THE SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201

JUN 23 1987

MEMORANDUM FOR ROBERT E. WINDOM, M.D.
ASSISTANT SECRETARY FOR HEALTH

SUBJECT: Implementation of the Federal Technology Transfer Act of 1986

I wholeheartedly support the President's aim of vigorously implementing the Technology Transfer Act of 1986. This Act promotes the use of new knowledge from the research laboratory to develop new products with potential application in the private as well as the public sector. It offers new incentives to government scientists and industry to participate in this process.

I am directing the Public Health Service to begin vigorous implementation of the new law within existing resources, to include entering into collaborative research arrangements with the private sector, arranging for the marketing of technological innovations made by PHS scientists, and representing HHS on Commerce's interagency committee.

Accordingly, I am delegating you the authority to carry out the major provisions of the Act. Since the Act offers significant new opportunities, in your implementation planning please consider:

- the structure and procedures necessary to manage effective implementation and operation of the Act, particularly certain common procedures and data systems, conduits for interaction with the private sector, and relationships with other Federal Agencies, including use of their services for invention management, where appropriate;

- the degree of decentralization and roles of my office, OASH and PHS agencies;

- recommendations concerning royalty sharing and a cash awards program;

- how to ensure the continued fulfillment of the Department's research mission, and at the same time, effectively promote the transfer of new knowledge from Federal to the private and non-Federal public sectors; and

- how to assess progress in transferring technology and the impact of the Act on HHS activities, including reporting requirements and the appropriate structure for review.

Commerce's interagency committee.

In your implementation of the Act, you should plan to use existing HHS mechanisms for information exchange, gradually building more systematic ones, as appropriate.

While the Technology Transfer Act applies principally to laboratories within the Public Health Service, I look to the PHS to develop procedures that we could apply HHS-wide, as appropriate. I would like you, after consultation with your agency heads and others as appropriate, to send me your detailed implementation plan within three months, including how you will address the issues discussed above, and any other issues for my consideration. In addition, please keep me advised on a periodic basis of progress in implementing the Act within the PHS.

Under your leadership, I know that PHS scientists will respond enthusiastically to the purpose as well as the opportunity created by this important legislation.

Otis R. Bowen, M.D.
Secretary

cc:
OPDIV Heads
STAFFDIV Heads

Otis R. Bowen, M.D.

ATTACHMENT III.

UNITED STATES DEPARTMENT OF COMMERCE
The Under Secretary for Economic Affairs
Washington, D.C. 20230

2 NOV 1987

MEMORANDUM FOR Douglas A. Riggs
General Counsel

FROM: Robert Ortner
Under Secretary for Economic Affairs

SUBJECT: Preparation of Materials Explaining the Application of the Employee Standards of Conduct to Activities Under the Technology Transfer Act of 1986

In your memorandum of February 11, 1987, you reviewed this Department's Employee Standards of Conduct for the purposes of the Federal Technology Transfer Act of 1986, and concluded that "our regulations establish adequate guidelines to cover situations under the law and do not require changes at this time." My office is now beginning to prepare materials for use in the Department's laboratories that will establish guidelines for employees in situations likely to arise under the Act. The purpose of this memorandum is to ask you to assign a member of your staff to work with Norm Latker, Director, Office of Federal Technology Management, in the preparation of these guidelines.

These guidelines would address problems that might arise in the course of this Department's implementation of the Act. Some examples of specific questions that should be discussed include:

- Could a Federal employee/inventor accept compensation as a consultant from a firm which is licensing that employee's invention from the Federal government?
- Could a Federal employee/inventor or co-inventor accept compensation for giving technical advice to a private firm on developing an invention that these employees made under a cooperative agreement with the laboratory?
- Could a Federal employee/inventor invest or become a stockholder in a firm which is licensing that employee's invention from the Federal government?
- Could a Federal employee/inventor become an officer in a firm which is licensing that employee's invention from the Federal government?

your staff to work with Norm Latker, Director, Office of Federal

- Could a Federal employee/inventor remain an employee and become an officer in a firm which, as a result of a cooperative agreement, has been granted in advance a patent license for all that employee's inventions arising under the agreement?

- Would a Federal employee/inventor who obtains a license from the government to use his or her own invention receive 15 percent of the royalties back from the government that he or she paid to the government for the right to use the invention?

- What restrictions are there on a former employee of a Federal laboratory negotiating a cooperative R&D agreement with that Federal laboratory?

- Under what circumstances can an employee of a laboratory leave the laboratory and become an employee of a company which has a cooperative agreement with the laboratory?

THE SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON D C 20201

JUN 23 1987

MEMORANDUM TO: Assistant Secretary for Health

SUBJECT: Delegation of Authority: Stevenson-Wydler Technology Innovation Act of 1980 as amended by the Federal Technology Transfer Act of 1986

I hereby delegate to the Assistant Secretary for Health all of the authorities under the Stevenson-Wydler Technology Innovation Act of 1980 (15 U.S.C. 3701 et seq.), as amended by the Federal Technology Transfer Act of 1986, P.L. 99-502, with respect to activities carried on within the Public Health Service, excluding the authority to promulgate regulations and to submit reports to the Congress. This authority is subject to redelegation in accordance with Executive Order No. 12591 of April 10, 1987.

This delegation is effective upon the date of signature.

Otis R. Bowen, M.D.
Secretary

THE SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON D.C. 20201

JUN 23 1987

MEMORANDUM TO: Assistant Secretary for Health

SUBJECT: Delegation of Authority: Stevenson-Wydler Technology Innovation Act of 1980 as amended by the Federal Technology Transfer Act of 1986

I hereby delegate to the Assistant Secretary for Health all of the authorities under the Stevenson-Wydler Technology Innovation Act of 1980 (15 U.S.C. 3701 et seq.), as amended by the Federal Technology Transfer Act of 1986, P.L. 99-502, with respect to activities carried on within the Public Health Service, excluding the authority to promulgate regulations and to submit reports to the Congress. This authority is subject to redelegation in accordance with Executive Order No. 12591 of April 10, 1987.

This delegation is effective upon the date of signature.

Otis R. Bowen, M.D.
Secretary

CHAPTER 1-901

DEPARTMENT PATENT ACTIVITIES

1-901-00 Purpose
10 Responsibilities

1-901-00 PURPOSE

This chapter describes the organization for patent activities within the Department.

1-901-10 RESPONSIBILITIES

A. Office of the Secretary

1. Assistant Secretary (Health and Scientific Affairs)

a. Evaluates current patent policy and develops policy to meet changing needs.

b. Makes determinations of rights in inventions and patents involving important policy considerations.

c. Maintains liaison with Congress on matters involving patent policy and programs and the Federal Council on Science and Technology.

2. Office of General Counsel

The General Counsel will designate a Department Patent Counsel who will be responsible for:

a. Patent Administration

1. Issuing patent administration procedures and recommending regulations for issuance by the Secretary.

2. Receiving reports of inventions by employees and holders of Department grants, fellowships and contracts.

3. Issuing licenses to applicants under patent applications and patents owned by the Government as represented by the Department and accepting licenses issued to the Government as represented by the Department.

