and the "reasonable pricing" clause. The "reasonable pricing" clause elicited the most discussion from industry, NIH scientists, and the public.

The NIH Director is now convening a follow-up Forum, solely on "reasonable pricing," to solicit additional advice and recommendations from primarily consumers and other public interest groups. The issues to be addressed are:

- *Paying back the Government investment: What kind of return is appropriate?*

  Is the public investment in products developed through licensing NIH technologies adequately reflected through the payment of royalties and the expeditious development of new products? If not, is it also suitable for NIH to become involved in "downstream" issues of marketing and distribution, such as the pricing of such products? How else could or should the public investment be reflected?

- *Paying back the Government investment: How much return is appropriate?*

  NIH currently obtains a financial payback from licensees for the right to develop Government technology in the form of license execution fees, minimum annual royalties, and royalties on net sales. NIH also ensures expeditious development through benchmarks and milestone requirements within the license. NIH negotiates this financial and "development" return on a case-by-case basis taking into account the type of technology, the amount of Government investment (both financial and intellectual), the stage of development of the technology, and the public health benefit or research value of the technology.

  If additional types of return are desired, should these also be tailored according to the amount of the NIH investment and the stage of the investment in the product development continuum? As with royalties and development benchmarks, should NIH negotiate additional types of payback on a case-by-case (or categorical) basis using the above criteria?

- *Paying back the Government investment: Balancing public payback and new product development*

  If scrutiny of product pricing is appropriate to ensure reflection of the public investment, are NIH licenses the right vehicle in which to require the scrutiny? If not, how and by whom should this be accomplished? If assumed by NIH, will this role conflict with the NIH technology transfer mission and hamper new product development? Is decreased new product development acceptable in return for having NIH play a role in the "downstream" marketing and distribution of the product? If not, how can NIH become involved without negatively affecting new product development?

NIH CRADA FORUM II
September 8, 1994

CRADA Forum II Invited Speakers

September 8, 1994

Dr. Thomas Mays
Director, Office of Technology Development
National Cancer Institute
Bldg. 31, Room 4A51
National Institutes of Health
Bethesda, MD 20892

Ms. Barbara M. McGarey, J.D.
Deputy Director
Office of Technology Transfer
National Institutes of Health
6011 Executive Blvd., Suite 325
Rockville, MD 20852

Dr. Harold Varmus
Director
Bldg. 1, Room 126
National Institutes of Health
Bethesda, MD 20892

CRADA Forum II Public Testimonies

September 8, 1994

Dr. Michael Rogawski
Epilepsy Research Branch
National Institute of Neurological Disorders and Stroke, NIH
Bethesda, MD

Mr. Chuck Ludlam
Vice President for Government Relations
Biotechnology Industry Organization (BIO)
Washington, DC

Mr. Ronald A. Rader
President
Biotechnology Information Institute
Rockville, MD

Mr. James Love
Director
Taxpayer Assets Project
Washington, DC

Ms. Eleanor J. Lewis
Director
Government Purchasing Project
Washington, DC

Mr. Christopher J. Doherty
Washington Director
New England Biomedical Research Coalition
Washington, DC

Dr. Vincent F. Simmon
President and Chief Executive Officer
Alpha 1 Biomedicals Inc.
Bethesda, MD

Ms. Ellen Stovall
Executive Director
National Coalition for Cancer Survivorship
Washington, DC

Ms. Virginia T. Ladd
President, Executive Director
American Autoimmune Related Diseases Association, Inc.
Detriot, MI

Ms. Penny Catterall
Director of Health Policy
Alliance for Aging Research
Washington, DC

Mr. Andrew Vogt (reading Dr. James Driscoll's statement)
Director for Policy
Direct Action for Treatment Access
San Francisco, CA

Mr. Joseph Slay
President
Martin Public Relations
(Speaking for Andrew's Buddies)
Richmond, VA

CRADA Forum II
Prepared Public Statements

September 8, 1994

- Karen Bernstein (BioCentury Publications, Inc.)
- Penny Catterall (Alliance for Aging Research)
- Christopher J. Doherty (New England Biomedical Research Coalition)
- James Driscoll (Direct Action for Treatment Access)
- Virginia T. Ladd (American Autoimmune Related Diseases Association, Inc.)
- Eleanor J. Lewis (Government Purchasing Project)
- James Love (Taxpayer Assets Project)
- Chuck Ludlam (Biotechnology Industry Organization)
- Leonard Minsky (National Coalition for Universities in the Public Interest)
- Vasiliana V. Moussatos (Private Citizen)
- Peter Staley (National Task Force on AIDS Drug Development)
- Ronald A. Rader (Biotechnology Information Institute)
- Eugene P. Schonfeld (National Kidney Association)
- Vincent F. Simmon (Alpha 1 Biomedicals, Inc.)
- Joseph Slay (Andrew's Buddies)
- Bradley Stillman (Consumer Federation of America)
- Ellen Stovall (National Coalition for Cancer Survivorship)

Reprint from August 29, 1994

BioCentury

ARTICLE REPRINT THE BERNSTEIN REPORT ON BIOBUSINESS

Commentary

Why pay the piper?

Two or three times a year, like clockwork, companies developing products with some component of government funding come under assault from proponents of price controls or other forms of restraint, who trot out proposals for greater federal control over the private sector.

Earlier this year, for example, Sen. David Pryor, D-Ark., introduced a bill (S. 2239) that would have imposed price controls on Medicare drugs developed with any NIH funding, whether through intramural (NIH) or extramural (university or research institute) programs. Rep. Ron Wyden, D-Ore., routinely makes similar proposals.

Fans of the pricing provisions in CRADAs will get a second chance to testify on the subject at a meeting to be held on Sept. 8, after complaints that they didn't get enough airtime for their side of the story at a meeting in July. The new hearing will hear "consumer and other public interest perspectives" on "how best to ensure that the public investment in products developed through licensing NIH technologies is adequately reflected."

Debates between protagonists and opponents of CRADA pricing clauses can sound a bit like the "am to—am not" arguments children have on playgrounds. That's because the two sides are speaking different languages: advocates of controls speak in moral terms of right and wrong; opponents speak in terms of business practicality.

Perhaps the best place to begin is with a summary of the arguments by the "controllers," based on testimony at congressional hearings by Ralph Nader and James Love of the Center for Study of Responsive Law, and Peter Arno, a professor at the Albert Einstein College of Medicine, as well as interviews with Girish Barua, a licensing specialist in the Office of Technology Transfer at NIH, and Steve Jenning, staff director of Wyden's subcommittee on regulation, business opportunities and technology. Their key points:

Government pays a substantial portion of drug development costs.

"Our guess is the government's expenditures for preclinical trials is considerably more than industry," Love says. He also estimates that the money the government spends on clinical trials is equal to 20-25 percent of the total spent in the U.S.

Government's contribution comes at the riskiest, early stages of development.

"The federal government plays a particularly important role in the highest-risk research projects, including basic research, where commercial payoffs are least certain," according to joint testimony by Nader and Love.

Jenning makes the same assumptions. "Where the government is of fundamental importance is in early-stage research and agent identification. This is a high-risk venture and is least attractive to the drug industry," he says. "When we take these huge risks the taxpayer deserves to see some return, particularly in the way resulting products are priced."

Nader adds that he believes that most of the costs of drug development come in the preclinical stage, with 85 percent of the costs accounted for by the time a drug enters Phase III.

'The kind of reverse look at ROI done by Wyden and Nader isn't the way it works in the real world. The real issue is, for the next $100 million needed to make it into a new drug, what's the ROI?'

— Jon Saxe, Saxe Associates Inc.

Exclusive licenses are monopolistic and shouldn't be allowed.

Arno is perhaps the strongest proponent of this view. He favors both reasonable pricing clauses and non-exclusive licenses, arguing that where the government has contributed significantly to the development of a new drug, it shouldn't confer a monopoly on companies.

"When the government assumes a substantial role in preclinical and clinical drug development, the risks to industry are greatly lessened. Does a rationale remain for the high prices still being charged?" he says.

A bolder approach than pricing clauses would be to refrain from granting a monopoly. At present, he argues, pharmaceutical companies aren't regulated like other monopolies, such as utilities. If the industry wants to operate in a competitive marketplace, it should live by competitive principles, which means stripping away the artificial protection of monopolies.

He opposes royalties because they skirt the issue of fair prices, and he assumes companies will simply further inflate their prices to cover the expense of royalties.

See next page

Commentary

Why pay the piper?

From previous page

The appropriate way for taxpayers to be reimbursed for their expenditures and risks is through price controls or non-exclusive licensing practices.

Nader, who dislikes the Bayh-Dole Act governing technology transfer, echoes the notion that exclusive rights funnel the fruits of public investment into the hands of a few. He quotes from a minority report on the 1980 act, in which Rep. Jack Brooks said, "Assigning automatic patent rights and exclusive licenses to companies or organizations for inventions developed at government expense is a pure giveaway of rights that properly belong to the people. . . .The federal government has the equivalent of a fiduciary responsibility to the taxpayers of the country. Property acquired with public funds should belong to the public."

Says Jenning, "If a government-sponsored drug is commercialized, government ought to have a seat at the table when the drug is priced."

Government can know what a reasonable price is.

"We know exactly what has been spent on development and we can estimate a reasonable profit," says NIH's Barua. "In most cases, 30 percent is a reasonable profit."

Still, setting prices requires much greater government information on company development costs than is currently available. According to Arno, to be effective, reasonable pricing clauses need more teeth. Drug companies should be required to disclose development costs, marketing and distribution expenses, prices of competing therapies, likely market entry of additional competing products, time to recovery of development costs, and profit margin built into the price.

Nader and Love add that "it is important that the firm provide historical data which shows when research and development expenses were incurred. . . . The historical information will be important to determine how much of the industry's expenditures on the development of a drug occur at the riskiest phases. Investment before clinical trials is a higher risk than investment after clinical trials. Investments in Phase I trials are more risky than investments in Phase II trials."

The issue is a moral one.

"Reasonable pricing is a legitimate concern," says Barua. "Federal funds are utilized to do research, and the public shouldn't have to pay through the nose for these drugs. It is not a political issue, it is a moral issue. We at NIH feel it is a very legitimate issue, and it will be very difficult to remove the reasonable pricing clause from NIH CRADAs. This is my personal opinion, I am not speaking for (NIH Director Dr. Harold) Varmus. Reasonable pricing is very legitimate from my point of view. I think it is a moral issue — the companies shouldn't be making huge profits on drugs."

So there you have it. The question is, how can government induce companies to accept deals that aren't commercially attractive? The short answer is, that as long as the economy is an open one, it can't. While companies will accept lower prices or non-exclusive licensing arrangements within certain parameters, once terms fall out of that range, companies will walk away. (And, in fact, they will have a fiduciary responsibility to do so. They aren't charities.)

Many already do walk away, refusing to deal with government-funded research. We also know of one company that has dealt with the problem by scrupulously avoiding taking any money for its own researchers as part of a government grant it recently received to perform joint research with a university.

"While we want to see technology come out of the government and be advanced, I don't want the threat of having spent tens of millions or more and have it tainted by a government grant that's a tiny fraction of that and have the government say five years from now, 'We'll control your price,'" the CEO explained.

The reality of choice

Maybe the best way to understand the problem is to step back and look at a parallel situation in a completely different context, in this case, the economic policies of a former British Labour Party government. The government in question tried to run an expansive (and inflationary) domestic economic policy, with the result that holders of sterling fled the currency, exchanging their pounds for more stable money. Ultimately the government had to change its policies.

'When I make a deal with a company, am I getting the right royalty? I don't know. The answer is, I get what the market will bear at the moment.'

— Frank Landsberger, Mount Sinai Medical Center

The point is that sterling holders weren't mean or greedy or selfish. Rather, the open structure of the international economy enabled them to make choices about where to put their money. The Labour government wasn't constrained by nasty speculators, it was constrained by the structure of the economic system.

The situation is the same with the debate over pricing and non-exclusivity clauses in CRADAs and licenses to government technology. While the government can try to run any kind of policy it wants to, the reality is that its potentially successful options are defined by the structure of our economic system, which leaves investors and companies free to pursue multiple

See next page

Commentary

Why pay the piper?

From previous page

investment opportunities.

Even assuming for the moment that proponents of pricing clauses and non-exclusivity agreements were morally correct, that fact wouldn't keep their policy from failing. And their chances of success wouldn't improve unless the entire underlying structure of the economy were changed.

Thus, we believe that efforts to enact price controls on drugs developed using federal technology are based on a fundamental disregard of the structure of our economic system. That's a hard argument to make to politicians or consumer advocates, but it's an argument that must be heard.

In fact, one of the most frustrating aspects of the argument is that it repeats the debate that took place over the enactment of Bayh-Dole in 1980.

Bayh-Dole was enacted precisely because technology developed by the government wasn't being used due to federal insistence that licenses be granted non-exclusively — providing a convenient case-history of what would happen if we went back to non-exclusive licenses. The Act grew out of concerns that the U.S. was losing its competitive edge as a result.

In his testimony in 1979, Sen. Birch Bayh complained that the government's underlying philosophy had been to retain title to technology even if it contributed only a small percentage of the funding for its development. Government had little success in attracting industry to develop and market products, because industry had little incentive to undertake the risk and expense.

The problem was especially serious in biomedical research, he said.

Moving beyond the over-riding structural issues, proponents of government pricing clauses and non-exclusive licenses raise several critical questions that need to be answered:

Where's the risk and who takes it?

Risk has two elements: the probability of success and the cost, according to Jon Saxe, president of Saxe Associates Inc. and former present and CEO of Synergen Inc. "Early on, the probability of success is very low, but you're not risking very much," he says. "By the time you enter clinicals, the probability is higher, but the amount of money you're risking is much greater."

The "controllers" argue that because the government is doing very early research, it should get venture-type returns. However, the proper comparison isn't with venture capital, but with early research licensed by universities.

As explained by Charles Casamento, chairman, president and CEO of RiboGene Inc., it's a fallacy to think one should get a greater reward as one does less work. Ultimately, that would imply infinite rewards for zero input. "The argument they're making is the earlier a company licenses a product, the more it should pay. Why should the company pay more as government puts less and less into it? That's ludicrous."

How should government obtain a return on its investment?

Unlike the ROI for a company, the government's return on investment can be defined in any number of ways, starting with broad goals such as international competitiveness, a better balance of trade, more corporate formation, greater employment, more tax revenues and better public health. A royalty stream from licensed technology would represent a narrower commercial goal.

Advocates of controls tend to focus on lower prices as the key goal, but as one former NIH staffer put it, the agency can't be a technology transfer champion at the same time it's regulating drug prices.

> ***'It's a fallacy to think one should get a greater reward as one does less work. Ultimately, that would imply infinite rewards for zero input.'***
>
> **— Charles Casamento, RiboGene CEO**

BioCentury would argue that the government is achieving all of the first set of goals, and may be achieving lower prices by fostering development of numerous competitive technologies, but that the goal of lower prices through price controls is unattainable due to the structural impediments discussed above.

The other important issue here is the need for companies to be able to calculate their costs. In testimony before the Joint Economic Committee in June, James Barrett, chairman and CEO of Genetic Therapy Inc., pointed out that companies can take the costs of royalties and fees into account as they develop products. However, he said, "there is no way for a private firm to evaluate the impact of the drug pricing clauses on the potential for commercial development of a product." By adding a layer of uncertainty, NIH makes it harder for companies or investors to calculate if it's worthwhile to develop a product. Adding the uncertainty of a cap on returns to the risks of drug development isn't an appealing mix.

How should the appropriate size of the return be calculated?

This is a critical point, and the "controllers" spend a great deal of time pointing to a few successful drugs and the government's meager return from them.

Post hoc, it's easy to pick a successful product and go back and say the government didn't get enough. But the only proper way to estimate the value of a technology is based on what was known at the time it was licensed.

That value can only be guessed at. "I look at technologies and say, 'How much is it worth?' — I haven't the foggiest idea,"

See next page

BioCentury
PUBLICATIONS INC.

PO Box 1246
San Carlos CA 94070-1246
Voice: 415/595-5333
Fax: 415/595-5589

Washington D.C.
Voice: 202/662-7431
Fax: 202/662-7433

DAVID FLORES
President & Publisher

KAREN BERNSTEIN
Vice President & Editor-in-Chief

ERIC PIERCE
Staff Writer

LAURA ERICKSON,
ROBERTA FRIEDMAN, Ph.D.
Contributing Editors

STEVE USDIN/KRIS HERBST
Contributing Editors/Washington

MARC SCHMITTER
Administration & Operations

JASON LORBER
Business Development

Editorial Advisory Board

BROOK BYERS
Partner/Kleiner Perkins Caufield & Byers

RONALD CAPE, Ph.D.
Chairman/Darwin Molecular Inc.

PETER DRAKE, Ph.D.
Executive Vice President
Vector Securities International Inc.

HARRY HIXSON JR., Ph.D.
Chairman/Somatix Therapy Inc.

DAVID LEATHERS
Director/Abingworth Management Limited

JANICE LeCOCQ
Chief Financial Officer/ICOS Corp.

JOEL MARCUS, Esq.
Managing Partner
Health Sciences Capital Partners

ROBERT McNEIL, Ph.D.
Partner/Sanderling

STELIOS PAPADOPOULOS, Ph.D.
Managing Director/PaineWebber Inc.

BioCentury™
The Bernstein Report on BioBusiness

Commentary

Why pay the piper?

From previous page

says Frank Landsberger, who does tech transfer for Mount Sinai Medical Center. "When I make a deal with a company, am I getting the right royalty? I don't know. The answer is, I get what the market will bear at the moment.

"When Mount Sinai or the government licenses, these are concepts. We've got a sequence and in theory it will cure male pattern baldness if 15 steps in between work out. Also, very seldom do you have four bidders lining up. As a reality, there's not much competition to license these."

BioCentury's discussions with companies indicate that NIH is licensing its technology for terms comparable to licenses for technology at similar stages of development from universities or elsewhere. Those terms seem to be pretty well standardized: about 3 percent for in vitro data, 3-7 percent for some animal data, 5-15 percent for large animal and some human data, and more for substantial efficacy data.

Furthermore, it's the licensee who puts a value on the technology by calculating how much more has to be invested and the likely return on investment. Thus for the NIH as the licensor to say it's spent X and should therefore get Y isn't the way technology is valued.

"Everything you've spent is sunk money — it's gone," says Saxe. "The prospective licensee has to make a return on investment analysis of what they have to invest to get it to market. It's always a future-looking analysis. The kind of reverse look at ROI done by Wyden and Nader isn't the way it works in the real world. The real issue is, for the next $100 million needed to make it into a new drug, what's the ROI?"

Should the government's investment in basic research even be considered risk capital?

Put another way, how should the government and the public (i.e., taxpayers) be rewarded for creating infrastructure?

"I don't think of government's basic research as risk capital," says John Wilkerson, chairman of The Wilkerson Group. "It's intellectual infrastructure. The government investment in highways is also infrastructure. The government sets a policy to make certain infrastructure investments; some are materialistic and some are intellectual. When they invest in highways, they never talk about the return."

What are companies contributing?

Lost in the debate is the contribution of companies undertaking CRADAs with government scientists. "Any CRADA we undertake with the government is involved in activities the institution probably would have done anyway," says Barrett. "The relationship with us facilitates the work, makes it cheaper for the government. In our brain tumor work, for example, we undertake all the product development costs, building the facility and providing GMP material to NIH investigators. They treat patients — their job is to do trials."

In the end, the value of technology is only what the market will bear. If the value of technology developed with some measure of government funding is squeezed at both ends — with non-exclusive licenses at the front end and price controls at the back end — there will come a time when technology wil languish on the shelf. At that point, all of the government's policy goals will be unmet: new products won't be developed and the government won't get any return at all.

We hope that the NIH, when it comes to make a decision on the issue, will face reality squarely and remove pricing clauses from CRADAs. But we fear that in the current anti-business environment, it will succumb to the political pressures of a few and duck the issue.

Alliance for Aging Research
2021 K Street, NW • Suite 305 • Washington, D.C. 20006 • 202/293-2856 • FAX 202/785-8574

STATEMENT OF PENELOPE CATTERALL
HEALTH POLICY DIRECTOR

ALLIANCE FOR AGING RESEARCH

NATIONAL INSTITUTES OF HEALTH
CRADA FORUM II
SEPTEMBER 8, 1994

Good afternoon. My name is Penny Catterall. I am the Director of Health Policy at the Alliance for Aging Research, an independent, non-profit group dedicated to promoting medical research into human aging. The Washington, D.C.-based Alliance has grown to become the nation's leading citizen advocacy organization for improving the health and vitality of older Americans by affecting both public and private research agendas.

As the panel knows, the United States is second to none in the development of new medical treatments, devices and core technologies. A favorable economic climate must be fostered for greater research and development in age-related diseases. Our emerging biotechnology industry must be nurtured. New ways to formulate cooperative research and development agreements (CRADAs) between government-sponsored research and private industry must be advanced.

These arrangements should focus on ways the government can work with business as a partner in innovation. However, the Alliance for Aging Research believes that the inclusion of a "reasonable pricing" clause in the model NIH CRADA agreement serves the contrary effect of driving business away from these critical partnerships.

Congress decided the public interest when it passed the Federal Technology and Transfer Act (FTTA) of 1986, and that law contains no mention of a reasonable pricing structure. To the contrary, to stimulate technology transfer, the FTTA authorizes the Federal government to enter into CRADAs with industry and provides incentives to both the Federal scientists and collaborating companies to do so. As discussed at CRADA Forum I, the reasonable pricing clause in the model agreement has deterred private companies from entering into CRADAs with the NIH and has caused pharmaceutical companies to refuse to provide NIH researchers with drugs to use as research tools.

Because government resources are being used to conduct the research the CRADAs are based on, the government should be compensated with fair and equitable royalties from cooperative arrangements. Industry must be prepared to negotiate fairly and honestly with government-funded researchers. Collaborative research that leads to healthy aging enriches lives, saves health care dollars, and ultimately benefits the American taxpayer. The Alliance urges the government to look beyond standard pricing and regulatory measures that inhibit industry cooperation and try bold, new experimentation in seeking arrangements to spur new health products as well as protect the investment of tax dollars.

James Roosevelt, Jr.
Executive Director
(617) 227-5020

Christopher J. Doherty
Washington Director
(202) 778-2313

NEW ENGLAND BIOMEDICAL RESEARCH COALITION
53 State Street, 36th Floor, Boston, Massachusetts 02109
750 17th Street, N.W. Suite 1200, Washington, D.C. 20006

STATEMENT OF CHRISTOPHER DOHERTY
WASHINGTON DIRECTOR
NEW ENGLAND BIOMEDICAL RESEARCH COALITION

NATIONAL INSTITUTES OF HEALTH
CRADA FORUM II
SEPTEMBER 8, 1994

My name is Chris Doherty. I am a health care attorney and serve as the Washington Director of the New England Biomedical Research Coalition. Previously, I worked in the U. S. Senate for nine years with Senator Edward Kennedy and for two years in Massachusetts state government.

The Coalition is an affiliation of New England teaching hospitals, universities, independent research institutes, health care companies and patient advocacy groups dedicated to preserving and fostering the collaborative biomedical research enterprise. A Board Member of the Coalition, Dr. Louis Lasagna, Dean of the Tufts Sackler School of Graduate Biomedical Sciences, submitted a written statement for the record at the first NIH CRADA Forum.

Before drawing any conclusions on the issue of price clauses, I hope the panel and the NIH will step back and remember Congress' major considerations in deciding to promote technology transfer among government, industry and academe. Congress' goals were to: 1) encourage technological innovation on behalf of American citizens; 2) enhance the international competitiveness of American industry; 3) maximize Federal research efforts; and 4) increase the level of public benefit from Government-sponsored research. The stated purpose of the Federal Technology Transfer Act (FTTA) is to "improve the transfer of commercially useful technologies from the Federal laboratories and into the private sector."

The FTTA contains nothing about reasonable relationship of price or price restrictions. On the contrary, it provides royalty payments and cash awards for government scientists in recognition of the fact that such financial incentives will enhance commercialization. Further, during deliberations on the bill, Members of Congress explicitly acknowledged that the law was designed to be a "boon to industry" and a stimulant to innovators and entrepreneurs.

Our Coalition does not advocate that NIH or any other federal laboratory lose the capability to write restrictions on price into a negotiated agreement. However, we do believe that such a clause should not be in the standard agreement. Because there is no legislative basis for it, such a clause should be an item for negotiation only. The law does not compel it and no other federal laboratory requires it.

Lessons on how to structure such agreements properly can be drawn from the more mature system of collaborative agreements between non-government research institutions and private industry. Collaborations between NIH and private industry are of more recent vintage, and only one has resulted in a product. These collaborations are primarily scientific in nature and their success largely depends on the development of a close working relationship, and the free exchange of ideas and information. Substantial attention is devoted to the design and implementation of the scientific aspects of collaborative projects and progress can and should be made toward simplifying the process and making it more attractive and accessible to smaller companies. NIH is doing that.

An important point that must be emphasized is that these collaborations involve important business issues -- issues that are not always clearly understood, but that must be sensibly addressed if collaborations are to succeed. Over the past decade, universities and research institutions have come to recognize and address the commercial realities of successful collaboration. They have acknowledged the importance of exclusive licensing, and have developed a relatively uniform approach to the negotiation of royalties and other licensing fees in sponsored research agreements. Universities have also recognized the critical need for flexibility in the negotiation of terms and conditions governing collaborative relationships.

Though we recognize that federal agencies differ from non-profits in many important ways, in their role as scientific, research and business partners with private industry, federal agencies should pattern their policies on those that have been developed, tested and proven by universities over the past twelve years. Federal agencies and others engaged in this debate must recognize -- as the universities clearly do -- that no two collaborative projects are identical. In fact, many involve a number of unique circumstances that must be taken into account in negotiating the respective responsibilities of the collaborators, as well as the attendant business arrangements. For example, in some cases a technology may not be patented or patentable. Thus, the government would have no ability to transfer intellectual property rights to its private-sector partner. In these cases, a

number of terms and conditions in the standard model CRADA do not make sense. For example, the standard exclusive licensing and royalty provisions are useless because there is no patent to license. Similarly, the so-called "reasonable pricing" clause, is likely to be inappropriate in this context.

Parties to these agreements should be able to negotiate terms and conditions that reflect the commercial realities of the situation, and to strike a fair balance between their respective interests. Some argue that the reasonable pricing clause should be eliminated altogether. Others, critics in the Congress and elsewhere, propose that additional restrictions be placed on private-sector CRADA partners. Our Coalition believes that a balance can be reached by retaining flexibility at the laboratory director and agency level to include "reasonable relationship to pricing" language in CRADAs where it is warranted. Making it mandatory drives away industry partners. We oppose changes in the CRADA process that unreasonably limit discretion to tailor terms and conditions to the particular circumstances of each collaborative research project, or to provide meaningful incentives necessary to attract private-sector research and development partners.

The Future Of Technology Transfer

In considering these policies, the CRADA Forum panelists and staff at NIH should look to the future. Perhaps there are ways to further enhance the goals of the technology transfer program by providing more incentives for members of the collaborative research enterprise to enter into important CRADAs that currently have no sponsors. There are many examples of important research projects that need more collaborative funding and resource pooling -- the development of anti-addiction therapies at NIDA; AIDS vaccine research at NIAID; the performance of long-term chemo-prevention trials at NCI -- to name a few.

If Congress decides to amend the Technology Transfer Act of 1986 we advocate that it do so to add incentives to funnel more private money into research. One of our technology transfer policy's greatest successes has been getting industry more involved in the funding of basic research. The policy has contributed to a significant increase in the funding of university R&D by industry. In the past decade, industry support of public and non-profit research grew faster than did any other source of funding. Since 1971, the portion of U.S. industry R&D expenditures going to academic institutions has nearly doubled. Greater government scrutiny and interference with funding

arrangements that it first set out to encourage, is not what we need to continue this funding trend.

Government oversight of industry's funding of collaborative biomedical research must reflect certain basic principles. First, basic research does not pay for itself. As Federal funding for such research declines, universities and research labs must retain the flexibility to negotiate agreements that attract industry funds. Second, innovations do not reach the marketplace by themselves; if industry is not allowed to profit from bringing innovative products to market, they will not be commercialized. Government should not deny business the incentive to take substantial risks that only comes from commensurate financial returns. Third, when taxpayers enjoy a return on their investment in basic research, the form of that return is the availability of innovative technologies and products to improve their quality of life and the lives of their loved ones. This is the kind of return envisioned by Congress when it identified the benefits of technology and industrial innovation: "improved standard of living, increased public and private sector productivity, creation of new industries and employment opportunities, improved public services and enhanced competitiveness of United States products in world markets."

Finally, these are not the best of times for the collaborative research enterprise. A recent "Government-University-Industry Research Roundtable" report concludes that "[C]urrently, there is considerable distrust by each party of the other's good faith, and doubt regarding the extent of constructive planning." The report goes on to state, "[T]here is a need to recreate a sense of partnership, trust, and shared vision among government, universitites, and industry about what we as a nation wish to accomplish." I hope that this Forum will go a long way towards recreating that necessary sense of partnership.

On a daily basis, scientists and physicians work, and patients and their loved ones watch, filled with hope that a new scientific breakthrough will bring a cure or treatment for illness. I have a personal stake in biomedical research. A loved one of mine has recently been diagnosed with an incurable disease. I sincerely hope that the researchers here and in the hospitals and private industry will do all they can, <u>together</u>, to conquer the disease. If not in time for her, then for me and you, and for all of our children. Thank you.

TESTIMONY OF DIRECT ACTION FOR TREATMENT ACCESS ON NIH 'FAIR PRICE' CLAUSES

Direct Action for Treatment Access (DATA) is a national patient advocacy organization centered in Palo Alto and San Francisco California. DATA is committed to defending patient choice in treatment options and to improving research and regulatory incentives for developing new treatments for AIDS, cancer, Alzheimer's and other serious diseases.

We are concerned that de facto price controls in the so called "fair price" clauses attached to National Institutes of Health (NIH) intramural cooperative research and development agreements (CRADAs) defeat the purpose of Congress in funding NIH research for serious diseases. That purpose is to generate products that can extend and improve the lives of patients. This can be achieved only if NIH research is transferred to private firms that develop products which are eventually approved by FDA and used to treat to patients. Increasingly, private firms are refusing NIH technology transfer agreements containing 'fair price' clauses.

Congress has rejected a similar de facto price control scheme: the Clinton Administration's proposal for a "breakthrough drug committee." As a result, it has become clear that NIH's "fair price" policy lacks a Congressional mandate. NIH enacted the policy by administrative fiat; NIH should now heed the intent of Congress and terminate the policy by fiat.

In addition to controverting the good purposes of Congress, NIH 'fair price' clauses impede our national effort against AIDS. The Public/Private Issues Subcommittee of the National AIDS Task Force has identified NIH's 1) "fair price" clauses and 2) its refusal to grant exclusive patent licenses as major barriers to the

rapid development of treatments for HIV/AIDS. Moreover, the barriers are not confined to HIV/AIDS. These same unwise CRADA policies impede development of treatments for cancer, Alzheimer's, and many other diseases.

