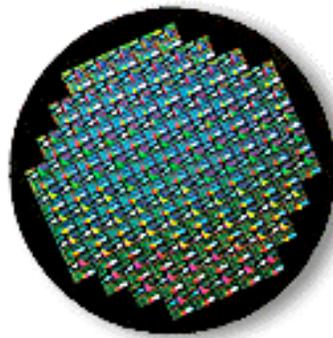


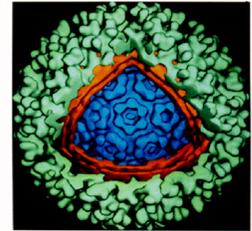
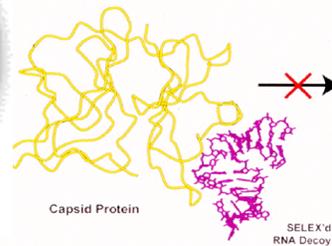
# Foreign Participation In CRADAs

## Executive Summary

(Full Document Version on <http://www.dtic.mil/techtransit/>)



### Alphavirus Assembly Disruption



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for  
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Research and Engineering  
(Office of Technology  
Transition)

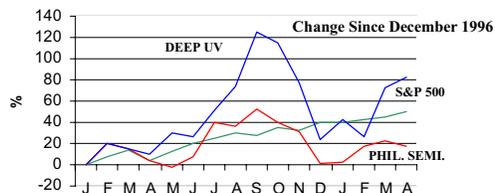


September, 1999

### High Technology, High Rewards

A new Index that goes by the ungainly name of Deep UV Photolithography Food Chain tracks the performance of five companies that make equipment used for etching tiny wires into the surfaces of microchips. The demand for this equipment has made these companies investor favorites.

	Ticker	Yesterday's closing price	Change year to date	Est. price to earnings ratio
ASM Lithography	ASMLF	\$95.75	41.9%	27.8
Cymer	CYMI	25.25	68.3	61.3
Dupont Photomask	DPMI	50.25	44.1	23.5
Etec Systems	ETEC	55.00	18.3	23.7
Photonics	PLAB	33.50	38.1	26.9



## Executive Summary

Technology transfer between the United States and foreign entities occurs through a variety of mechanisms. These include corporate joint ventures or alliances, contracts with the U.S. Government, use of subsidiaries, establishment by foreign companies of research facilities in the United States, international coauthorships in academic research, as well as multinational corporate (MNC) mergers and acquisitions. Cooperative Research and Development Agreements (CRADAs) are one of many mechanisms that U.S. Government R&D organizations use in working with private industry and academia. Moreover, CRADAs facilitate collaborations outside the normal contracting process and are valued for their flexibility, responsiveness, and explicit control of intellectual property (IP) that may result from collaborations. Although CRADAs have played a comparatively minor role in transferring technology to foreign entities, some policy makers are concerned about the increasing internationalization of R&D and how U.S. interests are addressed in this environment.

Technology transfer from the United States to foreign entities has always been a concern for policy makers and national security analysts—self-sufficiency and R&D leadership have been hallmarks of the U.S. defense industry. However, in the current global economy, distinguishing military technology from commercial technology can be difficult. In addition, R&D leadership is not necessarily concentrated in the U.S. defense laboratories or industry. Furthermore, the issues of whether foreign companies should be allowed to participate in U.S. Government sponsored research and the lack of formal guidance on such collaboration remain technology transfer concerns.\*

### Objective

This study reviews existing CRADAs, focusing on those CRADAs that include foreign participation, and analyzes the processes used by U.S. Government agencies in determining whether to include foreign partners in CRADAs. In addition, this study proposes criteria and procedural options, consistent with national security and the economic interests of the United States, that agencies should consider in evaluating potential foreign involvement in CRADAs.

### Approach

Analysis was conducted using extensive interviews with technology transfer practitioners and policy makers at various Federal agencies (e.g., Department of Energy [DOE], Department of Defense [DoD], National Institutes of Health [NIH], Department of Commerce [DoC]), as well as other study teams involved in evaluating foreign participation in CRADAs. In addition, existing research (e.g., case studies, cost share programs, academic literature) was reviewed and analyzed to understand how U.S. Government agencies and the military services interpret the legislative intent of various technology transfer statutes (i.e., Stevenson-Wydler Act, Technology Transfer Act of 1986 [15 USC 3701–3715 and 10 USC 2515]).