4. Maintaining records and documents incident to patent administration.

(1-901-10A continued)

b. Legal Services

1. Rendering legal interpretations with respect to all patent matters within the Department.

2. Making patent determinations within the framework of existing law, regulations and policy.

3. Providing legal advice on patent matters to the Assistant Secretary (Health and Scientific Affairs).

4. Furnishing legal counsel to the Department Patent Board.

5. Providing other legal services, such as conducting patent searches, filing and prosecuting patent applications, and drafting legal documents such as assignments and licenses incident to patent administration for which the Department has responsibility.

6. Maintaining liaison with other Federal departments and the public on legal matters in the administration of the Department's patent responsibilities.

3. Department Patent Board

The Department Patent Board shall be composed of the Deputy Under Secretary, as Chairman, and representatives from the following staff offices and operating agencies:

Assistant Secretary (Health and Scientific Affairs)
Assistant Secretary for Administration
Department Patent Counsel
Office of Education
Health Services and Mental Health Administration
Consumer Protection and Environmental Health Service
National Institutes of Health
Social and Rehabilitation Service

The Department Patent Board shall upon the request of the Assistant Secretary (Health and Scientific Affairs):

a. Advise the Assistant Secretary (Health and Scientific Affairs) on patent policy matters.

b. Provide the Assistant Secretary (Health and Scientific Affairs) a medium through which to evaluate the effectiveness of Department patent policy and the administration of such policy.

(1-901-10 A.2. continued)

c. Assist in the development of patent policy.

d. Provide a forum for discussion of all matters pertaining to inventions and patents.

e. Review proposed changes in regulations affecting policy.

B. Operating Agencies

The head of each operating agency is responsible, in accordance with Department policy, for:

1. Including patent clauses approved by the Department Patent Counsel in grants, contracts and fellowships as appropriate to implement the Department patent regulations and policies.

2. Educating employees, contractors, and grantees as to the need for reporting inventions.

3. Evaluating the impact of patent policy on agency programs and providing such advice as the Assistant Secretary (Health and Scientific Affairs) may require on the most effective means of relating patent policy and procedure to program objectives.

4. Assisting, as requested by the Department Patent Counsel, to obtain scientific evaluations of inventions and providing such other information and assistance as may be required.

5. Providing such other information or reports as the Assistant Secretary or Department Patent Counsel may request.

TO: PHS Technology Management Advisory Board

FROM: Dr. Lowell Harmison

As noted in Dr. Windom's September _____ memo, the first meeting of Board will be (day of week) October (date) in Room _____.

The agenda for our first meeting will be the schematic chart and its associated explanation attached. This is a suggested decision making process that ~~directors of authorized laboratories~~ the heads of Agencies, Centers and Institutes can move through in order to successfully implement Section 11 of the FTTA.

Identification of the decision making process will facilitate the assessment of laboratory resources required and, therefore, the most effective levels for delegation of authority and retention of laboratory oversight. The Board should determine what resources each authorized laboratory will utilize in moving through the decision making process to implement their delegated authorities. The decision making process will also focus on the administrative tools we need to develop and the need for review of potential conflict of interest.

The chart has two primary logic trees, which represent the important responsibilities delegated by Dr. Windom's memo. The first lists actions and decisions needed to identify laboratory projects with the potential for developing a useful technology, finding a private sector collaborator, negotiating and executing a cooperative agreement, conducting the cooperative research, and finally, assisting in marketing and collecting the benefits of the resulting technology. The second tree identifies

the actions and decisions neded for identifying patentable technology developed at the laboratory, evaluating its economic potential, finding a private sector licensee, negotiating and executing a licensing agreement, assisting in development of the licensed technology and finally, assisting in marketing and collecting the benefits of the technology.

I am also attaching for discussion model cooperative research and development and license agreements developed by the Department of Commerce. These instruments are models only and can be amended in any appropriate way to meet your present needs.

Also please come prepared to discuss future agenda items such as:

a) The implementation plan and procedures for the Secretary;

b) A royalty sharing and use policy;

c) Conflict-of-interest guidelines;

d) Review of and delegation requests from other PHS laboratories; and

e) Licensing of computer software and other technical data.

TO: PHS Technology Management Advisory Board

FROM: Dr. Lowell Harmison

As noted in Dr. Windom's September _____ memo, the first meeting of Board will be (day of week) October (date) in Room _____.

The agenda for our first meeting will be the schematic chart and its associated explanation attached. This is a suggested decision making process that the Heads of Agencies, Centers and Institutes can move through in order to successfully implement Section 11 of the FTTA.

Identification of the decision making process will facilitate the assessment of laboratory resources required and, therefore, the most effective levels for delegation of authority and retention of laboratory oversight. The Board should determine what resources each authorized laboratory will utilize in moving through the decision making process to implement their delegated authorities. The decision making process will also focus on the administrative tools we need to develop and the need for review of potential conflict of interest.

The chart has two primary logic trees, which represent the important responsibilities delegated by Dr. Windom's memo. The first lists actions and decisions needed to identify laboratory projects with the potential for developing a useful technology, finding a private sector collaborator, negotiating and executing a cooperative agreement, conducting the cooperative research, and finally, assisting in marketing and collecting the benefits of the resulting technology. The second tree identifies

and retention of laboratory oversight. The Board should

the actions and decisions neded for identifying patentable technology developed at the laboratory, evaluating its economic potential, finding a private sector licensee, negotiating and executing a licensing agreement, assisting in development of the licensed technology and finally, assisting in marketing and collecting the benefits of the technology.

I am also attaching for discussion model cooperative research and development and license agreements developed by the Department of Commerce. These instruments are models only and can be amended in any appropriate way to meet your present needs.

Also please come prepared to discuss future agenda items such as:

a) The implementation plan and procedures for the Secretary;

b) A royalty sharing and use policy;

c) Conflict-of-interest guidelines;

d) Review of and delegation requests from other PHS laboratories; and

e) Licensing of computer software and other technical data.

(1)

ART NORRIS REVISION OF LATKER DOCUMENT
RECEIVED AT 8/24/87 MEETINGS W/LATKER

In the attached June 23, 1987 memo, the Secretary delegated me the responsibility to implement the Federal Technology Transfer Act of 1986 (FTTA) within existing resources. As you will note, prior to further delegations to PHS laboratories, the Secretary requested that, after consultation with PHS agency heads and by the end of September, I prepare an implementation plan which responds to his concerns.

Implementation of this legislation represents such a dramatic shift in the way most PHS laboratories have done business in the past, that it will be important for you and your entire staff to understand its intent and basic provisions. Both the intent of the Congress and the President's Executive Order of April 10, 1987, require that we move quickly to implementation of the Act without becoming engaged in time consuming events which delay it. Accordingly, I intend to re-delegate authorities as quickly as possible. This may be an iterative process in which delegations require higher level or more intensive review initially until we have all learned more and are more secure in the kinds of guidelines that must be developed. I do not believe we can delay all implementation until comprehensive guidelines are developed.

The first step in responding to the Secretary's request is the identification of the decision making process involved in the successful management of technology by a laboratory director. I have, therefore, asked Dr. Lovell Harmison to chair an implementation task force to review the decision process associated with a laboratory's entry into cooperative research and development or license agreements under the authority of Section 11 of the FTTA. Identification of that process will facilitate the assessment of resources required and, therefore, the most effective levels for delegation of authority and retention of oversight. The task force will begin to determine what resources each PHS agency will utilize to undertake implementation of the Act. It will focus on the administrative tools we need to develop and the need for reviews of potential conflicts of interest.