The "fair price" clauses and lack of exclusive licensing affect every therapeutic product using intramural NIH research, even where the role of that research is minor. Because of the "fair price" clauses on CRADAs biotech and drug companies are bypassing NIH research. Biotech investors balk at financing development of any product subject to price controls. And major drug companies seek to avert agonizing CRADA ordeals such as Bristol-Myers endured at the hands of Rep. Ronald Wyden over taxol. The number of CRADAs has fallen sharply. Indeed, four of the largest research pharmaceutical companies, led by Merck, have told NIH that they plan to forgo new CRADAs until the "fair price" clauses are removed. Thus, price controls attached to CRADAs are obstructing development by the biotech and drug industries of new treatments utilizing NIH research.

NIH officials have stated that several promising AIDS and cancer discoveries made intramurally at NIH are not being developed into treatments because of the 'fair price' clause. Fluorinated ddC is an example. This drug promises the efficacy of nucleoside analogue antivirals without their toxicities. All currently approved nucleosides have severe toxicities which can either damage patients' quality of life or force them to stop treatment. Because of the 'fair price' clauses, AIDS patients are denied the benefits of fluorinated ddC and forced to take drugs that are more toxic and, possibly, less effective. The 'fair price' clause may be shortening the lives of people with AIDS and increasing their suffering. Surely this is not what Congress wants.

Why do private investors react so strongly against NIH's defacto price controls? Ordinarily, biotech and drug companies must

invest between 5 and 20 times as much as NIH to develop a product from NIH research. Moreover, the companies must assume the entire financial risk. Investors simply will not put up most of the money and assume a high risk unless that risk is balanced by the chance of high gains: price controls are designed to eliminate high gains.

NIH already gets fair compensation for its contribution through its royalty system. "Fair price" clauses, however, have nothing to do with fair compensation. They are imposed for extraneous political reasons. Indeed, they prevent fair compensation for important research by thwarting its development.

What is the solution? "Fair price" clauses, DATA suggests, must be limited to those few instances where NIH Bethesda does the entire research and development, and the company marketing NIH's product shoulders no risk. All other NIH technology transfer agreements should grant exclusive patents and be subject only to fair royalty agreements.

NIH must not let de facto price controls sideline research that could improve the prospects or ease the suffering of people fighting AIDS, cancer, Alzheimer's, and other terrible diseases. It is time for NIH to put these courageous people first.

Thank you for your thoughtful consideration of DATA's concerns.

JAMES DRISCOLL, PH. D.
DIRECTOR FOR POLICY

American
Autoimmune
Related Diseases Association, Inc.

A nonprofit association bringing a national focus to autoimmunity, the major cause of chronic diseases

STATEMENT OF VIRGINIA T. LADD, PRESIDENT & EXECUTIVE DIRECTOR

NATIONAL INSTITUTES OF HEALTH CRADA FORUM II
SEPTEMBER 8, 1994

- Lupus
- Insulin Dependent Diabetes Mellitus
- Multiple Sclerosis
- Crohn's Disease
- Pernicious Anemia
- Juvenile Diabetes
- Rheumatoid Arthritis
- Graves' Disease
- Anti-TMB Nephritis
- Cardiomyopathy
- Juvenile Arthritis
- Antiphospholipid (APL) Syndrome
- Rheumatic Fever
- Addison's Disease
- Myasthenia Gravis

Good afternoon. My name is Virginia Ladd. I am the President and Executive Director of the American Autoimmune Related Diseases Association, Inc. (AARDA), a nonprofit national organization dedicated to addressing the problem of autoimmunity, one of the major causes of chronic disease. AARDA was founded because there was no organization, institution or national voluntary health organization focused unilaterally on autoimmunity and the manifest problems commonly associated with all autoimmune diseases. The primary goal of AARDA is to center national attention on a collaborative effort toward research, funding, early detection and, ultimately, a cure for autoimmunity and its related diseases. Because of our commitment to this goal, we are strong proponents of biomedical research and, focusing on the subject of this forum, of collaboration between government and industry in the search for treatments and cures.

In people with autoimmune diseases, the immune system is unable to distinguish between foreign and natural substances in the body resulting in the immune system attacking healthy tissue and

Michigan National Bank Bldg. • 15475 Gratiot Ave. • Detroit Michigan 48205 • Phone (313) 371-8600 • Fax (313) 372-1512

organs. In short, the immune system turns on the "self," causing a variety of diseases and conditions that are categorized as autoimmune. There are more than 80 known autoimmune diseases (including lupus, rheumatoid arthritis, juvenile diabetes, and multiple sclerosis) and approximately 50 million Americans suffer from one or more of these diseases.

We understand that participants in the July 21 CRADA forum -- including industry representatives, members of the AIDS Drug Development Task Force Public/Private Issues Subcommittee, and NIH officials -- concluded that the inclusion of a so-called "reasonable pricing clause" in the standard NIH CRADA agreement acts as a barrier to collaborative biomedical research. As such a barrier, AARDA believes that the reasonable pricing clause should be removed from the standard agreement. When appropriate, however, on a case-by-case basis, the government should reserve the right to negotiate the inclusion of a reasonable pricing provision in particular CRADA agreements -- just as the government negotiates royalties, resource allocation and other important conditions.

AARDA agrees that a mandatory reasonable pricing clause drives away industry partners. We urge the NIH to allow individual laboratory directors the discretion to negotiate some reasonable pricing language in those CRADAs where it makes sense. If NIH is unable or unwilling to negotiate such agreements they should be able to contract with private consultants who know how to negotiate. New layers of bureaucracy should not be involved in the process. Faced with the disincentive presented by a pricing provision in the standard CRADA agreement, several companies have opted out of the CRADA process, including many small companies with novel and promising approaches. In turn, the development of effective therapies for autoimmune disorders that could possibly alleviate the suffering of millions of sick Americans may have been needlessly delayed or missed altogether.

GOVERNMENT PURCHASING PROJECT
PO BOX 19446
WASHINGTON, DC 20036
202/387-8054

Secretary Donna Shalala
Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, DC 20201

September 8, 1994

Dear Secretary Shalala:

The Government Purchasing Project writes to express its support for a reasonable pricing clause in contracts which transfer rights in federally funded pharmaceutical research to the private sector. We believe that a reasonable pricing mechanism is necessary for several reasons.

First, if the reasonable pricing mechanism is eliminated, the price consumers pay for many drugs will increase. In some cases, government funded programs such as Medicare and Medicaid pay for a majority of some specific prescription drug purchases. The elimination of a reasonable pricing mechanism will cause an increase in the monies spent by Medicare and Medicaid for those prescription drugs that formerly would have been subject to a reasonable pricing mechanism. Federal and state government purchases of drugs is significant if one considers all the expenditures made through Medicare; Medicaid; jails and prisons; students at state colleges; state-run institutions for the blind, handicapped, elderly, insane, deaf, retarded and disturbed, etc; and for participants in infant and maternal health programs and other government subsidized clinics for the poor.

In addition, the resulting increase in government spending described above may violate the Gramm-Rudman Section of the Budget Enforcement Act of 1990. Therefore, we believe the Office of Management and Budget should be consulted before NIH makes a final decision concerning the elimination of the reasonable pricing mechanism.

The elimination of the reasonable pricing mechanism will have an adverse impact on controlling health care costs. It will have a particularly significant adverse impact on government spending if and when a national health insurance system is created.

Further, the country's population is aging and with age, use of prescription drugs increases. Thus, the elimination of a reasonable pricing mechanism will subject an increasing number of people to increased medical costs.

For all of these reasons, we urge NIH to maintain and strengthen the reasonable pricing mechanism for federally funded pharmaceutical products.

Sincerely,

Eleanor J. Lewis
Director

Pricing of Drugs Developed with Public Funds

Comments Presented to the Second NIH CRADA Forum
September 8, 1994

James Love
Director, Taxpayer Assets Project

P.O. Box 19367, Washington, DC 20036
voice: 202/387-8030; fax: 202/234-5176; internet: love@tap.org

I. Introduction

My name is James Love. I work for the Center for Study of Responsive Law, where I am Director of Economic Studies and also the Director of the Taxpayer Assets Project (TAP), a group created by Ralph Nader to monitor the management and sale of government property, including intellectual property rights from government funded research. Beginning in 1991, TAP has undertaken a number of studies of the federal government's role in funding research and development for pharmaceutical drugs. I have presented testimony or comments on this subject to the U.S. Congress on several occasions, and I have written articles for public policy, trade and general interest publications. Prior to joining the Center for Study of Responsive Law I was senior economist for the Frank Russell Company, a large pension funding consulting firm, and I have held teaching and research positions at Princeton University, Rutgers University, and the National Bureau of Economic Research.

We are pleased that NIH is holding a second forum to solicit advice and recommendations from the public on the agency's use of Cooperative Research and Development Agreements (CRADAs). The first forum, held on July 21, 1994, was principally a forum for pharmaceutical and biotechnology companies to register objections to the NIH model reasonable pricing clause, which is included in some NIH CRADAs. One presumes, based upon the published notice and Draft Mandate, that this second forum is designed to provide additional balance to the comments provided by the industry at the July 21 forum.

II. The Timing and Notice of the Second CRADA FORUM

The Draft Mandate says that the NIH Director is asking for recommendations from "primarily consumers and other public interest groups." However, the presentations and advice received today will necessarily be limited, because the notice for the meeting was issued in late August, during peak vacation time, and the forum is being held three days after labor day. Because of the short timetable, consumers and public interest organizations have not been given an adequate opportunity to prepare for this meeting.

We ask that NIH give the public an additional 60 days to prepare comments on this important topic.

III. The Framing of the Issue

While the Draft Mandate for this Second CRADA forum says that the meeting will be "solely on 'reasonable pricing'", the organization of the three "issues" and panels are largely framed in the terms emphasized by the industry, which wants to eliminate the reasonable pricing clause, and persuade NIH officials to consider negotiated royalties or simply the availability of the drug as only public interest returns on the public's investments.

The first panel at the September 8th forum is asked if the public investment in R&D is "adequately reflected through the payment of royalties and the expeditious development of new products," or if NIH should be "involved in 'downstream' issues of marketing and distribution, such as the pricing of such products?" The second panel appears to be asked what types of royalty payments should be negotiated with the industry. Only the third panel focuses entirely on the reasonable pricing clause, and then only with a highly selective set of questions which focus on the potential conflicts between reasonable pricing and product development -- a trade-off which does not exist at all for some government funded drugs.

NIH could have organized the forum much differently, and indeed, if NIH had bothered to work closer with its critics, it would have avoided the appearance of yet another one-sided assault on the reasonable pricing clause. For example, the three panels could have been asked to consider such questions as:

* If a firm obtains rights to an invention developed principally with public funds, should the company be free to charge consumers what ever the market will bear, without limit?

* What can be done to prevent the public from paying twice for drug development, first as taxpayers, and then as consumers?

* Should the government routinely collect information on the economics of drug development and marketing, for those drugs developed with significant public support? For example, should the government obtain information on the annual sales revenue, manufacturing costs and marketing costs for ddI or Taxol?

* For those drugs which are developed with significant public support, how much of the sales revenue is obtained from patients who are insured by the government, through medicaid, medicare, the military or other programs?

* How should the public's investment in drug development be valued, when compared to the industry's investments? For example, should the government's investments be adjusted for risk, inflation and the time value of money, similar to the methodology typically used to reckon the private sector's costs of drug development?

* Was the methodology used by NIH to evaluate the "reasonableness" of the price of ddI or Taxol a good one? (Under this methodology, a drug such as levamisole could be increased in price by more than 1,700 percent and still be considered reasonably priced.)

* Should NIH use the median prices of drugs used for similar therapeutic purposes as a benchmark for a reasonable price? What if 95 percent of the cost of the drug's development was paid for by the taxpayers?

If NIH framed the reasonable pricing issue with questions such as these, the discussions would likely focus on constructive changes in the administration of the reasonable pricing clause, rather than a debate over whether or not to eliminate the clause.

IV. Why is the NIH Reasonable Pricing Clause Important?

Industry's heated opposition to the NIH reasonable pricing clause must seem like a mystery to some observers. On the one hand, the pharmaceutical industry is making extravagant assertions that the government's role in new drug development is extremely minor compared to that of private industry, and yet at the same time industry groups are becoming increasingly strident over the grave dangers of NIH reasonable pricing agreements for NIH research projects which involve NIH funded staff or contractors. If the government's role is as minor as we are constantly being told by the industry, then why is there so much industry concern about a fair pricing clause that only applies when the government is directly involved in the research?

Indeed, the NIH reasonable pricing clause, which has only been used in NIH CRADAs and patent licenses, does not apply to the more than $7 billion per year in grants and contracts to Universities and other institutions who obtain patent rights under the Bayh-Dole Act.

Why then is the NIH reasonably pricing clause so important? The answer is two fold. First, the one fifth of the NIH research budget which is spent on intramural research is a substantial amount of money that is highly productive in terms of new drug development. The new drugs which are developed with direct NIH involvement are important in terms of their efficacy, innovation and the severity of the illnesses which they treat. Unfortunately, because of the innovative nature of the drugs and the severity of the illnesses, companies know that it is possible to charge very high prices, as indicated by the prices of new drugs such as Ceredase, which costs some patients more than $500,000 for a year of treatment. Since a single new drug can generate billions of dollars in revenue, even if it has a tiny population of users, companies want to preserve as much pricing flexibility as possible.

Secondly, the existence of any reasonable pricing mechanisms creates a model which may someday be applied in broader applications. Apparently the current Congress isn't prepared to regulate drug prices, but if the "roll out" prices of drugs continue to soar and the cost of drugs becomes an increasingly important component of the nation's health care bill, there may be efforts to limit marketing exclusivity under the Orphan Drug Act, exercise government march-in rights under the Bayh-Dole Act, or apply price controls across the board when drugs are priced excessively. Before such actions are likely, the government will have to confront the thorny issue of a reasonable pricing methodology. The existence of a methodology for determining the reasonableness of a drug's price is thus perceived to be an important step toward broader efforts to reduce drug prices.

V. Will reasonable pricing mechanisms reduce industry investments in pharmaceutical R&D?

The pharmaceutical industry has raised the specter of huge reductions in industry R&D efforts if the government engages in any attempts to regulate drug prices, including those drugs developed with government support. This is an important question, which deserves thoughtful analysis. Of course, if all variables are held constant, except that drug prices are reduced, there will be a negative impact on private sector new drug R&D of some unknown magnitude. But, this simplistic scenario is not appropriate for several reasons.

1. The need for efficient R&D incentives.

First, there are limits on the public's ability to pay for drugs and new drug research. If that was not true, we would instantly increase the NIH budget by large multiples and cease all efforts to reduce drug prices through the use of generics, formularies, or other mechanisms. Attempts to control expenditures on pharmaceuticals are necessary, not because of moral outrage over drug company profits, but because as taxpayers and consumers we have limited resources. While everyone wants to encourage the private sector to participate in new drug R&D, it is important to consider the efficiency of the various financial incentives that reward industry R&D investments.

If a drug company is allowed to earn what amounts to a windfall on a government funded drug invention, it will have profits that may or may not be reinvested in R&D. But the effect of giving this windfall to a drug company is similar to dropping money on the company from an airplane -- it may have some impact on future R&D, but the incentive is highly inefficient.

Most of the companies which now obtain NIH licenses and CRADAs are large and face few liquidity constraints. R&D investments are forward looking. Current R&D spending will be funded if and only if the company expects future returns to be adequate. One might conceivably argue that companies expect to receive these windfalls from government funded drugs as a reward for R&D investments, but the evidence doesn't support even this rationale. The NIH has not linked the windfalls on government funded drug inventions to a company's past or future R&D performance. Bristol-Myers Squibb, for example, is a frequent beneficiary of government funded cancer research, despite the fact that the company has little to show for its own cancer R&D program.[1] Rather than award windfalls to companies who obtain government funded drug technology at bargain basement prices, the government should target its incentives toward those companies who invest and succeed in the R&D process.

[1]While Bristol-Myers Squibb is the world's largest vendor of cancer drugs, and by far the largest vendor of cancer drugs developed by government funded research, it has yet to discover a cancer drug on its own.

2. In a wide range of important cases, changes in drug prices will not delay or discourage development.

When the government's role in funding a new drug invention is extensive and the government controls the intellectual property rights, it can negotiate a lower consumer price without prejudicing the commercialization of the drug. For example, in the cases of ddI and Taxol, the government funded the preclinical research, sponsored the clinical trials, and controlled the intellectual property rights.[2] NIH could have awarded the ddI license or the Taxol CRADA to the firm that offered to charge the lowest consumer price or agreed to a pricing formula that would have benefited consumers, subject to whatever diligence requirements NIH believed were necessary.

We recognize the drug development process is complex, and in some cases it may be appropriate for NIH to waive or modify the fair pricing agreement, particularly when the government's contribution to the drug's development is minor or when NIH does not control the intellectual property rights.[3] However, there are both hard cases and easy cases, and the existence of hard cases should not provide a rationale for eliminating the reasonable pricing clause for both the hard and the easy cases.

3. The government can balance reasonable pricing or cost containment mechanisms with other instruments which increase investments in new drug R&D.

The NIH reasonable pricing clause is only one of several mechanisms that the government can use to control health care costs. Among the range of options are broader review of drug prices patented under the Bayh-Dole Act, loss of exclusive marketing rights under the Orphan Drug Act, deeper Medicaid and Medicare discounts, use of generic drugs and formularies or a general program of compulsory licensing or price controls for pharmaceutical drugs which do not face effective price competition. All of these mechanisms are designed to lower current expenditures on pharmaceutical drugs, and this is expected, in some measure, to reduce incentives for new drug R&D. Of course, if Congress extends insurance coverage for pharmaceutical drugs, this will increase demand and increase R&D incentives. Since the exact terms of any new health care are highly uncertain, it is difficult to predict what new initiatives will be enacted and what the net impact of will be on R&D. However, there are clearly other measures which can more than compensate for any negative impacts. For example. earlier this year several members of the U.S. Senate proposed that one percent of all health care premiums be devoted into a fund for health care R&D, vastly increasing the current level of federal support for health care R&D.

---

[2]These included a patent for ddI and exclusive rights to patient records for Taxol.

[3]Of course, NIH already has the authority to do this, and has often modified the model reasonable pricing agreement, even when there was no apparent rationale for the changes.

A somewhat different R&D proposal was discussed at a July 27, 1994 hearing of the Senate Committee on Governmental Affairs on the topic of pharmaceutical pricing. Dr. Peter Arno and James Love both separately recommended that the federal government require drug companies to reinvest a minimum percent of their gross sales into R&D projects. TAP recommended a 20 percent minimum R&D reinvestment, although this number could be subject to debate or change. What is important about this proposal, or the Senator's one percent of total premium's proposal, is that the government can guarantee that R&D levels are as high as are socially optimal. Indeed, if every company was required to reinvest 20 percent of revenues from pharmaceutical sales into new R&D projects, every generic drug company would become a source of venture capital for research on new drug therapies. While the government would set a minimum level of reinvestment, the companies would be free to follow market forces in choosing particular investment projects, as they are today.

Similar proposals are being considered elsewhere. A proposal regarding targeted R&D reinvestment was made by the Eastman Commission in Canada in 1985, although it was never implemented. We have urged national R&D royalties or R&D reinvestment requirements in Argentina and Brazil, two countries that are currently considering sweeping changes in laws regarding intellectual property rights for pharmaceutical drugs.[4]

VI. Higher royalties are not a substitute for a reasonable pricing clause.

While there is widespread amazement that NIH royalty income is so low, given the huge amounts of government R&D in pharmaceutical development, there is no support outside of the pharmaceutical industry to replace the reasonable pricing clause with higher royalties. Taxpayers have some interest in higher government royalties, particularly insofar as exports of the technology are concerned, but the overwhelming issue remains the prices the public faces as consumers. Any serious effort to get the government to recoup its

---

[4] Argentina and Brazil do not currently recognize patents on pharmaceutical drugs. Both countries are facing pressure from the United States to enact new patent laws. The United States negotiators are asking both countries to adopt provisions which are more strict than are required by the new GATT, and in respects, more strict than now exist for members of the European common market or in the United States. Brazil, which has a minimum wage of $65 per month, expects to face significant increases in the prices of medicines, as a result of the changes in the patent laws. My comments about the Argentina situation were made to a meeting of the Argentine Congress on May 10, 1994, and in May 12, 1994 comments delivered at the International forum on "Health Care Reform in the United States and the Situation in Latin America," held in San Carlos de Bariloche, Argentina, sponsored by the Centro Industrial de Laboratories Farmacéuticos Argentinos (CILFA), and the Association Latinoamericana de Industrias Farmacéuticas (ALIFAR). The written statement from the May 12, 1994 meeting is available upon request.

investments through royalties will fail on several counts. Among the more important considerations:

- Efficient royalty schemes would be complex, and in many important ways, even more complex to administer than a reasonable pricing clause.

- Truly aggressive royalty schemes would present a conflict between the nation's public health goals and its revenue maximization strategy. Should the government be party to a policy that denies poor segments of society access to a therapy in order to increase government royalties?

- Patients who have already paid for research as taxpayers will object to being asked to pay a second time as consumers.

From the standpoint of economic efficiency, the marginal cost of making a new pharmaceutical technology is often extremely low, and policies which artificially raise prices above marginal costs will reduce social welfare. When the R&D was funded by the taxpayers, the public interest is best served by policies which lead to lower consumer prices, not higher prices.

VII. Reasonable Pricing Methodology.

Over the past several years I have come across several versions of the NIH "model" reasonable pricing clause. The one distributed at the July CRADA forum read as follows:

> NIH have a concern that there be a reasonable relationship between the pricing of a licensed product, the public investment in that product, and the health and safety needs of the public. Accordingly, exclusive commercialization licenses granted for NIH intellectual property rights may require that this relationship be supported by reasonable evidence.

This model language is often modified through negotiations. The January 13, 1988 NIH license with Bristol-Myers for the development of ddI read as follows:

> LICENSEE acknowledges the concern of the Government that there be a reasonable relationship between licensee's pricing of Licensed Product and the health and safety needs of the public and that this relationship be supported by evidence.

The reasonable pricing clause for the National Cancer Institute's January 1991 (NCI)/Bristol-Myers Squibb Taxol CRADA read:

> NCI has a concern that there be a reasonable relationship between the pricing of Taxol, the public investment in Taxol research and development, and the health and safety needs of the public. Bristol-Myers Squibb acknowledges that concern, and agrees that these factors will be taken into account in establishing a fair market price for Taxol.

What happened to the "model" language? In the case of ddI, NIH removed the phrase "the public investment in that product." In the case of Taxol, the government removed the phrase about providing "evidence" to the government to support the reasonableness of the price. Both changes significantly weakened the provision.

In February 24, 1993 hearings before the Senate Committee on the Aging, then NIH Director Dr. Bernadine Healy was stung by criticism of the agency's feeble efforts to obtain lower prices for NIH funded drug inventions. She described the NIH reasonable pricing clause as though it had religious significance.

> The difficulty with the reasonable pricing clause is it was a spiritual statement. It was a statement of trust, of understanding that we thought that the companies should recognize the public investment, but in fact, if you look at the contractual agreement, there are no teeth. There is no mechanism at NIH for enforcing it. There is no contractual responsibility on the part of any of the partners to divulge information that would lead to a mechanism to achieve a price. There is not articulation of what pricing strategy might even be. . . .

In response, Senator Cohen and Dr. Bernadine had the following exchange:

> Senator Cohen. When you say it is a spiritual thing, or a spiritual provision, it is really a meaningless provision, is it not?
>
> Dr. Healy. I think spiritual things are very meaningful, but they aren't necessarily things you can put your arms around and act on and implement. I think that we believe at NIH that the statement that the public should have a return on its investment is an important thing to articulate in those relationships, even if we don't have the ability to function as a regulatory agency and even if we don't have the ability to put together the teams of economists and lawyers to figure out a price.
>
> Senator Cohen. Let me not engage in any kind of teleological argument with you about the value of spirit in our lives. Let me suggest to you that when the Government undertakes to put provisions in a contract which give the appearance that we are concerned and that we are going to insist upon "reasonable prices," when in fact we have no expertise, no basis, no ability to determine what a reasonable price is. We have no way to monitor what a

reasonable price is and no mechanism to enforce it. We are doing a greater disservice than by not having a clause in any event, because we are giving the appearance that we are doing something in fact, when we are doing nothing.

The problems in the present NIH fair pricing clause were well documented in the February 24, 1993 Senate hearing as well as in several hearings held by Representative Ron Wyden's House Subcommittee on Regulation and Technology. Rather than repeat criticisms that we have provided elsewhere, I will focus on the particular factors which are important for rehabilitating the usefulness of the reasonable pricing clause.

From the point of view of the contract language, it is fair to say that the model language is quite vague with respect to pricing methodology. Of course, NIH did itself no favors by weakening the clause in the ddI and Taxol contracts, particularly since the government was in a very strong bargaining position in both cases. Indeed, even with the modified contract terms that were used for ddI and Taxol, NIH still retained a good deal of power to insist on a much lower price. The evidence, however, suggests that NIH's principle problem was not the contract clauses, but the agency's lack of resolve in getting a better price for consumers. It is fair to say that many NIH officials are so hostile to the reasonable pricing clause that we expect them to actively sabotage the provision. One wonders how much matters would change if even a small fraction of the money to pay for the NIH developed therapies was paid for from the salaries of the NIH officials who are responsible for the reasonable pricing clause. We have concluded that many of the high paid NIH officials, all of whom enjoy excellent health care benefits, have little appreciation for the burdens faced by citizens who earn lower salaries and pay for medications out of pocket. The Secretary of Health and Human Services should consider a reorganization which places the responsibility for the reasonable pricing negotiations in the hands of an agency outside of NIH that has a clearer mandate to protect consumer interests.

The industry has rightly pointed out that the extremely vague language in the present model reasonable pricing clause presents uncertainty. Of course, the industry is unlikely to welcome reductions in that uncertainty, if a new more detailed methodology results in lower drug prices. Nevertheless, it is important to move beyond the "spiritual" statements of the present clause, to a more concrete methodology.

In order to move forward, beyond this increasingly tiresome debate over whether or not to control prices, it is a good idea to establish some basic concepts.

1. Information is important.

The government cannot do a good job of evaluating the reasonableness of a drug price without better data. One type of very useful data is the cost of R&D, disaggregated by key benchmarks, such as Phase I, II or III clinical trials or pre-clinical investments. The federal government has historically funded one fourth to one fifth of all clinical trials. These data alone would make a very useful database, but it would be even more useful if

the government had the power to compel reporting by the private sector as well. The government needs to collect and evaluate data on the probability of moving from one stage of R&D to another. There is also a great need for data on prices and sales revenues and production costs. Of course, NIH can obtain information of this type through contractual provisions, but the broader reporting under a statutory authority to compel disclosures would be preferred. Of course, it should be added that the price and sales revenue data are already available to the industry from private vendors such as Dun and Bradstreet's IMS service, and the industry already discloses detailed R&D data to its own trade associations and academic consultants, so the government would hardly be breaking new ground by compelling disclosure to the government.

2. Think globally.

The relevant market for pharmaceutical drugs is international. The relevant drug revenues are from international sales, not domestic sales. The government should routinely collect and study drug prices from other countries, including countries that use compulsory licensing to lower drug prices. The U.S. government should work with other countries to coordinate its data collections, and to set goals for sharing the burdens of R&D.

3. Reward companies for value added contributions to research.

In Taxol and ddI the government made a fundamental error. It evaluated prices based upon the costs of other drugs, rather than the value added contributions of the license holder or CRADA partner. It makes little sense to allow a firm that contributes one percent of the expected R&D costs to charge the same price as a firm that contributes 80 percent of the expected R&D costs.

4. Reward risk taking.

Investments in the riskier stages of development are more valuable than investments in more mature development stages. Out of pocket investments should be adjusted for risk. These rules apply to both the government and company investments. To appreciate these risks, the government needs to collect and analyze data on the R&D process, disaggreated by key R&D benchmarks, and to consider expectations rather than *ex post* results.

5. Don't underestimate the value of the government's research.

Industry consultants make generous adjustments to out of pocket investments, to reflect risks and the time value of money. For example, when the industry invests $1 in Phase I trials, the investment is counted as $11, to reflect inflation, risks and lost profits. Government officials report taxpayer investments in nominal terms, without any adjustments at all. This gives a distorted view of the relative contributions by the government and the industry. The largest area of undervaluing concerns pre-clinical research. The industry estimates that more than two thirds of the cost of a new drug is due

to the cost of pre-clinical research, once the investments are adjusted for risk and the time value of money.

6. When possible, rely upon market forces.

In a number of cases, NIH should be able to rely upon market forces to determine reasonable prices. If NIH can articulate a sound pricing rule or method, it should be possible to allow firms to competitively bid to obtain a CRADA or license agreement, on the basis of a bid variable that is related to the eventual consumer price. That bid variable could be the price itself, or a related item such as the gross or net revenue from sales, or even the years of marketing exclusivity.

7. Don't waive the reasonable pricing clause without a public interest finding and public comment.

NIH should retain the flexibility that it already has to waive or modify the reasonable pricing clause, but it should do so only after a finding that the wavier or modification was in the public interest, and after public comment.

8. Take the job seriously.

This is important stuff, and it deserves more than the symbolic attention that it has received in the past. Give more than the "appearance" that something is being done. The government has the opportunity to save taxpayers and consumers billions of dollars, and the industry stands to lose billions of dollars in windfalls on government funded research. Put together a team that is equal to the task.

STATEMENT OF CHUCK LUDLAM
VICE PRESIDENT FOR GOVERNMENT RELATIONS
BIOTECHNOLOGY INDUSTRY ORGANIZATION
AT THE
SECOND NATIONAL INSTITUTES OF HEALTH
CRADA FORUM
SEPTEMBER 8, 1994

My name is Chuck Ludlam and I am Vice President for Government Relations of the Biotechnology Industry Organization (BIO). BIO represents virtually every company with which NIH has CRADAs and licenses.

Since the first CRADA Forum we have seen major developments with the health care reform legislation on Capitol Hill which fundamentally change the issues at this second Forum. If any bill is enacted it is not likely to include any form of drug price controls.

If this is true, and NIH ratifies its current price review policy, it will be the only government agency with a drug price control program. This will ensure one result – it will isolate NIH from the drug development process and ensure that its inventions will be the least likely to be developed into products to treat deadly and costly diseases.

The NIH price review process creates perverse incentives. It will, for example, ensure that the CRADAs and licenses of the Department of Energy's genome program, which do not include any pricing review requirement, will be more attractive to CRADA and license partners than those of NIH's genome program, which do include the price review clause.

NIH price review will create a special incentive for companies to enter into agreements with the universities and foundation grantees of NIH, and the Army and Navy biomedical research programs, none of which include price control clauses, rather than with NIH.

NIH price review will amount to a form of self-imposed exile or quarantine for NIH scientists and their research.

Given the developments with health care reform and these perverse incentives, one could continue to advocate across-the-board drug price controls and argue that it is counter-productive for NIH to go it alone in imposing such controls. At the first Forum Peter Staley of the New York Treatment Action Group (TAG) testified that he supports across-the-board price controls but opposes the NIH price control scheme. I have attached a copy of Peter's eloquent statement to ensure that you have an opportunity to review it.

Going it alone on price controls carries obvious liabilities for NIH because biotechnology companies enter into CRADAs and license government technology on an entirely voluntary basis. No company is compelled to enter into CRADAs or licenses.