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\* Jacques Gansler, *Defense Conversion* (Cambridge, MA: MIT Press, 1995), p. 49.

This analysis was not intended to be comprehensive but only illustrative of how various organizations interpret provisions that deal with national security and economic security interests in public–private technology transfer partnerships. In addition to CRADAs (especially cases involving private sector “funds-in”), analysts considered practices and criteria in patent licensing and cost-shared contracting for technology development involving foreign entities.

As a point of departure, the study team used observations and insights gathered from the U.S. Government’s recent experience regarding possible inclusion of foreign partners (i.e., lithography toolmakers) in the Extreme Ultraviolet Lithography Limited Liability Corporation (EUV LLC) CRADA with the DOE laboratories. The issues associated with the EUV LLC CRADA and the potential inclusion of foreign entities illuminate how decision makers assess national security, economic security, and technology policy factors that arise from public–private partnerships in sensitive technology areas.

During the course of the study, the objective evolved somewhat to take account of related political developments. In part in response to the specific circumstances surrounding the EUV LLC, the Congress proposed legislative language in the form of an amendment offered by Rep. Tauscher to H.R. 2544.\* The amendment requires the Director of the Office of Science and Technology Policy (OSTP) to review policies and procedures Federal agencies use in gathering and considering the views of other agencies with respect to major proposed CRADAs (i.e., those that involve critical national security technology or may have a significant impact on domestic or international competitiveness). One aspect of the legislative language requires the Director of OSTP to determine the adequacy of existing procedures and methods for interagency coordination and to propose additional procedures, if necessary, for considering other agencies’ views regarding major CRADAs.

### **Internationalization of CRADAs**

Increasingly, R&D collaborations are conducted on a worldwide scale using multiple methods. Although the reasons are complex, globalization of the marketplace and rapid diffusion of new technology appear to be driven by competitive factors affecting all industries. These factors include rising R&D costs, risks associated with production, shortened product life cycles, increasing multidisciplinary complexity of applications, and intense foreign competition in domestic and global markets. In the last decade, foreign-funded research in the United States has concentrated in three industries, drugs and medicines (mostly funded by Swiss and British firms), industrial chemicals (mainly funded by German firms), and electrical and electronic equipment (one-third of which are funded by French affiliates).<sup>†</sup>

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\* Subsequent to this report, H.R. 2544 did not pass in the 105th Congress. A revised version, H.R. 209 (the Technology Transfer Commercialization Act of 1999), has passed the House and is currently under consideration in the Senate. In this version, each Federal agency with a Federally funded laboratory that has one or more CRADAs is required to submit a report to the Committee on National Security (CNS) of the National Technology and Security Council and to the Congress.

<sup>†</sup> National Science Board, *Science & Engineering Indicators—1998*. Washington, DC: US Government Printing Office (NSB 98-1), p.4-55.

In light of these trends, it is not surprising that the U.S. Government is also experiencing an increased interest on the part of foreign partners in R&D collaboration through CRADAs. In fact, this survey corroborated the perception that, overall, the number of CRADAs with foreign participation remains relatively small (less than 5% of all CRADAs). However, it does appear that number of CRADAs that involve foreign participation is increasing, albeit at a slower rate than number of private industry or academic R&D collaborations involving such foreign involvement.

Although most CRADAs are still characterized by small-scale agreements between researchers, usually valued at under \$50,000 (based on the estimated value of researchers' level of effort), some agencies have entered into CRADAs for scientific projects of significantly larger scale and using different types of financial arrangements. For example, a few cases of large "funds-in" CRADAs have permitted the private sector partner to pay for personnel, services, and property. In addition, umbrella CRADAs have facilitated multiparty (and multiple project) R&D in government and industry.

