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United States General Accounting Office
Washington, DC 20548

Accounting and Information
Management Division

B-284067

November 22, 1999

The Honorable Tom Bliley
Chairman
Committee on Commerce
House of Representatives

The Honorable Fred Upton
Chairman, Subcommittee on Oversight
and Investigations
Committee on Commerce
House of Representatives

Subject: *Financial Management: National Institutes of Health Research Invention Licenses and Royalties*

This letter responds to your request that we review information provided to your offices by the National Institutes of Health (NIH) related to the licensing of inventions developed under intramural research projects. Specifically, you asked that we (1) determine the extent of and reasons for the differences between the number of research inventions licensed under cooperative research and development agreements (CRADAs)[1] compared to inventions licensed under other intramural research projects (referred to in this report as non-CRADAs) and (2) review the internal controls that ensure proper accountability for royalty income resulting from these licenses.

This letter summarizes the information provided during an October 7, 1999, briefing to your offices on these two areas. As discussed at that time, we have additional work ongoing to review the adequacy of NIH's internal controls over royalty income. As agreed, we will provide that information separately and, accordingly, we are not making any recommendations regarding improvements to the internal control structure at this time. We requested comments on our slides from NIH officials. They generally agreed with the information and provided some clarifying comments that were incorporated into our slides as appropriate. The slides are included in enclosure 1.

[1]Such agreements provide for collaboration between federal and nonfederal entities.

Background

NIH performs biomedical research through both extramural and intramural projects. Extramural projects, which accounted for about $13 billion in funding in fiscal year 1999, are carried out through contracts and grants with nonfederal organizations such as universities, other nonprofit research organizations, and for-profit corporations. Intramural projects, which accounted for about $1.5 billion in funding in fiscal year 1999, are primarily conducted within NIH laboratories. For purposes of this review, we focused on intramural research, which includes both CRADA and non-CRADA research projects.

CRADAs, which are authorized by the Federal Technology Transfer Act of 1986, as amended, involve the federal government collaborating with state and local governments and private industry to perform research. Under this act, the federal government may provide personnel, services, facilities, and equipment for CRADA research but not direct funds. Nonfederal collaborators may provide personnel, services, equipment, and funds for such research.

Federal research can result in inventions, which are available for licensing under the Bayh-Dole Act of 1980,[2] as amended, or under the terms of the particular CRADA agreement. If the invention is developed under an extramural project, the contractor or grantee generally retains title to and profits from the invention, subject to certain terms and conditions. If the invention is developed by federal employees under a non-CRADA intramural project, the federal agency normally retains title to the invention and can license it to others who may then commercialize it. The federal government receives royalty income from inventions it licenses. For fiscal year 1998, NIH reported $40 million in royalty receipts.

Results in Brief

For a number of reasons, the number of licenses granted for the use of federal inventions is not an appropriate measure for comparing CRADA and non-CRADA research projects. The licensing information provided by NIH's Office of Technology Transfer to your office for the period January 1994 through June 1999 did not present comparable data for CRADA and non-CRADA projects. The 8 CRADA licenses were related to the 538 CRADAs established during this period, while the 1,021 non-CRADA licenses were related to research projects begun years or even decades earlier. While the information provided appears to show that NIH licensed more inventions developed under non-CRADAs than it did under CRADAs, licensing opportunities are different. Further, according to NIH officials, less federal funding is involved in CRADA research than in non-CRADA research.

[2]The Bayh-Dole Act of 1980, Public Law 96-517, section 6, had two purposes: (1) to allow universities, not-for-profit corporations, and small businesses to patent and commercialize their federally-funded inventions and (2) to allow federal agencies to grant exclusive licenses for their technology to provide more incentive to businesses.

We performed limited testing of the internal controls over royalty income and found some deficiencies that could impact the completeness and accuracy of royalty income. For example, NIH did not always promptly reconcile royalty income received, nor did it have integrated systems to track the royalty receipts. Further, while NIH had system documentation for the Invention Tracking System as implemented in 1992, that documentation had not been updated to reflect changes. Therefore, if the system fails, it would be more difficult to make necessary repairs, thus potentially affecting normal operations and increasing the risk of lost royalty income.

Licensing Data Is Not an Appropriate Measure for Comparing CRADA and Non-CRADA Research

NIH's licensing data is not an appropriate measure for comparing the research conducted under CRADAs versus that performed under non-CRADAs. The information that NIH provided to your office indicated that it had entered into 8 licensing agreements for CRADAs and 1,021 licensing agreements for non-CRADAs from January 1994 through June 1999. However, the CRADA licenses related to the 538 CRADAs entered into during this period, while the non-CRADA licenses were related to projects begun years or even decades earlier.