The biotechnology industry has just devoted an entire year vigorously opposing various proposals to impose drug price controls as part of the health care reform legislation. If biotechnology companies strongly oppose legislation to impose drug price controls, NIH should not expect that they will voluntarily agree to be bound by NIH's price controls.

Biotechnology companies and their investors believe that the NIH price review policy is a form of price controls. NIH may not wish to characterize its "reasonable price" clauses as price controls, but it is absolutely clear that biotechnology companies and their investors do hold this belief. In this case the perception of these executives and their investors is the reality and no amount of rhetoric will change that reality.

The biotechnology industry opposes drug price controls because these controls make it impossible for our companies and their investors to estimate the potential to generate a reasonable rate of return on their research investment. Investors will not provide the capital to fund research and firms cannot justify a research expenditure under these circumstances. Biotechnology research already involves extraordinary risk and the additional risk of price controls, coming at the very end of the drug discovery process, tips the balance against the investment.

Only one percent of the biotechnology industry is profitable, very few have revenue from sales of existing products, the industry as a whole lost $3.6 billion last year, and our capital markets are severely depressed. The biotechnology industry would prefer to be in a much stronger economic position, but it must seek to survive with the reality as it finds it. It must focus its research where it has the greatest prospects for generating a reasonable rate of return.

This economic reality cannot be ignored by NIH. This is the economic reality for the CRADA and licensing partners who are the most excited about developing NIH technology into commercial products.

When NIH technology is not successfully transferred and commercialized, needed therapies do not reach the bedsides of patients. This is the ultimate tragedy for consumers.

The threat here is not just the marginalization of NIH scientists and their research. Legislation has been introduced which would require NIH to control the prices of all products developed by its licensees and impose this requirement on CRADA partners and licensees under the NIH extramural program. For this panel and the NIH to ratify the current policy will invite Congress to enact this legislation. Enactment of this legislation would permanently disable both the intramural and extramural technology transfer programs of NIH.

This legislation would set a precedent which jeopardizes the CRADA and licensing program of every other government agency, all of which would suffer if price review clauses were included in their agreements.

As the NIH drug price control program undermines the effectiveness of the NIH technology transfer process, it also undermines the rationale for appropriations for NIH basic research and the Harkin-Hatfield proposal.

Unfortunately the NIH notice for this Forum fails to address any of these critical issues.

It fails to take recent developments with the health care reform legislative into account.

It fails to mention the perverse incentives created when NIH goes it alone on price controls.

It does not acknowledge the firm belief of biotechnology companies and their investors that these clauses operate as price controls.

It fails to recognize the difficult economic reality of the biotechnology industry.

Surprisingly it does not mention the interest of patients in the successful commercialization of NIH's basic research.

It fails to recognize the fundamental threat that this policy poses to the NIH extramural program and the technology transfer program of other agencies.

And, it fails to note the potential adverse impact on NIH appropriations and the Harkin-Hatfield proposal.

The issue which is raised -- protecting the government investment -- is a legitimate and important issue.

To begin with it is obvious that the government's and taxpayer's research investment is completely squandered when companies refuse to enter into CRADA and licensing

agreements.

When CRADAs or licenses are successfully negotiated, the government's financial investment is directly reimbursed when companies pay licensing fees and royalties to the government on the sales of any products developed from transferred technology.

Our companies expect to pay reasonable fees and royalties. There is no dispute about them. This is what is expected when one private company enters into an agreement with another.

In addition the government's larger economic interests are protected when these companies create jobs, pay taxes, and increase the competitiveness of America.

BIO has urged NIH to abandon the pricing clause altogether. The Panel may be tempted to recommend that NIH limit its pricing clauses only to very late stage development agreements, where NIH research has developed a drug which is essentially ready to be marketed to the public.

We submit that there aren't any drugs in this category and never will be. But, even if there were, such a restriction would ensure that NIH would have the greatest difficulty in licensing the products which could immediately provide medical benefits to patients. Barriers and disincentives for technology transfer in these cases would be not just be unwise, it would be tragic.

In addition, if NIH restricts its use of the pricing clause to these nonexistent or rare cases, it will still have a chilling effect on the whole technology transfer program. Every licensee would be concerned that any research it undertakes with the NIH would eventually, as it focuses more and more on a specific product, come under the pricing clause. Companies often enter into a series of CRADAs, each with its own specification of the work, and they would be reluctant to enter into the first CRADA for fear that the second or third or fourth would contain the pricing clause.

The Panel might also be tempted simply to clarify the terms of the clause and the process which will be followed in its implementation. The only impact this will have is to confirm the threat and the risk of entering into a CRADA or license with NIH. The issue is not vagueness about how the review will be conducted; it's the fact that the review is required and that this review supplants the market place as the arbiter of the prices for the drugs.

As a government agency which is uniquely familiar with the scientific discovery process, NIH knows that many experiments fail and that we need to learn from these failures. The pricing clause has failed, indeed, it has proven to be counter productive.

NIH must renew its commitment to the technology transfer process and provide for

government reimbursement through reasonable fees and royalties. It must abandon its unsuccessful experiment with price controls.

Thank you again for this opportunity to testify. I am happy to answer your questions.

Attached: Testimony of Peter Staley from First CRADA Forum

BIO
BIOTECHNOLOGY
INDUSTRY
ORGANIZATION

News Release

1625 K Street, N.W. · Suite 1100 · Washington, D.C. 20006 · (202) 857-0244 · FAX: (202) 857-0237

FOR IMMEDIATE RELEASE

CONTACT: Dan Eramian
Eric Christensen
(202) 857-0244

BIO PREDICTS NIH CRADA POLICY MAY LEAD TO 'SELF-IMPOSED EXILE' FOR NIH SCIENTISTS

(WASHINGTON, DC, September 7, 1994)...In testimony to be delivered tomorrow, the Biotechnology Industry Organization (BIO), predicts that National Institutes of Health (NIH) policies for Cooperative Research and Development Agreements (CRADAs) with private companies will, "amount to self-imposed exile or quarantine for NIH scientists and their research."

Chuck Ludlam, BIO government relations vice president, will testify before a NIH advisory panel that NIH CRADAs allowing the agency to review the prices of drugs developed through such agreements, is in fact a drug price control program. "This will ensure one result," Ludlam will say. "It will isolate NIH from the drug development process and ensure that its inventions will be the least likely to be developed into products to treat deadly and costly diseases."

(more)

Ludlam will further explain that, "NIH may not wish to characterize its 'reasonable price' clauses as price controls, but it is absolutely clear that biotechnology companies and their investors do hold this belief. In this case the perception of these executives and their investors is reality and no amount of rhetoric will change that reality."

Ludlam will note that the biotech industry opposes price controls because such controls make it difficult for companies to attract the investors necessary to fund the early stages of product development for new biotech drugs. It can take seven to 10 years, and millions of dollars to bring a biotech drug through the research and development, clinical trial and approval stages.

He will also explain that, "Legislation has been introduced which would require NIH to control the prices of all products developed by its licensees and impose this requirement on CRADA partners and licensees under the NIH extramural program...Enactment of this legislation would permanently disable both the intramural and extramural technology transfer programs of NIH," Ludlam will say.

(more)

"When CRADAs or licenses are successfully negotiated, the government's financial investment is directly reimbursed when companies pay licensing fees and royalties to the government on the sales of any products developed from transferred technology.

"Our companies expect to pay reasonable fees and royalties. There is no dispute about them. This is what is expected when one private company enters into an agreement with another," Ludlam will say.

"As a government agency which is uniquely familiar with the scientific discovery process, NIH knows that many experiments fail and that we need to learn from these failures. The pricing clause has failed, indeed, it has proven to be counter-productive," Ludlam will conclude.

BIO represents more than 540 companies, academic institutions, state biotechnology centers and other organizations involved in the research and development of health care, agricultural and environmental products.

(END)

National Coalition for Universities in the Public Interest

1806 T Street, N.W.
Washington, D.C. 20009
(202) 234-0041
Fax (202) 387-4549

September 7, 1994

Dr. Harold Varmus
Director, NIH
Bldg 1 Room 126
9000 Rockville Pk.
Bethesda, MD 20892

Mr. William Corr
Public Health Service
Room 716G
200 Independence Ave., S.W.
Washington, D.C. 20201

Dear Dr. Varmus and Mr. Corr;

NCUPI opposes any agreement by the government that would remove the federal government's current ability to review the prices of drugs created through CRADA's that would be marketed by pharmaceutical companies.

The Coalition has long opposed university-industry partnerships which served as a model for the CRADA on the grounds that research was perverted by an industrial relationship that emphasized product and profit outcomes at the expense of research integrity. In 1988, Ted Weiss's Governmental Operations Sub-committee held hearings titled "Are conflicts of interest hazardous to your health" which documented numerous instances of fraud and misconduct resulting from the university- industry connection . The Coalition believes that it is outrageous to ask the taxpayer to pay for research that aims at producing profitable products, since it has become clear that such "sponsored" research produces pharmaceuticals whose safety and effectiveness are often much exaggerated, and sometimes kill. (see Weiss, Hearing)

Before the Bayh-Dole Patent Law emendations in 1980, the government was also concerned that patent law protect taxpayers from the double burden of paying for research and paying monopolistic prices for the resulting inventions. Universities, for example, were forbidden to give exclusive licenses for developing and marketing such inventions on the grounds that monopolistic pricing would be the result, and that the taxpayer would pay twice for the same product - first to develop it, then to buy it. The government was right then to want to protect the taxpayer from rip-off pricing that would result from the granting of exclusive licenses, and, having dropped its objection to such exclusive licensing in order to promote technology transfer, it should maintain its vigilance on behalf of the consumer and taxpayer by retaining the price review now in place.

Sincerely,

Leonard Minsky

Leonard Minsky

September 1, 1994

Ms. Elyssa Tran
Office of Science Policy and Technology Transfer
NIH
Building 1, Room 218
9000 Rockville Pike
Rockville, MD 20892

Dear Ms. Tran:

I would like to submit my view for the 2nd CRADA Forum Panel as a consumer of the products of medical research. Athough I appreciate the idea that the federal government represents the public via tax dollars and also feel that the public should get something back from the money spent on medical research at NIH when it becomes commercially valuable, I don't think that putting restrictions on technology transfer will facilitate the production of new and better medical treatments. I am afraid that regulations, such as the reasonable pricing clause, will FURTHER discourage pharmaceutical and biotech companies from doing business with NIH. The result of this will be that research findings at NIH will be academically disseminated to the public but won't be directly translated into useful medical products or there will be a significant time lag. This means people will die sooner and have a lower quality of life.

NIH should be doing everything it can to facilitate the process--NOT restrict it. I would rather my tax dollars go into innovative research at NIH and have NIH hand over everything to someone who can rapidly put it into better treatments. People are dying. I would like more and better drugs and would rather pay high prices than see fewer and less effective drugs due to government restrictions. Although the intent is good, we are already benefiting by better treatments which is the bottom line. Don't mess up the bottom line by playing with less important points. The outcome here is most important.

Instead of forcing companies to not do business with NIH (or forcing them out of business) with a reasonable pricing clause, why not streamline the regulatory process at FDA by eliminating animal testing and using volunteer human subjects right after in vitro screens. This would reduce the time to market and reduce the price. We don't need more government barriers to better medical treatment, we need less.

Another aspect to this is that pharmaceutical and biotech companies are not greedy parasites on society. They are providing the treatments which improve and save our lives. If they need a high price to fund their development of new drugs then we have to pay it. Not only do they provide a service to society but they provide jobs and contribute to academic medical research, charities and the arts. They are a GOOD thing and they are productive--not a parasite!

Please do everything to ENHANCE the flow of technology transfer from NIH. Otherwise my tax dollars there ARE wasted!

Sincerely,

Vasiliana V. Moussatos

Vasiliana V. Moussatos
Registered Voter & Taxpayer
682 Whitney Avenue
New Haven, CT 06511
(203) 787-2527

INTELLECTUAL PROPERTY AND FAIR PRICING CLAUSES IN AGREEMENTS BETWEEN THE FEDERAL GOVERNMENT AND PRIVATE INDUSTRY RELATING TO RESEARCH ON PHARMACEUTICAL PRODUCTS FOR SERIOUS OR LIFE-THREATENING DISEASE

The Pulbic/Private Issues Subcommittee of the National Task Force on AIDS Drug Development has identified two barriers that may prevent the rapid development and evaluation of treatments for HIV/AIDS: 1) the National Institutes of Health (NIH) has declined to include clauses granting exclusive patent licenses for inventions made during research conducted under cooperative research and development agreements (CRADAs) and other research agreements with the pharmaceutical industry, and 2) the NIH began in 1989 to insist on the inclusion of so-called "fair price" or "reasonable price" clauses in CRADAs and other research agreements with the pharmaceutical industry.

The Subcommitee believes that these two policies have resulted in a stifling of collaboration between the federal government and the pharmaceutical industry, and could prevent the rapid development of treatments for HIV/AIDS. The lack of appropriate intellectual property clauses and the inclusion of fair pricing clauses represent administrative decisions that are not required by congressional enactment. The Subcommittee recommends that appropriate intellectual property clauses should be included in, and pricing clauses should be excluded from, CRADAs and other collaborative agreements relating to pharmaceutical products (including drugs, biologics, and medical devices) for serious or life-threatening diseases (an established category of products for which the FDA considers treatment INDs under 21 C.F.R. §312.34 and accelerated approval of NDAs under 21 C.F.R. subpart H).

The Subcommittee recognizes the issue of pharmaceutical prices as it relates to access to health care, but believes that any response to this issue should be comprehensive. By targeting only those pharmaceuticals resulting from collaboration between industry and government, the NIH has inadvertently stifled such collaboration.

As an alternative to fair pricing clauses, the payment of royalties to a government agency which develops and transfers a technology to a private firm for commercialization might be considered. This would serve to compensate for the public investment in a marketed product, provide additional revenues for government research, and provide a special incentive for government agencies to enter into collaborative agreements.

Biotechnology Information Institute
Publications and Information Services in Biotechnology and Pharmaceuticals

1700 Rockville Pike, Suite 400
Rockville, Maryland 20852

Phone: (301) 424-0255
Fax: (301) 424-0257

News Release: Originally released 8/22/94; revised 9/8/94 including new data for 43 NIH CRADAs

Federal Labs and NIH are Number One in Bio-Technology Transfer

The first comprehensive study clearly shows that federal (U.S. government) laboratories are by far the leaders in technology transfer in the biomedical, biotechnology and pharmaceutical areas. In these areas, the federal laboratories and the Public Health Service (PHS) and its main component, the National Institutes of Health (NIH), are number one in:

- inventions available for licensing;
- patents received and patent applications pending;
- inventions that have been licensed out; and
- therapeutics in active development (even compared to the largest pharmaceutical companies), both in terms of those licensed out and those being developed internally.

The federal labs, PHS and NIH are:

- the U.S. biotechnology and pharmaceutical industries' leading sources for new technologies, both new products and broadly enabling technologies;
- the leaders in collaborative research and development with the biotechnology and pharmaceutical industries, including therapeutics in development and clinical trials; and
- the source for many products and technologies in the marketplace. However, federal technology transfer is relatively new, and many (hundreds) more technologies and products are currently in development, both licensed inventions and those being developed collaboratively through CRADAs with industry. This includes well over 100 therapeutics having reached clinical trials.

Mr. Ronald A. Rader, President, Biotechnology Information Institute, Rockville, MD, has presented data from the *Federal Bio-Technology Transfer Directory*, a recently published reference book he authored describing all federal biomedical, biotechnology and pharmaceutical U.S. patents, patent applications, licenses granted and Collaborative Research and Development Agreements (CRADAs) from 1980-1993. This is the largest directory of biotechnology and pharmaceutical inventions available for licensing. The *Directory* describes 2,100 federal inventions (1,200 patents; 900 applications); nearly 1,000 licenses (including 270 exclusive and 640 nonexclusive patent licenses); and over 500 CRADAs; along with information about the commercial potential of inventions and the status of products/technologies in development and the marketplace. Much of this information has never before been published, particularly patent licenses and CRADAs. The 678-page book has over 400 pages of text/abstracts and 250 pages of indexes, including a 37,000 entry subject index. The *Federal Bio-Technology Transfer Directory* database will be available this fall.

The *Federal Bio-Technology Transfer Directory* shows that:

- Federal agencies and labs have 2,100 U.S. patents granted or pending in the biomedical, biotechnology and pharmaceutical ("biomedical/biotech") areas from 1980-1993. PHS (with 60%) and NIH (with 49%) are by far the leaders among federal agencies.

- Biotechnology is involved in the majority of federal bio-technology transfer. This includes over 50% of inventions; about 70% or more of patent licenses granted; and up to 70% of CRADAs. Biotechnology involvement is highest and has been increasing in recent years.
- The numbers of inventions, licenses and CRADAs are related to R&D funding, mandates and technology transfer efforts. The federal labs' biomedical/biotech R&D budget is about $2.5 billion/year. The NIH intramural R&D budget ($1.3 billion) is comparable to that of the largest pharmaceutical companies and over 40% of total U.S. biotechnology industry R&D funding.
- Most federal bio-technology transfer is recent and continues to increase steadily. Over 60% of inventions are from 1990-1993; 75% of CRADAs were active in 1993; and well over 1,000 federal biomedical/biotech patent applications are currently pending.
- The federal labs and PHS and NIH are consistently the leading recipients of U.S. patents in biotechnology and genetic engineering, including those with pharmaceutical uses.
- The federal labs, PHS and NIH are consistently among the leading recipients of drug and other bio-active agent patents, ranking with many of the world's largest pharmaceutical companies.

Licensing, particularly exclusive licensing, of federal inventions is an issue involving much public debate. This is especially true as PHS/NIH is currently considering dropping or significantly modifying its "reasonable pricing" clause in exclusive licenses and CRADAs.

The *Federal Bio-Technology Transfer Directory* shows that:

- About 27% of federal inventions have been licensed one or more times, including 34% of PHS and 32% of NIH inventions. These are rather high percentages of invention licensing, since only about 10% or less of inventions are ever used commercially.
- Nearly 1,000 licenses have been granted to industry, mostly from PHS (84%) and NIH (75%).
- The majority of invention licenses are nonexclusive (no restrictions on granting further licenses). PHS and NIH inventions are more likely to be licensed nonexclusively and to have more licenses/invention (licensed to more companies). A few inventions, mostly broadly enabling technologies and screening assays, have been licensed by up to 20 companies.
- About one-quarter of invention licenses are exclusive licenses, and about 40% of licensed inventions have been exclusively licensed. Many of these involve major commercial products in development. About 75% of federal and 87% of NIH exclusive licenses involve therapeutics-related inventions (mostly therapeutic agents). Many of these therapeutics-related licenses involve biopharmaceuticals and drugs in development.
- Over two-thirds of licensed inventions are therapeutics-related and about one-third of exclusively licensed therapeutics-related inventions have reached the clinical trials stage of development.

Regarding CRADAs, the *Federal Bio-Technology Transfer Directory* shows that:

- Collaborative R&D with industry ranges from basic speculative research through product development and testing, including clinical trials.
- PHS with 51% (279) and NIH with 37% (205) lead all federal agencies/labs with CRADAs in the biomedical/biotech areas. However, CRADAs remain an insignificant part of the PHS/NIH total R&D, unlike some other federal agencies/labs where CRADAs are up to 10% of total R&D.
- About two-thirds of federal, 73% of PHS and 80% of NIH CRADAs involve therapeutics-related technologies (mostly therapeutic agents). About one-third of all federal, PHS and NIH therapeutics-related CRADAs involve therapeutics that have reached the clinical trials stage. Many of these CRADAs involve ongoing clinical trials, with most conducted by PHS and NIH.

Mr. Rader has also documented that:

- The federal labs, PHS and NIH each rank number one or among the leaders in the number of drugs and biopharmaceuticals in development (even compared to the largest pharmaceutical companies), both in terms of those licensed out and those being developed internally.
- PHS and NIH rank among the top recipients of licensing income among U.S. universities and nonprofit research organizations—$12.2 million licensing royalty income in FY1992, with about 80% or more of this from the licensing of HIV diagnostic patents.
- Federal labs are filing over 450 new patent applications/year (PHS alone over 300), licensing activity is increasing, and CRADAs are growing rapidly (except for PHS/NIH).
- The PHS/NIH "reasonable pricing" exclusive licensing clause has contributed to many biotechnology and pharmaceutical companies of all sizes avoiding PHS/NIH CRADAs and licensing.
- Cancer and infectious diseases, particularly viral infections and HIV, are the main disease areas for federal inventions, licenses and CRADAs (most of these within PHS/NIH).
- Federal labs, PHS and NIH are each the leading recipients of antiviral/virus-related patents and have the most antiviral drugs and vaccines in development, including those licensed out and those being developed internally. NIH co-discovered HIV, claims co-discovery of the utility of AZT and exclusively licensed the next two drugs approved for HIV-infection (DDI; DDC).
- Federal labs in Maryland (particularly NIH) are the source for over 70% of federal biomedical/biotech inventions, licenses and CRADAs. These labs (and NIH alone) make the suburban MD/Montgomery county area the world's leading area for biomedical, biotechnology and pharmaceutical technology transfer opportunities. MD and DC organizations have over 70 CRADAs.

Although only a small portion of the nation's total R&D, the federal labs are a major national resource for inventions and technology transfer. The federal labs as a whole, and PHS and NIH each have the largest and most important portfolios of biomedical and biotechnology inventions available for licensing. Unlike corporate inventions, these are all available for licensing. Federal labs, PHS and NIH each are the most important sources for the licensing of new technologies and for collaborative R&D with the U.S. biotechnology and pharmaceutical industries. The federal and, especially, the PHS and NIH invention portfolios and technology transfer activities are unsurpassed in many areas including cancer; HIV, viral and other infectious diseases and vaccines; gene therapy and sequencing; therapeutics screening; radiopharmaceuticals; and fundamental aspects of molecular and cellular biology. Federal technology transfer is relatively new and more federal inventions are in development than are currently in the marketplace. Hundreds of examples are described in the *Federal Bio-Technology Transfer Directory*. Many federal inventions will form the basis for a significant portion of the U.S. biotechnology and pharmaceutical industries' future products and technologies. Federal inventions tend to be the types most needed by industry—fundamental breakthrough technologies (e.g., gene therapy), broadly enabling technologies (e.g., therapeutics screening assays) and biopharmaceuticals and drugs for diseases for which therapeutics are not available.

No technology, market or competitive assessment in the biomedical, biotechnology or pharmaceutical areas is complete without considering federal technology transfer. The *Federal Bio-Technology Transfer Directory* is the only information resource providing the biotechnology and pharmaceutical industries and the biomedical and life sciences research communities with access to federal technology transfer opportunities and activities.

[For further information including a 22-page study, contact: Mr. Ronald A. Rader, President, Biotechnology Information Institute, Phone: 301-424-0255; FAX: 301-424-0257].

Federal Labs, PHS and NIH Ranking in Bio-Technology Transfer

Inventions available for licensing	No. 1
Patents received	No. 1
Patent applications pending	No. 1
Patent licenses granted	No. 1
Industry source for new technologies	No. 1
Collaborative R&D with industry	No. 1
Therapeutics in dev.—licensed out	No. 1
Therapeutics in dev.—internally	No. 1
Therapeutics in dev.—collaborative R&D	No. 1
Therapeutics in clinical trials	No. 1
U.S. biotechnology patents	No. 1
U.S. biopharmaceutical patents	No. 1
U.S. genetic engineering patents	No. 1
U.S. drug/bio-active agent patents	Leader

Federal Bio-Technology Transfer by Agency[1]

Agency	Patents	Appl.	Licenses[2]	CRADAs
PHS	617	657	835 (188)	279
NIH	545	564	745 (178)	228
USDA	133	68	48 (8)	6
Army	120	57	38 (29)	127
DOE	118	52	29 (20)	60
NASA	88	19	18 (17)	1
Navy	78	33	20 (7)	38
Air Force	35	4	1	–
DOC	5	7	2 (1)	12
EPA	–	–	–	18
Total[3]	1,197	899	992 (270)	543

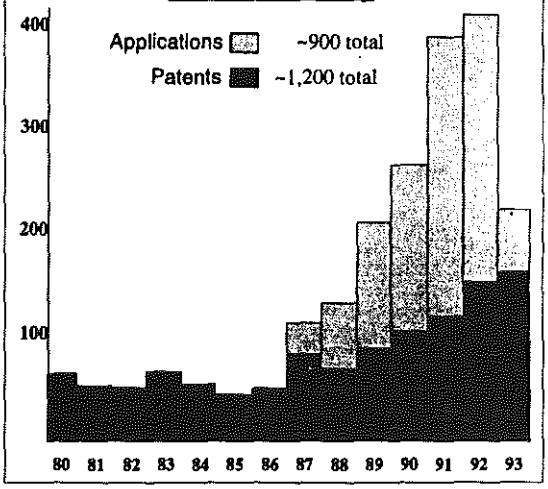
Federal Bio-Technology Transfer, 1980-1993[1]

	U.S. Govt.	PHS	NIH
Biomedical/biotech R&D 1993 ($ billion)	2.5	-	1.2
% of total biotech industry R&D	80%	-	39%
Inventions, 1980-1993	2,096	1,274	1,109
U.S. patents	1,197	617	545
Pending applications	899	657	564
Inventions, therapeutics-related	1,279	851	772
% of total inventions	61%	68%	70%
Inventions, biologics/biotech (%)	56%	57%	59%
Inventions, drugs/chemical technology (%)	47%	44%	46%
Patent (invention) licenses	992	835	745
Average licenses/licensed invention	1.76	1.95	2.09
Exclusive patent licenses	270	182	173
% of patent licenses	27%	23%	23%
Patent licenses, therapeutics-related	669	584	550
% of patent licenses	67%	70%	74%
Exclusive patent licenses, therapeutics-related	200	156	150
% of exclusive licenses	74%	83%	87%
involving inventions reaching clinical trials	68	56	56
% involving inventions reaching clinical trials	34%	36%	37%
Inventions (technologies) licensed	563	428	356
% of inventions	27%	34%	32%
reaching clinical trials stage	76	62	61
Exclusively licensed inventions	230	161	152
% of licensed inventions	41%	38%	43%
therapeutics-related reaching clinical trials	52	44	44
Inventions licensed, therapeutics-related	339	267	234
% of therapeutics-related inventions	27%	31%	30%
reaching clinical trials stage	69	61	60
% reaching clinical trials stage	20%	23%	26%
CRADAs	543	279	205
involving biologics/biotechnology	320	197	149
involving drugs/chemical technology	241	111	80
involving therapeutics technologies/uses	354	203	163
reaching clinical trials stage	140	74	61
involving biopharmaceuticals	232	149	123
% of CRADAs involving therapeutics	65%	73%	80%
% of CRADAs involving clinical trials	30%	30%	34%
% of CRADAs involving biopharmaceuticals	43%	53%	60%

Federal Tech. Transfer by Technology/Uses[1]

Tech./Uses	Patents	Appl.	Licenses[2]	CRADAs
Drugs/chemical	661	359	312 (137)	241
Biologics/biotech	480	606	734 (138)	320
Apparatus/devices	386	118	121 (45)	115
rDNA/genetic eng.	126	353	308 (67)	131
Genes-cloned/seq.	101	331	267 (63)	84
Antibodies	148	176	325 (46)	58
Therapeutics	679	600	669 (200)	332
Diagnostics	534	413	564 (88)	172
Cancer	186	162	240 (67)	74
Therapeutics	151	126	213 (55)	56
Diagnostics	70	81	137 (26)	17
Infectious Diseases	279	349	423 (82)	183
Viral/antiviral	136	240	329 (63)	112
HIV-infection	56	122	178 (34)	46
Therapeutics	50	106	166 (33)	45
Diagnostics	26	42	23	3
Radiopharm.	119	37	92 (23)	36
Screening (drugs)	63	129	164 (33)	31
Clinical trials stage	68	46	141 (75)	161

Inventions in the *Federal Bio-Technology Transfer Directory*



[1]Numbers refer to the total of patents, applications or CRADAs relevant to a technology/use or assigned to a federal agency/ laboratory. Entries are indexed with as many technologies/uses as are relevant. Data are not to be considered as official.
[2]Total of the licenses granted for licensed intellectual properties (U.S. patents or patent applications) followed by the number of exclusive licenses in parentheses. This is not the number of licensed inventions or company licensing packages.
[3]Totals for all federal agencies (Departments of Interior, Justice and Veterans Affairs not shown; negligible entries).

National Institutes of Health (NIH) Technology Transfer[1]

NIH Technology Transfer by Technology/Uses[2]

Tech./Uses[2]	Patents	Appl.	Licenses[3]
Totals			
Biotechnology/biologics	244	408	578 (98)
Biopharmaceuticals	156	297	431 (81)
Biopharm./clinical trials stage	20	18	79 (30)
Vaccines	60	87	200 (28)
Drugs/chemical technology	309	205	217 (92)
Drugs/clinical trials stage	35	18	60 (30)
Apparatus/devices	178	69	72 (7)
Medical devices/clin. trials stage	1	2	3 (3)
rDNA/genetic eng.	81	271	260 (55)
Genes-cloned/seq.	63	259	234 (52)
Therapeutics	351	421	550 (150)
Treatments/clinical trials stage	49	33	123 (57)
Diagnostics	234	244	426 (45)
Diagnostics/clinical trials stage	4	7	7
Gene therapy	9	36	40 (18)
Cancer	133	147	223 (57)
Treatments	112	118	202 (50)
Treatments/clinical trials stage	25	9	63 (22)
Diagnostics	50	69	123 (19)
Infectious Diseases	129	214	310 (56)
Viral/antiviral	93	181	290 (54)
HIV-infection	45	108	171 (32)
Treatments	28	78	80 (30)
Treatments/clinical trials stage	41	94	160 (31)
Diagnostics	21	35	110 (2)
Cardio/vascul./blood	84	60	96 (15)
Neurological	72	61	70 (33)
Radiopharm./treatments	59	25	88 (15)
Immunology (diverse aspects)	109	170	343 (45)
Antibodies	81	118	274 (34)
Screening (agent activity)	37	113	146 (24)
Clinical trials stage of development	49	35	124 (58)

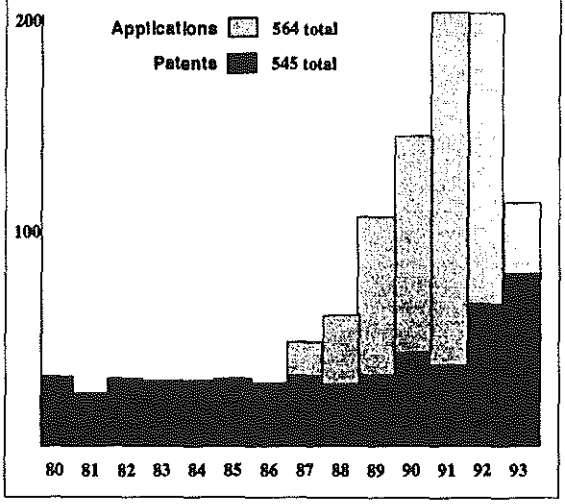
CRADA Activity by Technology/Uses[2]

Tech./Uses[2]	Federal	PHS	NIH
Totals	543	279	228
Biotechnology/biologics	320	197	161
Biopharmaceuticals	215	149	131
Biopharm./clinical trials stage	84	43	36
Vaccines	98	52	38
Drugs/chemical technology	241	111	94
Drugs/clinical trials stage	69	35	33
Apparatus/devices	115	25	17
Medical devices/clin. trials stage	19	3	3
rDNA/genetic engineering	131	100	90
Genes-cloned/sequenced	84	62	56
Therapeutics	354	203	179
Therapeutics/clinical trials stage	140	74	68
Diagnostics	179	86	50
Diagnostics/clinical trials stage	23	11	9
Gene therapy	16	11	11
Cancer	74	61	60
Treatments	56	46	46
Clinical trials stage	30	24	24
Diagnostics	17	14	14
Infectious Diseases	183	99	64
Viral/antiviral	112	78	56
HIV-infection	46	37	33
Therapeutics	45	36	33
Clinical trials stage	19	12	10
Diagnostics	3	3	1
Cardio/vascul./blood	33	19	13
Neurological	64	48	47
Radiopharm./treatments	36	14	13
Immunology (diverse aspects)	78	56	39
Antibodies	61	45	32
Screening (agent activity)	31	19	19
Clinical trials stage of development	161	85	578

PHS Technology Transfer by Organization

Organization	Patents	Appl.	Licenses[3]	CRADAs
NIH	545	564	745 (178)	228
CC	18	7	12 (1)	4
DCRT	1	1	-	1
NCI	185	248	419 (77)	79
NCHGR	-	-	-	-
NCRR	38	8	27 (3)	4
NEI	2	9	-	7
NHLBI	38	35	30 (6)	8
NIA	10	5	5 (4)	2
NIAAA	6	2	2 (1)	1
NIAID	62	84	108 (19)	35
NIAMS	1	3	1	-
NICHD	16	22	23 (6)	9
NIDA	2	2	1	3
NIDCD	-	-	-	-
NIDDK	49	51	29 (21)	21
NIDR	23	13	13 (6)	12
NIEHS	4	14	3 (1)	1
NIGMS	2	-	-	-
NIMH	42	26	29 (22)	24
NINDS	14	30	29 (6)	17
NINR	-	-	-	-
NLM	-	1	-	-
Extramural	32	2	13 (4)	-
CDC	24	52	85 (8)	39
FDA	48	41	5 (2)	12

NIH Inventions in the *Federal Bio-Technology Transfer Directory*



[1]Includes all U.S. patents, applications, licenses and CRADAs from 1980-FY1993 for which public domain information was available and U.S. patents through the end of 1993. Data are not recognized as official by any PHS/NIH or federal office. Criteria differ from those used by OTT (and are further explained in the *Federal Bio-Technology Transfer Directory).*

[2]Inventions and CRADAs are indexed with as many technology/uses as are relevant.