"Funds in" CRADAs, or other large-scale CRADAs, potentially introduce new considerations into R&D collaborations. In an era of downsizing and constrained funding, an industrial partner offering to put up a sizable amount of money for research could have a distorting impact on the resources and attention of the Federal laboratories—even though the agreements must be mission related. Could a large infusion of outside funding cause a potential divergence between the laboratory's interest in maintaining capabilities and the safeguards regarding U.S. national and economic security that are built into the CRADA review process? Although there is no evidence that such a divergence has occurred, some observers have indicated that this environment could make it more difficult for Federal laboratories to determine and protect the economic interests of the United States in the future.

Although the EUV LLC CRADA is unique, one of the concerns expressed by some agencies and Members of Congress focused on the size of the investment, the potential introduction of a foreign licensee, and the consideration of economic and national security. As a result of recent experiences, questions have emerged concerning the adequacy of current procedures for reviewing and approving CRADAs, especially those that may involve foreign participants. Questions include—

- Does the increasing size and type (e.g., funds-in) of CRADAs create additional need for oversight?
- Does the increasing internationalization of R&D, which could drive increased foreign participation in CRADAs, create a need for changes in the CRADA review process?
- If it were determined that additional oversight or changes were needed, how could this be done in a way that does not overly burden the process? This consideration may be particularly important for the vast majority (more than 95 percent) of small-scale CRADAs for which the present processes are most likely adequate.

The trend toward internationalization of R&D and CRADAs will likely increase in the future, thereby likely perpetuating the debate about foreign participation in U.S. Government R&D beyond case-specific CRADAs.

## General Findings

Some agencies and laboratories provide guidance or a model CRADA designed to streamline the process and encourage partnership efforts (see Exhibit ES.1). Typically, a model CRADA addresses rules and responsibilities regarding the following: definitions; the work statement; term, funding, and costs; personal property; disclaimers; product liability; obligations regarding proprietary information; obligations regarding protected CRADA information; rights in generated information; export control; reports and abstracts; pre-publication review; copyrights; reports of intellectual property use; march-in rights; U.S. competitiveness (in the case of DOE); assignment of personnel; *force majeure*; administration of the CRADA; records and accounting for government property; notice; disputes; modifications; termination; and project management.

### Exhibit ES.1 Model CRADAs on the Web

Agency	Web Site	Comments
DOE	<a href="http://www.doe.gov/techtran/cradam.html#ZZ0">http://www.doe.gov/techtran/cradam.html#ZZ0</a>	Also has model for joint ventures with small business
DoD	<a href="http://www.dtic.mil/techtransit/">http://www.dtic.mil/techtransit/</a>	Provides models for each Military Service
NIH	<a href="http://www.nih.gov:80/od/ott/crada_inf.htm">http://www.nih.gov:80/od/ott/crada_inf.htm</a>	Delineates roles and responsibilities for agency and collaborators

Under the Stevenson-Wydler Technology Innovation Act, as amended, the laboratory director is required, when deciding which CRADAs and licensing arrangements involving foreign parties to enter into, to address certain requirements regarding national and economic security. Specifically, the legislation requires agencies to—

- Give preference to substantial manufacture in the United States
- Ensure reciprocal access to foreign R&D and licensing arrangements
- Adhere to export control laws and re-transfers of strategic technology
- Determine whether the foreign entity has policies to control U.S. Intellectual Property Rights (IPR).

The specific language pertaining to these provisions of the Stevenson-Wydler Act are provided in Appendix A (see Executive Order 12591, Sec.4 International Science and Technology and 15 USC 3710a (c)(4)). Foreign entities are defined as *persons* or industrial organizations (where the entities are directly or indirectly controlled by a foreign company or government).

For the current study, representatives of several Executive agencies (or Executive departments) were interviewed to determine how they handle foreign participation in CRADAs. Interviews were conducted with technology transfer managers and/or general counsels who are involved in review and administration of CRADAs or Patent Licensing Agreements (PLA). In general, it appears that all agencies/departments engage in CRADAs with foreign participants only if no U.S. company has expressed an interest in the associated technology. This is particularly true where defense technologies are concerned.