In addition, licensing opportunities and federal funding are different for CRADAs and non-CRADAs. For example, some CRADAs do not offer licensing opportunities. Under a type of CRADA known as a "materials" CRADA, the government agrees to collaborate with industry to obtain essential research materials that cannot reasonably be obtained otherwise. NIH reported that of the 538 CRADAs established from January 1994 through June 1999, 321, or 60 percent, were materials CRADAs, while 217, or 40 percent, were standard CRADAs. Generally, materials CRADAs do not lead to licenses because the nonfederal collaborator maintains a proprietary right to the materials it contributes to the research as well as to any associated inventions. For example, NIH recently entered into a materials CRADA with a private firm to obtain proprietary compounds for research on the formation of blood cells in the living body. In this instance, because the compounds used by NIH for this research were wholly owned by the private firm, any enhancements to the compounds would accrue to the benefit of the private firm.

In addition, nonfederal collaborators, who are coinventors of the inventions developed in standard CRADA projects, are able to use and market these inventions without having to be granted a license from NIH. Under the terms of the CRADA agreement, the nonfederal collaborator has automatic rights of ownership to the inventions. Accordingly, there is no need for the collaborator to license the invention unless it wishes to be the exclusive user of that invention. In contrast, inventions resulting from non-CRADA projects have to be licensed to the private sector before private-sector entities can use these inventions.

According to NIH, the level of federal funding related to CRADA versus non-CRADA projects could affect the number of licenses granted. Under the Federal Technology Transfer Act, no direct federal funding is provided to nonfederal CRADA

collaborators. However, the use of NIH staff and facilities related to CRADA research is financed from the intramural research appropriations. While NIH officials were unable to provide an allocation of or an accounting for funds used for CRADA versus non-CRADA research, they said that most of the $1.5 billion appropriated to NIH for intramural research in fiscal year 1999 was used for non-CRADA projects.

Deficiencies in Internal Controls Could Affect Accuracy of Royalty Income

To review the internal controls that ensure proper accountability for royalty income, we performed limited testing which included: (1) reviewing audit work performed by the independent public accountant responsible for the financial statement audit of NIH and (2) performing some test work on a statistical sample of royalty income received during fiscal year 1999. Due to the timing of the briefing to your office, we did not complete the analyses of the sample results. However, we did find some deficiencies in internal controls over royalty income. For example, we found inefficiencies in NIH's systems and processes for maintaining data on royalty income received, and royalty income records were not always promptly reconciled to accounting records, raising the risk that mistakes would fail to be identified and corrected. We also found that one of the systems in use lacked current system documentation, increasing the risk of higher system maintenance costs and lost royalty income.

NIH's Office of Financial Management (OFM) receives and records royalty income. Because OFM and the Office of Technology Transfer (OTT) maintain separate systems, OFM forwards copies of original receipt documents to OTT so that it can determine whether NIH received proper amounts. At the end of each month, personnel from these offices are to perform reconciliations of royalty income receipts recorded in each of their systems. However, we found that the OTT's royalty income records were not always promptly reconciled with the OFM records. As of September 1999, these offices had not yet completed the reconciliation of royalty income for the period ended June 1999. Timely reconciliations could provide assurance that reported royalty income is accurate and complete. While OTT officials told us that these procedures were necessary to ensure accurate reporting of royalty income received, the clerical effort involved in entering the same data into two different systems is inefficient and introduces the possibility for errors. OTT and OFM could more efficiently record, retrieve and reconcile royalty income data if the OTT and OFM systems were integrated and the data shared among those needing that information.

During our review, we found that NIH's Invention Tracking System (ITS) which is used by OTT to maintain data on federal inventions, and the licenses and royalties resulting from them, lacked current system documentation. While NIH advised us that it subsequently located the original documentation provided when the system was implemented in 1992, the system has been upgraded since that time. If ITS fails, lack of current system documentation could impact OTT's ability to continue normal operations by inhibiting the ability to compare receipts with amounts owed, and therefore could increase the risk of lost income from royalties. In addition, lack of

current system documentation presents the risk of increased software maintenance costs in the event of additional system enhancements or modifications. OTT plans to replace ITS with a new system, the Technology Transfer Information Management System (TTIMS). At the time of our review, NIH officials told us that this system will be documented and is scheduled for implementation by December 2000. However, as of November 1999, they stated that the implementation date had been changed to June 2001.