I would like each agency to be represented on the task force by two participants: either you or your deputy and another principal official, who has been involved in technology management. I may also appoint some at-large members to represent other points of view. The first meeting of the task force will be _____.

The attached schematic chart and its associated explanation will be useful to your staff and the Task Force. The chart identifies the work steps and decisions which must be undertaken for laboratories to enter into cooperative research and development, license agreements, or

generally manage technology transfer. The chart has two primary logic trees, both of which represent important responsibilities under the Act. The first list actions and decisions needed to identify laboratory projects with the potential for developing a useful technology, finding a private sector collaborator, negotiating and executing a cooperative agreement, conducting the cooperative research, and finally, assisting in marketing and collecting the benefits of the resulting technology. The second tree identifies the actions and decisions needed for identifying patentable technology developed at the laboratory, evaluating its economic potential, finding a private sector licensee, negotiating and executing a licensing agreement, assisting in the development of the licensed technology and finally, assisting in marketing and collecting the benefits of the technology.

Since I am anxious to meet the Secretary's desire to proceed, I believe it is appropriate at this time to permit each PHS agency to commence negotiation of cooperative research and development and license agreements subject to review by my office. Recognizing that future actions taken with this authority must conform to clear guidelines, this will be an interim arrangement in which not only will my office review them, but we will assure close coordination with the Secretary's office.

To assist your staff and task force members, I am also attaching model cooperative research and development, and license agreements developed by the Department of Commerce. These instruments are models only and can be amended in any appropriate way to meet your needs. I have also attached a list of issues that are provided to give some appreciation for the number of details that must be considered during implementation.

DRAFT

MEMORANDUM FOR Director, NBS
Director, NTIS
Administrator, NOAA
A/S, NTIA

FROM: Robert Ortner
Under Secretary for Economic Affairs

SUBJECT: Authorization Under Section 11 of the Federal Technology Transfer Act

The Secretary of Commerce has delegated to me his authorities and responsibilities under Section 11 of the Federal Technology Transfer Act of 1986, (P.L. 99-502). Under the provisions of Section 11(a)(1) of that Act you are hereby authorized to enter into Cooperative Agreements between federally operated laboratories under your supervision and other federal agencies, units of state and local governments, industrial organizations, foundations, nonprofit organizations, and other persons. This authority is subject to limitations in Subsection 11(c) which are explained below.

Under agreements entered into pursuant to Subsection 11(a)(1), Government-operated Federal laboratories may accept, retain and use funds, personnel, services and property from collaborating parties, and in exchange may provide personnel, services and property, but not funds, to the collaborative effort. (See Subsection 11(b)(1)). The laboratories may also, in advance, grant licenses or assignments to collaborating parties for any invention made by a Federal employee under the agreement; and also in advance, may waive Federal government ownership to any inventions made by employees of the collaborating organization under the agreement. Licenses must be retained for Governmental use, however. (See Subsections 11(b)(2) and (3)). Under Subsection (11)(b)(4), where appropriate you should permit employees and former employees of laboratories to participate in the commercialization of inventions they made while in the service of the United States.

Your authority to enter into cooperative agreements under Subsection 11(a)(1) is subject to the provisions of Subsection 11(c). As provided for in Subsection 11(c)(1), the Department is preparing regulations on procedures for implementing this section. Implementation of Section 11, however, should not be delayed pending the issuance of these regulations. As required by Subsection 11(c)(3), the Department has reviewed its employee standards of conduct for conflict of interest, and has determined that no change is necessary. Any potential conflict of interest in a Federal laboratory arising from an agreement under Section 11 should be immediately reported to the Director, Office of Federal Technology Commercialization. Under Subsection 11(c)(4), in deciding what cooperative research and development agreements you enter, you should give special consideration to small business firms and consortia involving

small businesses, and should follow the requirements of Subsection 11(c)(4)(B) pertaining to preference for business units located in the United States.

In accord with Subsection 11(c)(5), any cooperative agreement entered into under Section 11(a)(1) should include a clause providing the Secretary of Commerce a 30-day period to disapprove or require the modification of the agreement. Please notify the Director, Office of Federal Technology Commercialization of the initiation of negotiations leading to a cooperative agreement under Section 11(a)(1). This notice should include:

1. Name of parties to the Proposed Agreement
2. Work Scope of Proposed Agreement
3. Resources to be made available by each participant
4. Disposition of Patent Rights

All royalties received under cooperative agreements negotiated under Section 11 of the Act shall be distributed as provided in Section 13. The Department does not intend to file an alternative plan for the sharing of royalties as provided by Subsection 13(a)(A)(ii).

In order to facilitate the drafting and negotiation of cooperative agreements, the Department plans a workshop in the near future to discuss model provisions and methods and options for commercialization available to DoC laboratories.

This memorandum does not apply to a procurement contract or cooperative agreement as these terms are used in 31 U.S.C. 6303, 6304, and 6305.

DEPARTMENT OF HEALTH & HUMAN SERVICES — Public Health Service

Memorandum

Date AUG -5 1987

From Director
National Center for Toxicological Research

Subject Technology Transfer -- BRIEFING

To The Deputy Assistant Secretary for Health
Through: ES/PHS _____

PURPOSE: You asked me to represent you at a session on technology transfer at the Department of Commerce from July 20-23 and at a meeting of the Executive Working Group of the Interagency Committee for Federal Laboratory Technology Transfer on July 23, 1987. This memorandum reports on events at those two sessions.

BACKGROUND: The Federal Technology Transfer Act of 1986 directs Federal agencies to take several steps to encourage the transfer of technology from Federal laboratories in the interest of global economic competitiveness. Executive Order 12591 of April 10, 1987, requires timely implementation of this Act, delegation of responsibilities to appropriate levels, and other cooperative items.

Because the Department of Commerce has coordinating responsibilities across the Federal government, an effort was developed to write training materials for use by government employees. A contract was awarded to Gulf South Research Institute (GSRI) to develop these materials. A meeting was convened from July 20-23, 1987, to critique the materials developed by GSRI.

GSRI was asked to develop a set of modules for three different audiences--lab scientists, technology transfer agents, i.e., those who staff the Office of Research and Technology Application (ORTA's), and laboratory management. Those of us at the session were asked to critique that effort. That task was made more difficult by the fact that the primary deliverable, a notebook with training materials, will not be available for review for several weeks.

The session on Friday, July 24, of the Executive Working Group was called in order to define future actions needed to follow the training materials and speed the implementation of the Act and the Executive Order.

DISCUSSION: In light of this, two conclusions can be made: (1) if the notebook contains all and describes all that it is said to include, the materials may be very useful; and (2) based on what was presented, without benefit of seeing the notebook, one would have to be concerned about its value to HHS. TAB A to this memorandum provides some detail of the session.

BECAUSE THE DEPARTMENT OF COMMERCE HAS COORDINATING RESPONSIBILITIES

THE EXECUTIVE WORKING GROUP: Items covered included a decision to decline the request of GAO to become members of the implementation group as well as the decision that FLC, as a private organization, could also not be included as part of the Federal Implementation Committee since it would then put the Committee under the Federal Advisory Act and, hence, open other meetings to all other outside groups.

