A Critical Study on the Cooperative Research and Development Agreements of U.S. Federal Laboratories: Technology Commercialization and the Public Interest

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Abstract

The U.S. federal government has poured billions of dollars into nanoscience. The national laboratories such as NASA, Oak Ridge, Argonne, Lawrence Berkeley, Los Alamos, Sandia, and Brookhaven are conducting numerous research and development projects involving nanomaterials. In many cases, development and commercialization of new nanomaterial-based products will involve research collaborations between federal research laboratories and industry. These technical collaborations are generally governed by contracts known as “CRADAs.”

In 1986, the Congress of the United States passed the Federal Technology Transfer Act to amend the original Stevenson-Wydler Technology Innovation Act of 1980, and created the “Cooperative Research and Development Agreements” (CRADAs). Under the CRADAs system, the federal laboratories provide equipment and/or personnel, while the cooperating contractors, mainly private enterprises, provide funds to jointly commercialize technology originally generated from the federal labs. After adoption of CRADAs, cooperation between federal labs and private industries became more interactive, and many successful inventions have been made.

In contrast to the Bayh-Dole Act model, under which the government provides funds for universities and private industries, the CRADAs model allows the government (federal labs) to provide equipment, facilities, and/or personnel for the contractors, instead of funds. Consequently, the ownership of the intellectual property rights in relation to the research results under the two systems shall be different as well.

This article introduces the CRADAs system, including relevant statistics of CRADAs, and pros and cons of the CRADAs system as discussed by various U.S. scholars. This article also argues that certain precautionary measures need to be adopted to prevent potential conflicts of interest and unfairness to small companies as some U.S. scholars have criticized.

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I. Introduction

1. Importance of Cooperative Research for the Academic, Government, and Private Sectors

In the era of the knowledge-driven economy, a nation’s research capacity is critical to its national power and economic growth. As science progresses, the work of research, and late stage commercialization, demands an increasing amount of capital for meaningful investment. For example, statistics have shown the financial capital needed for research and development of a new drug approximately exceeds 800 million U.S. dollars.¹ Therefore, conventional research-oriented organizations, consisting of government-owned laboratories, academic institutions, and some private firms, started to ally with one another for a strategic collaboration to divide research expenditures, lower research risks, and share research personnel, faculty and even results.²

Such cross-organizational collaboration began since as early as World War II, when private companies sponsored academic institutions for part of research expenditure and engaged in cooperative research work.³ The U.S. Ministry of National Defense has long engaged in research for both military and civilian use, and during World War II lauded research faculty of academic institutions for facilitating specific research projects for military benefit.⁴ Such cooperative research among academia, government, and the private sector was initially formed at the National Defense Research Committee, founded by President Roosevelt in 1941, and was further verified along with the foundation of Office of Scientific Research and Development (OSRD) in 1942.⁵

At the time, however, the private firms that joined in cooperative research with the government undervalued the intellectual property and its ownership derived from such cooperative research, resulting in royalty-free, non-exclusive licensing to those collaborating firms by the government as a common norm. Such licensing might have been adequate at that time because those firms were generally large monopolies like AT&T and Bell Laboratories, in which the lack of ownership or exclusive license of intellectual property rights would not undermine their competitive edges against smaller companies.⁶

Nevertheless, other European countries and Japan have risen since the 1970’s in technology research and development, and have seriously threatened the long-held position of America, as science giant and leader.⁷ Since the late 1970’s, research results obtained by federal laboratories or funded by federal monies are relegated and entitled to the government only. And any use of these

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¹ See Joseph A. DiMasi et al, The Price of Innovation: New Estimates of Drug Development Costs, 22 J. HEALTH ECON. 151 (2003). Note that the research work and results articulated in this article include not only laboratory tests and publications but also patent filing and research result commercialization.


⁵ Kuhlman, supra note 2, at 321.


research results by a third party must be approved only through a great deal of administrative and regulatory procedure, where the use, if approved, would only be non-exclusive in most cases. Odds stacked against the private sector’s reach to the research results reasonably sabotages the company’s interests and draws attention away from the U.S. governmental and public review. Consequently, the policies governing ownership of research results shall be further studied in this article, and changes recommended, bringing about greater research collaboration by the academia, government and private sector.

2. U.S. Legislation for Cooperative Scientific Research

Given the objectives above, since 1980, the U.S. Congress has enacted a series of laws to promote technology transfer with substantial mechanisms and incentives. As the government offices take the leading role in promoting national research and innovation, legislation for technology transfer regulates two types of research: the federally funded research, and the cooperative research between federal government and private sectors. The former provides the government funds to academic institutes and/or private companies for research, while in the latter, the federal laboratories and cooperating contractors specifically enter into CRADAs to jointly conduct research.

The Bayh-Dole Act of 1980 established more boundaries regarding patents and licenses for federally funded research and development. Before the enactment of the Bayh-Dole Act, the U.S. government was entitled to federally funded inventions developed under federal funding agreements, and exclusive licensing of such inventions to private firms was generally prohibited. Government offices set up the corresponding personnel in charge of patent filing and (non-exclusive) licensing of the research results to private firms. Private firms had been unable to obtain titles and/or exclusive license to research results of academic institutions, resulting in unprotected return on investment in commercialization. Therefore, the U.S. private firms had lacked interest in research results of academic institutions. In 1978, the U.S. government funded academia with over USD 30 billion, generating 28 thousand patents, of which only 4% interested private firms and were successfully licensed.

The above situation was improved after the enactment of the Bayh-Dole Act, which eradicated the traditional policy that entitled the federally funded research results to the government, and

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10 About recent history of the U.S. legislation, see FEDERAL LABORATORY CONSORTIUM, FLC TECHNOLOGY TRANSFER DESK REFERENCE-A COMPREHENSIVE INTRODUCTION TO TECHNOLOGY TRANSFER, Appendix (2006).

11 In U.S. laws, the term “contractor” describes the party which cooperates with the government, and the contract of cooperation defines the legal relationship and obligations between the contracting party and the government. In this article, the term “contractor” is used to describe any private entity or party which has cooperative relationship with the government.


permitted the academic institutes, except in exceptional circumstances, to obtain the ownership of the patented invention. Consequently, academic institutes would be able to exclusively license, or even transfer the patent rights of inventions to private firms. Furthermore, regarding the patent rights of the inventions withheld by the funding agency before the enactment of the Bayh-Dole Act, or in accordance with the exceptional-circumstances clause (35 U.S.C. § 202), the Bayh-Dole Act also allows the federally owned inventions to be licensed exclusively by a federal agency to private firms for practical application. In general, the implementation of the Bayh-Dole Act has brought about excellent beneficial impacts in the following ways:

- It effectively facilitates cooperation and exchange between academia and the private sector;
- It provides incentive for academic research staffs to take interest in practical demands of industry, and solves problems for industry;
- It unifies the diverging patent policies among different federal agencies, and reduces the costs of patent filing and management for federal agencies; and
- It indirectly promotes economic growth stimulated by successful commercialization of research results.