Scope and Methodology

To determine the extent of and reasons for the differences between the number of licenses granted as a result of CRADA versus non-CRADAs research, we reviewed and discussed with NIH management the reports provided to your office on the number of licenses granted for the period January 1994 through June 1999. We also reviewed related policies and legislation. We did not independently verify the data NIH provided representing the number of licenses granted as a result of CRADA and non-CRADA research during the specified time period.

In reviewing the internal controls over royalty income, we interviewed officials at the Office of Technology Transfer, the Office of Financial Management, and two of NIH's largest institutes—the National Cancer Institute and the National Institute of Allergy and Infectious Diseases. We also reviewed audit work performed by the independent public accountant responsible for the financial statement audit of NIH. In addition, we performed some limited internal control test work of a statistical sample of royalty income received during fiscal year 1999.

We conducted our work from July 1999 through September 1999 in accordance with generally accepted government auditing standards. We provided a draft of this letter and the enclosed slides to NIH for review and comment. NIH generally agreed with the content of our letter and provided clarifying comments that were incorporated into our letter as appropriate.

We are sending copies of this letter to Representative John D. Dingell, Ranking Minority Member, House Committee on Commerce; Representative Ron Klink, Ranking Minority Member, Subcommittee on Oversight and Investigations, House Committee on Commerce; the Honorable Donna E. Shalala, Secretary of Health and Human Services; Dr. Harold E. Varmus, Director of NIH; and other interested parties. Copies will also be made available to others upon request.

If you have any questions about this letter or the briefing, please contact me at (202) 512-4476. Key contributors to this assignment were Chinero Thomas, Rosa Ricks Harris, and Debra Rucker.

Gloria L. Jarmon
Director, Health, Education, and Human Services
Accounting and Financial Management

Enclosures

October 7, 1999, Briefing for the House Committee on Commerce

GAO Accounting and Information Management Division

National Institutes of Health

Research Invention Licenses and Royalties

Briefing for the House Committee on Commerce

October 7, 1999

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GAO Objectives

- To determine the extent and reasons for the differences between the number of licensing agreements executed under the Bayh-Dole Act (for non-CRADAs*) compared to CRADAs
- To review the National Institutes of Health (NIH) internal controls that ensure proper accountability for royalty income resulting from licenses

* CRADAs are cooperative research and development agreements between federal and nonfederal entities.

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Background

- Biomedical research, NIH's major function, is funded using two types of research:
  - extramural research is carried out by nonfederal organizations through grants and contracts
  - intramural research is conducted within NIH facilities
    - CRADAs
    - Non-CRADAs

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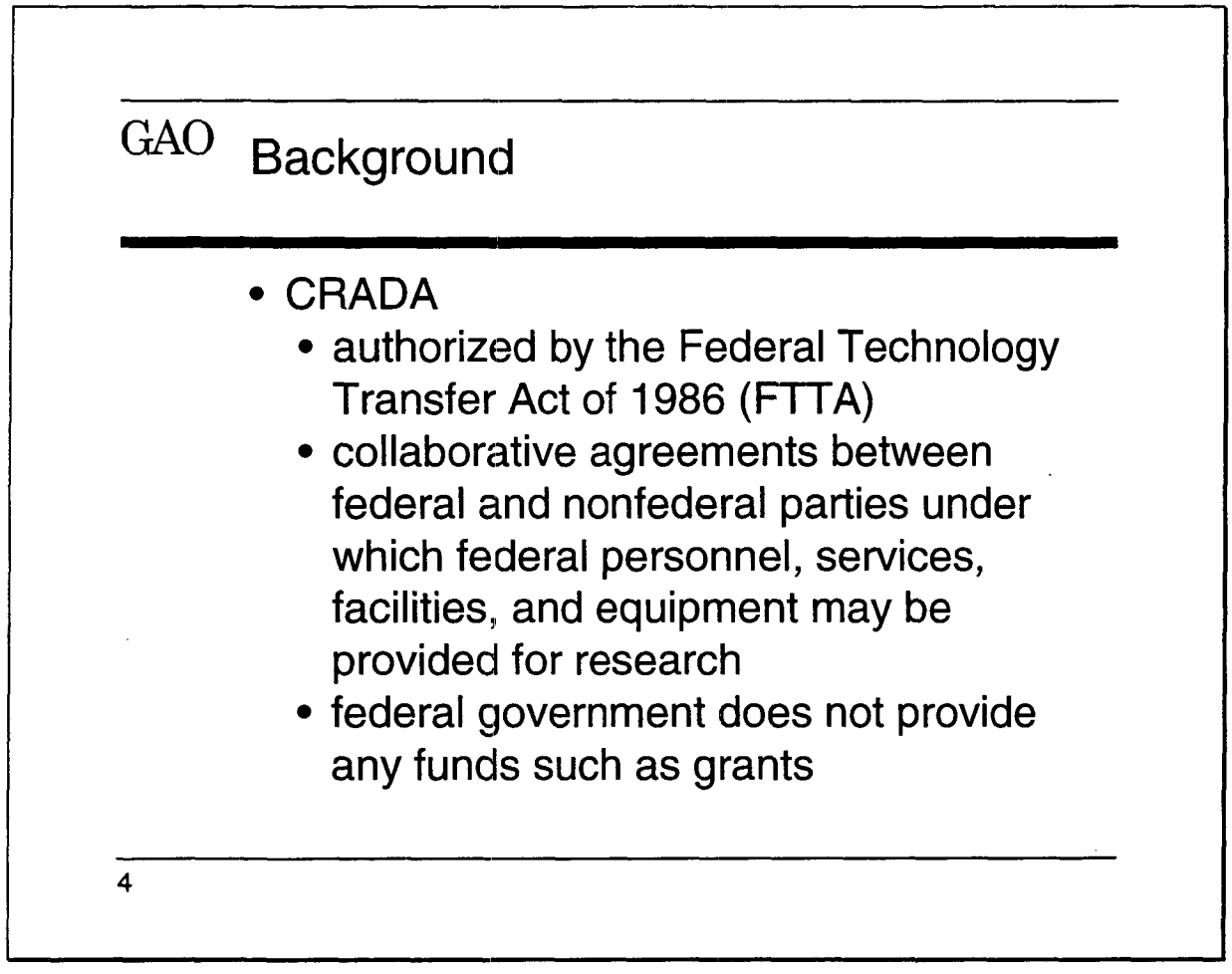
GAO Background
• CRADA
• authorized by the Federal Technology Transfer Act of 1986 (FTTA)
• collaborative agreements between federal and nonfederal parties under which federal personnel, services, facilities, and equipment may be provided for research
• federal government does not provide any funds such as grants
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GAO Background