The second item of business included a request by NASA for an assessment of Executive Order 10096 (1950) in light of the 1986 Technology Transfer Act. This request is already being addressed by the Department of Commerce and relates to consideration of whether or not the agency must undertake an evaluation as to the legitimacy of ownership prior to transfer of licensed material. The result of this inquiry will be provided at the subsequent meeting.

The third item of business was a review of the course given already that week. In general, the course was not overwhelmingly well received. The salient points were: (1) course did not provide enough material on research and development; (2) was too redundant; and (3) the after-the-fact course material was of less than optimal use. It was pointed out by Mr. Tip Parker that the contract was completed and there was no need to continue or modify at this time. The resulting product is to be provided to each course attendee on or before August 31, at which time it may be utilized as seen fit and reproduced as needed as long as the contractor is given credit for whatever of their material is accepted.

The fourth and final additional item is outlined in USDA's course to be provided September 17. The course outlined appeared to address many of the major points there, but the implementation discussion follows. This included:

1. A need for education among the research and regulatory leadership since there is the incorrect feeling among some that this represents a conflict of interest which it specifically does not.

2. That there is a concept that artificial barriers are being placed relative to implementation by procurement groups. This is placed outside the procurement process.

3. That laboratory personnel must be informed as to what constitutes a loss of proprietary rights relative to disbursement of ideas and concepts.

4. That, while it might be acceptable under the law for an agency not to accept for either themselves or their staff a benefit accruing from the transfer of technology, it is certainly not the intent of the law to encourage this, but rather where regulatory conflicts exist that they be resolved by the language, permitting full participation of said group in the end.

5. While under the law it is possible for a laboratory to become involved with a single R&D broker, it is of concern that this might develop into a perceived conflict of interest and hence, it might be better to develop a more apparent equality of access to information through either electronic systems or publication in the Federal Register, Commerce Business Daily, or some other group, to provide due notification to industrial development companies and have a review board to be responsible for evaluation of inquiries.

6. It is the opinion of the USDA consultants and staff that protecting proprietary information will be difficult under present FOI laws, however, that same can be protected best by the language up front by cooperative R&D contracts, since the research information and hence results from same would be paying owner by contract. Contracting needs to be further explored by the respective departments and agencies.

Finally, a schematic diagram for implementation and a PERT analysis for accomplishment is to be sent prior to the next scheduled meeting of the group which is September 9, 1987 at 10:00 a.m.

I have also attached, at TAB B, my memorandum to you describing the June 5 meeting of the Executive Working Group.

Ronald W. Hart, Ph.D.
Director, NCTR

2 Attachments:
Tab A - Notes on Technology Transfer Session, 7/20-23/87
Tab B - Copy of Report of June 5, 1987, Meeting of EWG

cc: Commissioner, FDA
Actg Assoc Comm for Mgmt & Opns, FDA
Executive Secretariat, FDA

Director, NCTR

TAB A -- Details of
7/20-23/87 Tech Trans-
fer Sessions

ATTACHMENT B

DEPARTMENT OF HEALTH & HUMAN SERVICES — **Public Health Service**

Memorandum

Date June 11, 1987

From Director, NCTR (HFT-1)

Subject Report of Meeting

To Deputy Assistant Secretary for Health, DHHS

Attached please find my summary minutes for the meeting at the Department of Commerce on implementation of the Technology Transfer Act of 1986. The meeting was an informative one as you may see by the attached information. The bottom line of the meeting was that there was a great diversity both in the needs of the various departments of the Executive branch and in the speed and effectiveness of implementation of the Technology Transfer Act of 1986. Also, although a diversity of opinions and approaches exist in these departments, there is a strong tendency to delegate authority to the lowest level, i.e., laboratory director.

In my opinion, the most effective of the participating departments appeared to be the Dept. of Agriculture. They have been judicious in delegating the responsibility of implementation of the Technology Transfer Act down to the level of the individual laboratory when appropriate, and have developed an alternative mechanism when this is not practical. The entrepreneurialism resulting from this "customization" process has expedited their activities in this area.

It appeared that the primary impediment identified by the members at the meeting to implementation of the Technology Transfer Act is the development of an automated information system to identify both products which are patentable or copyrightable, and resources and programs which are amenable to cooperative ventures between the private and public sector.

It also appeared that there was a problem concerning the sale or joint venture of copyrightable material, especially software development, which is presently subject to the Federal copyright law. The upshot of the discussion was that in order to permit this, the copyright laws may have to be altered and that this would, in all likelihood, require a separate piece of legislation.

The major action item resulting from the meeting was an agreement on the part of the member agencies at the meeting to participate in a technology transfer training program to take place in mid July and which will be provided by the Department of Commerce. HHS was allotted three slots for the program. I lobbied for and got concurrence for five slots for HHS with the suggested composition being: one from NIH, one from CDC and one from FDA (these individuals would subsequently train others

within the cooperating agencies); a fourth slot for a policy type individual whose primary role would be to participate in the first two days of the workshop; and the fifth individual's slot would be as an ad hoc observer/participant who would participate in all four days of the workshop along with the representatives from the various agencies within PHS. Neither this suggestion, nor the number of slots, was not set in concrete and, therefore, can be modified easily by yourself by calling Norm.

I appreciated the opportunity to participate and hope that you will give me the freedom to do so at future meetings of this group.

Sincerely,

Ronald W. Hart, Ph.D.
Director, NCTR

Attachment

SUMMARY MINUTES
MEETING OF THE COMMITTEE ON FEDERAL LABORATORIES
(EXECUTIVE WORKING GROUP)

JUNE 5, 1987

The meeting was called to order at 10:00 a.m. in room H-1851, Department of Commerce Building by Mr. Norman Latker, Director, Federal Technology Management Division, Office of the Assistant Secretary for Productivity, Technology and Innovation, Department of Commerce.

I. Mr. Latker summarized the role of the Department of Commerce relative to the Technology Transfer Act of 1986. He described its participation as a cross-cutting function, coordinating the activities of the various departments within the Executive Branch, in order to: a) develop model agreements that might then subsequently be modified by the various participating departments for either licensure of patentable material or the development of cooperative research and development programs between the public and private sector; b) the preparation and submission of a report to Congress in 1988 relative to the progress made in the implementation of the Technology Transfer Act of 1986 by the various departments of the Federal Government as well as the cost savings and returns to the Government resulting from the Act; and c) a generic training function for members of the various departments in the Executive Branch concerning the meaning of the Act, its implementation, and the procedures to implement it.

II. After his summary, Mr. Latker asked the Group members from the different units in the Executive Branch to describe the progress made thus far within their respective departments. That progress is summarized below.

A. Department of Defense. The Department of Defense has delegated its activities to LABCON, who has subsequently contracted with the Federal Laboratory Consortium, to develop an implementation strategy for the Technology Transfer Act. They will be briefing the LABCON Commander on this plan at the end of this month. At that point, they plan to develop new regulations if needed. They are essentially proposing a very decentralized approach with delegation directly to the various laboratories. For an example of the scope in DOD, the Army alone has approximately 35 laboratories, ranging in size between 100 FTEs up to approximately 1,000 FTEs, with the average size being 300 FTEs.

B. Department of Commerce. Commerce's approach has been similar to that of the Department of Defense. They first developed a flowchart, which is attached, for the decision-making process. It is also their decision to decentralize with the responsibilities being delegated directly to the laboratory directors. Commerce has made major progress in the implementation of the Technology Transfer Act.