The results of the survey of the agencies/departments, captured succinctly in Exhibit ES.2, provide some interesting insights and issues. Essentially, none of those interviewed felt additional layers of review outside the current processes would be necessary in most cases. Moreover, for the sample of agencies and departments surveyed in this study, only about 5 percent of their CRADAs were with foreign entities. This percentage is significantly below some of the percentages that are characteristic of academic and industrial collaborations that include foreign participants. This low percentage is even more significant when one considers the fact that the largest number of CRADAs with international participation is in the bio-medical areas (e.g., NIH, DoD), where many large, biomedical MNCs are headquartered outside the United States (see Exhibit ES.3).

In all cases, agencies have procedures in place to screen CRADAs that involve international participants, and there did not appear to be any significant deficiencies in implementing statutory and regulatory requirements. However, there were variations in the way agencies interpret and implement statutory and regulatory requirements. For example, not all agencies use the United States Trade Representative (USTR) to advise on trade and R&D reciprocity issues. Furthermore, the USTR does not necessarily have the resources and expertise to evaluate such R&D reciprocity issues.

This failure to consult with the USTR does not appear to be a significant issue; in most cases, the existing CRADAs are with close allies of the United States, and the approving agency need only consult as opposed to seek concurrence. Some agencies make their own determinations of reciprocity. However, the question remains—if all agencies were to seek USTR consultation, as spelled out in Executive Order 12591, would this over-tax the resources of the Trade Representative's office? Some agencies have already cited slow or unsatisfactory response by the USTR as a reason for not seeking regular foreign consultation. On the other hand, it is also worth noting that a number of agencies have had acceptable responses (in the range of 1 day to 2 weeks). However, some of those interviewed noted that the mandatory period for approval of a CRADA (30 days for government-owned, government-operated laboratories) and the consistent use of USTR consults by all agencies could conceivably lead to delays in the process as well as problems with compliance in the mandated period of time.

Executive Order 12591, as well as technology transfer legislation, addresses both economic and national security, however, no definitions or criteria for determining economic security or economic impact are given. In interviews, considerable concern was expressed about the possibility of burdening the CRADA approval process to the point that industry would find the process too problematic.

Another provision of existing legislation that has been interpreted differently by various agencies is the requirement to give preference to business units located in the United States that agree that any products embodying inventions made under the CRADA or produced through the use of such inventions will be manufactured substantially in the United States” (15 USC 3710a).

“Manufactured substantially” is not defined, but is left to the interpretation of those implementing the legislation. However, all agencies stressed the need for substantial U.S. manufacturing of the products resulting from CRADAs, although several agencies noted that this represents a preference only, not a statutory requirement.

**Exhibit ES.2 Overview for Foreign Participation, Various Agencies**

Component	Air Force	Army	Navy	NIST	DOE	NIH	USDA
United States first? <sup>1</sup>	Not clear <sup>3</sup>	Not always	Yes	Not always <sup>5</sup>	Not US only	Yes	Yes
Substantial U.S. mfg? <sup>2</sup>	Yes, with flexibility	Yes	Yes. Navy alternate clause used little.	Required for products sold in the United States	Yes, or alternative net benefits for US economy	Yes, if product substantially sold in United States	Yes; some foreign cos. considered US if mfg/R&D here
Trade Rep review?	Yes	Use USTR for gov't orgs., not foreign cos.	Yes	Not standard	Yes	Only in special cases (China, South Africa)	No
No./total of Int'l CRADAs	~ 3 since 1992	~ 25 since 1992 <sup>4</sup>	~ 24 since 1992	50/813 (since 1988)	25/1600 (up to spring 1998) <sup>6</sup>	26/237 (March 1988–Jan 1995)	16/ 340 (since FY95)
% of Int'l CRADAs	3.3 % DoD-wide			6%	1.5 %	11 %	5%

<sup>1</sup>“U.S. First” refers to the practice of some agencies not entering into a foreign CRADA if there is a U.S. company working in the same field. This is not a statutory requirement. It is also important to note that CRADA law expresses a “preference” for doing business with U.S.-located businesses but that patent-licensing laws do not contain such a preference.