[3]Total of the licenses granted for licensed intellectual properties (U.S. patents or patent applications) followed by the number of exclusive licenses in parentheses. This is not the number of licensed inventions or company licensing packages.

National Kidney Cancer Association

Suite 200
1234 Sherman Avenue
Evanston, IL 60202
708-328-4031
fax: 708-328-4425

August 30, 1994

Dr. Harold Varmus
Director
National Institutes of Health
Building 1, Room 126
9000 Rockville Pike
Bethesda, Maryland 20892

Dear Dr. Varmus:

Since I cannot attend your meeting on September 8 regarding the "fair price" clause in CRADA's, I'm writing you this letter and ask that you read it aloud at the meeting.

By way of introduction, I am President and Chief Executive Officer of the National Kidney Cancer Association, a non-profit charity which provides information to patients and physicians, sponsors research, and acts as an advocate on behalf of the nation's 75,000 kidney cancer patients.

I hold a Ph.D. in Management from the J. L. Kellogg Graduate School of Management at Northwestern. I have also worked as a new product consultant in the Advanced Methods Group of N.W. Ayer, a major advertising agency. In addition, I have started five high tech computer-related companies, including one that has been publishing economic information on research and development expenditures for 15 years. The customers of this company include every major drug company, Bell Labs, the Stanford Research Institute, Battelle Memorial Institute, major universities, and government agencies.

I have no financial interest in any drug, bio tech or health care company. I'm writing to you as a kidney cancer patient whose life may depend upon NIH and private industry efforts to find a cure for my disease.

NIH CRADA's are critical to the millions of Americans who suffer from diseases such as kidney cancer, AIDS, Alzheimers, and other diseases for which there are no effective treatments or cures. For this reason, the National Kidney Cancer Association is opposed to the inclusion of "fair price clauses" in CRADA's.

The "fair price clause" was motivated by politics and it is not based on sound economic principles. It is bad public policy and it will cause the failure of the NIH CRADA program as well as the failure of individual CRADA's.

There are basic economic truths and principles which must be recognised in the design and implementation of NIH's CRADA program. These truths may seem self evident, but they are not always honored. The social and political agenda of the NIH gets in the way, distorting rational economic thinking, leading to the failure of individual agreements and the CRADA program itself. Allow me to explain.

Economics

The NIH has a fiduciary responsibility to the taxpayers of the United States. NIH managers are entrusted with tangible assets such as buildings and equipment, and intangible assets such as knowledge, patents, and human resources. You are expected to manage these assets in a way that produces the maximum benefits for the public. The value of these benefits can always be measured in terms of money.

Even life itself can be measured in terms of money. Economists routinely estimate the value of human life in wrongful death lawsuits in order to determine appropriate damage claims. When social and political agenda setters deny this economic reality, NIH thinking gets confused.

In licensing NIH technology or in entering into a CRADA, the NIH contributes tangible and intangible assets to a private sector firm. The private sector firm which gets the assets must risk additional capital and add its own know-how in order to make a financial return. The willingness of a firm to enter into a CRADA depends heavily upon the potential return it can derive from the agreement.

All firms have alternative uses for their capital and know-how. Senior executives in the private sector have a fiduciary responsibility to their shareholders to invest capital for the highest possible return.

If the NIH makes CRADA's unattractive, firms will not invest in CRADA's and will put their money into other investments. Demand for CRADA's indicates how attractive NIH has made CRADA's as an investment option for the private sector.

The "fair price clause" makes CRADA's less attractive as an investment opportunity because they limit potential return on investment while such clauses do nothing to limit potential losses. From this perspective, "fair price" clauses create economic asymmetry--an "unfair deal" for investors. Weak demand for CRADA's with "fair price" clauses reflects this economic reality.

The market value of NIH assets or any CRADA is simply what someone is willing to pay to obtain the assets or participate in the CRADA.

These economic truths frame the whole question of the "fair price" clause in NIH CRADA's and how the NIH can best serve the public.

Auctioning CRADA's to Maximize Public Benefits

If the NIH truly wanted to maximize the benefit of CRADA's to the public, it would hold public auctions and offer each CRADA to all potential bidders.

Auctioning each CRADA would guarantee the government the highest price for its assets. By getting this best price, the NIH would automatically fulfill its fiduciary obligations to the people of the United States. Note that the price for a CRADA is not the same as the price for products derived from the CRADA.

The money from an auction would go either into the Treasury to benefit all taxpayers and citizens, or it could be retained by the NIH to fund additional research.

Effects on NIH Personnel

The effects of auctions on the NIH are important to consider. The product of the NIH is knowledge gained through the research process. Producing knowledge with the highest economic value is important because the economic value reflects potential benefit to society and the American people. Auctioning the product of the NIH could be extremely motivational for NIH scientists if managed properly. The challenge and recognition of producing a valuable chunk of know-how could add to the excitement and rewards of working at the NIH.

Effects on Successful Bidders

The effects of auctions on private companies are also important. The more a company pays for a CRADA, the greater its commitment to perform the follow on work and to create a tangible product from the CRADA. For example, a CEO can keep his job if he makes a small investment mistake. However, a board of directors will replace a CEO for making a big investment that doesn't pay off.

Thus, when the NIH obtains the highest possible price for a CRADA, it actually increases the probability that the CRADA will result in a product which is effective and marketed successfully. High prices drive commitment and motivation to succeed, and provide the greatest assurance of public benefit.

Many Precedents for Federal Auctions

There is wide precedent for auctions by government agencies. When the Federal government auctions public assets, it does not require "fair price" clauses as part of the transaction. Such a restriction would reduce the amount of money raised by the auction and reduce public benefit.

The Department of the Interior auctions oil leases on public lands. The value of the lease is uncertain and is only realized when a company invests in creating a working oil well. But can you imagine the government requiring a "fair price" clause in an oil lease and having the power to set oil prices for oil obtained from the leased site?

The Federal Communications Commission auctions off communication licenses such as cellular phone licenses. None of these licenses has a "fair price" clause or allows the government to set cellular telephone rates.

The Internal Revenue Service uses auctions when it liquidates the assets of a delinquent taxpayer. In the settlement of tax delinquent accounts, it is legally bound by the courts to obtain the highest possible price for a debtor's assets since any amounts realized over and above an IRS tax claim is refunded to the debtor or to his other creditors.

These auctions serve the public interest because they guarantee that the government has obtained the best price for the assets. The market of competing bidders determines the true economic value of the assets.

Lessons for NIH

The fact that the price mechanism works is indisputable. If auctions were adopted by NIH, they would provide instant feedback to the NIH on what characteristics make a CRADA attractive or unattractive to investors, including the "fair price" clause.

Through auctions, the NIH could offer CRADA's with and without the "fair price" clause. The percentage differences in auction prices would reflect the cost of the "fair price" clause to the public. By running a simple economic experiment, NIH can determine the effects of the "fair price" clause.

Auction Arithmetic Made Simple

How can the government hold an auction for something as intangible as a CRADA? Does an auction mean the end of royalties as part of CRADA's? These are simple matters to resolve.

To auction a CRADA, the NIH would offer a combination package of knowledge, patents, or a commitment to perform certain scientific work. The bidders would make a financial offer for the entire package. Acceptable bids would consist of a combination of: (1) a cash down payment, (2) a follow on stream of cash payments, and (3) a royalty percentage.

The net present value of the cash stream plus the net present value of expected royalty payments represents the total value of the bid. The highest bid value wins the CRADA.

One firm may offer all cash and no royalties. Another may even offer all royalties. Still others may offer a combination. In all cases, the net present value calculation reduces all bids to the same measure of value. Selecting the highest value bid follows logically.

---

where...

$$\text{Net Present Value} = \sum \frac{\text{Net Cash Flow}_t}{(1 + \text{Discount Rate})^t}$$

Government Failure to Auction Causes Problems

It should be noted that when the government has attempted to set prices for its assets without auctioning it has usually failed. A recent example is the sale of mining rights worth billions to a Canadian company for a few thousand dollars. This sale, widely criticized as failed public policy, was required by an obsolete and little known federal law from the last century.

Social and Political Considerations

Some people may argue that social and political considerations must be taken into account when NIH enters into a CRADA. Such people do not understand economics and how market prices always take into account social and political considerations. The public is always served when markets efficiently allocate resources to their best economic use.

The view that the government should have a role in setting final product prices when it contributes assets to development of a product is fundamentally flawed.

The government has no expertise in setting prices. It does no market research or consumer research. It operates no marketing system or channels of product distribution. It builds no inventories or manufacturing plants. It pays no sales commissions. It raises no capital. It has no responsibilities to customers. It provides no customer or end-user servicing for products created through a CRADA.

If the government wants to control prices, it should invest in all of the other factors of production required to bring a product to market and it should create and operate a state run enterprise. The history, however, of government managed enterprise is well known. The U.S. Postal Service is the classic example but there are many others.

I don't believe that NIH is prepared to create a state run product manufacturing and distribution system, and I don't believe the public wants to have a state run enterprise supplying critically needed products and services.

How NIH Can Assure the Public of Competitive Prices

I assume that the purpose of the "fair price" clause is to assure that products produced as a result of a CRADA are sold at a "fair price" to the public. However, NIH need not set prices to provide such assurance.

Since NIH is far removed from the public and ultimate end-users of a product, it is almost certain to set "wrong" prices, either too high or too low vis-a-vis the product's intrinsic market value. Given that the NIH cannot "get it right," it should not attempt to set prices or even bother having a "fair price" clause in a CRADA.

NIH can learn a lesson from the Federal Communications Commission. When the FCC auctioned off cellular phone licenses, it sold two licenses in every metropolitan area. A competitive market was created in each metropolitan area.

The NIH can do the same thing with its assets and CRADA's. If auctioning a CRADA guarantees the best price, auctioning the same CRADA twice is even better. Every CRADA would be sold to the two highest bidders. Two firms would get exclusive rights to the knowledge produced by the CRADA. Each bid would be less than if the CRADA offered 100 percent exclusivity to one company. However, the combined value of both bids may be higher than a single offer.

The dual bid situation, however, provides additional benefits to the public and assures the public of "fair prices" without the CRADA having a "fair price" clause or the NIH ever setting a price.

The two companies which win a CRADA bid would be forced to compete in order to get a financial return on their investment in the CRADA. This competition will benefit the public. One company will try to beat the other to market first. The other company, which comes to the market second, will be forced to cut prices to attract customers from the first company. In this fight to be first, companies will commit more resources to speed the process. Also, with two companies trying to commercialize the knowledge produced by the CRADA, the public has a higher probability of getting a viable product from the CRADA.

Corporate Considerations

The NIH may wonder why companies would bid for a CRADA knowing that another may share the same NIH knowledge. The reason is that having the same knowledge need not result in the same product. The same knowledge may be used to produce different products targeted to different diseases.

Even when companies produce the same product, they may employ different methods of production and may patent their production methods. Further, even when companies produce the same product with the same methods and target the same market, their marketing strategies may be different. The cellular telephone industry is an outstanding example of this form of competition.

Additional Economic Considerations

There is no need for further social or political considerations. The dual bid situation will maximize public benefits and competitive prices.

Moreover, NIH should recognize that corporate success itself is in the public interest. If a company profits from a product developed with NIH assistance, the government takes over one-third of the profits through the income tax system. It takes still more taxes from the people who are employed as a result of the success of the product. Thus, the government and the public directly benefit from the pricing policies of every company. NIH should hope that companies which invest in CRADA's succeed and make a lot of money.

The alternative is failure and public loss. When the NIH offers a CRADA and no company invests in the opportunity, there is no public benefit of any kind. When a company invests in a CRADA and no product is produced, the public receives no benefits.

When a company invests in a CRADA, produces a product but loses money, the company will eventually abandon the product if it cannot raise prices and earn a profit. In short, no public benefit can ever be generated without profits and a return on investment.

The public actually suffers a loss when a company loses money because scarce economic resources have been invested without producing a profitable result. Only when profits are generated does the public benefit. Profits indicate that the public has bought a product or service at a price which covers the costs of development, manufacturing, distribution, and capital.

The First Law of Doing Business: Know Thy Costs

The role of up-front payments and royalties are to assure the NIH and the public that transferring NIH assets to a private enterprise produces a return for the government and the public.

Assuming that the NIH knows its costs, it will never offer an asset or CRADA to the private sector for an amount less than the NIH's cost of producing its knowledge product. NIH itself can use profit as a measure of its own success.

The combined net present value of the two bids accepted for a CRADA should always exceed NIH's costs of producing the assets transferred to the private sector plus the cost of NIH's participation in the CRADA, which can be viewed as the NIH's cost of servicing its private sector customer. Anything less, and the NIH is not fulfilling its fiduciary responsibility to taxpayers. The fact that NIH is a Federal agency is irrelevant.

In Conclusion

In recent times, several consumer organizations have testified in Federal hearings regarding the need for government involvement in setting prices for drugs and health care services. Indeed, some people may attend your meeting on September 8 and complain about the high cost of drugs.

I have often observed that even when such people are educated and mean well, often they do not understand economics or how markets work. Good intentions or recognition of a problem do not guarantee clear thinking.

I know that you and other members of your panel will listen attentively and compassionately to the medical problems and horror stories so frequently trotted out by such people. However, you owe the American people clear, objective and dispassionate thinking, and you must not be misguided by those who believe government has a role in setting prices.

The laws of economics are greater than the laws of all governments, including ours. There is not a single economy in the world where state administered pricing has worked. Invariably such economies produce shortages and typically meet consumer demand through black markets rather than official channels.

I am not a right wing economist or even a laissez faire economist. I believe that the state has a role in administering the affairs of society, particularly in providing an environment where free markets and competition can flourish.

However, I remind you that the Soviet Union did not fail for lack of scientific know-how or from a shortage of government committees. It failed because a state run economy with administered prices failed to allocate resources effectively to meet the needs of the people. It is hubris to think that NIH can administer prices any better.

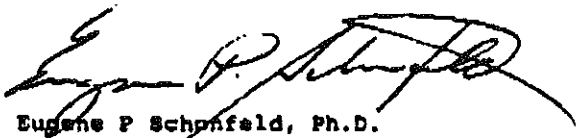
As a scientist, I want you to keep in mind that the laws of economics are just as real as the laws of physics. You cannot violate the laws of economics any more than you can violate the laws nature. You may create economic illusions just as one may create physical illusions. But illusions are not real or lasting. The notion of "fair price" is just one such illusion.

Failure to adhere to market principles will doom the NIH CRADA program. To a large degree, the decline in CRADA's since the "fair price" clause was introduced is significant proof of this assertion.

I urge you to create an environment where "competitive prices" determined by market forces are used to benefit the public.

As a cancer patient whose life may depend upon the success of the NIH and as an economist, I know that my best chances for survival rest on the effective allocation of research resources to health care problems. Misguided social or political thinking will not serve me well.

Sincerely,



Eugene P Schonfeld, Ph.D.
President and Chief Executive Officer
and kidney cancer patient

ALPHA 1
BIOMEDICALS, INC.

Vincent F. Simmon, Ph.D.
President and
Chief Executive Officer

Two Democracy Center
6903 Rockledge Drive • Suite 1200
Bethesda, Maryland 20817
301/564-4400 • Fax 301/564-4424

Ms. Elyssa Tran
Office of Science Policy and Technology Transfer
NIH
Bldg. 1, Room 218
9000 Rockville, MD 20892

August 25, 1994

Dear Ms. Tran,

I am writing to express my concern about a "reasonable price clause" in CRADAs. I would also like the opportunity to express my opinion at the upcoming meeting on Sept. 8.

Alpha 1 Biomedicals is one of hundreds of development stage biotechnology companies that rely on venture capital or public investment to develop new therapeutic products. Although there is technology of interest located very near to us at the NIH, we have avoided research contracts and CRADAs with the NIH because of the reasonable price clause. The potential for government intervention in pricing is a negative that far outweighs any value that might be achieved by being a partner with a US government research group. Unlike established pharmaceutical companies, we do not have a revenue and profit stream to provide the necessary financial resources to conduct research. Investors bet on us and on our peers in the hope that we will be able to bring one or more FDA regulated products to market. The additional risk of price controls has had a tremendous chilling effect on the ability of small companies to raise money for clinical trials and research.

Unfortunately, in the last few years, there have been more clinical disappointments in biotechnology than positive results. In truth, this is a mirror of the experience of profitable pharmaceutical companies; many potential drugs are tested, but few are ever approved. Finally, when a drug is approved, competition is sure to follow. One of the earliest biotechnology drugs was alpha interferon which was initially approved for the treatment of hairy-cell leukemia; there is now a better, non-biotechnology replacement, deoxycoformycin. Several hundred million dollars was invested in alpha interferon (initially by biotech companies (Genentech and Biogen among many) and by their licensees Schering-Plough and Roche) before interferon was approved for a very narrow indication. What would have been a reasonable price for alpha interferon if a) no other

indications were approved, and b) the approval of deoxycoformycin resulted in the loss of all interferon sales?
The moral of the story is that you can only tell if a drug price is (was) reasonable retrospectively. In the meantime, investors risk their money, managers, scientists and clinicians devote and risk their careers in the hope that their company, their drug will prove successful and there will be any return at all.

The government and the public already enjoy a form of cost recovery from successful drug developments. Profitable companies pay corporate taxes. The government also receives royalties in some cases. And the public benefits from improved health care, possibly at an overall reduction in health care costs. Epogen benefits patients on dialysis and is cost effective. So is GM-CSF. And so are many other drugs that have been approved or are waiting to be approved.

The risk of a "reasonable price clause" is very high. Rather than accept the clause, companies such as ours won't work under a CRADA. Therefore, some government research will be wasted, invented around, or ignored. The government won't receive royalties. The price of a drug cannot be deemed reasonable just because it is sufficient to recover the research investment. That won't pay for all the past drug development failures in a company or the future research that is needed to bring new drugs to market.

The "reasonable price" is best determined by the market. The large development investments in a drug are made by assessing the existing market first. Then assuming a successful product can be developed at some research cost and that the product can be shown to be safe and effective, and that it can be manufactured and sold at a profit. This system will not work if at the end of the day, the control of the price is determined based on some government committee's view of what a "reasonable price" should be.

Many pharmaceutical and biotechnology executives have reached the same conclusion that we have. If there is a "reasonable price clause" in the contract, then we are not interested.

Sincerely yours,

Vincent F. Simmon, Ph.D.

NIH "Reasonable Pricing" Clause Survey

1) Is your company currently a party to a Cooperative Research and Development Agreement (CRADA) or license with the National Institutes of Health (NIH)?

Yes ____ No ✓ If "yes" please provide details in a cover letter.

2) The current NIH "reasonable pricing" clause included in its CRADAs and licenses states:

"PHS [Public Health Service] may require Licensee to submit documentation in confidence showing a reasonable relationship between the pricing of a Licensed Product, the public investment in that product, and the health and safety needs of the public. This paragraph shall not restrict the right of Licensee to price a Licensed Product or Licensed Process so as to obtain a reasonable profit for its sale or use. This Paragraph does not permit PHS to set or dictate prices for Licensed Products or Licensed Processes."

a. Has your company entered into an agreement(s) with NIH which include(s) this clause or one similar to it?

Yes ____ No ✓

b. Would your company be willing, in the future, to enter into an agreement with NIH which included the "reasonable pricing" clause?

Yes ____ No ✓

c. If your answer to question 2b was "No", then might your company be interested in entering into agreements with NIH if the agreement would not include this clause?

Yes ✓ No ____

d. Are you, or would you be, concerned that the "reasonable pricing" clause would, in effect, permit NIH to set a ceiling on the price you could charge for a product you develop based on licensed technology?

Yes ✓ No ____

e. Are you, or would you be, concerned that the "reasonable pricing" clause will limit your ability to raise capital which would fund the development of the technology you are licensing?

Yes ✓ No ____

f. If agreements with university and foundation grantees of NIH (the extramural program) included "reasonable pricing" clauses, would this undermine your willingness to enter into such an agreement?

Yes ✓ No ____

3) Please circle all the disease areas your company is researching:

Arthritis	Cancer	Heart Disease	Stroke
AIDS	Alzheimer's	Diabetes	Hepatitis
Viral Infections	Bacterial Infections	Cystic Fibrosis	ALS
Multiple Sclerosis	Parkinson's	Epilepsy	Lupus

Other _____

4) We invite you to write a paragraph or two about your views on this issue for inclusion in the BIO report to accompany the survey results. The survey will be confidential, with results compiled in the aggregate; however, we would like to identify the names of companies which provide narrative statements.

PLEASE FAX SURVEY to Greg Riddle at (202) 857-0237 by 5:00 PM Friday, September 2, 1994. Thank you.

Richmond Times-Dispatch

RICHMOND, VIRGINIA 23293 Copyright © 1994 144th Year, No. 215 VIRGINIA'S NEWS LEADER CITY EDITION THURSDAY, AUGUST 4, 1994

CRIMP ON RESEARCH

Control Price of Drugs, And Lives May Be Lost

As the father of an 8-year-old fighting a deadly neuromuscular disease, I follow the health reform debate with more than a little interest. There is, of course, much that needs reforming, but there are dangerous ideas creeping through Congress that should be stopped dead in their tracks. One of the worst I know of is drug price controls.

If the prices of drugs are set by Washington, investment in pharmaceutical and biotech companies will dry up, research will slow down, and lives will be lost. It's that simple. And it's that bad.

JOSEPH SLAY

Sometime after my son Andrew was diagnosed with spinal muscular atrophy or SMA, I formed a little non-profit group called Andrew's Buddies to raise money in Richmond for SMA research. In a remarkable outpouring of support, the people of Richmond contributed over $200,000, which has been used to speed up the search for the gene that causes SMA. Their generosity has allowed the search for the rogue gene to move 20 times faster, and we are now closing in on its discovery.

BUT IT WILL TAKE more than bake sales to cure this disease, and others. The average cost for bringing a new drug to market is $300 million. It is a long and complex process, as well it should be, for a new drug to be reckoned effective and safe. And developing these new treatments requires major financial commitments from investors who can tolerate risk and who can tolerate waiting years before they see a return on their investment. Increase the risk or lessen the reward at the end of a long drug development pipeline, and investors will drift away.

The Clinton administration and several key committees in Congress are advocating price control provisions that would slow pharmaceutical research and development. One provision would give the Secretary of Health and Human Services the power to "blacklist" new drugs and deny Medicare coverage if HHS deems them too expensive.

Another proposal — something called the Prescription Drug Payment Review Commission — could determine the reasonableness of drug prices and make recommendations to Congress regarding payments for prescription drugs.

"Frankly, as a parent, I believe we should be doing everything possible to make sure pharmaceutical and biotech companies are thriving."

In other words, the ability of a company to see a return on its investment would be left up to the whim of a bureaucrat in Washington who is miles away from the realities of capital markets, miles away from research labs, and miles away from little children who are waiting for drugs that won't be coming.

Drug prices aren't the problem. Prescription drugs account for only 7 percent of the nation's health care bill, and their prices have been coming down. The rate of price increase for prescription drugs has been below the cost-of-living index for the past two years. And drugs can head off expensive surgery. They are the most cost-effective way to treat illness.

Frankly, as a parent, I believe we should be doing everything possible to make sure pharmaceutical and biotech companies are thriving. We should be dismantling bureaucratic obstacles to investment and growth, not erecting new ones.

And, we should be alert to any "reforms" that sound good on the surface but actually hamstring the pharmaceutical industry. One I've learned of recently is "unitary pricing," which could, in effect, eliminate discounts to purchasers of drugs. Unitary pricing will undermine the ability of the marketplace to control costs and will raise prices for those consumers who are using competition to negotiate lower prices.

Andrew Slay

THE INDUSTRY IS already on the right track. Since 1940, drugs have saved an estimated 1.6 million lives in just four disease areas alone — tuberculosis, polio, coronary heart disease, and cerebrovascular disease. In the process, there were savings of $141 billion in avoided health care costs. In the 1980s, pharmaceutical companies doubled their research budgets to $10 billion a year. And in the 1990s, they are incredibly close to new breakthroughs, even in the deadliest childhood diseases, like SMA that cripples thousands of children and kills more newborns than any other inherited disease.

This summer, our country marked the 25th anniversary of the Apollo landing. That was an inspiring accomplishment, but pharmaceutical research is the moonshot of the 1990s. If we strengthen — and not weaken — the researchers and corporations who create biotech miracles, we will accomplish something even more magnificent than the moon landing. We will look upon a child who had never been able to walk before and say, "One small step for a child . . . one giant leap for mankind."

■ *Richmond native Joe Slay is president of Martin Public Relations.*

Consumer Federation of America

September 7, 1994

Secretary Donna Shalala
Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, DC 20201

Dear Secretary Shalala:

Consumer Federation of America writes to express our support for a reasonable pricing clause in contracts which transfer rights in federally funded pharmaceutical research to the private sector. We believe a reasonable pricing clause is an important mechanism to protect the public from paying twice for inventions, first as taxpayers, and then as consumers.

At present some form of the National Institutes of Health (NIH) model reasonable pricing clause is used in some agency Cooperative Research and Development Agreements (CRADAs) and patent licenses, with modifications in the model clause negotiated between NIH and CRADA partner or license holder. This agreement was created by NIH after a public outrage over the pricing of AZT, a drug which benefited significantly from public investment.

The model NIH reasonable pricing agreement states:

> NIH have a concern that there be a reasonable relationship between the pricing of a licensed product, the public investment in that product, and the health and safety needs of the public. Accordingly, exclusive commercialization licenses granted for NIH intellectual property rights may require that this relationship be supported by reasonable evidence.

Apparently, it is common for NIH to significantly weaken the model language. For example, in the January 13, 1988 NIH license with Bristol-Myers for the development of ddI, NIH specifically deleted the phrase "the public investment in that product," from the reasonable pricing clause. Likewise, in the January 1991 National Cancer Institute's (NCI)/Bristol-Myers Squibb taxol CRADA, the reasonable pricing clause was modified to eliminate the phrase that required Bristol-Myers to provide NCI with evidence that its price was reasonable. Thus, it is clear that NIH has used the model reasonable pricing

1424 16th Street, N.W., Suite 604 • Washington, D.C. 20036 • (202) 387-6121

clause as a starting point for negotiations.

As you may know, NIH has been criticized for the way it administers the fair pricing clause. In the cases of ddI and Taxol, NIH allowed Bristol-Myers Squibb to price these products based upon some measure of median prices for similar therapies, without regard to the public's investment in the drugs,[1] and in neither case did the government obtain the types of information that were necessary to make better decisions. Former NIH Director Dr. Bernadine Healy described the agency's experience with the reasonable pricing clause at a February 24, 1994 hearing as follows:

> The difficulty with the reasonable pricing clause is it was a spiritual statement. It was a statement of trust, of understanding that we thought that the companies should recognize the public investment, but in fact, if you look at the contractual agreement, there are no teeth.

We had hoped that under this new Administration the government would learn from past mistakes and improve and strengthen the wording and administration of the reasonable pricing clause, so that the public enjoys more of the benefits from taxpayer funded research and development of new drugs. Instead, we now understand that NIH is considering an elimination of the reasonable pricing clause altogether. The arguments used by the industry for the elimination of the reasonably pricing clause appear to be twofold. First, in the limited number of cases where the reasonable pricing clause has been used (ddI and Taxol), it has done little to limit the prices of the drugs, and secondly, the existence of the reasonable pricing clause has a negative impact on investment in new drug R&D.

With respect to the first issue, the failures of NIH in its administration of the reasonable pricing clause can and should be corrected. The fact that NCI did a poor job evaluating the Taxol price (roughly twenty times production costs) should not be used to eliminate the reasonable pricing clause, but to develop a sounder methodology for determining a reasonable price, that takes into account the government's role in the development of the drug.

With respect to the second issue, it is clear that drug development is a very heterogeneous process, and it may, in some circumstances, be appropriate to modify a reasonable pricing clause for some CRADAs or license agreements, as NIH has done in the past. However, we believe NIH should develop a meaningful reasonable pricing clause and pricing methodology, which would be presumed to be adequate, and only allow modifications of the model reasonable pricing clause after public notice, and an agency finding that the modification was in the public interest. This provides a framework for balancing the public interest in reasonable pricing and new drug development in those cases where there is evidence that modifications of the agreement

---

[1]In the case of Taxol, there was also a controversy concerning the selection of the "benchmark" drugs which were used.

are needed to attract investment.

Clearly the government has more power to obtain lower consumer prices when the government's role in the development of the drug is extensive, and when the government controls important intellectual property rights, and has less power when the government's role is minor, or when it does not control intellectual property rights. NIH already has the authority to consider these factors when negotiating a reasonable pricing clause.