- CRADA (cont.)
  - nonfederal parties may provide funds, personnel, services, and equipment for research
  - research period is usually no longer than 4 years but could be longer with adequate justification

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GAO Background

- Two types of CRADAs
  - Standard CRADA- as described earlier
  - Materials CRADA - a CRADA with a term of 1 year or less under which the federal government obtains essential research materials from industry and does not include any other exchange of personnel or resources

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Background

- Non-CRADAs
  - regular intramural research involving solely federal staff
  - research period is usually much longer than for CRADAs

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Background

- Licensing of Research Inventions
  - Intramural research may result in federally owned inventions that can be patented and licensed
  - Licenses convey the right to make, use, or sell inventions
  - Bayh-Dole Act of 1980
    - allows federal agencies to grant licenses for the use of federally owned inventions

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GAO Background

- Licensing of Research Inventions (cont.)
  - NIH's Office of Technology Transfer (OTT)
    - administers licensing agreements
    - assumed this function from the Department of Commerce in 1994

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GAO Background

- Royalties
  - Royalties are received by NIH as a result of licensing of inventions. These can be in various forms including
    - execution fees
    - minimum annual fees
    - fees based on sales
    - patent fees
  - OTT reported about $40 million in royalty collections in fiscal year 1998

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GAO Scope and Methodology

- Reviewed procedures related to development, review, approval, and administration of CRADAs
- Reviewed policy for establishing and conducting CRADAs within NIH laboratories
- Reviewed policy related to licensing inventions developed in NIH laboratories

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GAO Scope and Methodology

- Reviewed OTT reports provided to the Committee on the number of executed licenses for CRADAs and non-CRADAs
- Reviewed policies and procedures for the receipt and distribution of royalties resulting from the licensing of inventions made at NIH

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GAO Scope and Methodology

- Selected and tested a statistical sample of royalty income received during fiscal year 1999
  - reviewed related licensing agreements and supporting documentation
- Reviewed internal controls over functional areas of royalties such as receiving, recording, and reconciliations

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GAO Scope and Methodology

- Interviewed NIH officials
  - Office of Technology Transfer (OTT)
  - Office of Financial Management (OFM)
  - National Cancer Institute (NCI)
  - National Institute of Allergy and Infectious Diseases (NIAID)
- Reviewed the independent public accountant's (IPA) workpapers related to their audit of NIH's financial statements

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GAO Scope and Methodology

- Our work was performed in accordance with generally accepted government auditing standards
- Work was performed between July and September 1999

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Number of Research Projects and Related Inventions and Licenses

	CRADA	Non-CRADA
Number of Active Projects as of 9/30/98	188[1]	2,606[2]
Inventions reported in FY 1998	19	269
Licenses issued in FY 1998 [3]	0	14

Note: Data for fiscal year 1998 is the most recent available. However, these data are not comparable for CRADAs and non-CRADAs because:

[1] CRADAs have distinct beginning and ending dates. The length of ongoing projects ranged from 3 months to 10 years.