The Stevenson-Wydler Technology Innovation Act of 1980 was the legislation enacted for cooperative research between federal government and private sectors, which aims to link the federal laboratories and industry for quick transition of federal laboratories owned research results to private commercialization. Consequently, the Stevenson-Wydler Technology Innovation Act requires that federal laboratories shall ensure federally funded research results to be fully capitalized by transferring inventions at best effort to States, local governments, and/or private firms. Furthermore, the Act requires that each federal laboratory shall establish an Office of Research and technology Applications (ORTA), which functions to provide and disseminate information on federally owned or originated inventions having potential commercial applications to private firms

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14 The funding agency may retain title to research results in some exceptional circumstances. See 35 U.S.C. § 202.

15 The scope of application for the Bayh-Dole Act does not allow only academic institutes but also private firms that receive federal funds and research assignment, to obtain the title to the patent of research results. However, in most cases, academic institutes receive federal funds and research assignment. In this article, “academic institute(s)” is used to represent any entity that receives federal funds and research assignment.


18 15 U.S.C. § 3710(a)(1): 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.

19 15 U.S.C. § 3710(b): 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.
of interest as well as to cooperate with and assist other agencies or institutes to provide technical assistance to private firms of interest.\textsuperscript{20}

This Act also authorized the Department of Commerce to establish the Center for the Utilization of Federal Technology (CUFT),\textsuperscript{21} which was later renamed as the National Technical Information Service in the Department of Commerce (NTIS), to serve as the exchange center for all federally owned patent and technology information. NTIS is obligated to collect all federally owned patent and technology information, and disseminate information to government agencies and private industry that may have particular needs.\textsuperscript{22} The Act also specifies that the President shall periodically award the National Technology and Innovation Medal, to individuals or companies, which 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.\textsuperscript{23}

Based on the same perspective, the U.S. Congress passed the \textit{Federal Technology Transfer Act (FTTA)} of 1986, which was later adopted into the \textit{Stevenson-Wydler Technology Innovation Act}, with enclosure of the Cooperative Research and Development Agreements (CRADAs) that established the legal basis for cooperative research between the federal laboratories and private sector, and the scope of application was expanded in later legislation.\textsuperscript{24}

According to the Stevenson-Wydler Technology Innovation Act, the term “CRADA” is defined as “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, intellectual property, 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, intellectual property, or other resources toward the conduct of specified research or development efforts which are consistent with the missions of the laboratory.”\textsuperscript{25} In short, the core system of CRADAs links the research resources of and builds the cooperative mechanism for both the federal laboratories and private sectors under cooperative research between federal and non-federal parties. The substantial mechanism can be broken down into several fundamental elements: private funds, government resources, cooperative research, and shared research results. Additionally, FTTA of 1986 stipulates that the head of the agency or laboratory, or such individual’s designee, shall pay each year at least 15 percent of the royalties or other payments to the inventor or co-inventors for encouraging them to participate in inventions related to livelihood economy, as well as related technology transfer.\textsuperscript{26}

\textsuperscript{20} Id.


\textsuperscript{22} For details for the Stevenson-Wydler Technology Innovation Act, see \textit{GENERAL ACCOUNTING OFFICE, FEDERAL AGENCY EFFORTS IN TRANSFERRING AND REPORTING NEW TECHNOLOGY} (GAO-03-47, 2002); see also Linda A. Mabry, \textit{Multinational Corporations and U.S. Technology Policy: Rethinking the Concept of Corporate Nationality}, 87 Geo. L.J. 563, 637-39 (1999).

\textsuperscript{23} 15 U.S.C. § 3711(b).


\textsuperscript{25} 15 U.S.C. § 3710(d)(1).

\textsuperscript{26} 15 U.S.C. § 3710c(a)(1)(A)(i):
As previously mentioned, the U.S. legislation regulates two types of cooperative research arrangements: government funded research regulated by the Bayh-Dole Act, and cooperation between federal government and private sectors regulated by the Stevenson-Wydler Technology Innovation Act. The former cooperation contains “government funds and private resources,” while the latter cooperation consists “government resources and private funds.” According to current U.S. legislation, the Bayh-Dole Act and the Stevenson-Wydler Technology Innovation Act, respectively being applicable to different potential contractors and situations, altogether build up a complete legal system for a variety of cooperation models between the academia, government, and private sectors.

### Table 1. Comparison between the Bayh-Dole Act and the Stevenson-Wydler Technology Innovation Act

<table>
<thead>
<tr>
<th></th>
<th>Bayh-Dole Act</th>
<th>Stevenson-Wydler Technology Innovation Act</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Cooperation Types</strong></td>
<td>Government funds</td>
<td>Cooperation between federal government and private sectors</td>
</tr>
<tr>
<td><strong>Main Party</strong></td>
<td>Federal agencies</td>
<td>Federal laboratories</td>
</tr>
<tr>
<td><strong>Potential Co-operating Contractors</strong></td>
<td>Universities, research institutes, or private firms</td>
<td>Other federal agencies; units of State or units of local government; industrial organizations, including: companies, partnerships, limited partnerships, and industry development organizations; public and private foundations; nonprofit organizations, including universities; or other third parties including licensees of federally owned inventions.</td>
</tr>
<tr>
<td><strong>Ownership of Research Results</strong></td>
<td>(1) Funded academic institute or private firm may retain the title to the research results. (2) Government agency obtains non-exclusive, irrevocable, royalty-free license.</td>
<td>(1) Basically, the government retains the title to the research results, and contractors obtain the exclusive license. (2) Contractors retain the title to the research results, if the result is solely developed by the contractors. (3) In (2), the government obtains non-exclusive, irrevocable, royalty-free license.</td>
</tr>
</tbody>
</table>

27 35 U.S.C.§ 202(c)(1),(2),(3),(6). The right to the research results herein is specified as patent rights only.

II. Essential Contents and Current Practice of CRADAs

1. Essential Contents of CRADAs

   A. Definition of the Federal Laboratories

      According to the Stevenson-Wydler Technology Innovation Act of 1980, the term of federal 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.”

      As abovementioned, a government-owned contractors-operator (GOCO) is also defined as a federal laboratory. Currently there are over 700 federal laboratories and research centers in U.S.

      Interestingly, the definition of federal laboratory is so general that it actually incurred a dispute about whether the Yellowstone National Park could be interpreted as a federal laboratory and then could legitimately execute CRADAs with private enterprises. In view of this example, it can be inferred that the scope of CRADAs is far more than generally recognized, and not limited to merely science and technology research-oriented federal laboratories.

   B. Mutually Shared Research Costs by Both Parties

      The essence of CRADAs is the shared research costs, where the government provides laboratory resources such as personnel, equipment, services, facility and/or other intellectual properties, while the cooperating contractors may also provide similar resources, in addition to private funds. The government cannot provide governmental funds to the cooperating contractors because any governmental fund may be considered as the procurement for cooperating contractors’ labor services, and thus the Federal Acquisition Regulation (FAR) and relevant regulations may comply.