C. Department of Agriculture. The Department of Agriculture has made good progress. They have already developed a plan for implementation of the Technology Tranfer Act and are using the flowcharts provided to them by the Department of Commerce for the decision-making process. They also have already developed, and are in the process of implementing, collaborative research and development agreements. They are also in the process of attempting to sell certain patentable or already patented items to the private sector. Unlike either Commerce or Defense Department, they have decided to use a more centralized approach. This is based on the fact that, with the exception of one laboratory, Beltsville, their laboratories have less than 200 FTE's, with over 70% of their laboratories having less than 35 FTEs. Beltsville is being delegated authority directly, and, in order to assure maximum participation without undue administrative burden being placed upon the rest of the small individual labs, Agriculture has also developed a centralized approach with representation from the various participating laboratories. In addition, they have developed a University Consortium (as only they and NCTR/FDA have). The University Consortium will work closely with the Technology Transfer Act providing expertise and acting as a conduit for transfer of technology.

D. Environmental Protection Agency. The Environmental Protection Agency, similar to the Department of Defense and Department of Commerce, is delegating authority down to the laboratory level. This approach was taken even though the laboratories are not large (have more than 200 FTEs). They have also taken a novel approach by attempting to work with their on-site contract employees in such a way as to make them co-inventors. They are still exploring ways to accomplish this. They strongly feel, as did the majority of the representatives at the meeting, that it is imperative for those establishments which have on-site contractors to bring these contractors into the process by some means. They also announced that they have made Technology Transfer a major initiative for the Environmental Protection Agency and have formed a high level task force to implement the Technology Transfer Act as expeditiously as possible. There appears to be tremendous interest within all sectors of EPA on implementation of the Act and cooperation across all groups.

E. Office of Science and Technology Policy. The OSTP representative gave strong endorsement for the Technology Transfer Act stating that this was to be one of the major initiatives of this Administration. It is apparent from his presentation that OSTP and OMB believe strongly that the government has real and substantial resources and that this information must somehow get out to the industrial sector. They believe that this can best be accomplished through a people-to--people exchange with industrial scientists, not only as a visiting scientist but actually working in cooperation with governmental scientists on site. He also pointed out, however, that this has not usually been done. The single exception that was mentioned was NCTR which has agreements with some of the trade associations located in Washington for representatives from these various trade associations to serve as guest workers at NCTR on projects of mutual interest.

F. Department of Health and Human Services. I had requested prior to the meeting that Phil Chen might feel more comfortable in giving the summary of progress in HHS. He delivered a summary of the HHS activities, primarily relevant to the National Institutes of Health. He made the statement that delegation was expected to come to the agency head, i.e., the Director of NIH. To implement this centralized policy, the Director, NIH had developed, through the Patent Policy Board, three subcommittees. These subcommittees were: 1) cooperative R&D agreements; 2) royalty distribution; and 3) administrative mechanism and data systems. He also mentioned that the Patent Policy Board had four major functions it was taking on: 1) training; 2) royalty rate; 3) the mechanisms for data gathering; and 4) development of computer gathering systems.

G. Department of Interior. The Department of the Interior explained that they had approximately eight laboratories, with most of their laboratory centers well below the 200 FTE level, with an average size of approximately 75 FTE's. Similar to most of the Executive branch, they are delegating authority directly down to these laboratories, and noted that R&D was already being done within these laboratories. This was being done predominately at the Bureau of Mines, which has a history of mainly using cooperative R&D programs with industry. They are in the process of developing a strategy for implementation of the Technology Transfer Act and, hopefully, they wish to accomplish this within the already presently operating system. However, they have also started to utilize the cooperative R&D model developed by the Department of Commerce for subsequent programs to be done with the private sector.

When the report from the various Executive departments were concluded, we proceeded to the next item on the agenda.

III. Training. Norman Latker turned the proceedings over to Mr. Tip Parker of his office. Mr. Parker described the need for a training program and stated that the Department of Commerce has already developed a basic training program and the materials to be used therein. This material includes information on: a) what laboratory managers can get out of both the 1984 and 1986 Acts on Technology Transfer Acts; b) what the scientific community within these laboratories can get out of these respective Acts; and c) what technology transfer people can get from implementation of these Acts. All of this material is available at this time the NTIS, as well as a series of video tapes which can be obtained either from NTIS, or from Mr. Latker's office within the Department of Commerce. Also, Commerce is planning to have a training session in mid-July to cover implementation of the Technology Transfer Act. They are requesting that one individual attend from each of the various agencies, as you will see in the attachment to the summary minutes. They are hoping that each of the agencies will supply not only a training specialist but also a policy person. The training specialist will be responsible for training other individuals within the given

department. HHS has been allotted three. However, because of the size and structure of our Department, I asked for the option of having five, which I think is acceptable to the Working Group if you feel it is useful. With five individuals, we could invite one representative from CDC, one from FDA, and one from NIH, as well as having two policy people at the meeting. For the meeting, it is intended that the policy individual will attend the first two days of the workshop and the trainers will attend all four days of the workshop. If we have two policy people, one of them could attend for the first two days and the second one could attend for all four days, writing an overall summary for the workshop. As soon as you have decided upon whether three or five is the appropriate number, it would be best to let Norm Latker at the Department of Commerce know.

The meeting was concluded at 12:00 noon and the materials attached were collected for your review.

Ellen Ummuser - handed out at meeting on Monday 6/22/87 @ NIH - FDA did not attend

Prepared by OOMS/OM
June 1987

Technology Transfer Act of 1986 (P.L. 99-502)

(Recommended Delegations of Authority for Carrying Out Major Provisions of the Act)

Authority	Delegate Authority to Agencies	Retain Authority in OASH	Comments
SECTION 2. Cooperative Research and Development Agreements (Section 12 of Stevenson-Wydler)			
12(a) General Authority			
Under the terms of the Technology Transfer Act of 1986 "each Federal agency may permit the director of any of its Government-operated Federal laboratories..."			
"(1) to enter into cooperative research and development agreements on behalf of such...agency with Federal agencies, ...industrial organizations,...public and private foundations...or other persons..."	yes, but with such exclusions as may be determined necessary by ASH		ASH delegation to PHS agencies should note that this authority can be redelegated to BIDs. (See 5(a)) Agencies will have to establish an oversight mechanism to ensure: no undesirable impact on agency mission and personnel; no conflicts of interest; competition and equity to extent possible.
"(2) to negotiate licensing agreements...for Government-owned inventions made at the laboratory and other inventions of Federal employees that may be voluntarily assigned to the Government."	*	*	*NTIS will be retained through an agreement (with ASH as the PHS signatory) to do this in conjunction with OGC and on behalf of PHS and its agencies. Agencies will, of course, be extensively involved and their advice and recommendations solicited. PHS will participate in NTIS license negotiations.

NOTE: For the purpose of this analysis, Federal agency is defined as the PHS, and the "director" of PHS Federal laboratories is defined as the heads of NIH, CDC, FDA, and ADAMHA. These definitions have been applied uniformly and consistently throughout this analysis.

Comments to Felix N.