[2] Non-CRADAs do not have distinct beginning and ending dates. NIH's system does not maintain the exact beginning date for intramural research projects. Based on best available system data, the length of these projects ranged from about 1 to 45 years.

[3] These licenses relate to the inventions reported in FY 1998.

Source: NIH officials

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Number of Licenses Reported from January 1994 through June 1999

- Based on data OTT provided to the Committee, the number of licenses for CRADAs and non-CRADAs were
  - non-CRADAs - 1021
  - CRADAs - 8

Source: NIH officials

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GAO Factors Which Could Contribute to the Differences

- Potential for inventions and licensing depends on type of CRADA
- Licensing opportunities are different for CRADAs and non-CRADAs
- Intramural research appropriations are provided for non-CRADA initiatives

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GAO Potential for Inventions and Licensing Depends on Type of CRADA

- Standard CRADA
  - 217 executed from January 1994 to June 1999
  - Generally, research performed using a standard CRADA has potential to result in an invention for federal and non-federal CRADA collaborators
  - Based on marketability, the nonfederal collaborator could license the invention

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Potential for Inventions and Licensing Depends on Type of CRADA (cont.)

- Materials CRADA
  - 321 were executed from January 1994 through June 1999
  - Generally, most materials CRADAs do not result in inventions because the research material is considered proprietary to the collaborator that provided the material

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Licensing Opportunities are Different for CRADAs versus Non-CRADAs

- CRADA
  - The CRADA agreement grants automatic right of ownership of an invention to nonfederal collaborators who are coinventors of the inventions
    - Nonfederal collaborators do not need a license from NIH to use the invention
    - However, nonfederal collaborators need a license if they wish to be the exclusive users of the invention

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Licensing Opportunities are Different for CRADAs versus Non-CRADAs

- Non-CRADA
  - As authorized by the Bayh-Dole Act, nonfederal parties need to obtain a license to use federally owned inventions

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Intramural Research Appropriations are Provided for Non-CRADA Initiatives

- According to NIH officials, about $1.5 billion provided for intramural research in fiscal year 1999
- No specific allocation or accounting for funds for CRADA research
- However, NIH staff salaries and facilities use related to CRADA research are also financed from this appropriation
- As stipulated by the FTTA, no direct federal funding is provided to nonfederal collaborators

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GAO Intramural Research Appropriations are Provided for Non-CRADA Initiatives (cont.)

- Other funds/resources that support CRADA research
  - NIH received about $9.5 million from nonfederal parties for the period October 1998 to May 1999
    - these funds are used by NIH to support the CRADA research

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GAO Results of Review of Internal Controls Over Royalties

- OTT did not maintain system documentation for its Invention Tracking System (ITS) which may
  - impact OTT's ability to continue normal operations if the system fails
  - increase OTT's risk of lost revenue from royalties
  - result in increased software maintenance costs

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Results of Review of Internal Controls Over Royalties

- OTT's ITS will be replaced with a new system - Technology Transfer Information Management System (TTIMS)
- TTIMS is scheduled for implementation by December 2000

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Results of Review of Internal Controls Over Royalties

- Royalty receipts were not posted promptly from the OFM suspense account to the proper general ledger account which could result in inaccurate reporting of royalty receipts
  - $34 million was in the suspense account as of July 1999

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Results of Review of Internal Controls Over Royalties

- OTT and OFM royalty receipt records were not promptly reconciled which may affect the accuracy and completeness of royalty receipts
  - as of September 1999, the royalty receipt reconciliation had not been performed for the month ended June 1999

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Results of Review of Internal Controls Over Royalties

- Duplicate efforts/systems to maintain royalties at NIH could result in inefficient management of royalties
  - OTT and OFM systems are not integrated and perform similar functions

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Related GAO Products

Technology Transfer: Administration of the Bayh-Dole Act by Research Universities (GAO/RCED-98-126; May 7, 1998).

Technology Transfer: Number and Characteristics of Inventions Licensed by Six Federal Agencies (GAO/RCED-99-173; June 18, 1999).

Technology Transfer: Reporting Requirements for Federally Sponsored Inventions Need Revision (GAO/RCED-99-242; August 12, 1999).

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