   C. Federal Laboratories May Transfer the Patent and Other Rights Derived from Research Results to the Cooperating Contractors

      Federal laboratories may exclusively or non-exclusively license the patent rights derived from the research results to the cooperating contractors, or even in advance waive any title to research results derived from CRADAs. However, in practice, federal laboratories rarely waive the rights to research results in advance. As mentioned, such waiver only has precedence in the research result solely completed by the cooperating contractors.

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32 See Everett M Rogers et al, Cooperative Research and Development Agreement (CRADA) as Technology Transfer Mechanisms, 28(2) R&D MANAGEMENT 79, 80 (1998). In this article, it is summarized as “private funds and government resources.”


34 See Kneller, supra note 28, at 352.
D. Federal Laboratories Researchers May Conditionally Practice Technology Commercialization

Under certain conditions, federal laboratories allow researchers to practice further commercialization activities for research results derived from CRADAs. In such situations, federal laboratories shall resolve the underlying conflicts of interest incurred during the process of commercialization activities.35

E. Selection of Cooperating Contractors Shall Abide by Specified Principles

In the selection of cooperating contractors for CRADAs, the federal laboratory directors shall take priority in the following: (1) small business firms, (2) consortia participated in by small business firms, (3) business firms that substantially produce in U.S. When cooperating contractors are global businesses, the federal laboratory directors shall take into account whether the government of the cooperating contractors would approve similar cooperation agreements executed with the U.S. business.36

F. Faster Review for CRADA Proposals by Federal Departments

Competent authorities in charge of federal laboratories shall consider and make a decision on the CRADAs proposed by the federal laboratory directors within thirty days (GOGO) or ninety days (GOCO), which is much shorter than the six to nine month period specified by the early CRADAs regulation of the 1990's.37

G. Formulation of Standard CRADA

Competent authorities in charge of federal laboratories shall formulate the standard template for CRADAs to facilitate subsequent CRADA enactment.38 Currently, different institutions have drawn up a number of CRADAs versions, and there is no uniform CRADA available.39

H. Regulations for the March-in Right

i. Conception of the March-in Right

When the U.S. Congress reviewed the Bayh-Dole Act in 1979, a dispute was raised that an enterprise may acquire a license granted by an academic institution at low cost and cease further commercialization of acquired research results afterwards. The purpose of such license acquisition mainly serves to prevent its commercial competitors from obtaining this research result and to secure its current market share, rather than furthering product development and economic facilitation, resulting in a completely opposite outcome antagonistic towards the original legislative intent. The U.S. Congress considered this possibility and afterwards inserted the march-in right into the Bayh-Dole Act, in order to secure the rights of the federal agency with regard to the proper management of the academic institute’s research results. The Stevenson-Wydler Technology Innov-
tion Act also stipulates the march-in right for the government, in which the legislative intent and specifications resemble the Bayh-Dole Act.

ii. Timing for Government’s March-in

If a laboratory assigns title or grants an exclusive license to such an invention, the Government shall retain the right—

(i) to require the collaborating party to grant to a responsible applicant a nonexclusive, partially exclusive, or exclusive license to use the invention in the applicant’s licensed field of use, on terms that are reasonable under the circumstances; or

(ii) if the collaborating party fails to grant such a license, to grant the license itself.40

iii. Exercise of the March-in Right

The Government may exercise its march-in right only in exceptional circumstances and only if the Government determines that—41

(i) the action is necessary to meet health or safety needs that are not reasonably satisfied by the collaborating party;

(ii) the action is necessary to meet requirements for public use specified by Federal regulations, and such requirements are not reasonably satisfied by the collaborating party; or

(iii) the collaborating party has failed to comply with an agreement containing provisions described in 15 U.S.C. § 3710a(c)(4)(B) (to give small business priority).42

iv. Income Accruing to the Federal Laboratory under CRADAs

A Federal laboratory that enters into a CRADA may use or obligate royalties or other income accruing to the laboratory under such agreement with respect to any invention only—43

(i) for payments to inventors;

(ii) to reward scientific, engineering, and technical employees of the laboratory, including developers of sensitive or classified technology, regardless of whether the technology has commercial applications;44

(iii) to further scientific exchange among the laboratories of the agency;45

(iv) for education and training of employees consistent with the research and development missions and objectives of the agency or laboratory, and for other activities that increase the potential for transfer of the technology of the laboratories of the agency.46

41 Id.
(v) for payment of expenses incidental to the administration and licensing of intellectual property by the agency or laboratory with respect to inventions made at that laboratory, including the fees or other costs for the services of other agencies, persons, or organizations for intellectual property management and licensing services.\textsuperscript{47}

v. Preference for Small Business Firms

The laboratory director in deciding which CRADAs to enter into shall give special consideration to small business firms, and consortia involving small business firms.\textsuperscript{48} Such consideration is widely recognized as a preference for small business firms, which aims at fostering small business firms for joint technical cooperation and technology transfer.

vi. Regulations for Conflicts of Interest

Any agency using the authority given it under subsection (a) of 15 U.S.C. § 3710a shall review standards of conduct for its employees for resolving potential conflicts of interest to make sure that adequate guidelines are established for situations likely to arise through the use of this authority. If, in implementing such resolution, 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 competent committees in the U.S. Congress.\textsuperscript{49}

2. Effects of CRADAs Implementation

Like the Bayh-Dole Act, the Stevenson-Wydler Technology Innovation Act and CRADAs have had a significant impact on technology transfer. Government offices, such as the Center for Utilizing Federal Technology (CUFT) and the National Technical Information Service (NTIS), have amassed substantial statistics about CRADAs execution and implementation for long-term follow-up. With regard to the executed CRADAs, the number of active CRADAs has leaped from 98 in 1988 to about 1300 by the end of 1992.\textsuperscript{50} Other indicators in Table 2 below also show that CRADAs implementation even after only five years has made significant impact on the number of patent applications filed, patents issued, patents licensed, and the amount of license income.

<table>
<thead>
<tr>
<th>FY</th>
<th>1987</th>
<th>1991</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of Patent Applications Filed</td>
<td>848</td>
<td>1936</td>
</tr>
<tr>
<td>Number of Inventions Disclosed</td>
<td>2662</td>
<td>4200</td>
</tr>
<tr>
<td>Number of Licenses Granted by Federal Agencies</td>
<td>128</td>
<td>261</td>
</tr>
<tr>
<td>License Income (USD)</td>
<td>4.9M</td>
<td>18M</td>
</tr>
</tbody>
</table>

The tables below demonstrate the substantial numbers of patent applications filed, patents issued, patents licensed, and the amount of license income under CRADAs from 2001 to 2009.


\textsuperscript{51} Id.
According to Table 3 above, from 2001 to 2009 except few years, the number of active CRADAs has been steadily climbing from 3,760 to 7,733 CRADAs, resulting in a 205.7% growth. If compared with the numbers in 1988 and 1992, the growth has been relatively higher, which in turn promotes other forms of development of federal laboratories and academic institutes or business firms.

Table 4 demonstrates no significant increase on the numbers of patent applications filed and patents issued, yet not the number of inventions disclosed. This phenomenon could be caused by high costs of patent applications. After decades of patent maintenance and accumulation, technology application offices may take more caution in evaluating the cost and benefits of patent filing and maintenance, and in deciding whether to file more patent applications.