Authority	Delegate Authority to Agencies	Retain Authority in OASH	Comments
12(b) Enumerated Authority			
Under agreements entered into...a Government-operated laboratory may...			
"(1) accept, retain, and use funds,... from collaborating parties..."	yes		
"(2) grant or agree to grant in advance, to a collaborating party, patent licenses or assignments...in any invention made in whole or in part by a Federal employee under the agreement, retaining a non-exclusive, non-transferrable...paid up license to practice or have the invention practiced throughout the world by or on behalf of the Government..."	yes		The delegation will be qualified in that ASH will retain authority to review and modify all agreements involving waiver of or significant delimitation of the Government's opportunity to realize royalties and other income from Government-owned inventions.
"(3) waive, subject to reservation by the Government of a non-exclusive, irrevocable, paid up license to practice the invention...in whole or in part, any right of ownership which the Federal Government may have..."	yes		Same as above.
12(c) Contract Considerations			
"(1) A Federal agency may issue regulations on suitable procedures for implementing the provisions of this section..."	yes	yes	ASH will issue overall operating procedures and each PHS agency may supplement with procedures it judges necessary.
"(3)(A) Any agency using authority given it under subsection (a) shall review employee standards of conduct for resolving potential conflicts of interest to make sure they adequately establish guidelines for situations likely to arise through the use of this authority..."	yes		Agencies will be expected to institute procedures to ensure that conflicts of interest do not occur.

Authority	Delegate Authority to Agencies	Retain Authority in OASH	Comments
"(4) The laboratory director in deciding what cooperative research and development agreements to enter into shall - (A) give special consideration to small business firms..." "(B) give preference to business units located in the United States..."	yes		
"(5)(A) If the head of the agency or his designee desires an opportunity to disapprove or require the modification of any such agreement, the agreement shall provide a 30-day period within which such action must be taken beginning on the date the agreement is presented to him or her by the head of the laboratory concerned."	yes		ASH should retain "review" authority over agreements regarding waiver or delimitation of the Governments opportunity to realize royalties. The 30-day limit will ensure that ASH or agency head review will not unduly delay the process.
"(B) ...the head of the agency or such designee shall transmit a written explanation of such disapproval or modification to the head of the laboratory concerned."	yes	yes	
"(6) Each agency shall maintain a record of all agreements entered into under this section."	yes	yes	ASH should retain a central PHS repository of summary information. Each PHS agency will be expected to maintain detailed records and be able to provide OASH information on an as-needed basis.
SECTION 3. Establishment of Federal Laboratory Consortium for Technology Transfer (Section 11 of Stevenson-Wydler).			
11(e) Establishment of Federal Laboratory Consortium for Technology Transfer			
"(2)...The representatives to the Consortium shall include a senior staff member of each Federal laboratory which is a member of the Consortium and a representative appointed from each Federal agency with one or more member laboratories."	No delegation needed		ASH (or his designee) should represent the HHS in these activities. Each PHS agency will be, or can be, involved as participating laboratories, or ASH can designate one to serve as his representative.

Authority	Delegate Authority to Agencies	Retain Authority in OASH	Comments
"(7)(A)...an amount equal to .005 percent of that portion of the research and development budget of each Federal agency that is to be utilized by the laboratories of such agency for a fiscal year (1987-1991) shall be transferred by such agency to the National Bureau of Standards..."	yes		
SECTION 4. Utilization of Federal Technology (Section 11 of the Stevenson-Wydler Act)			
11. Utilization of Federal Technology			
"(a)(3) Each laboratory director shall ensure that efforts to transfer technology are considered positively in laboratory job descriptions, employee promotion policies, and evaluation of the job performance of scientists and engineers in the laboratory."	yes		
"(f) Each Federal agency which operates or directs one or more Federal laboratories shall report annually to the Congress, as part of the agency's annual budget submission, on the activities to the provisions of this Section."	Not applicable		
SECTION 6. Rewards for Scientific, Engineering, and Technical Personnel of Federal Agencies (A new Section following Section 12 of the Stevenson-Wydler Act).			
Section 13. Rewards for Scientific, Engineering, and Technical Personnel of Federal Agencies			
"The head of each Federal agency...shall use the appropriate statutory authority to develop and implement a cash awards program to reward its scientific, engineering, and technical personnel..."	yes	yes	ASH should allow each PHS agency to administer its own unique cash awards program, but should retain right to approve awards over a certain amount.

Authority	Delegate Authority to Agencies	Retain Authority in OASH	Comments
SECTION 7. Distribution of Royalties Received by Federal Agencies (A new Section following Section 13).			
Section 14. Distribution of Royalties Received by Federal Agencies			
(a) In General - "(1)...any royalties or other income received by a Federal agency from the licensing or assignment of inventions under agreements entered into under Section 12,.. shall be retained by the agency whose laboratory produced the invention and shall be disposed of as follows:	yes		
(A)(i) The head of the agency or his designee shall pay at least 15 percent of the royalties or other income the agency receives on account of any invention to the inventor..."	yes		Memo of agreement with NTIS to be signed by ASH would provide that NTIS will distribute funds in accord with a PHS agency approved list of awardees. Policy regarding level of payment remains in OASH.
"(B) The balance of the royalties or other income shall be transferred by the agency to its Government-operated laboratories, with the majority share of the royalties or other income from any invention going to the laboratory where the invention occurred..."	yes		Each PHS agency is the lab., and as such administers the balance of the royalties transferred to it by ASH.
"...funds so transferred...may be used or obligated by that laboratory during the fiscal year in which they are received or during the succeeding fiscal year -"	yes		

Authority	Delegate Authority to Agencies	Retain Authority in OASH	Comments
** "i. for payment of expenses incidental to the administration and licensing of inventions...;"		yes	OM would be delgated responsibility for dispersing monies to those responsible for administering (and patenting) inventions. Agreement with NTIS, and addendum thereto, will cover the payment for licensing activities and foreign patent activities.
"ii. to reward scientific, engineering and technical employees of that laboratory;"	yes		
"iii. to further scientific exchange among the Government-operated laboratories;"	yes		Reports will be submitted to OASH.
"iv. or for education and training of employees..."	yes		Reports will be submitted to OASH.
"(b) Certain Assignments - If the invention involved was one assigned to the Federal agency - (1) by a contractor, grantee, or participant in a cooperative agreement with the agency, or (2) by an employee of the agency... the agency unit that was involved in such assignment shall be considered to be a laboratory for purposes of this Section."	yes		ASH should receive periodic notification of such assignments.
"(c) Reports - (1) In making their annual budget submissions Federal agencies shall submit...both Houses of the Congress, summaries of the amount of royalties or other income received and expenditures made..."		yes	Supporting information will come from NTIS and PHS agencies.

Authority	Delegate Authority to Agencies	Retain Authority in OASH	Comments
SECTION 8. Employee activities (a new Section following Section 14).			
Section 15. Employee Activities			
"(a)...the agency may condition the inventor's right to title on the timely filing of a patent application..."	yes		GC will also be involved.
SECTION 9. Miscellaneous and Conforming Amendments			
"(d) Additional Definitions			
(8) "Federal agency means any executive agency as defined in Section 105 of title 5, United States Code..."			

Prepared by: John Burckhardt, DMPA/OOMS
Jawnee Steele, DMPA/OOMS

By the attached June 23, 1987 memo the Secretary delegated to me the responsibility to vigorously implement the Federal Technology Transfer Act of 1986 (FTTA) within existing resources. As you will note, prior to further delegations to PHS laboratories the Secretary requested me to prepare for his review, after consultation with PHS agency heads, an implementation plan which responds to his concerns by the end of September.