<sup>2</sup> This category refers to how an agency handles the substantial manufacturing preference, although all agencies have discretion to waive this requirement. An unmodified “Yes” response means substantial U.S. manufacturing is required in all cases. Also, although patent-licensing law applies this requirement only when the licensee intends to sell the resulting product in the United States, the CRADA law does not address where a product will be sold.

<sup>3</sup> Prior to CRADA signing, the potential partner is investigated by AFRL International, AF Security Command, and SAF International Affairs, which consults with the State Department. DIA is also consulted.

<sup>4</sup> CRADAs included are traditional CRADAs for cooperative R&D. Not included are “short form” CRADAs, which are similar to Material Transfer Agreements (MTA). Inclusion of these instruments (which do require USTR review) would increase the Army’s total number of CRADAs by about 40.

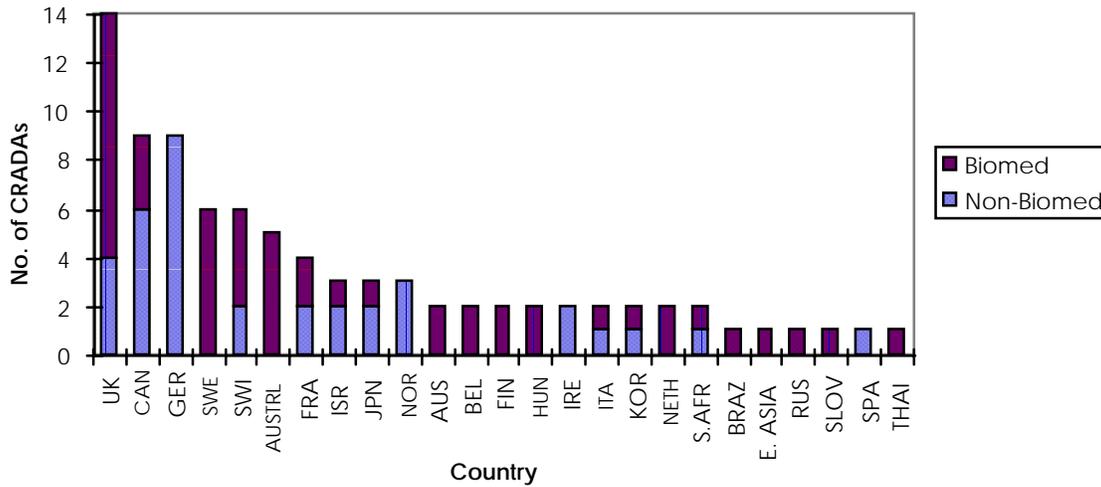
<sup>5</sup> Many foreign partners in CRADAs may also be involved in Consortia with U.S. firms prior to CRADA application.

<sup>6</sup> ~ 12 since 1990 in Defense Programs

<sup>7</sup> 20 percent of patent licenses are issued to non-domestic licensees.

Most agencies (i.e., NIH, DOE) have an “alternative benefit assessment” that can be applied in cases where the foreign or U.S. companies do not believe that they can comply with the substantial manufacturing requirement. Other agencies require U.S. manufacturing (and R&D) if the company plans to sell in the U.S. marketplace.

### Exhibit ES.3 DoD CRADAs with Non-U.S. Partners



Source: Booz·Allen Analysis

Because of the variations in the way agencies implement these requirements, the study team believes that greater clarity, through the development of Government-wide guidance, would assist agencies in assessing key issues associated with CRADAs with international participation. In fact, although the study team did not detect significant problems resulting from the lack of formal guidance on implementation of these requirements, technology transfer practitioners agreed that a standardized checklist or set of questions for use in screening such CRADAs would be useful. The likely result of such guidance would be greater harmonization and improvement of procedures across Federal agencies and laboratories when considering CRADAs that might involve international participation, while at the same time, still affording individual agencies and laboratories the discretion to tailor guidelines to conform to specific situations.

### Implementation Issues and Recommendations

In meetings with technology transfer practitioners from numerous agencies, a general consensus was reached that a standardized checklist or set of questions for use in screening CRADAs would be beneficial. Such a checklist would ensure that all the key issues associated with international participation in CRADAs were considered and that all applicable legislative and regulatory requirements concerning national security and economic competitiveness were addressed.