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53 Id.

54 See NIST supra note 52, at 10; DOC, at 23.

55 The factors in patent filing costs vary in the followings: nature of technology, information provided to the patent agent, and degree of invention disclosure, etc. After the patent application is filed, a system for patent application management would be required to archive and categorize all generated documentation, including drafts, office letters, receipts and invoices, etc. Additionally, an accounting system would be needed to track costs spent during the patent application, especially when tracking of the costs of patent filing and maintenance is sometimes a big issue in many countries. See Stephen P. Auvil & Wendy C. Martin, Working with Patent Counsel and Managing the Patenting Process, AUTM Technology Transfer Practice Manual 3rd Edition, Vol. Two Part 1, Chapter 8.5, 193, at 199-200, 209-10 (2006).
Table 5. Statistics of Patents of Research Results Licensed by Federal Laboratories from Fiscal Year 2001 to 2009\textsuperscript{56}

<table>
<thead>
<tr>
<th>FY</th>
<th>2001</th>
<th>2002</th>
<th>2003</th>
<th>2004</th>
<th>2005</th>
<th>2006</th>
<th>2007</th>
<th>2008</th>
<th>2009</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of Patents Licensed</td>
<td>4394</td>
<td>6065</td>
<td>6497</td>
<td>7567</td>
<td>9577</td>
<td>10186</td>
<td>10352</td>
<td>11098</td>
<td>10913</td>
</tr>
<tr>
<td>Amount of License Income (Mil. USD)</td>
<td>80.27</td>
<td>88.72</td>
<td>97.29</td>
<td>99.52</td>
<td>144.86</td>
<td>138.69</td>
<td>149.9</td>
<td>170.9</td>
<td>154.28</td>
</tr>
</tbody>
</table>

Table 5 reveals that under CRADAs, the number of patents licensed by U.S. federal laboratories has significantly increased from 4,394 in 2001 to around 11,000 in 2008 and 2009, bringing about a growth of 260%. The amount of license income also reached a phenomenal USD 170 million in 2008 (although slightly decreased in 2009), which became a large portion of revenue for federal laboratories.

3. Examples and Disputes of CRADAs

There are many examples of CRADAs. In the abovementioned NIST Report, there are many successes where institutions facilitated the development of new products under CRADAs. However, the most controversial CRADA signed was regarding a new anti-cancer drug Taxol by the U.S. National Cancer Institute (NCI) and Bristol-Myers Squibb (BMS).\textsuperscript{57} The CRADA with BMS successfully helped develop an important anti-cancer drug, but subsequently a number of controversies arose, and thus it is frequently used as a complex example of CRADA for both CRADAs practice and potential conflicts of interest.

NCI spent thirty years on research of an anti-cancer drug Taxol and achieved initial success on its verified medical effect. Though was Taxol to be officially produced into market, a new drug application (NDA) attached with a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such drug was required to be submitted to the Food and Drug Administration (FDA) according to the U.S. Federal Food, Drug, and Cosmetic Act.\textsuperscript{58} However, a research organization such as NCI was neither capable of mass production of such drug or a sufficiently full description for the new drug application (NDA).

In order to successfully market Taxol, on August 1, 1989, NCI solicited bids in the Federal Register for a CRADA to develop Taxol commercially. BMS had the most experience with developing cancer drugs and with large-scale drug marketing in the United States. Further, some BMS officials were familiar with Taxol through previous employment at NCI. In 1991, NCI signed a CRADA with BMS to obtain FDA approval to commercially develop Taxol.\textsuperscript{59} Certain provisions in the CRADA

\textsuperscript{56} See NIST supra note 52, at 14-17DOC, at 29-30.


\textsuperscript{58} 21 U.S.C. § 355(b)(1)(D).

\textsuperscript{59} Frisvold & Day-Rubenstein, supra note 57, at 562.
were highly protective of BMS, such as the following: (i) NCI would provide its own raw clinical trial data exclusively to BMS; (ii) NCI would urge outside researchers it funded at universities and hospitals to cooperate with BMS; and (iii) NCI would work exclusively with BMS to develop and market Taxol. Reciprocally, BMS would provide NCI with enough Taxol to undergo clinical trials and other research, as well as funds for certain research projects.60

Furthermore, it is noteworthy that the initial version of CRADA included “a reasonable pricing clause,” which stated that 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.”61 The final version of the CRADA signed in 1991, however, excluded the reasonable pricing clause at the insistence of BMS.62

These exclusively protective provisions aroused much public concern, though some scholars considered these provisions necessary protection for BMS’ investment, given that Taxol was not allowed for patent protection at then.63 Nonetheless, in addition to these CRADA provisions, NCI further negotiated with the Bureau of Land Management (BLM) to grant BMS exclusive access to yew bark, the original ingredient of Taxol, on federal lands.64 Consequently, even without particular patent protection, BMS literally exclusively controlled proprietary medical data needed for FDA approval and exclusive rights to harvest bark on federal lands.

It is generally regarded that NCI and BLM did not charge BMS proportionally large prices for the exclusive access of harvesting yew bark. From 1993 to 2002, BMS generated revenue of USD 9 billion in Taxol sales, and the U.S. government only charged BMS USD 35 million as “tax”.65 Therefore, the U.S. government has come under moderate criticism for not responding accordingly, especially in the omission of the reasonable pricing clause.66 Nevertheless, certain scholars doubted that a policy of high mark-up pricing for harvesting yew bark by BLM would have caused BMS to boost drug price and ultimately sabotage overall welfare of cancer patients.67

III. Pros and Cons of CRADAs

According to the tables above, it seems that the implementation of CRADAs has had a positive influence since its inception in 1981. Both the number of CRADAs and patents licensed, and the amount of license income have shown progressive growth yearly. However, regarding the overall effectiveness of CRADAs, no consensus has been reached by U.S. federal agencies and scholars. The following multi-perspective summary examines the pros and cons of CRADAs, including criticisms leveled and suggestions proposed.

60 See Kelly A. Day & George B. Frisvold, Medical Research and Genetics Resources Management: the Case of Taxol, CONTEMP. POL’Y ISSUES, at 1, 1-11 (1993).
61 See Frisvold & Day-Rubenstein, supra note 57, at 563, also Kane, supra note 57, at 317.
63 Frisvold & Day-Rubenstein, supra note 57, at 563.
64 Id.
65 See U.S. GENERAL ACCOUNTING OFFICE, supra note 62, at 3.
67 Frisvold & Day-Rubenstein, supra note 57, at 564-65.
1. Benefits of CRADAs

It is generally recognized that the legislation of the Federal Technology Transfer Act in 1986 was fundamental in assigning individual laboratories the right to manage intellectual properties and resulting royalty income.68 That is, federal laboratories have the right to retain royalty income as much as 5% of the annual institutional budget for technology transfer fees, payments to inventors, and costs of further scientific research and development.69 Without such retained royalty income, Federal laboratories may not be able to engage in relevant collaborative research and technology transfer.