In those cases where the government has played an extensive role in the development of a drug and it controls the intellectual property rights, there is a very strong presumption that the agency should seek a low consumer price for the drug. For example, if the government has funded drug development through Phase III trials, and holds the patent for a drug, it should investigate licensing mechanisms which allow competitive bidding based upon a low consumer price, or a similar mechanism that would benefit consumers.

Finally, it is important to recall that most of the NIH funding for new drug development is channeled through Universities and other research institutions which obtain intellectual property rights under the Bayh-Dole Act. The Bayh-Dole Act has always provided for compulsory licensing under government "march-in" rights if drug companies do not make the technology available to public on reasonable terms. If NIH totally eliminates the reasonable pricing clause it will lower the public interest accountability for drugs developed directly by the government below that which now exists for research funded at the university level.

Thank you for considering these comments.

Sincerely,

Bradley Stillman
Legislative Counsel

STATEMENT OF ELLEN STOVALL, EXECUTIVE DIRECTOR
THE NATIONAL COALITION FOR CANCER SURVIVORSHIP
BEFORE THE NIH CRADA FORUM II
SEPTEMBER 8, 1994

Good afternoon. My name is Ellen Stovall. I am here today in my role as Executive Director of the National Coalition for Cancer Survivorship and as a 22 year survivor of two bouts with cancer. The National Coalition for Cancer Survivorship is the largest nonprofit cancer group whose membership is comprised of thousands of individuals, community cancer organizations and most of this country's leading cancer treatment institutions. NCCS has spawned many grassroots cancer groups throughout the country and was one of several organizations that founded the National Breast Cancer Coalition in 1991; however, NCCS's central mission always has been to advocate on behalf of people with <u>all</u> types of cancer. While we are pleased to count among our members hundreds of physicians, nurses and social workers, our most important constituency are the 8 million people living in this country today, including myself, who have received a diagnosis of cancer; and it is on their behalf that I offer this statement.

Like people with AIDS and other chronic and life-threatening illnesses, people living with a diagnosis of cancer frequently must face the devastating fact that there is no known cure for their disease. Until more is known about the prevention and control of cancer, our greatest hope lies in the discovery and development of new anticancer agents. The National Coalition for Cancer Survivorship strongly endorses any initiative—public, private or collaborative—that will increase the prospects for cancer survival.

NCCS feels very strongly that restrictive pricing enforcement would discourage collaboration between the government and private sector. We do not support the use of the pricing clause in Cooperative Research and Development Agreements (CRADAs), because we cannot support any mechanism that would create disincentives to the private or public development of new agents discovered through federally-funded research. As it is, there are few industrial sponsors seeking to participate in public/private cooperative initiatives; thus we believe the dollars involved would not be significant enough to run the risk of discouraging any qualified partner in such development efforts. Furthermore, we feel that if NIH plays a larger role in the "downstream" marketing and distribution of new products, the likely result will be the decrease in new product development. This is an unacceptable trade-off for people with cancer whose lives are dependent on more effective and less debilitating therapies.

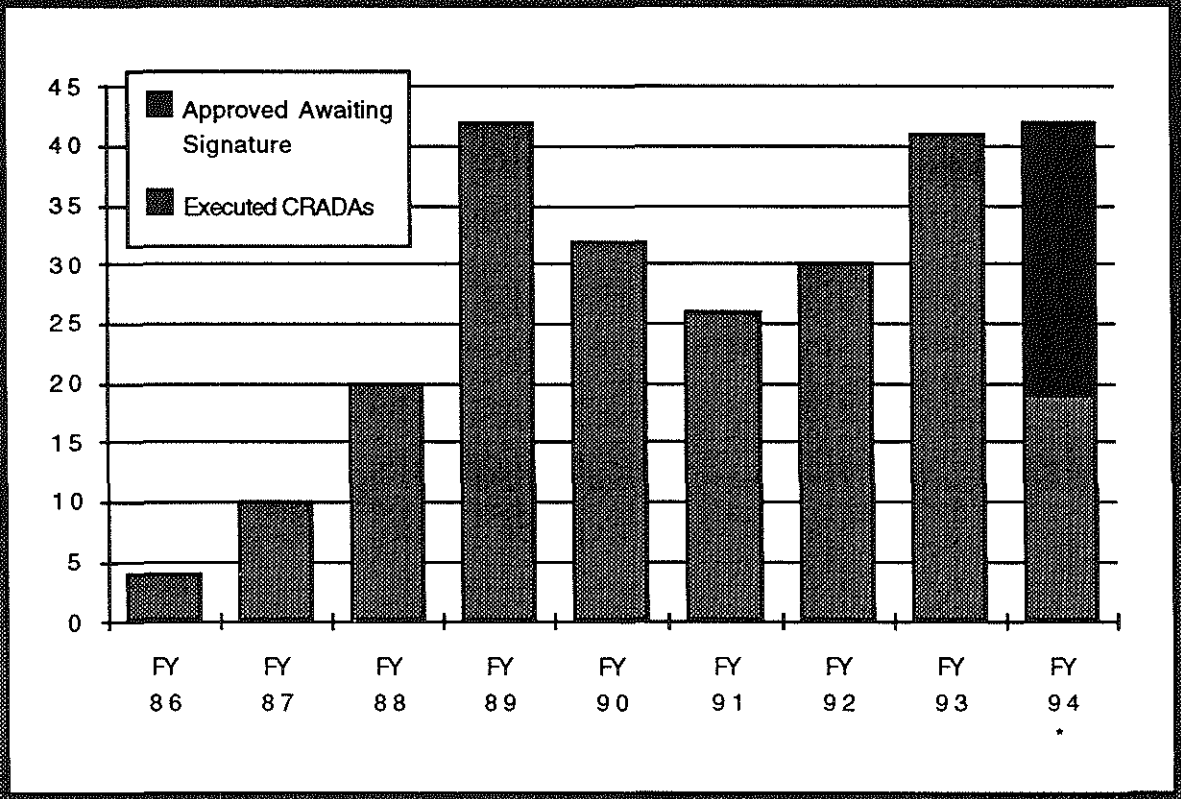
NCCS has been very involved in working with other cancer organizations to increase funding for cancer research, and through that process we have become painfully aware of the lack of adequate NIH funding to carry forth the promising basic research that will result in new treatments for cancer. We are very concerned that to burden the Institutes with laborious and detailed pricing evaluations and negotiations would result in taking away valuable time and resources from what should be its main emphasis—the rapid development of new products that will add measurable quality to the lives of people dealing with this devastating disease that will strike one in three Americans and kill one in four. If NIH plays any role regarding CRADA agreements, it should be one of creating a positive environment that offers incentives and not discouragement to the private sector. As a result, people with cancer and other life threatening diseases will be able to realize the benefits of new product development so vital to their ultimate survival.

Appendix C

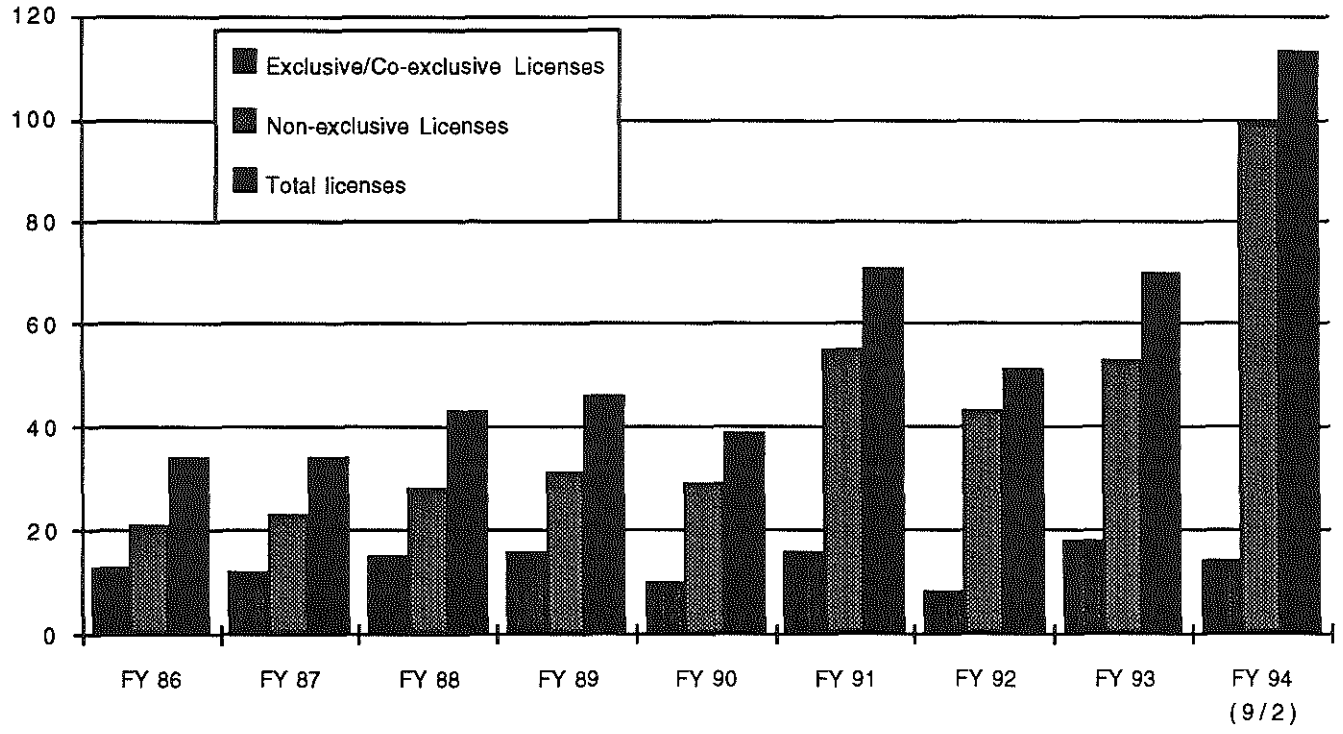
Other Background Materials

Technology Transfer Activities at NIH

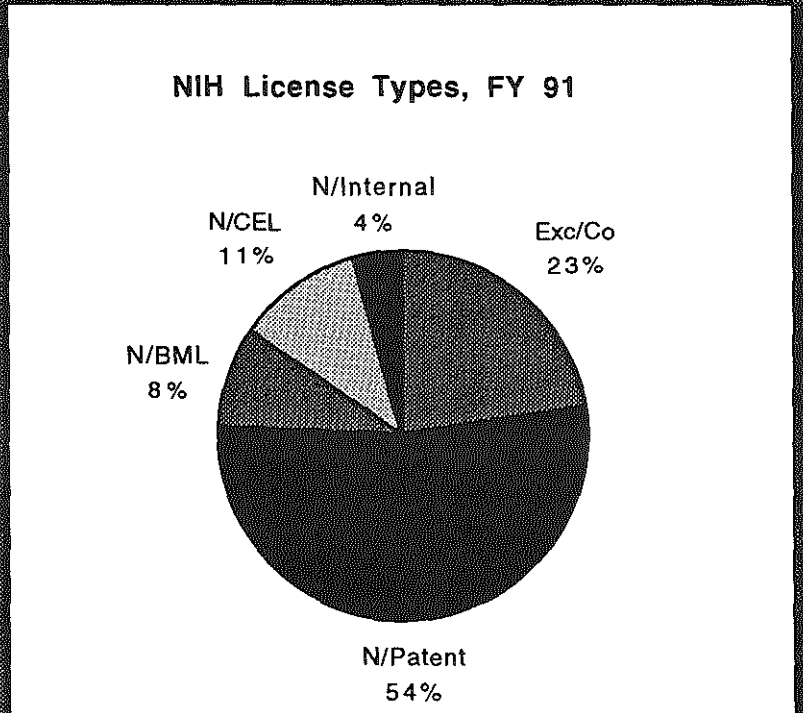
NIH CRADAs Executed by FY

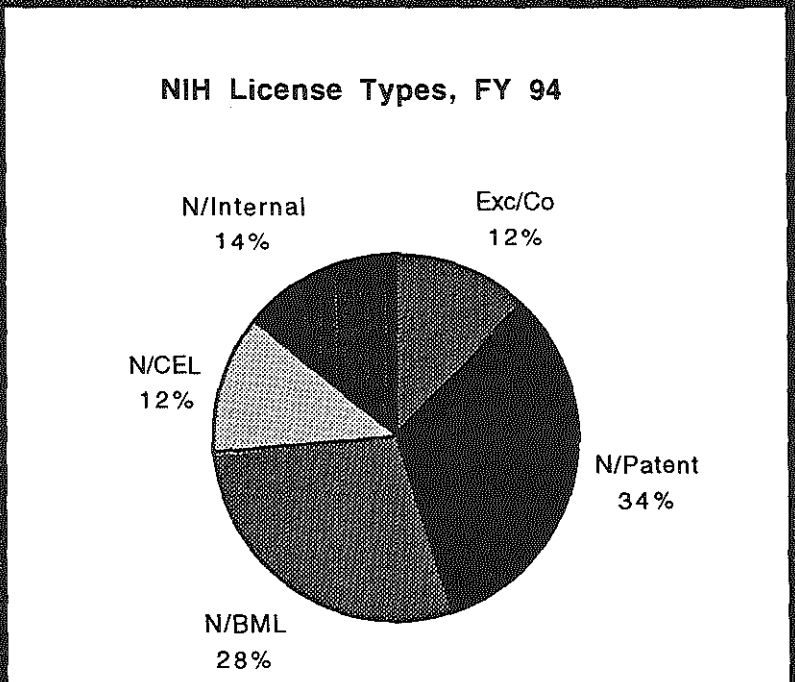


NIH Licenses Executed By FY

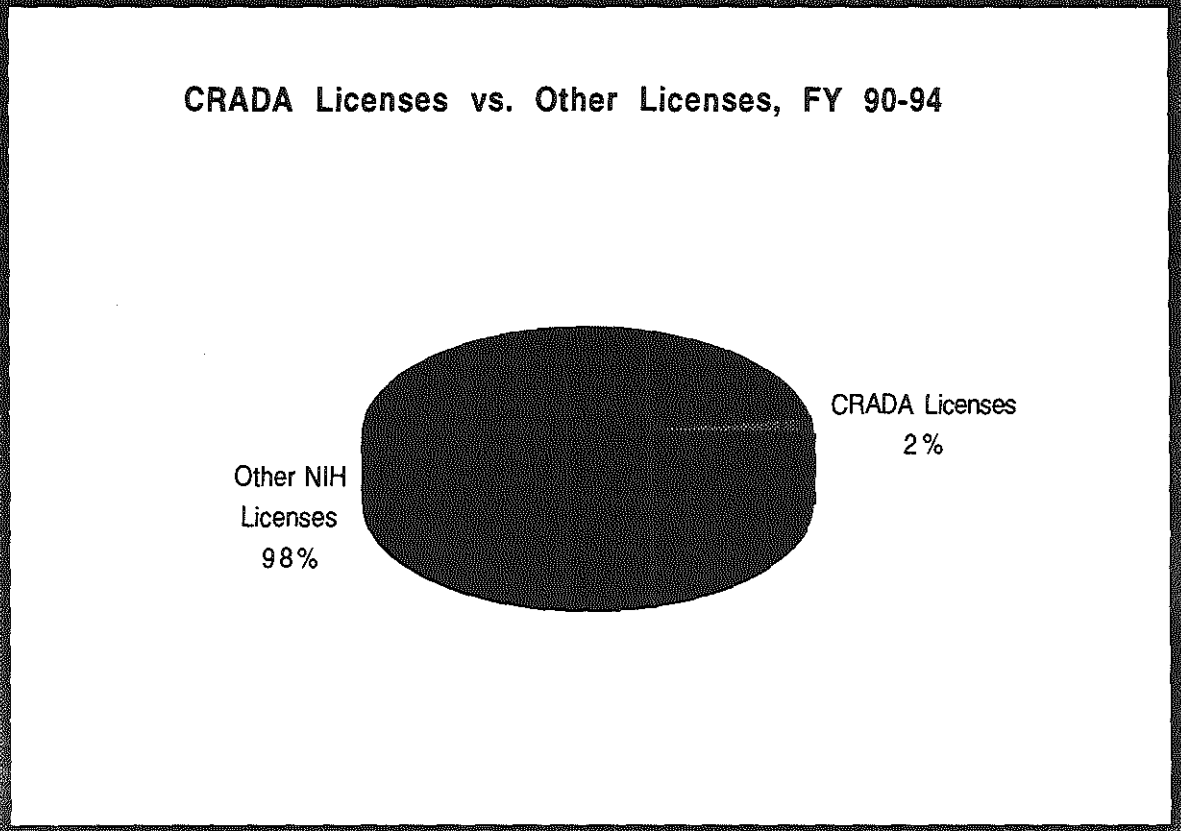


NIH License Types

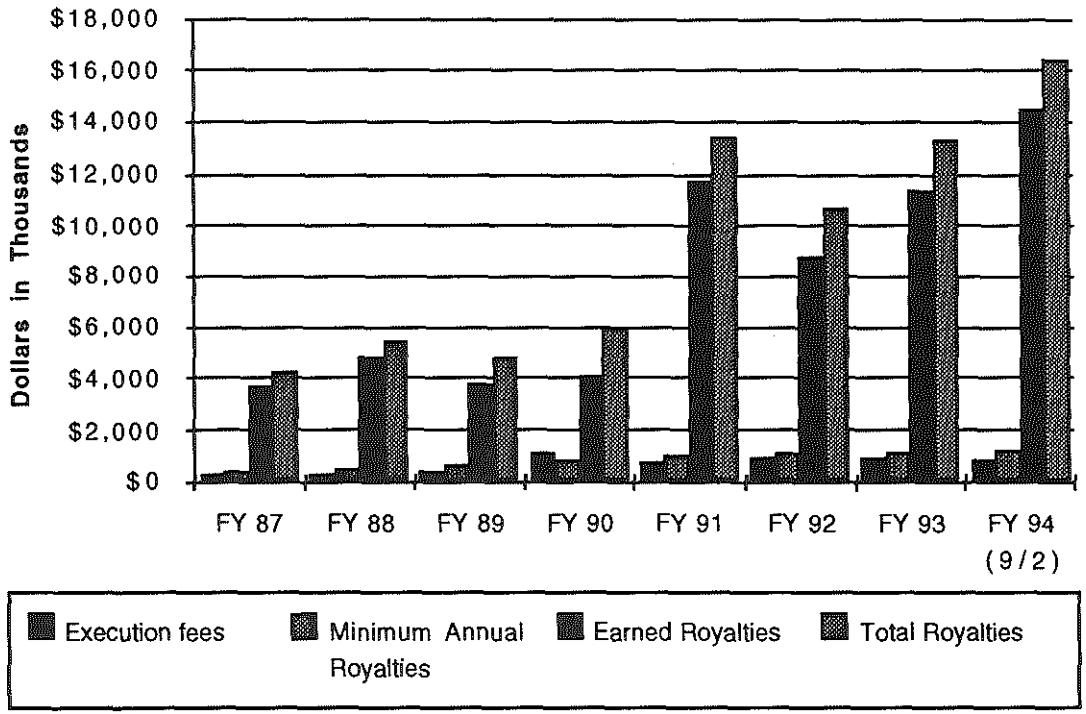




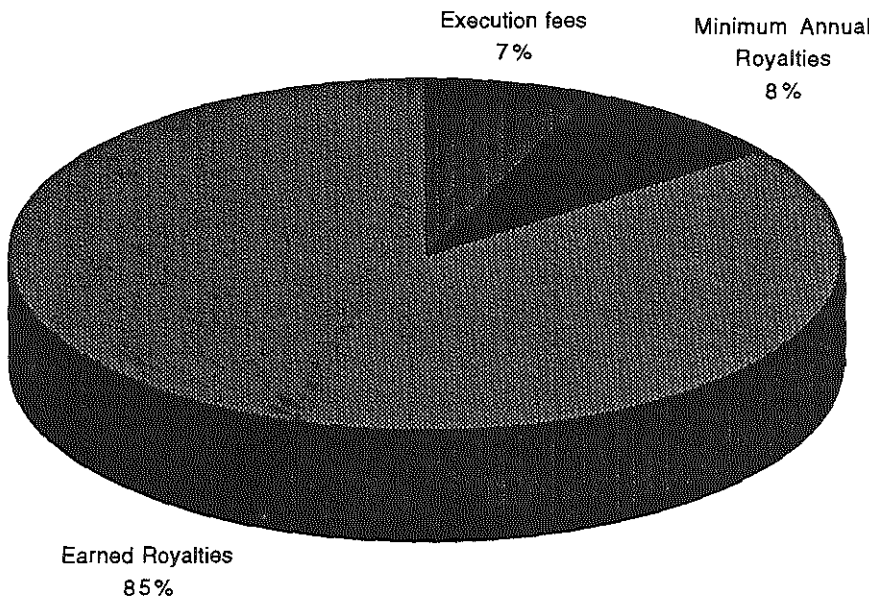
CRADA Licenses vs. Other Licenses



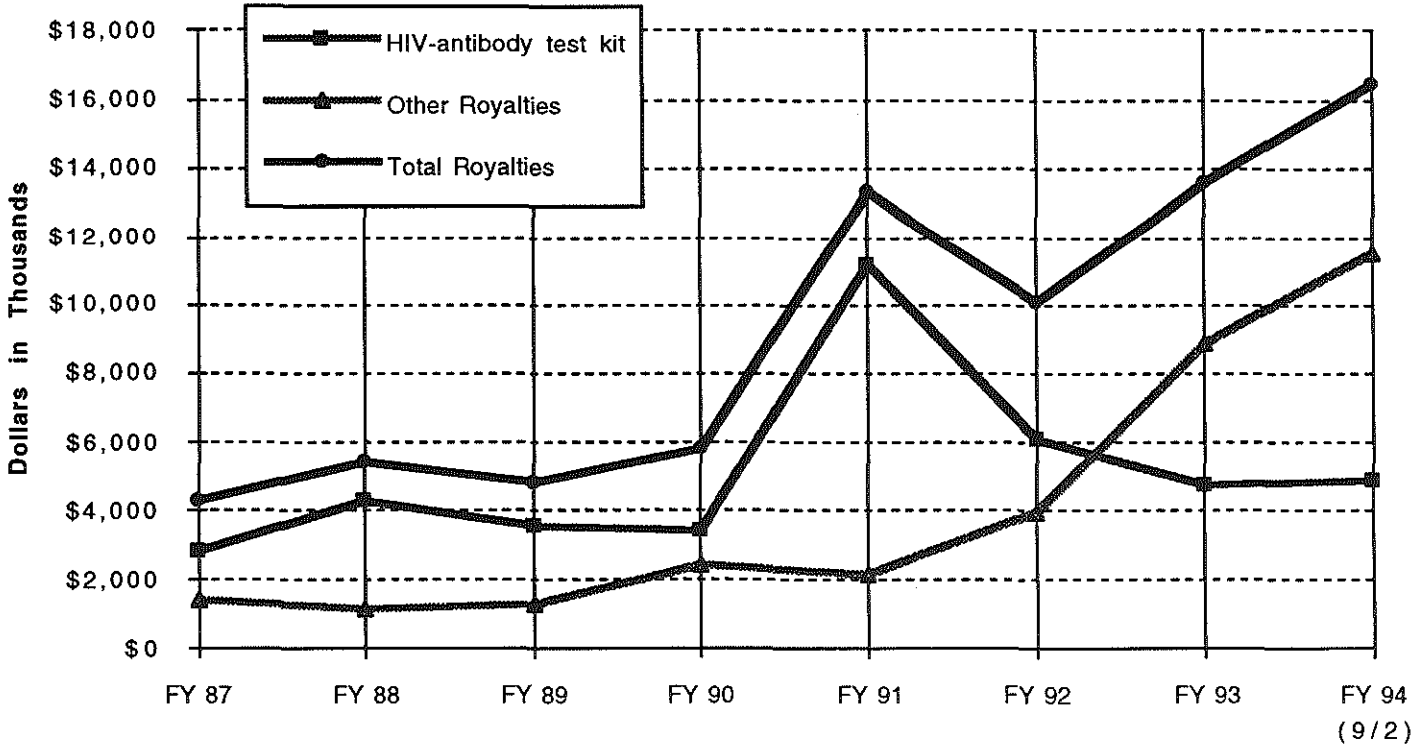
NIH Royalty Types By FY



NIH Royalty Types, FY 93



NIH Royalties By FY



Related Technology Transfer Policies and Legislation

Public Law 96-480
96th Congress

An Act

To promote United States technological innovation for the achievement of national economic, environmental, and social goals, and for other purposes.

Oct. 21, 1980
[S. 1250]

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled, That this Act may be cited as the "Stevenson-Wydler Technology Innovation Act of 1980".

Stevenson-Wydler Technology Innovation Act of 1980
15 USC 3701 note.

SEC. 2. FINDINGS.

15 USC 3701.

The Congress finds and declares that:

(1) Technology and industrial innovation are central to the economic, environmental, and social well-being of citizens of the United States.

(2) Technology and industrial innovation offer an improved standard of living, increased public and private sector productivity, creation of new industries and employment opportunities, improved public services and enhanced competitiveness of United States products in world markets.

(3) Many new discoveries and advances in science occur in universities and Federal laboratories, while the application of this new knowledge to commercial and useful public purposes depends largely upon actions by business and labor. Cooperation among academia, Federal laboratories, labor, and industry, in such forms as technology transfer, personnel exchange, joint research projects, and others, should be renewed, expanded, and strengthened.

(4) Small businesses have performed an important role in advancing industrial and technological innovation.

(5) Industrial and technological innovation in the United States may be lagging when compared to historical patterns and other industrialized nations.

(6) Increased industrial and technological innovation would reduce trade deficits, stabilize the dollar, increase productivity gains, increase employment, and stabilize prices.

(7) Government antitrust, economic, trade, patent, procurement, regulatory, research and development, and tax policies have significant impacts upon industrial innovation and development of technology, but there is insufficient knowledge of their effects in particular sectors of the economy.

(8) No comprehensive national policy exists to enhance technological innovation for commercial and public purposes. There is a need for such a policy, including a strong national policy supporting domestic technology transfer and utilization of the science and technology resources of the Federal Government.

(9) It is in the national interest to promote the adaptation of technological innovations to State and local government uses. Technological innovations can improve services, reduce their costs, and increase productivity in State and local governments.

(10) The Federal laboratories and other performers of federally funded research and development frequently provide scientific

79-139 O - 80 (313)

and technological developments of potential use to State and local governments and private industry. These developments should be made accessible to those governments and industry. There is a need to provide means of access and to give adequate personnel and funding support to these means.

(11) The Nation should give fuller recognition to individuals and companies which have made outstanding contributions to the promotion of technology or technological manpower for the improvement of the economic, environmental, or social well-being of the United States.

15 USC 3702.

SEC. 3. PURPOSE.

It is the purpose of this Act to improve the economic, environmental, and social well-being of the United States by—

(1) establishing organizations in the executive branch to study and stimulate technology;

(2) promoting technology development through the establishment of centers for industrial technology;

(3) stimulating improved utilization of federally funded technology developments by State and local governments and the private sector;

(4) providing encouragement for the development of technology through the recognition of individuals and companies which have made outstanding contributions in technology; and

(5) encouraging the exchange of scientific and technical personnel among academia, industry, and Federal laboratories.

15 USC 3703.

SEC. 4. DEFINITIONS.

As used in this Act, unless the context otherwise requires, the term—

(1) "Office" means the Office of Industrial Technology established under section 5 of this Act.

(2) "Secretary" means the Secretary of Commerce.

(3) "Director" means the Director of the Office of Industrial Technology, appointed pursuant to section 5 of this Act.

(4) "Centers" means the Centers for Industrial Technology established under section 6 or section 8 of this Act.

(5) "Nonprofit institution" means an organization owned and operated exclusively for scientific or educational purposes, no part of the net earnings of which inures to the benefit of any private shareholder or individual.

(6) "Board" means the National Industrial Technology Board established pursuant to section 10.

(7) "Federal laboratory" means any laboratory, any federally funded research and development center, or any center established under section 6 or section 8 of this Act that is owned and funded by the Federal Government, whether operated by the Government or by a contractor.

(8) "Supporting agency" means either the Department of Commerce or the National Science Foundation, as appropriate.

Office of Industrial Technology, establishment. 15 USC 3704.

SEC. 5. COMMERCE AND TECHNOLOGICAL INNOVATION.

(a) IN GENERAL.—The Secretary shall establish and maintain an Office of Industrial Technology in accordance with the provisions, findings, and purposes of this Act.

(b) DIRECTOR.—The President shall appoint, by and with the advice and consent of the Senate, a Director of the Office, who shall be

compensated at the rate provided for level V of the Executive Schedule in section 5316 of title 5, United States Code.

(c) DUTIES.—The Secretary, through the Director, on a continuing basis, shall—

(1) determine the relationships of technological developments and international technology transfers to the output, employment, productivity, and world trade performance of United States and foreign industrial sectors;

(2) determine the influence of economic, labor and other conditions, industrial structure and management, and government policies on technological developments in particular industrial sectors worldwide;

(3) identify technological needs, problems, and opportunities within and across industrial sectors that, if addressed, could make a significant contribution to the economy of the United States;

(4) assess whether the capital, technical and other resources being allocated to domestic industrial sectors which are likely to generate new technologies are adequate to meet private and social demands for goods and services and to promote productivity and economic growth;

(5) propose and support studies and policy experiments, in cooperation with other Federal agencies, to determine the effectiveness of measures with the potential of advancing United States technological innovation;

(6) provide that cooperative efforts to stimulate industrial innovation be undertaken between the Director and other officials in the Department of Commerce responsible for such areas as trade and economic assistance;

(7) consider government measures with the potential of advancing United States technological innovation and exploiting innovations of foreign origin; and

(8) publish the results of studies and policy experiments.

(d) REPORT.—The Secretary shall prepare and submit to the President and Congress, within 3 years after the date of enactment of this Act, a report on the progress, findings, and conclusions of activities conducted pursuant to sections 5, 6, 8, 11, 12, and 13 of this Act and recommendations for possible modifications thereof. Report to President and Congress.

SEC. 6. CENTERS FOR INDUSTRIAL TECHNOLOGY. 15 USC 3705.

(a) ESTABLISHMENT.—The Secretary shall provide assistance for the establishment of Centers for Industrial Technology. Such Centers shall be affiliated with any university, or other nonprofit institution, or group thereof, that applies for and is awarded a grant or enters into a cooperative agreement under this section. The objective of the Centers is to enhance technological innovation through—

(1) the participation of individuals from industry and universities in cooperative technological innovation activities;

(2) the development of the generic research base, important for technological advance and innovative activity, in which individual firms have little incentive to invest, but which may have significant economic or strategic importance, such as manufacturing technology;

(3) the education and training of individuals in the technological innovation process;

(4) the improvement of mechanisms for the dissemination of scientific, engineering, and technical information among universities and industry;

(5) the utilization of the capability and expertise, where appropriate, that exists in Federal laboratories; and

(6) the development of continuing financial support from other mission agencies, from State and local government, and from industry and universities through, among other means, fees, licenses, and royalties.

(b) ACTIVITIES.—The activities of the Centers shall include, but need not be limited to—

(1) research supportive of technological and industrial innovation including cooperative industry-university basic and applied research;

(2) assistance to individuals and small businesses in the generation, evaluation and development of technological ideas supportive of industrial innovation and new business ventures;

(3) technical assistance and advisory services to industry, particularly small businesses; and

(4) curriculum development, training, and instruction in invention, entrepreneurship, and industrial innovation.