In addition, to supplement the existing criteria for CRADAs, the team devised the following illustrative elements that could be included in a comprehensive checklist:

- An identification of all potential participants in the CRADA, not just signatories. Any intention to involve a non-U.S. participant, whether as part of the supplier base, technology integrator, etc., should be disclosed at the outset or whenever the possibility of such participation became known.

- Detailed plans (e.g., a commercialization plan) concerning the contemplated use of the technology developed as part of the CRADA. For example, is there an intention to commercialize the technology developed by the CRADA? If so, then the competitive technologies, extended enterprise, as well as direct and indirect benefits should be addressed.
- A detailed rationale for inclusion of international, rather than domestic partners. Although most agencies have adopted policies that favor U.S. firms, a discussion of why foreign participation is essential and the alternatives that have been explored regarding domestic partners would help clarify issues at the outset.
- A requirement that all CRADAs with potential international participation and not meeting standard criteria (such as being a “major CRADA”) automatically receive more intensive review within agencies. This review would act as an early-warning system for CRADAs that might raise sensitive issues.
- Consistent means for assessing statutory and regulatory requirements of export controls, reciprocal access, substantial manufacture, and intellectual property protection.

These elements are meant to be treated as additional guidance or serve as the basis for the issuance of formal instructions. They are not meant to replace existing criteria but are intended to supplement existing practices when potential or proposed international entities may be involved.

## **Process Issues and Recommendations**

Although procedural issues were not a major concern at the outset of the study (i.e., since spring 1998), the Congress has focused on interagency process changes as a means to address perceived deficiencies in the CRADA review process as demonstrated by the EUV LLV experience. The Tauscher amendment to H.R. 2544, as originally drafted, as well as companion legislation introduced by Senator Rockefeller (S. 2120), would have required criteria for interagency review of a CRADA that involves “national security, or relates to a project which may have a significant impact on domestic or international competitiveness.” However, the version of H.R. 2544 that ultimately passed the House contained considerably more flexibility for the Executive Branch (i.e., OSTP) to review and determine the adequacy of existing procedures and methods for interagency coordination, and to recommend additional procedures, if any, for gathering and considering the views of other agencies on certain CRADAs. Although the Congress adjourned before the Senate acted on H.R. 2544, there was no substantive disagreement with the House language (see footnote on page ES2).

It is important to note that despite criticism of the EUV-LLC and the resulting Tauscher amendment, the Congress continues to strongly support the CRADA concept as a tool for industry–government cooperation. Congressional personnel interviewed during this study agreed that the hallmark of CRADAs is flexibility and expressed the strong desire not to hamstring or encumber the CRADA process for the vast majority of cases for which the current process

appears to be appropriate and adequate. Moreover, the Congress did not take the position that international involvement is to be avoided, but in fact, recognized that there are instances where foreign participation is essential to further technology development.

However, congressional officials noted that some “major,” far-reaching CRADAs have emerged in recent years that involve cutting-edge technology, the world’s largest companies, and occasionally consortia of Federal laboratories.\* Because of their potential to affect industry sectors, their suppliers, and jobs within the United States, the report language questions whether these CRADAs may have outgrown the current CRADA approval process. Accordingly, the House recommended that OSTP review and upgrade, if necessary, existing approval procedures for these major CRADAs. OSTP was charged with identifying criteria to separate out the small minority of major CRADAs that would benefit from interagency review. While calling for some change “to solve potential problems through better interagency coordination,” the House bill clearly states that new procedures are to be added only to the extent that existing procedures are inadequate, and that “any new procedures are to lead to expedited, substantive interagency decisions” that minimize burdens on agencies.

### **Definition of a Major CRADA**

Overall, this analysis has found that although CRADAs undergo satisfactory review at the agency level, the Government may benefit from an interagency review process that could assist in evaluating future major CRADAs involving international partners. However, to minimize unnecessary burdens for the vast majority of CRADAs, some clarification concerning what a major CRADA is must be provided.