Additionally, joint research with federal laboratories enables cooperating contractors to make practical use of emerging technical expertise, reduce research uncertainty, and explore development scope.70 Public benefits of technology transfer, helped by cooperating contractors, include 1) facilitating the foundation and early stage research results of federal laboratories, 2) curtailing the amount of time required to market the research results, and 3) making governmentally funded research results of federal laboratories to open to the public.71

2. Restrictions on Cooperating Contractors Regulated by CRADAs

CRADAs policy specifies a number of restrictions placed on private business cooperating contractors about the execution procedure with, and IP rights granted by, federal laboratories:

(i) cooperating contractors may be licensed the patent right of the research result that is solely developed by cooperating contractors. However, cooperating contractors seldom retain such rights. For instance, Public Health Service (PHS) model CRADA grants CRADA collaborators only an exclusive option to elect an exclusive or nonexclusive commercialization license.72 Furthermore, copyright protection is not available for any work of the United States Government, consequently the CRADA collaborators are not entitled to claim copyrights of any publication jointly produced with the United States Government.73

(ii) the exclusive license to the CRADA collaborators shall be subject to the irrevocable, nonexclusive, royalty-free right of the United States Government to practice or have practiced the invention, therefore the CRADA collaborators cannot retain full right of the research results.74

(iii) despite a lack of restrictions on the CRADA collaborators’ qualifications, the Federal Technology Transfer Act specifies the federal agency shall give first preference to any local small business firms, whose number of employees does not exceed 500, and are located in the United States and owned by U.S. permanent residents.75

68 See Kneller, supra note 28, at 353.
72 See Kneller, supra note 28, at 352.
74 37 C.F.R. § 404.7(a)(2)(i), (b)(2).
75 37 C.F.R. § 404.7(a)(1)(iv):
(iv) the CRADA collaborators are required to substantially manufacture the inventions made under the cooperative research and development agreement or produced through the use of such inventions in the United States, that is, the core parts should be manufactured in the United States.76

3. Criticisms on CRADAs

i. More Restrictive and Less Appealing CRADAs

Certain scholars and working professionals consider CRADAs an essential bridging channel for cooperation between federal laboratories and cooperating contractors, and thus should be promoted for further facilitation of U.S. economic development and scientific and technical research. Nonetheless, the laws may have imposed over-restrictive regulations upon the ownership of intellectual property and relating issues, causing CRADAs to become less appealing to cooperating contractors. Such criticisms may be categorized as below:

(i) Ownership of Intellectual Property Rights

CRADA restrictions on private business cooperating contractors, prompted negative comments from private business. From the private business perspective, the fact that under most circumstances, government agencies could retain the right to the intellectual properties will hinder the business model for CRADAs research collaboration. Owing to the concern from private business, in 1994 Senator Rockefeller proposed to change the current scheme by mandating transfer of ownership of patent rights derived under CRADAs to the private sector;77 but this bill was rejected because the House believed the passage of this proposal would deprive negotiating power of federal laboratories contemplating collaboration with private industrial partners and therefore result in unfavorable positions for the U.S. government and public.78

(ii) Prolonged Administration Procedures

Before federal laboratories enter into a CRADA with a collaborating contractor, it is required to announce this in the Federal Register unless such federal laboratory ensures that only this one particular collaborating contractor is qualified for the specific collaborative research project. In addition to the abovementioned restrictions of CRADAs upon cooperating contractors, an individual government agency could itself retain the right to impose specific regulations and requirements on CRADAs.79 Consequently, many industrial partners are reluctant to enter into CRADAs with federal laboratories in light of potential prolonged administration procedures and excessive time consumption.80

(iii) Lack of Protection to U.S. Research Results

“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.”


77 See Senate Bill 1537, Rockefeller, and its House counterpart, H.R. 3590, Morella.

78 See Wisner, supra note 50, at 198.


Another criticism is that the original intent of CRADAs served to boost the U.S. national competitiveness, but actually CRADAs practice benefited non-U.S. based industry as well, and hence lost the first-mover advantage in the global market.\(^{81}\) The Federal Technology Transfer Act specified that special preference shall be given to business units located in the United States which encourages that products embodying inventions made under CRADAs will be manufactured substantially in the United States. However, the reciprocal beneficial policy allowed federal laboratories to select foreign businesses whose governments permits U.S. agencies, organizations, or other persons to enter into CRADAs and licensing agreements.\(^{82}\)

### ii. CRADAs as Wrongful Public Policy with Outweighed Shortcomings to U.S. Public

Other scholars took an opposite stance from those who considered CRADAs overly restrictive and hardly appealing. They deemed CRADAs as a generally damaging and wrongful public policy, and advocated abolishing them. Three reasons for that could be categorized as below:

#### iii. Resultant Political Bribery and Conflicts of Interest

CRADAs are the contracts entered by federal laboratories and cooperating contractors with the following features: CRADAs provisions could be negotiated by federal laboratories and cooperating contractors without public review, and no third party has any authority to suggest and comment differently. In order to facilitate government-industry cooperation, project staffs tend to overestimate the output of a project and underestimate necessary costs. Moreover, because the Federal Technology Transfer Act regulates that project staff involved in the product commercialization could be entitled to 15 percent of revenue sharing, consequently, such statutory regulation triggers government agency to be more eager than private sector to achieve patent licensing, resulting likelihood of underestimation of research results.\(^{83}\)

#### iv. Back-to-back Funding to Large Business

The Federal Technology Transfer Act clearly specifies the preference to small business firms, but as a practical matter, it runs otherwise because federal laboratories usually have large-scale projects with high cost beyond many mid-to-small business firms’ financial reach. As a result, federal laboratories tend to select large business firms which have adequate resources and staffs for the project. It turns out that CRADAs model virtually provides back-to-back funding to large business firms: first, they are allowed access to federal laboratories’ personnel and facility for research, and second, research success grants them exclusive license. It would have adverse effects to small business firms’ competition and survival, and contradict the legislative intent for CRADAs and the purported special preference for small business firms.\(^{84}\)

#### v. Current Industrial Environment Does Not Need Realization of Governmentally Funded Commercialization Given Different Time Background

Some academic publications state that in the early years of biotechnology R&D, the gap between biotechnology research results and its commercialization was broad, and the regulatory infrastructure bearing upon the introduction and uses of biotechnologies was necessary to shorten the time to market through a cooperation model. However, endorsement and direct and generous support of the federal government did not come around until the CRADAs system in 1986. Now that bio-

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\(^{81}\) See Wisner, supra note 50, at 196.


\(^{84}\) Id., at 556-59.
technology and licensing capacity have grown mature, private investors including venture capitalists are becoming fond of the biotechnology industry and practical applications of biotechnologies, while government’s regulation and funding through CRADAs may no longer provide support to the biotechnology industry, but only sell federally funded research results to private sectors for fairly low fees.85

4. The U.S. Government’s Response to and Reflection on Criticisms of CRADAs

To address the critics on CRADAs above, the U.S. government has taken some measures for improvement, some of which succeeded while others fell short. Improving efforts by the U.S. government are illustrated below, along with author’s commentary.