Each Center need not undertake all of the activities under this subsection.

(c) REQUIREMENTS.—Prior to establishing a Center, the Secretary shall find that—

(1) consideration has been given to the potential contribution of the activities proposed under the Center to productivity, employment, and economic competitiveness of the United States;

(2) a high likelihood exists of continuing participation, advice, financial support, and other contributions from the private sector;

(3) the host university or other nonprofit institution has a plan for the management and evaluation of the activities proposed within the particular Center, including:

(A) the agreement between the parties as to the allocation of patent rights on a nonexclusive, partially exclusive, or exclusive license basis to and inventions conceived or made under the auspices of the Center; and

(B) the consideration of means to place the Center, to the maximum extent feasible, on a self-sustaining basis;

(4) suitable consideration has been given to the university's or other nonprofit institution's capabilities and geographical location; and

(5) consideration has been given to any effects upon competition of the activities proposed under the Center.

(d) PLANNING GRANTS.—The Secretary is authorized to make available nonrenewable planning grants to universities or nonprofit institutions for the purpose of developing a plan required under subsection (c)(3).

Inventions, title acquisition.

(e) RESEARCH AND DEVELOPMENT UTILIZATION.—(1) To promote technological innovation and commercialization of research and development efforts, each Center has the option of acquiring title to any invention conceived or made under the auspices of the Center that was supported at least in part by Federal funds: *Provided,* That—

(A) the Center reports the invention to the supporting agency together with a list of each country in which the Center elects to file a patent application on the invention;

(B) said option shall be exercised at the time of disclosure of invention or within such time thereafter as may be provided in the grant or cooperative agreement;

(C) the Center intends to promote the commercialization of the invention and file a United States patent application;

(D) royalties be used for compensation of the inventor or for educational or research activities of the Center;

(E) the Center make periodic reports to the supporting agency, and the supporting agency may treat information contained in such reports as privileged and confidential technical, commercial, and financial information and not subject to disclosures under the Freedom of Information Act; and

(F) any Federal department or agency shall have the royalty-free right to practice, or have practiced on its behalf, the invention for governmental purposes.

The supporting agency shall have the right to acquire title to any patent on an invention in any country in which the Center elects not to file a patent application or fails to file within a reasonable time.

Supporting agency licensing rights.

(2) Where a Center has retained title to an invention under paragraph (1) of this subsection the supporting agency shall have the right to require the Center or its licensee to grant a nonexclusive, partially exclusive, or exclusive license to a responsible applicant or applicants, upon terms that are reasonable under the circumstances, if the supporting agency determines, after public notice and opportunity for hearing, that such action is necessary—

(A) because the Center or licensee has not taken and is not expected to take timely and effective action to achieve practical application of the invention;

(B) to meet health, safety, environmental, or national security needs which are not reasonably satisfied by the contractor or licensee; or

(C) because the granting of exclusive rights in the invention has tended substantially to lessen competition or to result in undue market concentration in the United States in any line of commerce to which the technology relates.

U.S. Courts of Claims, petition.

(3) Any individual, partnership, corporation, association, institution, or other entity adversely affected by a supporting agency determination made under paragraph (2) of this subsection may, at any time within 60 days after the determination is issued, file a petition to the United States Court of Claims which shall have jurisdiction to determine that matter de novo and to affirm, reverse, or modify as appropriate, the determination of the supporting agency.

Antitrust laws.

(f) ADDITIONAL CONSIDERATION.—The supporting agency may request the Attorney General's opinion whether the proposed joint research activities of a Center would violate any of the antitrust laws. The Attorney General shall advise the supporting agency of his determination and the reasons for it within 120 days after receipt of such request.

15 USC 3706.

SEC. 7. GRANTS AND COOPERATIVE AGREEMENTS.

(a) IN GENERAL.—The Secretary may make grants and enter into cooperative agreements according to the provisions of this section in order to assist any activity consistent with this Act, including activities performed by individuals. The total amount of any such grant or cooperative agreement may not exceed 75 percent of the total cost of the program.

(b) ELIGIBILITY AND PROCEDURE.—Any person or institution may apply to the Secretary for a grant or cooperative agreement available under this section. Application shall be made in such form and manner, and with such content and other submissions, as the Direc-

tor shall prescribe. The Secretary shall act upon each such application within 90 days after the date on which all required information is received.

(c) TERMS AND CONDITIONS.—

(1) Any grant made, or cooperative agreement entered into, under this section shall be subject to the limitations and provisions set forth in paragraph (2) of this subsection, and to such other terms, conditions, and requirements as the Secretary deems necessary or appropriate.

(2) Any person who receives or utilizes any proceeds of any grant made or cooperative agreement entered into under this section shall keep such records as the Secretary shall by regulation prescribe as being necessary and appropriate to facilitate effective audit and evaluation, including records which fully disclose the amount and disposition by such recipient of such proceeds, the total cost of the program or project in connection with which such proceeds were used, and the amount, if any, of such costs which was provided through other sources.

15 USC 3707.

SEC. 8. NATIONAL SCIENCE FOUNDATION CENTERS FOR INDUSTRIAL TECHNOLOGY.

(a) ESTABLISHMENT AND PROVISIONS.—The National Science Foundation shall provide assistance for the establishment of Centers for Industrial Technology. Such Centers shall be affiliated with a university, or other nonprofit institution, or a group thereof. The objective of the Centers is to enhance technological innovation as provided in section 6(a) through the conduct of activities as provided in section 6(b). The provisions of sections 6(e) and 6(f) shall apply to Centers established under this section.

(b) PLANNING GRANTS.—The National Science Foundation is authorized to make available nonrenewable planning grants to universities or nonprofit institutions for the purpose of developing the plan, as described under section 6(c)(3).

(c) TERMS AND CONDITIONS.—Grants, contracts, and cooperative agreements entered into by the National Science Foundation in execution of the powers and duties of the National Science Foundation under this Act shall be governed by the National Science Foundation Act of 1950 and other pertinent Acts.

42 USC 1861 note.

15 USC 3708.

SEC. 9. ADMINISTRATIVE ARRANGEMENTS.

(a) COORDINATION.—The Secretary and the National Science Foundation shall, on a continuing basis, obtain the advice and cooperation of departments and agencies whose missions contribute to or are affected by the programs established under this Act, including the development of an agenda for research and policy experimentation. These departments and agencies shall include but not be limited to the Departments of Defense, Energy, Education, Health and Human Services, Housing and Urban Development, the Environmental Protection Agency, National Aeronautics and Space Administration, Small Business Administration, Council of Economic Advisers, Council on Environmental Quality, and Office of Science and Technology Policy.

(b) COOPERATION.—It is the sense of the Congress that departments and agencies, including the Federal laboratories, whose missions are affected by, or could contribute to, the programs established under this Act, should, within the limits of budgetary authorizations and appropriations, support or participate in activities or projects authorized by this Act.

(c) ADMINISTRATIVE AUTHORIZATION.—

(1) Departments and agencies described in subsection (b) are authorized to participate in, contribute to, and serve as resources for the Centers and for any other activities authorized under this Act.

(2) The Secretary and the National Science Foundation are authorized to receive moneys and to receive other forms of assistance from other departments or agencies to support activities of the Centers and any other activities authorized under this Act.

(d) COOPERATIVE EFFORTS.—The Secretary and the National Science Foundation shall, on a continuing basis, provide each other the opportunity to comment on any proposed program of activity under section 6, 8, or 13 of this Act before funds are committed to such program in order to mount complementary efforts and avoid duplication.

SEC. 10. NATIONAL INDUSTRIAL TECHNOLOGY BOARD. 15 USC 3709.

(a) ESTABLISHMENT.—There shall be established a committee to be known as the National Industrial Technology Board.

(b) DUTIES.—The Board shall take such steps as may be necessary to review annually the activities of the Office and advise the Secretary and the Director with respect to—

(1) the formulation and conduct of activities under section 5 of this title;

(2) the designation and operation of Centers and their programs under section 6 of this Act including assistance in establishing priorities;

(3) the preparation of the report required under section 5(d); and

(4) such other matters as the Secretary or Director refers to the Board, including the establishment of Centers under section 8 of this Act, for review and advice.

The Director shall make available to the Board such information, personnel, and administrative services and assistance as it may reasonably require to carry out its duties. The National Science Foundation shall make available to the Board such information and assistance as it may reasonably require to carry out its duties.

(c) MEMBERSHIP, TERMS, AND POWERS.—

(1) The Board shall consist of 15 voting members who shall be appointed by the Secretary. The Director shall serve as a nonvoting member of the Board. The members of the Board shall be individuals who, by reason of knowledge, experience, or training are especially qualified in one or more of the disciplines and fields dealing with technology, labor, and industrial innovation or who are affected by technological innovation. The majority of the members of the Board shall be individuals from industry and business.

(2) The term of office of a voting member of the Board shall be 3 years, except that of the original appointees, five shall be appointed for a term of 1 year, five shall be appointed for a term of 2 years, and five shall be appointed for a term of 3 years.

(3) Any individual appointed to fill a vacancy occurring before the expiration of the term for which his or her predecessor was appointed shall be appointed only for the remainder of such term. No individual may be appointed as a voting member after serving more than two full terms as such a member.

(4) The Board shall select a voting member to serve as the Chairperson and another voting member to serve as the Vice Chairperson. The Vice Chairperson shall perform the functions of the Chairperson in the absence or incapacity of the Chairperson.

(5) Voting members of the Board may receive compensation at a daily rate for GS-18 of the General Schedule under section 5332 of title 5, United States Code, when actually engaged in the performance of duties for such Board, and may be reimbursed for actual and reasonable expenses incurred in the performance of such duties.

45 FR 69201

15 USC 3710.

SEC. 11. UTILIZATION OF FEDERAL TECHNOLOGY.

(a) POLICY.—It is the continuing responsibility of the Federal Government to ensure the full use of the results of the Nation's Federal investment in research and development. To this end the Federal Government shall strive where appropriate to transfer federally owned or originated technology to State and local governments and to the private sector.

Technology transfer.

(b) ESTABLISHMENT OF RESEARCH AND TECHNOLOGY APPLICATIONS OFFICES.—Each Federal laboratory shall establish an Office of Research and Technology Applications. Laboratories having existing organizational structures which perform the functions of this section may elect to combine the Office of Research and Technology Applications within the existing organization. The staffing and funding levels for these offices shall be determined between each Federal laboratory and the Federal agency operating or directing the laboratory, except that (1) each laboratory having a total annual budget exceeding $20,000,000 shall provide at least one professional individual full-time as staff for its Office of Research and Technology Applications, and (2) after September 30, 1981, each Federal agency which operates or directs one or more Federal laboratories shall make available not less than 0.5 percent of the agency's research and development budget to support the technology transfer function at the agency and at its laboratories, including support of the Offices of Research and Technology Applications. The agency head may waive the requirements set forth in (1) and/or (2) of this subsection. If the agency head waives either requirement (1) or (2), the agency head shall submit to Congress at the time the President submits the budget to Congress an explanation of the reasons for the waiver and alternate plans for conducting the technology transfer function at the agency.

Waiver.
Submittal to Congress

(c) FUNCTIONS OF RESEARCH AND TECHNOLOGY APPLICATIONS OFFICES.—It shall be the function of each Office of Research and Technology Applications—

(1) to prepare an application assessment of each research and development project in which that laboratory is engaged which has potential for successful application in State or local government or in private industry;

(2) to provide and disseminate information on federally owned or originated products, processes, and services having potential application to State and local governments and to private industry;

(3) to cooperate with and assist the Center for the Utilization of Federal Technology and other organizations which link the research and development resources of that laboratory and the Federal Government as a whole to potential users in State and local government and private industry; and

(4) to provide technical assistance in response to requests from State and local government officials.

Agencies which have established organizational structures outside their Federal laboratories which have as their principal purpose the transfer of federally owned or originated technology to State and local government and to the private sector may elect to perform the functions of this subsection in such organizational structures. No Office of Research and Technology Applications or other organizational structures performing the functions of this subsection shall substantially compete with similar services available in the private sector.

(d) CENTER FOR THE UTILIZATION OF FEDERAL TECHNOLOGY.—There is hereby established in the Department of Commerce a Center for the Utilization of Federal Technology. The Center for the Utilization of Federal Technology shall— Establishment

(1) serve as a central clearinghouse for the collection, dissemination and transfer of information on federally owned or originated technologies having potential application to State and local governments and to private industry;

(2) coordinate the activities of the Offices of Research and Technology Applications of the Federal laboratories;

(3) utilize the expertise and services of the National Science Foundation and the existing Federal Laboratory Consortium for Technology Transfer; particularly in dealing with State and local governments;

(4) receive requests for technical assistance from State and local governments and refer these requests to the appropriate Federal laboratories;

(5) provide funding, at the discretion of the Secretary, for Federal laboratories to provide the assistance specified in subsection (c)(4); and

(6) use appropriate technology transfer mechanisms such as personnel exchanges and computer-based systems.

(e) AGENCY REPORTING.—Each Federal agency which operates or directs one or more Federal laboratories shall prepare biennially a report summarizing the activities performed by that agency and its Federal laboratories pursuant to the provisions of this section. The report shall be transmitted to the Center for the Utilization of Federal Technology by November 1 of each year in which it is due.

SEC. 12. NATIONAL TECHNOLOGY MEDAL. 15 USC 3711.

(a) ESTABLISHMENT.—There is hereby established a National Technology Medal, which shall be of such design and materials and bear such inscriptions as the President, on the basis of recommendations submitted by the Office of Science and Technology Policy, may prescribe.

(b) AWARD.—The President shall periodically award the medal, on the basis of recommendations received from the Secretary or on the basis of such other information and evidence as he deems appropriate, to individuals or companies, which in his judgment are deserving of special recognition by reason of their outstanding contributions to the promotion of technology or technological manpower for the improvement of the economic, environmental, or social well-being of the United States.

(c) PRESENTATION.—The presentation of the award shall be made by the President with such ceremonies as he may deem proper.

15 USC 3712 SEC. 13. PERSONNEL EXCHANGES.

The Secretary and the National Science Foundation, jointly, shall establish a program to foster the exchange of scientific and technical personnel among academia, industry, and Federal laboratories. Such program shall include both (1) federally supported exchanges and (2) efforts to stimulate exchanges without Federal funding.

15 USC 3713 SEC. 14. AUTHORIZATION OF APPROPRIATIONS.

(a) There is authorized to be appropriated to the Secretary for purposes of carrying out section 6, not to exceed $19,000,000 for the fiscal year ending September 30, 1981, $40,000,000 for the fiscal year ending September 30, 1982, $50,000,000 for the fiscal year ending September 30, 1983, and $60,000,000 for each of the fiscal years ending September 30, 1984, and 1985.

(b) In addition to authorizations of appropriations under subsection (a), there is authorized to be appropriated to the Secretary for purposes of carrying out the provisions of this Act, not to exceed $5,000,000 for the fiscal year ending September 30, 1981, $9,000,000 for the fiscal year ending September 30, 1982, and $14,000,000 for each of the fiscal years ending September 30, 1983, 1984, and 1985.

(c) Such sums as may be appropriated under subsections (a) and (b) shall remain available until expended.

(d) To enable the National Science Foundation to carry out its powers and duties under this Act only such sums may be appropriated as the Congress may authorize by law.

15 USC 3714 SEC. 15. SPENDING AUTHORITY.

No payments shall be made or contracts shall be entered into pursuant to this Act except to such extent or in such amounts as are provided in advance in appropriation Acts.

Approved October 21, 1980.

LEGISLATIVE HISTORY

HOUSE REPORT No. 96-1199 (Comm. on Science and Technology).
SENATE REPORT No. 96-781 (Comm. on Commerce, Science, and Transportation)
CONGRESSIONAL RECORD, Vol. 126 (1980):
May 28, considered and passed Senate.
Sept. 8, considered and passed House, amended.
Sept. 26, Senate concurred in certain House amendments, disagreed to others, and concurred in remainder with amendments.
Oct. 1, House receded from its amendments and concurred in Senate amendments.
WEEKLY COMPILATION OF PRESIDENTIAL DOCUMENTS, Vol. 16, No. 43:
Oct. 21, Presidential statement.

Public Law 99-502
99th Congress

An Act

To amend the Stevenson-Wydler Technology Innovation Act of 1980 to promote technology transfer by authorizing Government-operated laboratories to enter into cooperative research agreements and by establishing a Federal Laboratory Consortium for Technology Transfer within the National Bureau of Standards, and for other purposes.

Oct. 20 1986
[H.R. 3773]

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

Federal Technology Transfer Act of 1986.
Commerce and trade.
Government organization and employees.

SECTION 1. SHORT TITLE.

This Act may be cited as the "Federal Technology Transfer Act of 1986".

15 USC 3701 note.

SEC. 2. COOPERATIVE RESEARCH AND DEVELOPMENT AGREEMENTS.

The Stevenson-Wydler Technology Innovation Act of 1980 is amended by redesignating sections 12 through 15 as sections 16 through 19, and by inserting immediately after section 11 the following:

15 USC 3701 note.
15 USC 3711-3714.
15 USC 3710a.

"SEC. 12. COOPERATIVE RESEARCH AND DEVELOPMENT AGREEMENTS.

"(a) GENERAL AUTHORITY.—Each Federal agency may permit the director of any of its Government-operated Federal laboratories—

"(1) to enter into cooperative research and development agreements on behalf of such agency (subject to subsection (c) of this section) with other Federal agencies; units of State or local government; industrial organizations (including corporations, partnerships, and limited partnerships, and industrial development organizations); public and private foundations; nonprofit organizations (including universities); or other persons (including licensees of inventions owned by the Federal agency); and

State and local governments.
Business and industry.
Schools and colleges.

"(2) to negotiate licensing agreements under section 207 of title 35, United States Code, or under other authorities for Government-owned inventions made at the laboratory and other inventions of Federal employees that may be voluntarily assigned to the Government.

"(b) ENUMERATED AUTHORITY.—Under agreements entered into pursuant to subsection (a)(1), a Government-operated Federal laboratory may (subject to subsection (c) of this section)—

"(1) accept, retain, and use funds, personnel, services, and property from collaborating parties and provide personnel, services, and property to collaborating parties;

"(2) grant or agree to grant in advance, to a collaborating party, patent licenses or assignments, or options thereto, in any invention made in whole or in part by a Federal employee under the agreement, retaining a nonexclusive, nontransferrable, irrevocable, paid-up license to practice the invention or have the invention practiced throughout the world by or on behalf of the Government and such other rights as the Federal laboratory deems appropriate; and

Patents and trademarks.

91-139 O - 86 (519)

"(3) waive, subject to reservation by the Government of a nonexclusive, irrevocable, paid-up license to practice the invention or have the invention practiced throughout the world by or on behalf of the Government, in advance, in whole or in part, any right of ownership which the Federal Government may have to any subject invention made under the agreement by a collaborating party or employee of a collaborating party; and

"(4) to the extent consistent with any applicable agency requirements and standards of conduct, permit employees or former employees of the laboratory to participate in efforts to commercialize inventions they made while in the service of the United States.

Regulations.

"(c) CONTRACT CONSIDERATIONS.—(1) A Federal agency may issue regulations on suitable procedures for implementing the provisions of this section; however, implementation of this section shall not be delayed until issuance of such regulations.

"(2) The agency in permitting a Federal laboratory to enter into agreements under this section shall be guided by the purposes of this Act.

"(3)(A) Any agency using the authority given it under subsection (a) shall review employee standards of conduct for resolving potential conflicts of interest to make sure they adequately establish guidelines for situations likely to arise through the use of this authority, including but not limited to cases where present or former employees or their partners negotiate licenses or assignments of titles to inventions or negotiate cooperative research and development agreements with Federal agencies (including the agency with which the employee involved is or was formerly employed).

"(B) If, in implementing subparagraph (A), an agency is unable to resolve potential conflicts of interest within its current statutory framework, it shall propose necessary statutory changes to be forwarded to its authorizing committees in Congress.

"(4) The laboratory director in deciding what cooperative research and development agreements to enter into shall—

Small business.

"(A) give special consideration to small business firms, and consortia involving small business firms; and

Business and industry.
International agreements.

"(B) give preference to business units located in the United States which agree that products embodying inventions made under the cooperative research and development agreement or produced through the use of such inventions will be manufactured substantially in the United States and, in the case of any industrial organization or other person subject to the control of a foreign company or government, as appropriate, take into consideration whether or not such foreign government permits United States agencies, organizations, or other persons to enter into cooperative research and development agreements and licensing agreements.

"(5)(A) If the head of the agency or his designee desires an opportunity to disapprove or require the modification of any such agreement, the agreement shall provide a 30-day period within which such action must be taken beginning on the date the agreement is presented to him or her by the head of the laboratory concerned.

"(B) In any case in which the head of an agency or his designee disapproves or requires the modification of an agreement presented under this section, the head of the agency or such designee shall

transmit a written explanation of such disapproval or modification to the head of the laboratory concerned.

"(6) Each agency shall maintain a record of all agreements entered into under this section. Records.

"(d) DEFINITION.—As used in this section—

"(1) the term 'cooperative research and development agreement' means any agreement between one or more Federal laboratories and one or more non-Federal parties under which the Government, through its laboratories, provides personnel, services, facilities, equipment, or other resources with or without reimbursement (but not funds to non-Federal parties) and the non-Federal parties provide funds, personnel, services, facilities, equipment, or other resources toward the conduct of specified research or development efforts which are consistent with the missions of the laboratory; except that such term does not include a procurement contract or cooperative agreement as those terms are used in sections 6303, 6304, and 6305 of title 31, United States Code; and

"(2) the term 'laboratory' means a facility or group of facilities owned, leased, or otherwise used by a Federal agency, a substantial purpose of which is the performance of research, development, or engineering by employees of the Federal Government.

"(e) DETERMINATION OF LABORATORY MISSIONS.—For purposes of this section, an agency shall make separate determinations of the mission or missions of each of its laboratories.

"(f) RELATIONSHIP TO OTHER LAWS.—Nothing in this section is intended to limit or diminish existing authorities of any agency.".

SEC. 3. ESTABLISHMENT OF FEDERAL LABORATORY CONSORTIUM FOR TECHNOLOGY TRANSFER.

Section 11 of the Stevenson-Wydler Technology Innovation Act of 1980 (15 U.S.C. 3710) is amended— *Post*, p. 1791.

(1) by redesignating subsection (e) as subsection (f); and

(2) by inserting after subsection (d) the following:

"(e) ESTABLISHMENT OF FEDERAL LABORATORY CONSORTIUM FOR TECHNOLOGY TRANSFER.—(1) There is hereby established the Federal Laboratory Consortium for Technology Transfer (hereinafter referred to as the 'Consortium') which, in cooperation with Federal Laboratories and the private sector, shall—

"(A) develop and (with the consent of the Federal laboratory concerned) administer techniques, training courses, and materials concerning technology transfer to increase the awareness of Federal laboratory employees regarding the commercial potential of laboratory technology and innovations;

"(B) furnish advice and assistance requested by Federal agencies and laboratories for use in their technology transfer programs (including the planning of seminars for small business and other industry);

"(C) provide a clearinghouse for requests, received at the laboratory level, for technical assistance from States and units of local governments, businesses, industrial development organizations, not-for-profit organizations including universities, Federal agencies and laboratories, and other persons, and—

"(i) to the extent that such requests can be responded to with published information available to the National Tech-

nical Information Service, refer such requests to that Service, and

"(ii) otherwise refer these requests to the appropriate Federal laboratories and agencies;

"(D) facilitate communication and coordination between Offices of Research and Technology Applications of Federal laboratories;

"(E) utilize (with the consent of the agency involved) the expertise and services of the National Science Foundation, the Department of Commerce, the National Aeronautics and Space Administration, and other Federal agencies, as necessary;

"(F) with the consent of any Federal laboratory, facilitate the use by such laboratory of appropriate technology transfer mechanisms such as personnel exchanges and computer-based systems;

"(G) with the consent of any Federal laboratory, assist such laboratory to establish programs using technical volunteers to provide technical assistance to communities related to such laboratory;

"(H) facilitate communication and cooperation between Offices of Research and Technology Applications of Federal laboratories and regional, State, and local technology transfer organizations;

"(I) when requested, assist colleges or universities, businesses, nonprofit organizations, State or local governments, or regional organizations to establish programs to stimulate research and to encourage technology transfer in such areas as technology program development, curriculum design, long-term research planning, personnel needs projections, and productivity assessments; and

"(J) seek advice in each Federal laboratory consortium region from representatives of State and local governments, large and small business, universities, and other appropriate persons on the effectiveness of the program (and any such advice shall be provided at no expense to the Government).

"(2) The membership of the Consortium shall consist of the Federal laboratories described in clause (1) of subsection (b) and such other laboratories as may choose to join the Consortium. The representatives to the Consortium shall include a senior staff member of each Federal laboratory which is a member of the Consortium and a representative appointed from each Federal agency with one or more member laboratories.

"(3) The representatives to the Consortium shall elect a Chairman of the Consortium.

"(4) The Director of the National Bureau of Standards shall provide the Consortium, on a reimbursable basis, with administrative services, such as office space, personnel, and support services of the Bureau, as requested by the Consortium and approved by such Director.

"(5) Each Federal laboratory or agency shall transfer technology directly to users or representatives of users, and shall not transfer technology directly to the Consortium. Each Federal laboratory shall conduct and transfer technology only in accordance with the practices and policies of the Federal agency which owns, leases, or otherwise uses such Federal laboratory.

Reports.

"(6) Not later than one year after the date of the enactment of this subsection, and every year thereafter, the Chairman of the Consor-

tium shall submit a report to the President, to the appropriate authorization and appropriation committees of both Houses of the Congress, and to each agency with respect to which a transfer of funding is made (for the fiscal year or years involved) under paragraph (7), concerning the activities of the Consortium and the expenditures made by it under this subsection during the year for which the report is made.

"(7)(A) Subject to subparagraph (B), an amount equal to 0.005 percent of that portion of the research and development budget of each Federal agency that is to be utilized by the laboratories of such agency for a fiscal year referred to in subparagraph (B)(ii) shall be transferred by such agency to the National Bureau of Standards at the beginning of the fiscal year involved. Amounts so transferred shall be provided by the Bureau to the Consortium for the purpose of carrying out activities of the Consortium under this subsection.

"(B) A transfer shall be made by any Federal agency under subparagraph (A), for any fiscal year, only if—

"(i) the amount so transferred by that agency (as determined under such subparagraph) would exceed $10,000; and

"(ii) such transfer is made with respect to the fiscal year 1987, 1988, 1989, 1990, or 1991.

"(C) The heads of Federal agencies and their designees, and the directors of Federal laboratories, may provide such additional support for operations of the Consortium as they deem appropriate.

"(8)(A) The Consortium shall use 5 percent of the funds provided in paragraph (7)(A) to establish demonstration projects in technology transfer. To carry out such projects, the Consortium may arrange for grants or awards to, or enter into agreements with, nonprofit State, local, or private organizations or entities whose primary purposes are to facilitate cooperative research between the Federal laboratories and organizations not associated with the Federal laboratories, to transfer technology from the Federal laboratories, and to advance State and local economic activity.

"(B) The demonstration projects established under subparagraph (A) shall serve as model programs. Such projects shall be designed to develop programs and mechanisms for technology transfer from the Federal laboratories which may be utilized by the States and which will enhance Federal, State, and local programs for the transfer of technology.

"(C) Application for such grants, awards, or agreements shall be in such form and contain such information as the Consortium or its designee shall specify.

"(D) Any person who receives or utilizes any proceeds of a grant or award made, or agreement entered into, under this paragraph shall keep such records as the Consortium or its designee shall determine are necessary and appropriate to facilitate effective audit and evaluation, including records which fully disclose the amount and disposition of such proceeds and the total cost of the project in connection with which such proceeds were used.". Records.

SEC. 4. UTILIZATION OF FEDERAL TECHNOLOGY.

(a) RESPONSIBILITY FOR TECHNOLOGY TRANSFER.—Section 11(a) of the Stevenson-Wydler Technology Innovation Act of 1980 (15 U.S.C. 3710(a)) is amended—

(1) by inserting "(1)" after "POLICY.—"; and

(2) by adding at the end thereof the following new paragraphs:

(2) Technology transfer, consistent with mission responsibilities, is a responsibility of each laboratory science and engineering professional.

"(3) Each laboratory director shall ensure that efforts to transfer technology are considered positively in laboratory job descriptions, employee promotion policies, and evaluation of the job performance of scientists and engineers in the laboratory.".

(b) RESEARCH AND TECHNOLOGY APPLICATIONS OFFICES.—(1) Section 11(b) of such Act (15 U.S.C. 3710(b)) is amended—

(A) by striking out "a total annual budget exceeding $20,000,000 shall provide at least one professional individual full-time" and inserting in lieu thereof "200 or more full-time equivalent scientific, engineering, and related technical positions shall provide one or more full-time equivalent positions";

(B) by inserting immediately before the next to last sentence the following new sentence: "Furthermore, individuals filling positions in an Office of Research and Technology Applications shall be included in the overall laboratory/agency management development program so as to ensure that highly competent technical managers are full participants in the technology transfer process.";

(C) by striking out "requirements set forth in (1) and/or (2) of this subsection" in the next to last sentence and inserting in lieu thereof "requirement set forth in clause (2) of the preceding sentence"; and

(D) by striking out "either requirement (1) or (2)" in the last sentence and inserting in lieu thereof "such requirement".

(2) Section 11(c) of such Act (15 U.S.C. 3710(c)) is amended—

(A) by striking out paragraph (1) and inserting in lieu thereof the following:

"(1) to prepare application assessments for selected research and development projects in which that laboratory is engaged and which in the opinion of the laboratory may have potential commercial applications;";

(B) by striking out "the Center for the Utilization of Federal Technology" in paragraph (3) and inserting in lieu thereof "the National Technical Information Service, the Federal Laboratory Consortium for Technology Transfer,", and by striking out "and" after the semicolon;

(C) by striking out "in response to requests from State and local government officials." in paragraph (4) and inserting in lieu thereof "to State and local government officials; and"; and

(D) by inserting immediately after paragraph (4) the following new paragraph:

State and local governments.

"(5) to participate, where feasible, in regional, State, and local programs designed to facilitate or stimulate the transfer of technology for the benefit of the region, State, or local jurisdiction in which the Federal laboratory is located."

(c) DISSEMINATION OF TECHNICAL INFORMATION.—Section 11(d) of such Act (15 U.S.C. 3710(d)) is amended—

(1) by striking out "(d)" and all that follows down through "shall—" and inserting in lieu thereof the following:

(d) DISSEMINATION OF TECHNICAL INFORMATION.—The National Technical Information Service shall—";

(2) by striking out paragraph (2);

(3) by striking out "existing" in paragraph (3), and redesignating such paragraph as paragraph (2);

(4) by striking out paragraph (4) and inserting in lieu thereof the following:

"(3) receive requests for technical assistance from State and local governments, respond to such requests with published information available to the Service, and refer such requests to the Federal Laboratory Consortium for Technology Transfer to the extent that such requests require a response involving more than the published information available to the Service;"; State and local governments.