For example, the DOE CRADA with the EUV LLC highlights some key aspects that could make CRADAs controversial. In this arrangement, the intellectual property and U.S. manufacturing provisions are carefully defined to ensure U.S. manufacture for a specified time period (i.e., assured first access) and to impose the same provisions on licensees of the technology. One prominent element of the controversy involves the *potential* inclusion of international lithographic toolmakers and the large amount of “funds-in” from industry. Some analysts have noted that this arrangement may threaten the well-being of U.S.-based toolmakers who are already party to the agreement. However, others have noted that the commitment of global semiconductor manufacturing leaders to the toolmaking industry, as well as the current provisions for control over manufacture (through licensing provisions), are a good example of how Federal laboratories can accommodate multinational industries and serve the public interest.

Controversy has not been a stranger to collaborations in the past.<sup>+</sup> An example of the need for careful scrutiny of R&D collaborations occurred in an agreement between Scripps Research Institute and Sandoz in 1992. In this case, NIH renegotiated a Sponsored Research Agreement (which is similar to, but not a CRADA) involving the not-for-profit Scripps Research Institute and Sandoz (Swiss-based) pharmaceutical company. Originally, Sandoz was to provide \$300

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\*See House Report 105-620 Part 1—Technology Transfer Commercialization Act of 1998, to accompany H.R. 2544, section 6—*Review of Cooperative Research and Development Agreement Procedures*.

<sup>+</sup> *CRADA Mania*, Scientific American, October 1993.

million over 10 years for rights to the commercial fruits of the Federally funded research at Scripps. The agreement was not acceptable to the then-director of the NIH, Bernadine Healy, who felt it gave Sandoz “excessive control” of research and IP. About this time, NIH had developed guidelines to deal with the perception and controversy associated with serving the public interest. The institute found that more specificity in the field of use (FOU) is a critical part of developing an appropriate CRADA.\*

Although no definitive definition of a major CRADA would accommodate all appropriate situations, there are a range of possibilities and illustrative criteria that could assist in narrowing the scope of CRADAs to be reviewed on an interagency basis.

Based on the House Science Committee’s report language, it is obvious that there is no intention for all CRADAs to undergo interagency review; quite the contrary, only a “handful” of major CRADAs raise issues that the Committee believed would benefit from such a review. Likewise, because most of the concern about the potential effect of these major CRADAs on American jobs and companies centered on foreign participation in CRADAs, it seems appropriate to further limit the scope of the CRADAs requiring review to those involving foreign partners and meeting appropriate criteria.

To refine the subset of CRADAs triggering interagency review, it may be useful to consider a series of filters, or a funnel approach. The first filter concerns CRADAs with international participation. Based on data provided by agencies, the study team estimated that application of this criterion alone would eliminate 95 percent of all CRADAs, because, on average, only about 5 percent of CRADAs involve foreign participation. The second and subsequent filters could be drawn from the following list of illustrative criteria:

- Type of CRADA (i.e., funds-in, facility share, advanced product development, etc.)
- Monetary Threshold (i.e., comparison of the level of effort proposed with the laboratory budget for the area of concern)
- Critical Technologies (This criterion was qualitative, and no list was deemed specific enough, at this time, to serve as a good filter.)
- Sensitive Industries (This criterion was also qualitative, and no list was deemed specific enough, a this time, to serve as a good filter.)
- Waiver of U.S. Manufacturing Requirement (i.e., where the U.S. manufacturing requirement is expected to be waived and the foreign partner does not have both R&D and manufacturing in the United States in the field of use of the statement of work).

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\* As a result of the experience with Sandoz and Scripps, the NIH adopted several policy changes to avoid similar problems with their collaborative mechanisms in the future. Four changes, in particular, were incorporated into the CRADA review process: 1) evaluate the level of effort to be provided compared with the laboratory budget in the area of concern, 2) ensure that the CRADA has intellectual involvement by all parties (i.e., not money only), 3) evaluate whether a CRADA is the appropriate mechanism for the collaboration proposed, and 4) evaluate the level of the Principal Investigator’s time commitment in the agreement.