A. Attempt to Include Reasonable Pricing Clause

To address the issues of “policy bribery” and “cheap selling on government owned research results,” in 1989 NIH attempted to include the “reasonable pricing clause” in the CRADA entered into with cooperating contractors, which requested the cooperating contractor to agree to demonstrate the reasonable connections between product price, the prior public investment(s) on this product research, and the demand of public safety and health.86

The author suggests the clause is considered to be well-intended, and committed implementation of this clause would help greatly on the skeptical pricing issue. Although this clause, to a certain extent, would interfere with the pricing mechanism in a free market economy, it differs because the cooperating contractor would benefit substantially in cooperation with the federal laboratories while regular private firms would bear all costs and risks of research and development if they choose to not enter into a CRADA. In addition, NIH research results are usually very closely related to public health and sanitation. In order to better protect such important values, the free market mechanism should not be the only mechanism that we can rely upon. Therefore, thoughtful design and inclusion of this clause is suggested (details will be further discussed later in this article).

However in practice, this clause was strongly opposed by private sectors, especially the biotech industry,87 as the clause controlled strictly the setting of the pricing structure, and thus significantly decreased private firms’ desire to cooperate with federal laboratories under CRADAs. Under influence of many groups of interest, U.S. Senators, including Wyden and few others, also opposed such action by NIH.88 Eventually, under great pressure, it was announced in 1994 that this clause would no longer exist in CRADAs because of the reluctance of the private sector and thus a lack of protection of public benefits.89


88 See NIH, supra note 86.

89 See Kuhlman, supra note 2, at 359.
B. Prevention and Control of Conflicts of Interest

To address the abovementioned criticisms on conflicts of interest caused by CRADAs, federal laboratories and pertaining administrative bodies began to set up guidelines and request conflicts of interest avoidance from researchers. NIH, for instance, requested principal investigators involved in CRADAs to disclose their financial interests. Furthermore, NIH set up ethics counselors to affirm absence of conflicts of interest prior to entering into each individual CRADA, or to prepare for any potential conflicts of interest. Part-time jobs outside research work, such as company consultant, technical advisor, or independent director (hereinafter referred to as “extramural activities”), all require pre-approval from ethics counselors. In general, if a research staff has above defined extramural activities with any private company, such research staff would not be allowed to participate in any cooperative research related to that company.

It is suggested by the author that while prevention of conflicts of interest does carry significant weight, the possibility of conflicts of interest lies everywhere business is conducted. Under that assumption, conflicts of interest could rarely, if ever, be fully prevented. In the CRADA context, the ‘cons’ would outweigh the ‘pros’ if the opportunity for cooperation between government and private sector is forfeited in order to avoid potential conflicts of interest. Appropriate preventive measures, if taken, may effectively prevent conflicts of interest and/or control damage. In the author’s view, ethics counselors set up by NIH provides a good example in terms of avoiding conflicts of interest while not interfering too deeply with cooperation between government and private sector (details will be further discussed later in this article).

C. Prevention on Inadequate Commercialization by Cooperating Contractors

Another criticism of CRADAs comes from doubtful efforts of cooperating contractors for commercialization. One of the CRADAs’ objectives results from the non-commercial oriented nature of federal laboratories, and hence cooperation with private firms and/or capable academic institutes would allow them responsibility for subsequent research result commercialization. However, the cooperating contractor might not invest sufficient follow-up commercialization efforts of the research results, owing to, perhaps, a shift in consumers’ preference, prohibitive commercialization costs, among other things.

To address such an issue, the Federal Technology Transfer Act (FTTA) regulates with the march-in right, that is, the government shall retain the right (i) to require the collaborating party to grant to a responsible applicant a nonexclusive, partially exclusive, or exclusive license to use the invention.

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91 Another viewpoint holds that the conflicts of interest between federal laboratories and contractors is not severe, and relevant regulations should be loosened up like NIH’s approaches so that research staffs of federal laboratories could possess company’s stock share and provide more consulting service to avoid elites crossing to enterprises or universities. See generally, Thomas N. Bulleit, Jr., Public-Private Partnership in Biomedical Research: Resolving Conflicts of Interest Arising under the Federal Technology Transfer Act of 1986, 4 J.L. & HEALTH 1 (1989/1990).

92 This criticism is often mentioned as minor rather than major in critiques, so the author does not include it in the above “Critiques on CRADAs.”


tion in the applicant’s licensed field of use, on terms that are reasonable under the circumstances; or (ii) if the collaborating party fails to grant such a license, to grant the license itself. However, on top of the march-in right, several government agencies also include a “reasonable best effort clause” in CRADAs of subordinate federal laboratories. For example, NIH includes such a clause in its CRADA template and requests the cooperating contractor to put forth a reasonable best effort to promote the product into market.

Based on diverging opinions on the definition of reasonable best effort, it may be difficult to have a uniform standard and approach in litigation as to how to determine a cooperating contractor make the reasonable best effort to commercialize a research result, leading to a limited practical use for the clause. However, such clauses might still function to remind cooperating contractors of obligations to promote and realize commercialization, otherwise a march-in right and/or penalty for breach of contract might be executed. Inclusion of this clause also signifies that public health and safety offices, such as NIH, would not fall under criticism for randomly entering into CRADAs with private sector in pursuit of 15% licensing income and in negligence of government-sponsored research investment and public needs.

5. Academic Suggestions for Improvement of CRADAs

On top of all the above efforts by the government, academics also make numerous suggestions on CRADAs’ improvement. It is generally recognized that only the private sector would be able to commercialize basic research results of federal laboratories on an effective, large scale. To a certain degree, “cooperative research” inevitably means that the government needs to give up all or a part of ownership of research results as incentive to encourage participation of private sector in cooperative research. On the other hand, however, taxpayers would ask for return of every penny of government funds. So the fundamental problem of CRADAs to be resolved involves how to elevate government investment return without losing business attractiveness. Suggestions from U.S. academics are offered below:

A. Research Progress to Be Monitored by U.S. Government

In addition to the march-in right and reasonable best effort clauses, studies have suggested that federal laboratories should request the cooperating contractors to keep full documentation of research and commercialization progress under CRADAs, which could enable the government to keep track of the commercialization progress and use as reference for future cooperation candidates.

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95 A few U.S. scholars have different opinions on the objective and design of the march-in right. They assert that the march-in right is unnecessary because it would increase uncertainty in CRADAs, and renders private firms unwilling to cooperate with federal laboratories. See William A. Eklund, *Intellectual Property Rights in Joint Research Ventures with the National Laboratories*, 17 HASTINGS COMM. & ENT. L.J. 841, 848 (1995); Mark Stevenson, *Technology Transfer and March-in at the National Institute of Health: Introducing Uncertainty into an Era of Private-Public Partnership*, 50 ADMIN. L. REV. 515, 518-19 (1998).