In order to respond to the Secretary's request, I believe we must first identify the decision making process which must be undertaken to successfully manage technology by a laboratory director who is permitted to enter into cooperative research and development or license agreements under the authority of Section 11 of the FTTA. Identification of the decision making process will make assessment of necessary resources and, therefore, the most productive levels for delegation of authority and retention of oversight easier. Further, this should enhance our ability to focus on the necessity of developing administrative tools and identifying when reviews for potential conflict-of-interest need to be undertaken.

Given the above, my staff has developed the attached schematic chart and explanation. In short, the chart identifies the work steps and decisions which I believe must be undertaken to successfully manage technology at a laboratory with authority to enter into cooperative research and development or license agreements. The chart has two primary logic trees. The first identifies the actions and decisions that need to be undertaken to identify laboratory projects that have the potential of resulting in a useful technology, finding a private sector collaborator, negotiating and executing a cooperative agreement, conducting the cooperative research, and finally, assisting in marketing and collecting the benefits of resulting technology. The second tree identifies the actions and decisions that need to be undertaken to identify patentable technology developed at the laboratory, evaluating its economic potential, finding a private sector licensee, negotiating and executing a licensing agreement, assisting in the development of the licensed technology and finally, assisting in marketing and collecting the benefits of the technology.

To proceed further, I have asked Dr. Lowell Harmison to chair an implementation task force to review the schematic chart and begin to determine what resources each PHS agency will utilize to undertake implementation of the Act as suggested by the schematic. I would like each agency to be represented on the task force by two participants: your deputy, who will represent you personally, and another principal official, who has been involved in technology management. The first meeting of the task force will be _____.

Since I am anxious to meet the Secretary's desire to proceed, I believe it is appropriate at this time to permit each PHS agency to commence negotiation of cooperative research and development

[illegible] The second tree identifies the actions and decisions that [illegible]

and license agreements subject to review by my and the Secretary's office. To assist you in that regard, I am attaching the cooperative research and development and license agreements developed by the Department of Commerce to meet their legislative mandate to assist agencies in implementing the FTTA. These instruments are models only and can be amended in any appropriate way to meet your needs.

By the attached June 23, 1987 memo the Secretary delegated to me the responsibility to vigorously implement the Federal Technology Transfer Act of 1986 (FTTA) within existing resources. As you will note, prior to further delegations to PHS laboratories the Secretary requested me to prepare for his review, ~~and~~ after consultation with PHS agency heads, an implementation plan which responds to his concerns by the end of September.

In order to respond to the Secretary's request, I believe we must first identify the decision making process which must be undertaken to successfully manage technology by a laboratory director who is permitted to enter into cooperative research and development or license agreements under the authority of Section 11 of the FTTA. Identification of the decision making process will make assessment of necessary resources and, therefore, the most productive levels for delegation of authority and retention of oversight easier. Further, this should enhance our ability to focus on the necessity of developing administrative tools and identifying when reviews for potential conflict-of-interest need to be undertaken.

Given two

~~Based on~~ the above, my staff has developed the attached schematic chart and explanation. In short, the chart identifies the work steps and decisions which I believe must be undertaken to successfully manage technology at a laboratory with authority to enter into cooperative research and development or license agreements. The chart has ~~the~~ primary logic trees. The first identifies the actions and decisions that need to be undertaken to identify laboratory projects that have the potential of resulting in a useful technology, finding a private sector collaborator, negotiating and executing a cooperative agreement, conducting the cooperative research, and finally, assisting in marketing and collecting the benefits of resulting technology. The second ~~three~~ identifies the actions and decisions that need ~~to be undertaken~~ to identify patentable technology developed at the laboratory, evaluating its economic potential, finding a private sector licensee, negotiating and executing a licensing agreement, assisting in the development of the licensed technology and finally, assisting in marketing and collecting the benefits of the technology.

free

period of each

To proceed further, I have asked Dr. Lowell Harmison to chair an implementation task force to review the schematic chart and begin to determine what resources PHS agencies will utilize to undertake ~~to~~ implement the Act as suggested by the schematic. I would like each agency to be represented on the task force by two participants: your deputy, who will represent you personally, and another principal official, who has been involved in technology management. The first meeting of the task force will be _____.

Since I am anxious to meet the Secretary's ~~and~~ desire to proceed, I believe it is appropriate at this time to permit each PHS agency to commence negotiation of ~~CRDAs~~ and license agreements subject

Cooperative Research and Development

identifies the actions and decisions that need to be undertaken

to review by my and the Secretary's office. To assist you in that regard, I am attaching the ~~CRDA~~ cooperative research and development agreement and license agreement developed by the Department of Commerce to meet their legislative mandate to assist ~~us in proceeding~~ agencies in implementing the FTTA. These instruments are models only and can be amended in any appropriate way to meet your needs.

PROPOSED SYSTEM FOR MANAGING TECHNOLOGY IN FEDERAL LABORATORIES

PART 1

Part 1a. Background

The Federal Government funds or performs about half of all the research and development done in the United States today. Much of this effort is to meet unique, Government needs, particularly for the military establishment. But it is increasingly evident that the future of the country also depends on how well the results of all U.S. R&D are used by U.S. industry to advance the economy. For example, in a world of intensifying economic competition based on new technologies, the Federal R&D budget is about the same as Japan's total R&D expenditures, but nearly all of their R&D is to develop products for domestic use and export.

Federal laboratories have always transferred the discoveries and technologies they produce to meet the needs of their R&D sponsors. These laboratories have made major contributions to Man's knowledge, created technologies used in products and services the public depends on today, trained outstanding researchers, and led the world in many fields.

Recently, however, has there been Government-wide emphasis on increasing interactions between Federal laboratories and U.S. industry to benefit both the economy and the laboratories. Since 1980, a series of related statutes has been enacted to help promote industry/laboratory interaction. Briefly, these are:

- P.L. 96-480 -- which included provisions to encourage transfer of technology to State and local governments and the private sector.

- P.L. 96-517 -- which allowed small business and nonprofit organizations to own and license the inventions they create with Federal R&D funding. This Act was applied to some nonprofit organizations that operate Federal laboratories for Federal agencies under contract and also authorized the agencies to issue exclusive licenses on patented inventions they own.

- P.L. 98-620 -- which amended P.L. 96-517 by ensuring that most small business and nonprofit contractors that operate Federally-owned laboratories have the right to own and manage their inventions.

- P.L. 98-622 -- which provided a low cost way for an inventor or Federal agency to protect the royalty-free right to use an invention by filing a Statutory Invention Registration with the Patent Office.

- P.L. 99-502 -- which allows Government-operated laboratories to make cooperative research and development agreements with industry, license their inventions, share royalties with inventors, and use royalties for a variety of other purposes.

On April 10, President Reagan signed Executive Order 12591, which directs Federal agencies to encourage and facilitate technology transfer and collaboration of their laboratories with the private sector by implementing Public Laws 96-517, 98-620 and 99-502. The Order also directs agencies to comply with his 1983 Patent Policy Memorandum which applies to laboratories run by for-profit contractors.