(5) by redesignating paragraphs (5) and (6) as paragraphs (4) and (5), respectively; and

(6) by striking out "(c)(4)" in paragraph (4) as so redesignated and inserting in lieu thereof "(c)(3)".

(d) AGENCY REPORTING.—Section 11(f) of such Act (15 U.S.C. 3710(e)) (as redesignated by section 3(1) of this Act) is amended—

(1) by striking out "prepare biennially a report summarizing the activities" in the first sentence and inserting in lieu thereof "report annually to the Congress, as part of the agency's annual budget submission, on the activities"; and Reports.

(2) by striking out the second sentence.

SEC. 5. FUNCTIONS OF THE SECRETARY OF COMMERCE. 15 USC 3710.

Section 11 of the Stevenson-Wydler Technology Innovation Act of 1980 (as amended by the preceding provisions of this Act) is further amended by adding at the end thereof the following new subsection:

"(g) FUNCTIONS OF THE SECRETARY.—(1) The Secretary, in consultation with other Federal agencies, may—

"(A) make available to interested agencies the expertise of the Department of Commerce regarding the commercial potential of inventions and methods and options for commercialization which are available to the Federal laboratories, including research and development limited partnerships;

"(B) develop and disseminate to appropriate agency and laboratory personnel model provisions for use on a voluntary basis in cooperative research and development arrangements; and

"(C) furnish advice and assistance, upon request, to Federal agencies concerning their cooperative research and development programs and projects.

"(2) Two years after the date of the enactment of this subsection and every two years thereafter, the Secretary shall submit a summary report to the President and the Congress on the use by the agencies and the Secretary of the authorities specified in this Act. Other Federal agencies shall cooperate in the report's preparation. Reports.

"(3) Not later than one year after the date of the enactment of the Federal Technology Transfer Act of 1986, the Secretary shall submit to the President and the Congress a report regarding— Reports.

"(A) any copyright provisions or other types of barriers which tend to restrict or limit the transfer of federally funded computer software to the private sector and to State and local governments, and agencies of such State and local governments; and Copyrights. State and local governments.

"(B) the feasibility and cost of compiling and maintaining a current and comprehensive inventory of all federally funded training software."

SEC. 6. REWARDS FOR SCIENTIFIC, ENGINEERING, AND TECHNICAL PERSONNEL OR FEDERAL AGENCIES.

The Stevenson-Wydler Technology Innovation Act of 1980 (as amended by the preceding provisions of this Act) is further amended by inserting after section 12 the following new section:

15 USC 3710b.

"SEC. 12. REWARDS FOR SCIENTIFIC, ENGINEERING, AND TECHNICAL PERSONNEL OF FEDERAL AGENCIES.

"The head of each Federal agency that is making expenditures at a rate of more than $50,000,000 per fiscal year for research and development in its Government-operated laboratories shall use the appropriate statutory authority to develop and implement a cash awards program to reward its scientific, engineering, and technical personnel for—

"(1) inventions, innovations, or other outstanding scientific or technological contributions of value to the United States due to commercial application or due to contributions to missions of the Federal agency or the Federal government, or

"(2) exemplary activities that promote the domestic transfer of science and technology development within the Federal Government and result in utilization of such science and technology by American industry or business, universities, State or local governments, or other non-Federal parties.".

SEC. 7. DISTRIBUTION OF ROYALTIES RECEIVED BY FEDERAL AGENCIES.

The Stevenson-Wydler Technology Innovation Act of 1980 (as amended by the preceding provisions of this Act) is further amended by inserting after section 13 the following new section:

15 USC 3710c.

"SEC. 13. DISTRIBUTION OF ROYALTIES RECEIVED BY FEDERAL AGENCIES.

"(a) IN GENERAL.—(1) Except as provided in paragraphs (2) and (4), any royalties or other income received by a Federal agency from the licensing or assignment of inventions under agreements entered into under section 12, and inventions of Government-operated Federal laboratories licensed under section 207 of title 35, United States Code, or under any other provision of law, shall be retained by the agency whose laboratory produced the invention and shall be disposed of as follows:

"(A)(i) The head of the agency or his designee shall pay at least 15 percent of the royalties or other income the agency receives on account of any invention to the inventor (or co-inventors) if the inventor (or each such co-inventor) was an employee of the agency at the time the invention was made. This clause shall take effect on the date of the enactment of this section unless the agency publishes a notice in the Federal Register within 90 days of such date indicating its election to file a Notice of Proposed Rulemaking pursuant to clause (ii).

Effective date.
Federal Register, publication.

Regulations.

"(ii) An agency may promulgate, in accordance with section 553 of title 5, United States Code, regulations providing for an alternative program for sharing royalties with inventors who were employed by the agency at the time the invention was made and whose names appear on licensed inventions. Such regulations must—

"(I) guarantee a fixed minimum payment to each such inventor, each year that the agency receives royalties from that inventor's invention;

"(II) provide a percentage royalty share to each such inventor, each year that the agency receives royalties from that inventor's invention in excess of a threshold amount;

"(III) provide that total payments to all such inventors shall exceed 15 percent of total agency royalties in any given fiscal year; and

"(IV) provide appropriate incentives from royalties for those laboratory employees who contribute substantially to the technical development of a licensed invention between the time of the filing of the patent application and the licensing of the invention.

"(iii) An agency that has published its intention to promulgate regulations under clause (ii) may elect not to pay inventors under clause (i) until the expiration of two years after the date of the enactment of this Act or until the date of the promulgation of such regulations, whichever is earlier. If an agency makes such an election and after two years the regulations have not been promulgated, the agency shall make payments (in accordance with clause (i)) of at least 15 percent of the royalties involved, retroactive to the date of the enactment of this Act. If promulgation of the regulations occurs within two years after the date of the enactment of this Act, payments shall be made in accordance with such regulations, retroactive to the date of the enactment of this Act. The agency shall retain its royalties until the inventor's portion is paid under either clause (i) or (ii). Such royalties shall not be transferred to the agency's Government-operated laboratories under subparagraph (B) and shall not revert to the Treasury pursuant to paragraph (2) as a result of any delay caused by rulemaking under this subparagraph. Regulations.

"(B) The balance of the royalties or other income shall be transferred by the agency to its Government-operated laboratories, with the majority share of the royalties or other income from any invention going to the laboratory where the invention occurred; and the funds so transferred to any such laboratory may be used or obligated by that laboratory during the fiscal year in which they are received or during the succeeding fiscal year—

"(i) for payment of expenses incidental to the administration and licensing of inventions by that laboratory or by the agency with respect to inventions which occurred at that laboratory, including the fees or other costs for the services of other agencies, persons, or organizations for invention management and licensing services;

"(ii) to reward scientific, engineering, and technical employees of that laboratory;

"(iii) to further scientific exchange among the Government-operated laboratories of the agency; or

"(iv) for education and training of employees consistent with the research and development mission and objectives of the agency, and for other activities that increase the licensing potential for transfer of the technology of the Government-operated laboratories of the agency.

Any of such funds not so used or obligated by the end of the fiscal year succeeding the fiscal year in which they are received shall be paid into the Treasury of the United States.

"(2) If, after payments to inventors under paragraph (1), the royalties received by an agency in any fiscal year exceed 5 percent of the budget of the Government-operated laboratories of the agency for that year, 75 percent of such excess shall be paid to the Treasury

of the United States and the remaining 25 percent may be used or obligated for the purposes described in clauses (i) through (iv) of paragraph (1)(B) during that fiscal year or the succeeding fiscal year. Any funds not so used or obligated shall be paid into the Treasury of the United States.

Wages.

"(3) Any payment made to an employee under this section shall be in addition to the regular pay of the employee and to any other awards made to the employee, and shall not affect the entitlement of the employee to any regular pay, annuity, or award to which he is otherwise entitled or for which he is otherwise eligible or limit the amount thereof. Any payment made to an inventor as such shall continue after the inventor leaves the laboratory or agency. Payments made under this section shall not exceed $100,000 per year to any one person, unless the President approves a larger award (with the excess over $100,000 being treated as a Presidential award under section 4504 of title 5, United States Code).

"(4) A Federal agency receiving royalties or other income as a result of invention management services performed for another Federal agency or laboratory under section 207 of title 35, United States Code, shall retain such royalties or income to the extent required to offset the payment of royalties to inventors under clause (i) of paragraph (1)(A), costs and expenses incurred under clause (i) of paragraph (1)(B), and the cost of foreign patenting and maintenance for such invention performed at the request of the other agency or laboratory. All royalties and other income remaining after payment of the royalties, costs, and expenses described in the preceding sentence shall be transferred to the agency for which the services were performed, for distribution in accordance with clauses (i) through (iv) of paragraph (1)(B).

"(b) CERTAIN ASSIGNMENTS.—If the invention involved was one assigned to the Federal agency—

"(1) by a contractor, grantee, or participant in a cooperative agreement with the agency, or

"(2) by an employee of the agency who was not working in the laboratory at the time the invention was made,

the agency unit that was involved in such assignment shall be considered to be a laboratory for purposes of this section.

"(c) REPORTS.—(1) In making their annual budget submissions Federal agencies shall submit, to the appropriate authorization and appropriation committees of both Houses of the Congress, summaries of the amount of royalties or other income received and expenditures made (including inventor awards) under this section.

"(2) The Comptroller General, five years after the date of the enactment of this section, shall review the effectiveness of the various royalty-sharing programs established under this section and report to the appropriate committees of the House of Representatives and the Senate, in a timely manner, his findings, conclusions, and recommendations for improvements in such programs.".

SEC. 8. EMPLOYEE ACTIVITIES.

The Stevenson-Wydler Technology Innovation Act of 1980 (as amended by the preceding provisions of this Act) is further amended by inserting after section 14 the following new section:

Patents and trademarks. Business and industry. 15 USC 3710d.

"SEC. 15. EMPLOYEE ACTIVITIES.

"(a) IN GENERAL.—If a Federal agency which has the right of ownership to an invention under this Act does not intend to file for

a patent application or otherwise to promote commercialization of such invention, the agency shall allow the inventor, if the inventor is a Government employee or former employee who made the invention during the course of employment with the Government, to retain title to the invention (subject to reservation by the Government of a nonexclusive, nontransferrable, irrevocable, paid-up license to practice the invention or have the invention practiced throughout the world by or on behalf of the Government). In addition, the agency may condition the inventor's right to title on the timely filing of a patent application in cases when the Government determines that it has or may have a need to practice the invention.

"(b) DEFINITION.—For purposes of this section, Federal employees include 'special Government employees' as defined in section 202 of title 18, United States Code.

"(c) RELATIONSHIP TO OTHER LAWS.—Nothing in this section is intended to limit or diminish existing authorities of any agency.".

SEC. 9. MISCELLANEOUS AND CONFORMING AMENDMENTS.

(a) REPEAL OF NATIONAL INDUSTRIAL TECHNOLOGY BOARD.—Section 10 of the Stevenson-Wydler Technology Innovation Act of 1980 (15 U.S.C. 3709) is repealed.

(b) CHANGES IN TERMINOLOGY OR ADMINISTRATIVE STRUCTURE.—(1) Section 3(2) of the Stevenson-Wydler Technology Innovation Act of 1980 is amended by striking out "centers for industrial technology" and inserting in lieu thereof "cooperative research centers". 15 USC 3702.

(2) Section 4 of such Act is amended— 15 USC 3703.

(A) by striking out "Industrial Technology" in paragraph (1) and inserting in lieu thereof "Productivity, Technology, and Innovation";

(B) by striking out "'Director' means the Director of the Office of Industrial Technology" in paragraph (3) and inserting in lieu thereof "'Assistant Secretary' means the Assistant Secretary for Productivity, Technology, and Innovation";

(C) by striking out "Centers for Industrial Technology" in paragraph (4) and inserting in lieu thereof "Cooperative Research Centers";

(D) by striking out paragraph (6), and redesignating paragraphs (7) and (8) as paragraphs (6) and (7), respectively; and

(E) by striking out "owned and funded" in paragraph (6) as so redesignated and inserting in lieu thereof "owned, leased, or otherwise used by a Federal agency and funded".

(3) Section 5(a) of such Act is amended by striking out "Industrial Technology" and inserting in lieu thereof "Productivity, Technology, and Innovation". 15 USC 3704.

(4) Section 5(b) of such Act is amended by striking out "DIRECTOR" and inserting in lieu thereof "ASSISTANT SECRETARY", and by striking out "a Director of the Office" and all that follows and inserting in lieu thereof "an Assistant Secretary for Productivity, Technology, and Innovation.".

(5) Section 5(c) of such Act is amended—

(A) by striking out "the Director" each place it appears and inserting in lieu thereof "the Assistant Secretary";

(B) by redesignating paragraphs (7) and (8) as paragraphs (9) and (10), respectively; and

(C) by inserting immediately after paragraph (6) the following new paragraphs:

"(7) encourage and assist the creation of centers and other joint initiatives by State of local governments, regional organizations, private businesses, institutions of higher education, nonprofit organizations, or Federal laboratories to encourage technology transfer, to stimulate innovation, and to promote an appropriate climate for investment in technology-related industries;

"(8) propose and encourage cooperative research involving appropriate Federal entities, State or local governments, regional organizations, colleges or universities, nonprofit organizations, or private industry to promote the common use of resources, to improve training programs and curricula, to stimulate interest in high technology careers, and to encourage the effective dissemination of technology skills within the wider community;".

15 USC 3705. (6) The heading of section 6 of such Act is amended to read as follows:

"SEC. 6. COOPERATIVE RESEARCH CENTERS."

(7) Section 6(a) of such Act is amended by striking out "Centers for Industrial Technology" and inserting in lieu thereof "Cooperative Research Centers".

(8) Section 6(b)(1) of such Act is amended by striking out "basic and applied".

(9) Section 6(e) of such Act is amended to read as follows:

"(e) RESEARCH AND DEVELOPMENT UTILIZATION.—In the promotion of technology from research and development efforts by Centers under this section, chapter 18 of title 35, United States Code, shall apply to the extent not inconsistent with this section.".

35 USC 200 *et seq.*

(10) Section 6(f) of such Act is repealed.

15 USC 3707. (11) The heading of section 8 of such Act is amended by striking out "CENTERS FOR INDUSTRIAL TECHNOLOGY" and inserting in lieu thereof "COOPERATIVE RESEARCH CENTERS".

(12) Section 8(a) of such Act is amended by striking out "Centers for Industrial Technology" and inserting in lieu thereof "Cooperative Research Centers".

15 USC 3714. (13) Section 19 of such Act (as redesignated by section 2 of this Act) is amended by striking out "pursuant to this Act" and inserting in lieu thereof "pursuant to the provisions of this Act (other than sections 12, 13, and 14)".

(c) RELATED CONFORMING AMENDMENT.—Section 210 of title 35, United States Code, is amended by adding at the end thereof the following new subsection:

"(e) The provisions of the Stevenson-Wydler Technology Innovation Act of 1980, as amended by the Federal Technology Transfer Act of 1986, shall take precedence over the provisions of this chapter to the extent that they permit or require a disposition of rights in subject inventions which is inconsistent with this chapter.".

Ante, p. 1785.

15 USC 3703. (d) ADDITIONAL DEFINITIONS.—Section 4 of such Act (as amended by subsection (b)(2) of this section) is further amended by adding at the end thereof the following new paragraphs:

"(8) 'Federal agency' means any executive agency as defined in section 105 of title 5, United States Code, and the military departments as defined in section 102 of such title.

"(9) 'Invention' means any invention or discovery which is or may be patentable or otherwise protected under title 35, United States Code, or any novel variety of plant which is or may be

protectable under the Plant Variety Protection Act (7 U.S.C. 2321 et seq.).

"(10) 'Made' when used in conjunction with any invention means the conception or first actual reduction to practice of such invention.

"(11) 'Small business firm' means a small business concern as defined in section 2 of Public Law 85-536 (15 U.S.C. 632) and implementing regulations of the Administrator of the Small Business Administration.

"(12) 'Training technology' means computer software and related materials which are developed by a Federal agency to train employees of such agency, including but not limited to software for computer-based instructional systems and for interactive video disc systems.".

(e) REDESIGNATION OF SECTIONS TO REFLECT CHANGES MADE BY PRECEDING PROVISIONS.—(1) Such Act (as amended by the preceding provisions of this Act) is further amended by redesignating sections 11 through 19 as sections 10 through 18, respectively. 15 USC 3710-3714.

(2)(A) Section 5(d) of such Act is amended by inserting "(as then in effect)" after "sections 5, 6, 8, 11, 12, and 13 of this Act". 15 USC 3704.

(B) Section 8(a) of such Act is amended by striking out the last sentence. 15 USC 3707.

(C) Section 9(d) of such Act is amended by striking out "or 13" and inserting in lieu thereof "10, 14, or 16". 15 USC 3708.

(3) Section 13(a)(1) of such Act (as redesignated by paragraph (1) of this subsection) is amended by striking out "section 12" in the matter preceding subparagraph (A) and inserting in lieu thereof "section 11". 15 USC 3710c.

(4) Section 18 of such Act (as redesignated by paragraph (1) of this subsection) is amended by striking out "sections 12, 13, and 14" and inserting in lieu thereof "sections 11, 12, and 13". 15 USC 3714.

(f) CLARIFICATION OF FINDINGS AND PURPOSES.—(1) The second sentence of section 2(10) of such Act (15 U.S.C. 3701(10)) is amended by inserting ", which include inventions, computer software, and training technologies," immediately after "developments".

(2) Section 3(3) of such Act (15 U.S.C. 3702(3)) is amended by inserting ", including inventions, software, and training technologies," immediately after "developments".

Approved October 20, 1986.

LEGISLATIVE HISTORY—H.R. 3773:

HOUSE REPORTS: No. 99-415 (Comm. on Science and Technology) and No. 99-953 (Comm. of Conference).
SENATE REPORTS: No. 99-283 (Comm. on Commerce, Science, and Transportation).
CONGRESSIONAL RECORD:
Vol. 131 (1985): Dec. 9, considered and passed House.
Vol. 132 (1986): Aug. 9, considered and passed Senate, amended.
Oct. 3, Senate agreed to conference report.
Oct. 7, House agreed to conference report.

O

TITLE III—MISCELLANEOUS AMENDMENTS TO STEVENSON-WYDLER TECHNOLOGY INNOVATION ACT OF 1980

SEC. 301. COOPERATIVE RESEARCH AND DEVELOPMENT AGREEMENTS. Patents and trademarks.

Section 12 of the Stevenson-Wydler Technology Innovation Act of 1980 (15 U.S.C. 3710a) is amended—

(1) in subsection (a)(2), by striking "at the laboratory and other inventions" and inserting in lieu thereof "or other intellectual property developed at the laboratory and other inventions or other intellectual property"; and

(2) in subsection (b)—

(A) by striking "and" at the end of paragraphs (2) and (3);

(B) by redesignating paragraph (4) as paragraph (5); and

(C) by inserting after paragraph (3) the following new paragraph:

"(4) determine rights in other intellectual property developed under an agreement entered into under subsection (a)(1); and".

SEC. 302. REWARDS.

Section 13(1) of the Stevenson-Wydler Technology Innovation Act of 1980 (15 U.S.C. 3710b(1)) is amended by inserting "computer software," after "inventions, innovations,".

SEC. 303. DISTRIBUTION OF ROYALTIES.

(a) Section 14(a)(1)(A) of the Stevenson-Wydler Technology Innovation Act of 1980 (15 U.S.C. 3710c(a)(1)(A)) is amended—

(1) in clause (i), by striking "was an employee of the agency at the time the invention was made" and inserting in lieu thereof "has assigned his or her rights in the invention to the United States"; and

(2) in clause (ii), by striking "who were employed by the agency at the time the invention was made and whose names appear on licensed inventions" and inserting in lieu thereof "under clause (i)".

(b) This section shall be effective as of October 20, 1986. Effective date. 15 USC 3710c note.

Pub.L. 99–502, § 4(d)(2), in subsec. (f) as so redesignated struck out provision which had required that the report be transmitted to the Center for the Utilization of Federal Technology by Nov. 1 of each year in which it was due.

Subsec. (g). Pub.L. 99–502, § 5, added subsec. (g).

Superconductivity: National Action Plan on Superconductivity Research and Development. Secretary of Energy's superconductivity research and development program and submission of annual reports to Congress respecting technology transfer activities, see 15 U.S.C.A. § 5203.

Legislative History. For legislative history and purpose of Pub.L. 96–480, see 1980 U.S.Code Cong. and Adm.News, p. 4892. See, also, Pub.L. 99–502, 1986 U.S. Code Cong. and Adm. News, p. 3442; Pub.L. 100–418, 1988 U.S.Code Cong. and Adm.News, p. 1547; Pub.L. 100–519, 1988 U.S.Code Cong. and Adm. News, p. 3269; Pub.L. 101–189, 1989 U.S. Code Cong. and Adm. News, p. 838.

EXECUTIVE ORDERS

EXECUTIVE ORDER NO. 12591

Apr. 10, 1987, 52 F.R. 13414, as amended Ex.Ord. No. 12618, Dec. 22, 1987, 52 F.R. 48661

FACILITATING ACCESS TO SCIENCE AND TECHNOLOGY

By the authority vested in me as President by the Constitution and laws of the United States of America, including the Federal Technology Transfer Act of 1986 [Public Law 99–502] [Pub.L. 99–502, Oct. 20, 1986, 100 Stat. 1785], the Trademark Clarification Act of 1984 [Public Law 98–620] [Pub.L. 98–620, Nov. 8, 1984, 98 Stat. 3335], and the University and Small Business Patent Procedure Act of 1980 [Public Law 96–517] [Pub.L. 96–517, Dec. 12, 1980, 94 Stat. 3015], and in order to ensure that Federal agencies and laboratories assist universities and the private sector in broadening our technology base by moving new knowledge from the research laboratory into the development of new products and processes, it is hereby ordered as follows:

Section 1. Transfer of Federally Funded Technology.

(a) The head of each Executive department and agency, to the extent permitted by law, shall encourage and facilitate collaboration among Federal laboratories, State and local governments, universities, and the private sector, particularly small business, in order to assist in the transfer of technology to the marketplace.

(b) The head of each Executive department and agency shall, within overall funding allocations and to the extent permitted by law:

(1) delegate authority to its government-owned, government-operated Federal laboratories:

(A) to enter into cooperative research and development agreements with other Federal laboratories, State and local governments, universities, and the private sector; and

(B) to license, assign, or waive rights to intellectual property developed by the laboratory either under such cooperative research or development agreements and from within individual laboratories.

(2) identify and encourage persons to act as conduits between and among Federal laboratories, universities, and the private sector for the transfer of technology developed from federally funded research and development efforts;

(3) ensure that State and local governments, universities, and the private sector are provided with information on the technology, expertise, and facilities available in Federal laboratories;

(4) promote the commercialization, in accord with my Memorandum to the Heads of Executive Departments and Agencies of February 18, 1983, of patentable results of federally funded research by granting to all contractors, regardless of size, the title to patents made in whole or in part with Federal funds, in exchange for royalty-free use by or on behalf of the government;

(5) administer all patents and licenses to inventions made with federal assistance, which are owned by the non-profit contractor or grantee, in accordance with Section 202(c)(7) of Title 35 of the United States Code as amended by Public Law 98–620 [35 U.S.C.A. § 202(c)(7)],

without regard to limitations on licensing found in that section prior to amendment or in Institutional Patent Agreements now in effect that were entered into before that law was enacted on November 8, 1984, unless, in the case of an invention that has not been marketed, the funding agency determines, based on information in its files, that the contractor or grantee has not taken adequate steps to market the inventions, in accordance with applicable law or an Institutional Patent Agreement;

(6) implement, as expeditiously as practicable, royalty-sharing programs with inventors who were employees of the agency at the time their inventions were made, and cash award programs; and

(7) cooperate, under policy guidance provided by the Office of Federal Procurement Policy, with the heads of other affected departments and agencies in the development of a uniform policy permitting Federal contractors to retain rights to software, engineering drawings, and other technical data generated by Federal grants and contracts, in exchange for royalty-free use by or on behalf of the government.

Sec. 2. Establishment of the Technology Share Program. The Secretaries of Agriculture, Commerce, Energy, and Health and Human Services and the Administrator of the National Aeronautics and Space Administration shall select one or more of their Federal laboratories to participate in the Technology Share Program. Consistent with its mission and policies and within its overall funding allocation in any year, each Federal laboratory so selected shall:

(a) Identify areas of research and technology of potential importance to long-term national economic competitiveness and in which the laboratory possesses special competence and/or unique facilities;

(b) Establish a mechanism through which the laboratory performs research in areas identified in Section 2(a) as a participant of a consortium composed of United States industries and universities. All consortia so established shall have, at a minimum, three individual companies that conduct the majority of their business in the United States; and

(c) Limit its participation in any consortium so established to the use of laboratory personnel and facilities. However, each laboratory may also provide financial support generally not to exceed 25 percent of the total budget for the activities of the consortium. Such financial support by any laboratory in all such consortia shall be limited to a maximum of $5 million per annum.

Sec. 3. Technology Exchange—Scientists and Engineers. The Executive Director of the President's Commission on Executive Exchange shall assist Federal agencies, where appropriate, by developing and implementing an exchange program whereby scientists and engineers in the private sector may take temporary assignments in Federal laboratories, and scientists and engineers in Federal laboratories may take temporary assignments in the private sector.

Sec. 4. International Science and Technology. In order to ensure that the United States benefits from and fully exploits scientific research and technology developed abroad,

(a) The head of each Executive department and agency, when negotiating or entering into cooperative research and development agreements and licensing arrangements with foreign persons or industrial organizations (where these entities are directly or indirectly controlled by a foreign company or government], shall, in consultation with the United States Trade Representative, give appropriate consideration:

(1) to whether such foreign companies or governments permit and encourage United States agencies, organizations, or persons to enter into cooperative research and development agreements and licensing arrangements on a comparable basis;

(2) to whether those foreign governments have policies to protect the United States intellectual property rights; and

(3) where cooperative research will involve data, technologies, or products subject to national security export controls under the laws of the United States, to whether those foreign governments have adopted adequate measures to prevent the transfer of strategic technology to destinations prohibited under such national security export controls, either through participation in the Coordinating Committee for Multilateral Export Controls (COCOM) or through other international agreements to which the United States and such foreign governments are signatories.

(b) The Secretary of State shall develop a recruitment policy that encourages scientists and engineers from other Federal agencies, academic institutions, and industry to apply for assignments in embassies of the United States; and

(c) The Secretaries of State and Commerce and the Director of the National Science Foundation shall develop a central mechanism for the prompt and efficient dissemination of science and technology information developed abroad to users in Federal laboratories, academic institutions, and the private sector on a fee-for-service basis.

Sec. 5. Technology Transfer from the Department of Defense. Within 6 months of the date of this Order, the Secretary of Defense shall identify a list of funded technologies that would be potentially useful to United States industries and universities. The Secretary shall then accelerate efforts to make these technologies more readily available to United States industries and universities.

Sec. 6. Basic Science and Technology Centers. The head of each Executive department and agency shall examine the potential for including the establishment of university research centers in engineering, science, or technology in the strategy and planning for any future research and development programs. Such university centers shall be jointly funded by the Federal Government, the private sector, and, where appropriate, the States and shall focus on areas of fundamental research and technology that are both scientifically promising and have the potential to contribute to the Nation's long-term economic competitiveness.

Sec. 7. Reporting Requirements. (a) Within 1 year from the date of this Order, the Director of the Office of Science and Technology Policy shall convene an interagency task force comprised of the heads of representative agencies and the directors of representative Federal laboratories, or their designees, in order to identify and disseminate creative approaches to technology transfer from Federal laboratories. The task force will report to the President on the progress of and problems with technology transfer from Federal laboratories.

(b) Specifically, the report shall include:

(1) a listing of current technology transfer programs and an assessment of the effectiveness of these programs;

(2) identification of new or creative approaches to technology transfer that might serve as model programs for Federal laboratories;

(3) criteria to assess the effectiveness and impact on the Nation's economy of planned or future technology transfer efforts; and

(4) a compilation and assessment of the Technology Share Program established in Section 2 and, where appropriate, related cooperative research and development venture programs.

Sec. 8. Relation to Existing Law. Nothing in this Order shall affect the continued applicability of any existing laws or regulations relating to the transfer of United States technology to other nations. The head of any Executive department or agency may exclude from consideration, under this Order, any technology that would be, if transferred, detrimental to the interests of national security.

RONALD REAGAN

§ 3710a. Cooperative research and development agreements

(a) General authority

Each Federal agency may permit the director of any of its Government-operated Federal laboratories, and, to the extent provided in an agency-approved joint work statement, the director of any of its Government-owned, contractor-operated laboratories—

(1) to enter into cooperative research and development agreements on behalf of such agency (subject to subsection (c) of this section) with other Federal agencies; units of State or local government; industrial organizations (including corporations,

partnerships, and limited partnerships, and industrial development organizations); public and private foundations; nonprofit organizations (including universities); or other persons (including licensees of inventions owned by the Federal agency); and

(2) to negotiate licensing agreements under section 207 of Title 35, or under other authorities (in the case of a Government-owned, contractor-operated laboratory, subject to subsection (c) of this section) for inventions made or other intellectual property developed at the laboratory and other inventions or other intellectual property that may be voluntarily assigned to the Government.

(b) Enumerated authority

Under agreements entered into pursuant to subsection (a)(1) of this section, a Government-operated Federal laboratory, and, to the extent provided in an agency-approved joint work statement, a Government-owned, contractor-operated laboratory, may (subject to subsection (c) of this section)—

(1) accept, retain, and use funds, personnel, services, and property from collaborating parties and provide personnel, services, and property to collaborating parties;

(2) grant or agree to grant in advance, to a collaborating party, patent licenses or assignments, or options thereto, in any invention made in whole or in part by a laboratory employee under the agreement, retaining a nonexclusive, nontransferrable, irrevocable, paid-up license to practice the invention or have the invention practiced throughout the world by or on behalf of the Government and such other rights as the Federal laboratory deems appropriate;

(3) waive, subject to reservation by the Government of a nonexclusive, irrevocable, paid-up license to practice the invention or have the invention practiced throughout the world by or on behalf of the Government, in advance, in whole or in part, any right of ownership which the Federal Government may have to any subject invention made under the agreement by a collaborating party or employee of a collaborating party;

(4) determine rights in other intellectual property developed under an agreement entered into under subsection (a)(1) of this section; and

(5) to the extent consistent with any applicable agency requirements and standards of conduct, permit employees or former employees of the laboratory to participate in efforts to commercialize inventions they made while in the service of the United States.

A Government-owned, contractor-operated laboratory that enters into a cooperative research and development agreement under

subsection (a)(1) of this section may use or obligate royalties or other income accruing to such laboratory under such agreement with respect to any invention only (i) for payments to inventors; (ii) for the purposes described in section 3710c(a)(1)(B)(i), (ii), and (iv) of this title; and (iii) for scientific research and development consistent with the research and development mission and objectives of the laboratory.

(c) Contract considerations

(1) A Federal agency may issue regulations on suitable procedures for implementing the provisions of this section; however, implementation of this section shall not be delayed until issuance of such regulations.

(2) The agency in permitting a Federal laboratory to enter into agreements under this section shall be guided by the purposes of this chapter.