98 See Malinowski and O’Rourke, supra note 85, at 233.

99 Id., at 234.
B. Technology Transfer Income by U.S. Government Shall Have Designated Use

It is academically considered that financial benefits derived from cooperative research with and/or licensing to a private company shall be reinvested into relevant research and/or promotion of research results commercialization, such as other research funding, clinical experiment budgets, and drug price compensation for public healthcare, etc., because such cooperative research and/or licensing are intended for public interest rather than private profits.\(^{100}\)

Nonetheless, the author recognized that the FTTA permits federal laboratories to retain the licensing income within 5% of the total institutional annual budget for technology transfer costs, research staff rewards, and replenishment of research funding, etc.\(^{101}\) Thus, the abovementioned general consideration about reinvestments should be subject and applicable to current laws. However, it is noteworthy that the drug price compensation, especially for rare diseases,\(^{102}\) shall practically resolve the overpricing issue for a number of drugs. This suggestion, on behalf of the public interest, seems to provide an applicable use of research results by a greater number of people.

While a key factor in CRADAs is to boost the return of government investment while maintaining business attractiveness to private firms, one public criticism is that there were too much private profits and too little government investment returns, the Taxol controversy being one example. Hence, use of government licensing income for drug price compensation or public subsidy for drug purchase would further aggravate public criticism about excessive private profiting, despite facilitating drug accessibility and affordability. It would satisfy more public needs if the private company that is benefited from government-assisted researches could contribute back to product pricing, rather than that the government allocating the licensing income for drug price compensation, and instead for funding other research. Consequently, such a suggestion as drug price compensation, as innovative as it seems, may not be the real key to the CRADAs problem.

C. Comprehensive Perspectives and Suggestions for CRADAs

In light of statistics on CRADAs practice, the author believes that CRADAs is proven to be functional and worthwhile. Otherwise, the number of CRADAs executed and derivative licensing income would not have grown steadily for the past two decades. During the past twenty years, according to NIST report, the emergence of various high technologies and inventions enhanced the general quality of life and promoted public health and safety. Those high-tech products might have never come to realization without cooperation between the government and private sector, and private commercialization licensed by the government, because private sector would lack motive to invest funding, time, and manpower for expensive commercialization, without government granting an exclusive license as protection.\(^ {103}\)

From the perspective of federal laboratories, cooperative research with private companies and/or academic institutes reduces research costs, part of which will be borne by the cooperating contractors. Moreover, idea exchanges among interdisciplinary professionals tend to spur creative

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\(^{100}\) See Malcolm Skolnick et al., The BRCA1 Gene: Commercialization vs. the Public Interest, HEALTH L. NEWS, Mar. 1995, at 2.

\(^{101}\) 15 U.S.C. § 3710a(c)(4)(B), and supra text “Pros and Cons - Benefits of CRADAs.”

\(^{102}\) Pharmaceutical companies may not want to invest in producing drugs for rare diseases (i.e., orphan drugs) due to limited market scale. Additionally, rare disease drugs, if produced, may have higher price and would require government subsidiary. See Mae Thamer et al., A Cross-national Comparison of Orphan Drug Policies: Implications for the U.S. Orphan Drug Act, 23 J. HEALTH POL. POL’Y & L. 265 (1998).

\(^{103}\) See Kenneth Sutherlin Dueker, Biobusiness on Campus: Commercialization of University-Developed Biomedical Technologies, FOOD & DRUG L. J. 453, 466 (1997).
thinking and novel ideas, leading to research breakthroughs,\textsuperscript{104} which might appeal more strongly than research cost-down to federal laboratories and research staffs.

Based on the U.S. literature cited by the author, the CRADAs system is rarely considered as an erroneous public policy or a loss-outweighing-benefit system regardless of the several criticisms,\textsuperscript{105} and allegations of the cheap selling of government funded research results.\textsuperscript{106} It is observed that CRADAs system is still acknowledged as the public policy by the majority of scholars and experts in the U.S. There are criticisms about prolonged administrative procedures in CRADAs execution, or insufficient attractiveness to contracting candidates.\textsuperscript{107} However, such a scheme serves to balance private and public profits. It would only exacerbate the problem of conflicts of interest if all IP rights of research results are assigned to private contractors or if the timeframe for CRADAs execution is curtailed and current announcement procedure forsaken.\textsuperscript{108} Meanwhile, the public would be hindered in sharing the fruit of research results co-developed by the government and private sector, which is against the legislative intent of CRADAs.

Furthermore, the author supposes the criticism in regard with redundancy of government sponsorship resulted from a current mature biotechnology industry,\textsuperscript{109} and back-to-back funding to large business firms, may be an overstatement. FTFA specifies the federal laboratories shall give special consideration to small business firms, and consortia involving small business firms,\textsuperscript{110} in order to secure small and/or middle business firms’ participation in government cooperative research. Thus, large business firms shall not be further excluded given the right of equality in the U.S. Constitution; otherwise it would unreasonably and illegally breach the large business firms’ right. And the fact that only large business firms are practically capable of federal laboratories’ research results is not subject to legal review. It would be absurd to forfeit the potential of research results only on the rationale that much sponsorship will be given to large business firms instead of small ones.

In addition, it is also biased to claim that the current biotechnology industry is too mature for commercialization sponsorship. It is widely known that the biotechnology industry requires enormous investment,\textsuperscript{111} while only few companies could draw the attention of venture capitalists. It is arbitrary to state that the biotechnology industry no longer requires government sponsorship, especially when certain orphan drugs might never go in production without government funding. In addition, cooperative research shall never be restricted to the phase of commercialization, because many novel ideas and technologies arise from the mutual flow that happens during cooperative research between the government and federal laboratories.

As a result, the CRADAs system is considered as a proper public policy in this article. Nonetheless, the CRADAs system does possess many flaws as discussed by previous studies. In the following paragraphs, the author proposes suggestions for amendment to the CRADAs system to address these flaws.

\begin{itemize}
  \item \textsuperscript{104} See Kathleen A. Denis, \textit{University Licensing and Technology Transfer}, 666 PLI/PAT 317, 332 (2001).
  \item \textsuperscript{105} Nathan A. Adams, \textit{supra} note 83.
  \item \textsuperscript{106} Michael J. Malinowski and Maureen A. O’Rourke, \textit{supra} note 85.
  \item \textsuperscript{107} See \textit{supra} text “Pros and Cons – Benefits of CRADAs.”
  \item \textsuperscript{108} Id.
  \item \textsuperscript{109} Id.
  \item \textsuperscript{110} See \textit{supra} text “Essential Content and Current Practice – Essential Content of CRADAs.”
  \item \textsuperscript{111} See Joseph A. DiMasi et al., \textit{supra} note 1.
\end{itemize}
1. **The Reasonable Pricing Clause Set Forth by NIH Shall Be Continued and Adopted by Other Agencies**

The most highly criticized part of CRADAs is the government being less of profit recipient than the private cooperating contractor under the cooperative research. Thus, the government shall have secured the “income” generated under cooperative research to ease such criticism. The income could be categorized into the research cost-down, or received licensing fees, and ultimately and most importantly, the publicly accessible commercialization realized from the research results of federal laboratories that fulfills the primary goal of cooperative research.\(^{112}\)

Consequently, the government shall pay close attention to ensuring reasonable pricing for public access to commercialized research results, which in return could generate the greatest benefits from cooperative research for the government. Accordingly, the reasonable pricing clause once set forth by NIH from 1989 to 1994 shall rightly fulfill this objective,\(^{113}\) and this clause shall be promoted rather than abolished so that uniform inclusion of this clause could be adopted in various CRADAs versions owned by different federal laboratories.\(^{114}\)

This clause was deemed an inappropriate policy when NIH abolished it for fear of possible interference with market economy and decreased likelihood of private firms entering into CRADAs.\(^{115}\) But this clause is returned to the table here because the level of government interference shall vary when the research results co-developed by the government and private sector, in nature, differ from the ones solely funded and developed by private sector. Based on basic principles of a market economy, the research results solely developed by the private sector shall require the least government regulation on allocation of results ownership and utilization of IP rights for generating maximized value, provided that such use does not constitute misuse of IP rights.