The list above is not comprehensive, but is intended to be illustrative only. It provides a preliminary basis for discussion among agencies about what constitute appropriate criteria for CRADA consultation by other agencies. The most important aspect of such triggers is that they be quickly and easily ascertained in order to permit consistent application in the most efficient manner. As will be discussed in the following paragraphs, it is important for an interagency group to agree on consensus criteria to identify these major CRADAs, and these criteria should be shared on an interagency basis. Many practitioners believe that reducing many of these criteria to a readily administratable form will be a difficult challenge.

## **Interagency Review Process**

After the criteria defining the character of CRADAs to be reviewed by an interagency group have been established, the next issue is what kind of interagency review process should be used. Because the congressional report language emphasizes use of existing procedures, to the extent possible, to minimize burdens on Federal agencies, the study team's focus has been on current interagency mechanisms that might be appropriate for the CRADA review process.

After examining various interagency mechanisms and discussing options with agencies' representatives, the study team arrived at the preferred option of using an existing mechanism. The Interagency Working Group (IAWG) on Technology Transfer is a existing group that could serve as a coordinating body for the sharing of inputs on CRADAs with international participation that meet interagency agreed-on criteria.

The IAWG on Technology Transfer was created following passage of the Federal Technology Transfer Act in 1986, as a way for the Department of Commerce (DoC) to carry out its statutory role under the legislation. The Secretary of the DoC invited other agencies involved in science and technology R&D with potential for commercialization to become members of the Interagency Committee. The Group initially focused on methods for commercialization, assistance to agencies regarding their cooperative R&D projects, and preparation of a model CRADA agreement. As interest in collaborative research with industry has increased in the past decade, agency participation has broadened to include NIST, DoD, DOE, NIH, SBA, NASA, and USDA. In addition to sharing best practices in technology transfer, the Group has also helped to coordinate agencies' positions on issues such as the application of the GATT Subsidies Code to government research programs during the Uruguay Round, management of technology transfer programs generally, and most recently, agencies comments on H.R. 2544 (now H.R. 209).

The Interagency Committee was formed of Assistant Secretary-level representatives from various agencies and is chaired by Commerce's Assistant Secretary for Technology Policy. Most of the Committee's work, however, is accomplished through the IAWG on Technology Transfer, which is composed of senior managers from the agencies and departments responsible for technology transfer.

Of all the current interagency mechanisms reviewed, the IAWG alone had the advantage of being both a working-level technical group and higher-level policy/political committee for addressing issues. In addition, the IAWG is composed of technology transfer practitioners (i.e., subject-

matter experts) and has effectively served as a coordinating body on various technology transfer questions.

The following illustration demonstrates how the IAWG could serve as an effective consultative body for sharing insights on major CRADAs.

After the criteria regarding what constitutes a major CRADA are agreed to by agencies, any proposed CRADA agreement triggering these criteria would be identified by the responsible agency and in consultation with other IAWG agencies before a final approval decision was made. The consultation could be made several ways—for example, through posting on an intranet to which all member agencies had access or in the form of a written notification to the IAWG chair, which would then be distributed to all members. Optimally, an e-mail or electronic system should be devised, because the goal would be to avoid delays and ensure that the interagency review takes place within a limited time frame (e.g., 2 weeks).

Within the prescribed time frame, other agencies would then have the opportunity to review the proposed CRADA. The IAWG would serve as the first-order forum for vetting any questions and addressing concerns raised by agencies. If it were unable to satisfactorily address an agency's concerns regarding the CRADA, the IAWG would refer the matter to the Assistant-Secretary level Interagency Committee. At this point, appropriate political-level review among agencies would be assured, while at the same time allowing responsibility and authority for the final decision to be retained by the proposing agency. The benefit of this “default to decision” process is the increased sharing of CRADAs with international partners that could raise potential issues, but doing so in a time-limited, semi-automatic process.

Although no system is perfect, the study team believes this type of consultative IAWG process could effectively avoid unnecessary delays, provide for a thorough vetting of the issues associated with proposed CRADAs, and preserves ultimate decision-making authority for the proposing agency, subject to consideration of issues raised by other agencies. Such a process is also consistent with the intent of the proposed legislation, H.R. 2544 (now H.R.209), and the existing Executive Order (12591).