An objective of these new policies is to require Government laboratories to manage the technology they produce as an asset. This paper proposes a system for managing technology that laboratories may use as a guide in developing their own internal processes. Part 1 of the paper describes the flow and logic of the system, while Part 2 (beginning on page 10) provides additional considerations and suggestions for implementation.

Part 1: An Integrated Plan

While there are many forms of technology transfer, this paper concentrates on two--collaboration with other organizations and management of patentable inventions in Government-operated laboratories. The proposed system of actions and decisions has been developed as a basis for discussion. The system is intended to operate on a decentralized basis with agencies determining how far down the organization to delegate authorities.

The schematic chart titled "Managing Technology in a Government-Operated Laboratory" that follows Part 1 shows the kinds of decisions that we believe will lead to the best use of the new authorities. This is a generalized presentation that considers domestic patents only, applies to unclassified work only, and omits some details. The system emphasizes laboratory/industry cooperation and patent licensing because of the new authorities. It is not intended to detract from the wide range of other typical laboratory interactions such as publication of papers, consultation, and personnel exchanges.

Each rectangle in the chart represents a work step or series of actions, while each oval indicates a decision step. While the chart does not indicate who should make each decision, we believe that by identifying and describing them, agencies or laboratories will recognize the need to designate who should contribute and who should have the authority to make each decision. Regardless of who makes a decision, the chart assumes the necessary close cooperation among:

- Laboratory researchers and scientists
- Research managers
- Technology transfer officers
- ~~Patent~~ Attorneys (Including Patent Attorneys)

The chart has three points of entry. The first follows Step 1 when a proposal for a cooperative R&D project is received from outside the laboratory. The second is Step 2 when an internal proposal for a laboratory project is being initiated. The third is Step 15 PRELIMINARY VALUE SCREEN, where when the laboratory makes a preliminary decision on whether an employee's discovery or idea may be a valuable and patentable invention.

The chart has ten triangles that say "end." This means the end of what the chart is intended to show -- not the end of activity for the laboratory, an employee, the technology transfer officer, or a patent attorney.

Part 1b. Step-by-Step Explanation

Step 1, LABORATORY SOLICITS COOPERATORS. A laboratory may encourage outside proposals for cooperative R&D projects. The chart shows R&D proposals being received in response to this encouragement but omits the obvious evaluation and decision steps that would preceed a cooperative project.

> (Part 2a, Techniques for Finding R&D Cooperators and Licensees discusses ways to publicize a laboratory's interest in undertaking cooperative R&D projects; page 10.)

Step 2, PROJECT INITIATION--CONSIDER MEANS OF COMMUNICATING AND TRANSFERRING RESULTS. This is the first large rectangle. When a new R&D project is being considered, it is normal to think about how the results of a project will be communicated to the sponsor as well as deciding whether or not the project should be funded. With the new authorities, labs should also ask at this stage whether the project may have commercial potential and whether a private sector organization (be might) interested in helping or cooperating on the project. A related question is whether the project can be modified to meet the original sponsor's needs and increase its interest for a private sector organization. The chart compresses these considerations into two decisions. Step 2-A, LABORATORY WILL FUND? YES leads to Step 2-B, SEEK COOPERATOR? If 2-B is YES, the laboratory will seek a cooperator. If NO, the laboratory will proceed to do the work on its own.

Taking advantage of the commercial potential and possibility of R&D cooperation at an early stage may have several benefits for the laboratory, including:

- The sooner a commercializing firm becomes involved in developing a technology, the greater the chances of commercial success.

- The private sector may supplement Federal funds for conducting laboratory R&D.

- Other parties may bring knowledge and expertise to the project that increase its chances of meeting the Government sponsor's needs.

- Working with outsiders can enrichen the job of laboratory staff in many ways.

If the R&D project is expected to lead to an item the Government will purchase, there may be an opportunity to expand the market for the item. This can spread both the development and manufacturing costs among private as well as Government users, thus lowering the total cost to the Government.

Step 3, DECIDE HOW TO FIND COOPERATOR. If the project appears to have commercial potential and may be of interest to a cooperator, the next step is to decide how to find one.

(Part 2b. Techniques for Finding R&D Cooperators and Licensees discusses some ways this can be done; page 10.)

Step 4, SEEK COOPERATOR. This involves carrying out the plan for finding a cooperator.

Step 5, FIND COOPERATOR? NO. (If YES, go to Step 7)

Step 6, LABORATORY CONTINUE THE PROJECT? The decision at Step 2-B to proceed may have been conditioned on finding a cooperator. If none is found, the laboratory will have to decide whether or not to proceed on its own.

Step 7, RESOLVE CONFLICTS OF INTEREST. If a cooperator is found, before an agreement is executed, it is necessary to ensure that conditions which might lead to an apparent or real conflict of interest are identified and provided for.

(Part 2a. Conflict of Interest discusses a number of aspects of conflict of interest, including situations where the term is sometimes missused; page 16.)

Step 8, NEGOTIATE AND EXECUTE AGREEMENT. Under ~~P.L. 99-502,~~ the Federal Technology Transfer Act cooperative R&D agreements are not procurement contracts, grants, or cooperative agreements as these instruments have been established by the Federal Grant and Cooperative Agreement Act. As a result, neither the Federal Acquisition Regulation nor

Government-wide assistance policies apply. This gives labs wide latitude to negotiate terms and conditions with cooperators that meet the needs of the particular parties. Model agreements are being developed as a point of departure to assist labs in developing the agreements they may need.

A prime objective of some cooperative R&D projects may be to produce inventions that can lead to marketable products. In other cases, inventions may be a possible outcome but not an objective or perhaps not even likely. Since it is often impossible to anticipate when an invention will occur, it is best to assume that any R&D project has a chance of producing one, and the rights to a resulting invention should be established in the agreement.

Step 9, CONDUCT COOPERATIVE PROJECT.

(Part 2b. Types of R&D Cooperation suggests different types of shared projects that labs may find beneficial. Page 12.)

Step 10, MAKE INVENTIONS. An oversimplification that includes all of the steps necessary to identify, describe, and protect an invention.

Step 11, TRANSFER TECHNOLOGY PER AGREEMENT. This ~~is where the results of the project are divvied up among~~ the original sponsor, the cooperating partner, the lab, and individual investigators in accordance with the agreement. It includes project reports, rights to publish, demonstration models, and patent rights if any.

Step 12, RECEIVE AND DISTRIBUTE ROYALTIES. Agencies must follow the statutory requirements and select among the options for using royalties the Government receives from licensed or assigned inventions.

Step 13, LABORATORY PERFORMS WORK. Going back to Step 2, if a project is not seen as having cooperative R&D potential, or the lab was unable to find a cooperator (Step 6), the lab will consider the merits of the proposal and decide whether or not to do the work on its own just as it has always done. If it goes ahead, a lab employee may report a discovery or an idea that could be an invention.

Step 14, EMPLOYEE DONATES IDEA. Under the new law, a Government employee may voluntarily assign an invention that may be entirely unrelated to his or her job. This is to give employees an opportunity to have their ideas evaluated, patented, and managed by a laboratory if the lab agrees. It ~~is~~ also ~~to~~ provides an additional source of ideas to laboratories and the Government which might otherwise ~~just~~ die for lack of follow-up.

~~results of the project are divvied up among~~ the original sponsor,