To the contrary, the research results co-developed by the government and private sector have a different story because such results involve the use of federal laboratories’ devices, staffs, and other government-owned IP rights.\(^{116}\) Therefore, the government shall be obligated to restrict the ownership and utilization of such results to avoid the abovementioned criticisms, including back-to-back funding to large business firms.\(^{117}\) While this clause will inescapably reduce the private firms’ desire to enter into CRADAs, it should be noted that the primary objective of CRADAs only serves to produce products and benefit the public quality of life, but not to boost the number of CRADAs executed. The setup of the reasonable pricing clause would indicate that the cooperating contractor is optimistic about the commercialization and profiting of research results, if the contractor still decides to work under CRADAs. In contrast, reluctance on the part of a private company entering into CRADAs with the reasonable pricing clause suggests that the potential profits come from the sponsorship and benefits directly from the government, instead of from the commercial competence of the product. So the pricing restriction would cut down profits and scare off the unconfident contracting candidates.

\(^{112}\) See supra text “Preamble – Importance of Cooperative Research for the Academic, Public, and Private Sectors,” and “U.S. Legislation for Scientific Cooperative Research.”

\(^{113}\) See supra text “Pros and Cons – Academic Suggestions for Improvement of CRADAs.”

\(^{114}\) CRADA has no universal version and is drafted by each federal laboratory based on individual needs. See supra text “Essential Content and Current Practice – Essential Content of CRADAs.”

\(^{115}\) See supra text “Pros and Cons – Academic Suggestions for Improvement of CRADAs.”

\(^{116}\) See supra text “Essential Content and Current Practice – Essential Content of CRADAs.”

\(^{117}\) Nathan A. Adams, supra note 83.
As a result, it is suggested in this article that the reasonable pricing clause should exist to help select private firms that would still decide to cooperate with the government under CRADAs, rather than private firms that only crave direct sponsorship and benefits from the government. Therefore, a triple win situation will occur where the public has access to new in-demand products with reasonable prices, the government eliminates criticisms about conflicts of interest and cheap selling of government-funded research results, and the private sector gains profits from successful commercialization instead of direct sponsorship and benefits from the government. Consequently, the reasonable pricing clause shall deserve further promotion as a fitting policy.

2. Preventive Measures for the Conflicts of interest Shall be Respected

Closely related to the reasonable pricing clause is the precaution and prevention of conflicts of interest. The example of Taxol suggests the fact that a cooperating contractor who unfairly gains more than the government would arouse the public suspicion of conflicts of interest, illegal private profiting, or even cheap selling of government-funded research results. However, prediction on commercialization success would be very difficult. And it is also unfair to determine a fair amount of licensing fees charged in the beginning of cooperative research by federal laboratories in evidence of later on commercialization success. Nevertheless, public suspicion of the conflicts of interest will always arise when the government neglects appropriate preventive measures, and eventually it will influence the practice of cooperative research under CRADAs.

For that reason, under the cooperation scheme of the Bayh-Dole Act—the cooperative research between academic institutes and private sector—scholars have appealed that the academia, government, and NPOs, such as Government-University-Industry Research Roundtable (GUIRR), should jointly set up preventive measures for the conflicts of interest to eliminate negative impacts from the conflicts of interest in university-industry cooperation. In the same vein, federal laboratories shall take notice on control and prevention of the conflicts of interest in CRADAs. It is mentioned above that NIH requires researchers to disclose their financial interest, and sets up ethics counselors to review the existence of conflicts of interest. Such practical approaches are great

118 Research results from the government and universities are categorized as early stage research results that require substantial investment for further commercialization. So generally, the price for license fee is relatively low. According to reports from the Association of University Technology Manager (AUTM), average license income for university technology transfer is 2%-2.3% of the final product price, which is significantly lower than regular commercial license fee. See AUTM Economic Impact Survey, October 24, 1996, cited in COGR, TECHNOLOGY TRANSFER IN U.S. RESEARCH UNIVERSITIES: DISPELLING COMMON MYTH 3 (2000). As a result, it is not strong enough of a reason to accuse the government of profiting from contractors simply because of NCI’s low license income is compared to a pharmaceutical company’s high profit.

119 Government-University-Industry Research Roundtable (GUIRR) was founded in 1984, and serves as the communication platform for science and technology research leaders in industry, government and academia. The GUIRR operation is funded by the U.S. National Academy of Sciences, National Academy of Engineering, and Academy of Medical Sciences, etc. Discussions and decisions made on GUIRR have enormous influence on U.S. scientific research environment. For more details about GUIRR, see http://www7.nationalacademies.org/guirr/ (last visited Dec. 22, 2011).


121 See supra text “Pros and Cons - The U.S. Government’s Response to and Reflection on Critics on CRADAs.”
examples for other institutions. Furthermore, the author believes that in the event actual conflicts of interest arise, the research staffs and technology transfer staffs shall be penalized; in the mean time, the cooperating contractor in such an event shall be restricted of candidacy for further cooperation under federal laboratories’ CRADAs.\footnote{Scholars have suggested similar approaches for cooperation model under the Bayh-Dole Act, that the funding agency can make decision on decreasing or withdrawing funds to funded academic institutes that arouse conflicts of interest. See generally National Research Council, \textit{Bits of Power: Issues in Global Access to Scientific Data}, Committee on Issues in the Transborder Flow of Scientific Data, available at http://www.nap.edu/readingroom/books/BitsOfPower/ (last visited Dec. 20, 2011).}

It is assured that if different institutions could stipulate and execute the adequate preventive policies for conflicts of interest, it shall eliminate adverse effects caused by the conflicts of interest and allow CRADAs more opportunity for further promotion and development.

\section*{IV. Conclusion}

CRADA is believed to be a successful legal scheme because it links the federal laboratories and industry for quick transition of federal laboratory-owned research results to private commercialization. Through its unique design, federal laboratories contributes equipment and personnel, while the private industry provides funds; the cooperation by both the government and private sectors make research results further developed into viable products. The public enjoys the fruits of scientific research and in turn, the economy is simultaneously stimulated by the consumption of new products. With the adoption of preventive measures against conflicts of interest and reasonable pricing clauses to ensure public access to commercialized research results, the CRADA system will become a better legal scheme to create more benefits for government, private enterprises and the public.