(3)(A) Any agency using the authority given it under subsection (a) of this section shall review standards of conduct for its employees for resolving potential conflicts of interest to make sure they adequately establish guidelines for situations likely to arise through the use of this authority, including but not limited to cases where present or former employees or their partners negotiate licenses or assignments of titles to inventions or negotiate cooperative research and development agreements with Federal agencies (including the agency with which the employee involved is or was formerly employed).

(B) If, in implementing subparagraph (A), an agency is unable to resolve potential conflicts of interest within its current statutory framework, it shall propose necessary statutory changes to be forwarded to its authorizing committees in Congress.

(4) The laboratory director in deciding what cooperative research and development agreements to enter into shall—

(A) give special consideration to small business firms, and consortia involving small business firms; and

(B) give preference to business units located in the United States which agree that products embodying inventions made under the cooperative research and development agreement or produced through the use of such inventions will be manufactured substantially in the United States and, in the case of any industrial organization or other person subject to the control of a foreign company or government, as appropriate, take into consideration whether or not such foreign government permits United States agencies, organizations, or other persons to enter into cooperative research and development agreements and licensing agreements.

(5)(A) If the head of the agency or his designee desires an opportunity to disapprove or require the modification of any such agreement presented by the director of a Government-operated laboratory, the agreement shall provide a 30-day period within which such action must be taken beginning on the date the agreement is presented to him or her by the head of the laboratory concerned.

(B) In any case in which the head of an agency or his designee disapproves or requires the modification of an agreement presented, by the director of a Government-operated laboratory under this section, the head of the agency or such designee shall transmit a written explanation of such disapproval or modification to the head of the laboratory concerned.

(C)(i) Any agency which has contracted with a non-Federal entity to operate a laboratory shall review and approve, request specific modifications to, or disapprove a joint work statement that is submitted by the director of such laboratory within 90 days after such submission. In any case where an agency has requested specific modifications to a joint work statement, the agency shall approve or disapprove any resubmission of such joint work statement within 30 days after such resubmission, or 90 days after the original submission, whichever occurs later. No agreement may be entered into by a Government-owned, contractor-operated laboratory under this section before both approval of the agreement under clause (iv) and approval under this clause of a joint work statement.

(ii) In any case in which an agency which has contracted with a non-Federal entity to operate a laboratory disapproves or requests the modification of a joint work statement submitted under this section, the agency shall promptly transmit a written explanation of such disapproval or modification to the director of the laboratory concerned.

(iii) Any agency which has contracted with a non-Federal entity to operate a laboratory or laboratories shall develop and provide to such laboratory or laboratories one or more model cooperative research and development agreements, for the purposes of standardizing practices and procedures, resolving common legal issues, and enabling review of cooperative research and development agreements to be carried out in a routine and prompt manner.

(iv) An agency which has contracted with a non-Federal entity to operate a laboratory shall review each agreement under this section. Within 30 days after the presentation, by the director of the laboratory, of such agreement, the agency shall, on the basis of such review, approve or request specific modification to such agreement. Such agreement shall not take effect before approval under this clause.

(v) If an agency fails to complete a review under clause (iv) within the 30-day period specified therein, the agency shall submit to the Congress, within 10 days after the end of that 30-day period, a report on the reasons for such failure. The agency shall, at the end of each successive 30-day period thereafter during which such failure continues, submit to the Congress another report on the reasons for the continuing failure. Nothing in this clause relieves the agency of the requirement to complete a review under clause (iv).

(vi) In any case in which an agency which has contracted with a non-Federal entity to operate a laboratory requests the modification of an agreement presented under this section, the agency shall promptly transmit a written explanation of such modification to the director of the laboratory concerned.

(6) Each agency shall maintain a record of all agreements entered into under this section.

(7)(A) No trade secrets or commercial or financial information that is privileged or confidential, under the meaning of section 552(b)(4) of Title 5, which is obtained in the conduct of research or as a result of activities under this chapter from a non-Federal party participating in a cooperative research and development agreement shall be disclosed.

(B) The director, or in the case of a contractor-operated laboratory, the agency, for a period of up to 5 years after development of information that results from research and development activities conducted under this chapter and that would be a trade secret or commercial or financial information that is privileged or confidential if the information had been obtained from a non-Federal party participating in a cooperative research and development agreement, may provide appropriate protections against the dissemination of such information, including exemption from subchapter II of chapter 5 of Title 5.

(d) Definitions

As used in this section—

(1) the term "cooperative research and development agreement" means any agreement between one or more Federal laboratories and one or more non-Federal parties under which the Government, through its laboratories, provides personnel, services, facilities, equipment, or other resources with or without reimbursement (but not funds to non-Federal parties) and the non-Federal parties provide funds, personnel, services, facilities, equipment, or other resources toward the conduct of specified research or development efforts which are consistent with the missions of the laboratory; except that such term does not include a procurement contract or cooperative agreement as those terms are used in sections 6303, 6304, and 6305 of Title 31;

(2) the term "laboratory" means—

(A) a facility or group of facilities owned, leased, or otherwise used by a Federal agency, a substantial purpose of which is the performance of research, development, or engineering by employees of the Federal Government;

(B) a group of Government-owned, contractor-operated facilities under a common contract, when a substantial purpose of the contract is the performance of research and development for the Federal Government; and

(C) a Government-owned, contractor-operated facility that is not under a common contract described in subparagraph (B), and the primary purpose of which is the performance of research and development for the Federal Government,

but such term does not include any facility covered by Executive Order No. 12344, dated February 1, 1982, pertaining to the Naval nuclear propulsion program; and

(3) the term "joint work statement" means a proposal prepared for a Federal agency by the director of a Government-owned, contractor-operated laboratory describing the purpose and scope of a proposed cooperative research and development agreement, and assigning rights and responsibilities among the agency, the laboratory, and any other party or parties to the proposed agreement.

(e) Determination of laboratory missions

For purposes of this section, an agency shall make separate determinations of the mission or missions of each of its laboratories.

(f) Relationship to other laws

Nothing in this section is intended to limit or diminish existing authorities of any agency.

(g) Principles

In implementing this section, each agency which has contracted with a non-Federal entity to operate a laboratory shall be guided by the following principles:

(1) The implementation shall advance program missions at the laboratory, including any national security mission.

(2) Classified information and unclassified sensitive information protected by law, regulation, or Executive order shall be appropriately safeguarded.

(Pub.L. 96–480, § 12, as added and renumbered § 11, Pub.L. 99–502, §§ 2, 9(e)(1), Oct. 20, 1986, 100 Stat. 1785, 1797; renumbered § 12, Pub.L. 100–418, Title V, § 5122(a)(1), Aug. 23, 1988, 102 Stat. 1438; Pub.L. 100–519, Title III, § 301, Oct. 24, 1988, 102 Stat. 2597; Pub.L. 101–189, Div. C, Title XXXI, § 3133(a), (b), Nov. 29, 1989, 103 Stat. 1675–1677.)

Historical and Statutory Notes

References in Text. Executive Order No. 12344, referred to in subsec. (d)(2), is set out as a note under 42 U.S.C.A. § 7158.

1989 Amendment. Subsec. (a). Pub.L. 101–189, § 3133(a)(1)(A), inserted ", and, to the extent provided in an agency-approved joint work statement, the director of any of its Government-owned, contractor-operated laboratories" after "Government-operated Federal laboratories" in provisions preceding par. (1).

Subsec. (a)(2). Pub.L. 101–189, § 3133(a)(1)(B), (C), substituted "(in the case of a Government-owned, contractor-operated laboratory, subject to subsection (c) of this section) for inventions made or other intellectual property developed at the laboratory and other inventions or other intellectual property that" for "for Government-owned inventions made or other intellectual property developed at the laboratory and other inventions or other intellectual property of Federal employees that".

Subsec. (b). Pub.L. 101–189, § 3133(a)(2)(A), inserted ", and, to the extent provided in an agency-approved joint work statement, a Government-owned, contractor-operated laboratory," after "Government-operated Federal laboratory" in provisions preceding par. (1).

Pub.L. 101–189, § 3133(a)(2)(C), following numbered paragraphs, added undesignated provisions that a Government-owned, contractor-operated laboratory that enters into a cooperative research and development agreement under subsec. (a)(1) of this section may use or obligate royalties or other income accruing to such laboratory under such agreement with respect to any invention only (i) for payments to inventors; (ii) for the purposes described in section 3710c(a)(1)(B)(i), (ii), and (iv) of this title, and (iii) for scientific research and development consistent with the research and development mission and objectives of the laboratory.

Subsec. (b)(2). Pub.L. 101–189, § 3133(a)(2)(B), substituted "a laboratory employee" for "a Federal employee".

Subsec. (c)(3)(A). Pub.L. 101–189, § 3133(a)(3), substituted "standards of conduct for its employees" for "employee standards of conduct".

Subsec. (c)(5)(A). Pub.L. 101–189, § 3133(a)(4), inserted "presented by the director of a Government-operated laboratory" after "any such agreement".

Subsec. (c)(5)(B). Pub.L. 101–189, § 3133(a)(5), inserted "by the director of a Government-operated laboratory" after "an agreement presented".

Subsec. (c)(5)(C). Pub.L. 101–189, § 3133(a)(6), added subpar. (C).

Subsec. (c)(7). Pub.L. 101–189, § 3133(a)(7), added par. (7).

Subsec. (d)(2). Pub.L. 101–189, § 3133(a)(8)(B), designated existing provisions in part as subpar. (A), added subpars. (B) and (C), and added provision, following subpar. (C), that such term does not include any facility covered by Executive Order No. 12344, dated February 1, 1982, pertaining to the Naval nuclear propulsion program.

Subsec. (d)(3). Pub.L. 101–189, § 3133(a)(8)(A), (C), added par. (3).

Subsec. (g). Pub.L. 101–189, § 3133(b), added subsec. (g).

1988 Amendment. Subsec. (a)(2). Pub.L. 100–519, § 301(1), inserted reference to other intellectual property, wherever appearing.

Subsec. (b)(4), (5). Pub.L. 100–519, § 301(2), added par. (4). Former par. (4) redesignated (5).

Magnetic Levitation Technology. Secretary of the Army, in cooperation with the Secretary of Transportation, authorized to conduct research and development activities on magnetic levitation technology with funds ($1,000,000 authorized for fiscal year 1990 and $4,000,000 authorized for fiscal year 1991) to remain available until expended, see section 417 of Pub.L. 101–640, set out as a note under 33 U.S.C.A. § 2313.

Contract Provisions. Section 3133(d) of Pub.L. 101–189; as amended Pub.L. 101–510, Div. A, Title VIII, § 828(a), Nov. 5, 1990, 104 Stat. 1607, provided that:

"(1) Not later than 150 days after the date of enactment of this Act [Nov. 29, 1989], each agency which has contracted with a non-Federal entity to operate a Government-owned laboratory shall propose for inclusion in that laboratory's operating contract, to the extent not already included and subject to paragraph (6), appropriate contract provisions that—

"(A) establish technology transfer, including cooperative research and development agreements, as a mission for the laboratory under section 11(a)(1) of the Stevenson-Wydler Technology Innovation Act of 1980 [section 3710(a)(1) of this title];

"(B) describe the respective obligations and responsibilities of the agency and the laboratory with respect to this part [sections 3131 to 3133 of Pub.L. 101-189]; and section 12 of the Stevenson-Wydler Technology Innovation Act of 1980 [this section];

"(C) require that, except as provided in paragraph (2), no employee of the laboratory shall have a substantial role (including an advisory role) in the preparation, negotiation, or approval of a cooperative research and development agreement if, to such employee's knowledge—

"(i) such employee, or the spouse, child, parent, sibling, or partner of such employee, or an organization (other than the laboratory) in which such employee serves as an officer, director, trustee, partner, or employee—

"(I) holds a financial interest in any entity, other than the laboratory, that has a substantial interest in the preparation, negotiation, or approval of the cooperative research and development agreement; or

"(II) receives a gift or gratuity from any entity, other than the laboratory, that has a substantial interest in the preparation, negotiation, or approval of the cooperative research and development agreement; or

"(ii) a financial interest in any entity, other than the laboratory, that has a substantial interest in the preparation, negotiation, or approval of the cooperative research and development agreement, is held by any person or organization with whom such employee is negotiating or has any arrangement concerning prospective employment;

"(D) require that each employee of the laboratory who negotiates or approves a cooperative research and development agreement shall certify to the agency that the circumstances described in subparagraph (C)(i) and (ii) do not apply to such employee;

"(E) require the laboratory to widely disseminate information on opportunities to participate with the laboratory in technology transfer, including cooperative research and development agreements; and

"(F) provides for an accounting of all royalty or other income received under cooperative research and development agreements.

"(2) The requirements described in paragraph (1)(C) and (D) shall not apply in a case where the negotiating or approving employee advises the agency that reviewed the applicable joint work statement under section 12(c)(5)(C)(i) of the Stevenson-Wydler Technology Innovation Act of 1980 [subsec. (c)(5)(C)(i) of this section] in advance of the matter in which he is to participate and the nature of any financial interest described in paragraph (1)(C), and where the agency employee determines that such financial interest is not so substantial as to be considered likely to affect the integrity of the laboratory employee's service in that matter.

"(3) Not later than 180 days after the date of enactment of this Act [Nov. 29, 1989], each agency which has contracted with a non-Federal entity to operate a Government-owned laboratory shall submit a report to the Congress which includes a copy of each contract provision amended pursuant to this subsection.

"(4) No Government-owned, contractor-operated laboratory may enter into a cooperative research and development agreement under section 12 of the Stevenson-Wydler Technology Innovation Act of 1980 [this section] unless—

"(A) that laboratory's operating contract contains the provisions described in paragraph (1)(A) through (F); or

"(B) such laboratory agrees in a separate writing to be bound by the provisions described in paragraph (1)(A) through (F).

"(5) Any contract for a Government-owned, contractor-operated laboratory entered into after the expiration of 150 days after the date of enactment of this Act [Nov. 29, 1989] shall contain the provisions described in paragraph (1)(A) through (F)."

"(6) Contract provisions referred to in paragraph (1) shall include only such provisions as are necessary to carry out paragraphs (1) and (2) of this subsection."

[Pub.L. 101-510, Div. A, Title VIII, § 828(b), Nov. 5, 1990, 104 Stat. 1607, provided that: "Paragraph (6) of 3133(d) of such Act [par. 6 of this note] as added

by subsection (a), shall apply only to contracts entered into after the date of enactment of this Act [Nov. 5, 1990]."]

Legislative History. For legislative history and purpose of Pub.L. 99-502, see 1986 U.S. Code Cong. and Adm. News, p. 3442. See, also, Pub.L. 100-418, 1988 U.S.Code Cong. and Adm. News, p. 1547; Pub.L. 100-519, 1988 U.S. Code Cong. and Adm.News, p. 3269; Pub.L. 101-189, 1989 U.S. Code Cong. and Adm. News, p. 838.

SUBJECT: PHS POLICY FOR ENSURING FAIRNESS OF ACCESS IN COOPERATIVE RESEARCH AND DEVELOPMENT AGREEMENTS

I. PURPOSE

This document establishes guidelines for PHS Federal Laboratories to ensure fairness in the process of initiating and developing a Cooperative Research and Development Agreement (CRADA).

II. BACKGROUND

The purpose of the Federal Technology Transfer Act of 1986 is to facilitate the transfer of commercially useful technologies from the Federal Laboratories into the private sector through collaborations under CRADAs. These agreements are intended to increase research and development interactions between Federal Laboratories and industry through joint participation in collaborative projects, including the provision of personnel, services and property. In addition, industry, but not the Federal Government, may provide funding.

The legislation gives the Federal Laboratories authority to negotiate terms and conditions with a wide range of parties. Although the legislation does not specify that CRADAs must be competed, the law does require that consideration shall be given to small business firms and consortia involving small business firms, and preference be given to business units located in the United States which agree that products resulting from the CRADAs shall be manufactured substantially in the United States.

Since procurement rules do not apply to CRADAs, the Federal Laboratories have considerable flexibility in determining how and with whom to enter into collaborations. However, the manner in which collaborators or sponsors are selected is important to both the importance and reality of fairness. The question of fairness will be viewed as particularly important by others who view themselves as qualified when the private sector partner selected stands to benefit substantially as a result of the collaboration.

Many legitimate collaborations between government and industry scientists have grown from informal exchanges between them. The policy described is intended to assist in allowing participation in CRADAs by a wide range of organizations, many of which do not have established relationships with PHS scientists.

III. APPLICABILITY

Four PHS agencies operate research laboratories which are affected by the Act: National Institutes of Health; Alcohol, Drug Abuse and Mental Health Administration; Centers for Disease Control; and Food and Drug Administration. For the purposes of this policy, each of these agencies is considered a PHS Federal Laboratory.

IV. POLICY

"The policy of the PHS is to facilitate the development of CRADAs with the private sector through a process that will ensure fairness and implement the preferences established by the Federal Technology Transfer Act."

V. GUIDELINES

This section establishes guidelines on the activities that PHS Federal Laboratories are encouraged to engage in, but are not limited to, to ensure that the opportunity to participate in a CRADA is given to all potentially interested organizations.

A. PUBLIC NOTIFICATION ACTIVITIES

The various public notification activities are described below.

1. Routine Announcements

Each PHS Federal Laboratory should implement a process for periodically informing outside parties of available collaborative opportunities and for encouraging access to the Federal Laboratories by industry. Federal Laboratories are encouraged to use at least one of the following activities on an annual basis:

(a) General Announcements. Publish an announcement which generally outlines the types of research opportunities available for collaboration and identifies a central point for interested parties to contact. General announcements can be made through the Federal Register; Commerce Business Daily; scientific, professional, and trade journals; or association publications.

(b) Industry Collaboration Forums. Conduct or participate in an Industry Collaboration Forum to bring together interested Federal Laboratory scientists and private sector company or other outside representatives.

(c) Directory Listing. If financially feasible, develop a directory listing of potential Federal Laboratory scientist collaborators, areas of research interests, and Government-owned patents available for licensing. This information would be provided at cost to all interested parties upon request. The general announcement could indicate that this directory is available.

Once an area of research that the Federal Laboratory is interested in collaborating on is included in a routine announcement, no additional public notification is needed before entering into a CRADA.

contractor ownership of the invention. Moreover, if the agency is concerned only about specific uses or applications of the invention, it shall consider leaving title in the contractor with additional conditions imposed upon the contractor's use of the invention for such applications or with expanded government license rights in such applications.

(d) A determination not to allow the contractor to retain title to a subject invention or to restrict or condition its title with conditions differing from those in the clause at § 401.14(a), unless made by the head of the agency, shall be appealable by the contractor to an agency official at a level above the person who made the determination. This appeal shall be subject to the procedures applicable to appeals under § 401.11 of this part.

§ 401.16 Submissions and inquiries.

All submissions or inquiries should be directed to Federal Technology Management Policy Division, telephone number 202-377-0659, Room H4837, U.S. Department of Commerce, Washington, DC 20230.

PART 404—LICENSING OF GOVERNMENT OWNED INVENTIONS

Sec.

AUTHORITY: 35 U.S.C. 208; sec. 3(g) of DOO 10-1.

SOURCE: 50 FR 9802, Mar. 12, 1985, unless otherwise noted.

§ 404.1 Scope of part.

This part prescribes the terms, conditions, and procedures upon which a federally owned invention, other than an invention in the custody of the Tennessee Valley Authority, may be licensed. It supersedes the regulations at 41 CFR Subpart 101-4.1. This part does not affect licenses which (a) were in effect prior to July 1, 1981; (b) may exist at the time of the Government's acquisition of title to the invention, including those resulting from the allocation of rights to inventions made under Government research and development contracts; (c) are the result of an authorized exchange of rights in the settlement of patent disputes; or (d) are otherwise authorized by law or treaty.

§ 404.2 Policy and objective.

It is the policy and objective of this subpart to use the patent system to promote the utilization of inventions arising from federally supported research or development.

§ 404.3 Definitions.

(a) "Federally owned invention" means an invention, plant, or design which is covered by a patent, or patent application in the United States, or a patent, patent application, plant variety protection, or other form of protection, in a foreign country, title to which has been assigned to or otherwise vested in the United States Government.

(b) "Federal agency" means an executive department, military department, Government corporation, or independent establishment, except the Tennessee Valley Authority, which has custody of a federally owned invention.

(c) "Small business firm" means a small business concern as defined in section 2 of Pub. L. 85-536 (15 U.S.C. 632) and implementing regulations of the Administrator of the Small Business Administration.

(d) "Practical application" means to manufacture in the case of a composition or product, to practice in the case of a process or method, or to operate in the case of a machine or system; and, in each case, under such condi-

tions as to establish that the invention is being utilized and that its benefits are to the extent permitted by law or Government regulations available to the public on reasonable terms.

(e) "United States" means the United States of America, its territories and possessions, the District of Columbia, and the Commonwealth of Puerto Rico.

§ 404.4 Authority to grant licenses.

Federally owned inventions shall be made available for licensing as deemed appropriate in the public interest. Federal agencies having custody of federally owned inventions may grant nonexclusive, partially exclusive, or exclusive licenses thereto under this part.

§ 404.5 Restrictions and conditions on all licenses granted under this part.

(a)(1) A license may be granted only if the applicant has supplied the Federal agency with a satifactory plan for development or marketing of the invention, or both, and with information about the applicant's capability to fulfill the plan.

(2) A license granting rights to use or sell under a federally owned invention in the United States shall normally be granted only to a licensee who agrees that any products embodying the invention or produced through the use of the invention will be manufactured substantially in the United States.

(b) Licenses shall contain such terms and conditions as the Federal agency determines are appropriate for the protection of the interests of the Federal Government and the public and are not in conflict with law or this part. The following terms and conditions apply to any license:

(1) The duration of the license shall be for a period specified in the license agreement, unless sooner terminated in accordance with this part.

(2) The license may be granted for all or less than all fields of use of the invention or in specified geographical areas, or both.

(3) The license may extend to subsidiaries of the licensee or other parties if provided for in the license but shall be nonassignable without approval of the Federal agency, except to the successor of that part of the licensee's business to which the invention pertains.

(4) The licensee may provide the license the right to grant sublicenses under the license, subject to the approval of the Federal agency. Each sublicense shall make reference to the license, including the rights retained by the Government, and a copy of such sublicense shall be furnished to the Federal agency.

(5) The license shall require the licensee to carry out the plan for development or marketing of the invention, or both, to bring the invention to practical application within a period specified in the license, and to continue to make the benefits of the invention reasonably accessible to the public.

(6) The license shall require the licensee to report periodically on the utilization or efforts at obtaining utilization that are being made by the licensee, with particular reference to the plan submitted.

(7) Licenses may be royalty-free or for royalties or other consideration.

(8) Where an agreement is obtained pursuant to § 404.5(a)(2) that any products embodying the invention or produced through use of the invention will be manufactured substantially in the United States, the license shall recite such agreement.

(9) The license shall provide for the right of the Federal agency to terminate the license, in whole or in part, if:

(i) The Federal agency determines that the licensee is not executing the plan submitted with its request for a license and the licensee cannot otherwise demonstrate to the satisfaction of the Federal agency that it has taken or can be expected to take within a reasonable time effective steps to achieve practical application of the invention;

(ii) The Federal agency determines that such action is necessary to meet requirements for public use specified by Federal regulations issued after the date of the license and such requirements are not reasonably satisfied by the licensee;

(iii) The licensee has willfully made a false statement of or willfully omitted a material fact in the license appli-

cation or in any report required by the license agreement; or

(iv) The licensee commits a substantial breach of a covenant or agreement contained in the license.

(10) The license may be modified or terminated, consistent with this part, upon mutual agreement of the Federal agency and the licensee.

(11) Nothing relating to the grant of a license, nor the grant itself, shall be construed to confer upon any person any immunity from or defenses under the antitrust laws or from a charge of patent misuse, and the acquisition and use of rights pursuant to this part shall not be immunized from the operation of state or Federal law by reason of the source of the grant.

§ 404.6 Nonexclusive licenses.

(a) Nonexclusive licenses may be granted under federally owned inventions without publication of availability or notice of a prospective license.

(b) In addition to the provisions of § 404.5, the nonexclusive license may also provide that, after termination of a period specified in the license agreement, the Federal agency may restrict the license to the fields of use or geographic areas, or both, in which the licensee has brought the invention to practical application and continues to make the benefits of the invention reasonably accessible to the public. However, such restriction shall be made only in order to grant an exclusive or partially exclusive license in accordance with this subpart.

§ 404.7 Exclusive and partially exclusive licenses.

(a)(1) Exclusive or partially exclusive domestic licenses may be granted on federally owned inventions three months after notice of the invention's availability has been announced in the FEDERAL REGISTER, or without such notice where the Federal agency determines that expeditious granting of such a license will best serve the interest of the Federal Government and the public; and in either situation, only if;

(i) Notice of a prospective license, identifying the invention and the prospective licensee, has been published in the FEDERAL REGISTER, providing opportunity for filing written objections within a 60-day period;

(ii) After expiration of the period in § 404.7(a)(1)(i) and consideration of any written objections received during the period, the Federal agency has determined that;

(A) The interests of the Federal Government and the public will best be served by the proposed license, in view of the applicant's intentions, plans, and ability to bring the invention to practical application or otherwise promote the invention's utilization by the public;

(B) The desired practical application has not been achieved, or is not likely expeditiously to be achieved, under any nonexclusive license which has been granted, or which may be granted, on the invention;

(C) Exclusive or partially exclusive licensing is a reasonable and necessary incentive to call forth the investment of risk capital and expenditures to bring the invention to practical application or otherwise promote the invention's utilization by the public; and

(D) The proposed terms and scope of exclusivity are not greater than reasonably necessary to provide the incentive for bringing the invention to practical application or otherwise promote the invention's utilization by the public;

(iii) The Federal agency has not determined that the grant of such license will tend substantially to lessen competition or result in undue concentration in any section of the country in any line of commerce to which the technology to be licensed relates, or to create or maintain other situations inconsistent with the antitrust laws; and

(iv) The Federal agency has given first preference to any small business firms submitting plans that are determined by the agency to be within the capabilities of the firms and as equally likely, if executed, to bring the invention to practical application as any plans submitted by applicants that are not small business firms.

(2) In addition to the provisions of § 404.5, the following terms and conditions apply to domestic exclusive and partially exclusive licenses;

(i) The license shall be subject to the irrevocable, royalty-free right of the

Government of the United States to practice and have practiced the invention on behalf of the United States and on behalf of any foreign government or international organization pursuant to any existing or future treaty or agreement with the United States.

(ii) The license shall reserve to the Federal agency the right to require the licensee to grant sublicenses to responsible applicants, on reasonable terms, when necessary to fulfill health or safety needs.

(iii) The license shall be subject to any licenses in force at the time of the grant of the exclusive or partially exclusive license.

(iv) The license may grant the licensee the right of enforcement of the licensed patent pursuant to the provisions of Chapter 29 of Title 35, United States Code, or other statutes, as determined appropriate in the public interest.

(b)(1) Exclusive or partially exclusive licenses may be granted on a federally owned invention covered by a foreign patent, patent application, or other form of protection, provided that;

(i) Notice of a prospective license, identifying the invention and prospective licensee, has been published in the FEDERAL REGISTER, providing opportunity for filing written objections within a 60-day period and following consideration of such objections;

(ii) The agency has considered whether the interests of the Federal Government or United States industry in foreign commerce will be enhanced; and

(iii) The Federal agency has not determined that the grant of such license will tend substantially to lessen competition or result in undue concentration in any section of the United States in any line of commerce to which the technology to be licensed relates, or to create or maintain other situations inconsistent with antitrust laws.

(2) In addition to the provisions of § 404.6 the following terms and conditions apply to foreign exclusive and partially exclusive licenses:

(i) The license shall be subject to the irrevocable, royalty-free right of the Government of the United States to practice and have practiced the invention on behalf of the United States and on behalf of any foreign government or international organization pursuant to any existing or future treaty or agreement with the United States.

(ii) The license shall be subject to any licenses in force at the time of the grant of the exclusive or partially exclusive license.

(iii) The license may grant the licensee the right to take any suitable and necessary actions to protect the licensed property, on behalf of the Federal Government.

(c) Federal agencies shall maintain a record of determinations to grant exclusive or partially exclusive licenses.

§ 404.8 Application for a license.

An application for a license should be addressed to the Federal agency having custody of the invention and shall normally include:

(a) Identification of the invention for which the license is desired including the patent application serial number or patent number, title, and date, if known;

(b) Identification of the type of license for which the application is submitted;

(c) Name and address of the person, company, or organization applying for the license and the citizenship or place of incorporation of the applicant;

(d) Name, address, and telephone number of the representative of the applicant to whom correspondence should be sent;

(e) Nature and type of applicant's business, identifying products or services which the applicant has successfully commercialized, and approximate number of applicant's employees;

(f) Source of information concerning the availability of a license on the invention;

(g) A statement indicating whether the applicant is a small business firm as defined in § 404.3(c)

(h) A detailed description of applicant's plan for development or marketing of the invention, or both, which should include:

(1) A statement of the time, nature and amount of anticipated investment of capital and other resources which applicant believes will be required to bring the invention to practical application;

(2) A statement as to applicant's capability and intention to fulfill the plan, including information regarding manufacuturing, marketing, financial, and technical resources;

(3) A statement of the fields of use for which applicant intends to practice the invention; and

(4) A statement of the geographic areas in which applicant intends to manufacture any products embodying the invention and geographic areas where applicant intends to use or sell the invention, or both;

(i) Identification of licenses previously granted to applicant under federally owned inventions;

(j) A statement containing applicant's best knowledge of the extent to which the invention is being practiced by private industry or Government, or both, or is otherwise available commercially; and

(k) Any other information which applicant believes will support a determination to grant the license to applicant.

§ 404.9 Notice to Attorney General.

A copy of the notice provided for in § 404.7 (a)(1)(i) and (b)(1)(i) will be sent to the Attorney General.

§ 404.10 Modification and termination of licenses.

Before modifying or terminating a license, other than by mutual agreement, the Federal agency shall furnish the licensee and any sublicensee of record a written notice of intention to modify or terminate the license, and the licensee and any sublicensee shall be allowed 30 days after such notice to remedy any breach of the license or show cause why the license shall not be modified or terminated.

§ 404.11 Appeals.

In accordance with procedures prescribed by the Federal agency, the following parties may appeal to the agency head or designee any decision or determination concerning the grant, denial, interpretation, modification, or termination of a license:

(a) A person whose application for a license has been denied.

(b) A licensee whose license has been modified or terminated, in whole or in part; or

(c) A person who timely filed a written objection in response to the notice required by § 404.7(a)(1)(i) or § 404.7(b)(1)(i) and who can demonstrate to the satisfaction of the Federal agency that such person may be damaged by the agency action.

§ 404.12 Protection and administration of inventions.

A Federal agency may take any suitable and necessary steps to protect and administer rights to federally owner inventions, either directly or through contract.

§ 404.13 Transfer of custody.

A Federal agency having custody of a federally owned invention may transfer custody and administration, in whole or in part, to another Federal agency, of the right, title, or interest in such invention.

§ 404.14 Confidentiality of information.

Title 35, United States Code, section 209, provides that any plan submitted pursuant to § 404.8(h) and any report required by § 404.5(b)(6) may be treated by the Federal agency as commercial and financial information obtained from a person and privileged and confidential and not subject to disclosure under section 552 of Title 5 of the United States Code.