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

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, excluding the authority to promulgate regulations and to submit reports to the Congress. This authority may be redelegated.

This delegation is effective upon the date of signature.

Otis R. Bowen, M.D.
Secretary

BILLING CODE: 4160-17

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Stevenson-Wydler Technology Innovation Act of 1980
As Amended by the Federal Transfer Technology Act of 1986

Notice is hereby given that on the Secretary of Health and Human Services delegated to the Assistant Secretary for Health, with authority to redelegate, all the authorities vested in the Secretary under the Stevenson-Wydler Technology Innovation Act of 1980 (15 U.S.C. 3701 et seq.), as amended by the Federal Transfer Technology Act of 1986, P.L. 99-502, excluding the authority to promulgate regulations and to submit reports to the Congress.

This delegation was effective on

_____ _____

Date

Otis R. Bowen, M.D.
Secretary

Presidential Documents

Executive Order 12591 of April 10, 1987

Facilitating Access to Science and Technology

By the authority vested in me as President by the Constitution and laws of the United States of America, including the Federal Technology Transfer Act of 1986 (Public Law 99–502), the Trademark Clarification Act of 1984 (Public Law 98–620), and the University and Small Business Patent Procedure Act of 1980 (Public Law 96–517), and in order to ensure that Federal agencies and laboratories assist universities and the private sector in broadening our technology base by moving new knowledge from the research laboratory into the development of new products and processes, it is hereby ordered as follows:

Section 1. *Transfer of Federally Funded Technology.*

(a) The head of each Executive department and agency, to the extent permitted by law, shall encourage and facilitate collaboration among Federal laboratories, State and local governments, universities, and the private sector, particularly small business, in order to assist in the transfer of technology to the marketplace.

(b) The head of each Executive department and agency shall, within overall funding allocations and to the extent permitted by law:

(1) delegate authority to its government-owned, government-operated Federal laboratories:

(A) to enter into cooperative research and development agreements with other Federal laboratories, State and local governments, universities, and the private sector; and

(B) to license, assign, or waive rights to intellectual property developed by the laboratory either under such cooperative research or development agreements and from within individual laboratories.

(2) identify and encourage persons to act as conduits between and among Federal laboratories, universities, and the private sector for the transfer of technology developed from federally funded research and development efforts;

(3) ensure that State and local governments, universities, and the private sector are provided with information on the technology, expertise, and facilities available in Federal laboratories;

(4) promote the commercialization, in accord with my Memorandum to the Heads of Executive Departments and Agencies of February 18, 1983, of patentable results of federally funded research by granting to all contractors, regardless of size, the title to patents made in whole or in part with Federal funds, in exchange for royalty-free use by or on behalf of the government;

(5) implement, as expeditiously as practicable, royalty-sharing programs with inventors who were employees of the agency at the time their inventions were made, and cash award programs; and

(6) cooperate, under policy guidance provided by the Office of Federal Procurement Policy, with the heads of other affected departments and agencies in the development of a uniform policy permitting Federal contractors to retain rights to software, engineering drawings, and other technical data generated by Federal grants and contracts, in exchange for royalty-free use by or on behalf of the government.

Sec. 2. *Establishment of the Technology Share Program.* The Secretaries of Agriculture, Commerce, Energy, and Health and Human Services and the Administrator of the National Aeronautics and Space Administration shall select one or more of their Federal laboratories to participate in the Technology Share Program. Consistent with its mission and policies and within its overall funding allocation in any year, each Federal laboratory so selected shall:

(a) Identify areas of research and technology of potential importance to long-term national economic competitiveness and in which the laboratory possesses special competence and/or unique facilities;

(b) Establish a mechanism through which the laboratory performs research in areas identified in Section 2(a) as a participant of a consortium composed of United States industries and universities. All consortia so established shall have, at a minimum, three individual companies that conduct the majority of their business in the United States; and

(c) Limit its participation in any consortium so established to the use of laboratory personnel and facilities. However, each laboratory may also provide financial support generally not to exceed 25 percent of the total budget for the activities of the consortium. Such financial support by any laboratory in all such consortia shall be limited to a maximum of $5 million per annum.

Sec. 3. *Technology Exchange—Scientists and Engineers.* The Executive Director of the President's Commission on Executive Exchange shall assist Federal agencies, where appropriate, by developing and implementing an exchange program whereby scientists and engineers in the private sector may take temporary assignments in Federal laboratories, and scientists and engineers in Federal laboratories may take temporary assignments in the private sector.

Sec. 4. *International Science and Technology.* In order to ensure that the United States benefits from and fully exploits scientific research and technology developed abroad,

(a) The head of each Executive department and agency, when negotiating or entering into cooperative research and development agreements and licensing arrangements with foreign persons or industrial organizations (where these entities are directly or indirectly controlled by a foreign company or government), shall, in consultation with the United States Trade Representative, give appropriate consideration:

(1) to whether such foreign companies or governments permit and encourage United States agencies, organizations, or persons to enter into cooperative research and development agreements and licensing arrangements on a comparable basis;

(2) to whether those foreign governments have policies to protect the United States intellectual property rights; and

(3) where cooperative research will involve data, technologies, or products subject to national security export controls under the laws of the United States, to whether those foreign governments have adopted adequate measures to prevent the transfer of strategic technology to destinations prohibited under such national security export controls, either through participation in the Coordinating Committee for Multilateral Export Controls (COCOM) or through other international agreements to which the United States and such foreign governments are signatories.

(b) The Secretary of State shall develop a recruitment policy that encourages scientists and engineers from other Federal agencies, academic institutions, and industry to apply for assignments in embassies of the United States; and

(c) The Secretaries of State and Commerce and the Director of the National Science Foundation shall develop a central mechanism for the prompt and efficient dissemination of science and technology information developed abroad to users in Federal laboratories, academic institutions, and the private sector on a fee-for-service basis.

Sec. 5. *Technology Transfer from the Department of Defense.* Within 6 months of the date of this Order, the Secretary of Defense shall identify a list of funded technologies that would be potentially useful to United States industries and universities. The Secretary shall then accelerate efforts to make these technologies more readily available to United States industries and universities.

Sec. 6. *Basic Science and Technology Centers.* The head of each Executive department and agency shall examine the potential for including the establishment of university research centers in engineering, science, or technology in the strategy and planning for any future research and development programs. Such university centers shall be jointly funded by the Federal Government, the private sector, and, where appropriate, the States and shall focus on areas of fundamental research and technology that are both scientifically promising and have the potential to contribute to the Nation's long-term economic competitiveness.

Sec. 7. *Reporting Requirements.* (a) Within 1 year from the date of this Order, the Director of the Office of Science and Technology Policy shall convene an interagency task force comprised of the heads of representative agencies and the directors of representative Federal laboratories, or their designees, in order to identify and disseminate creative approaches to technology transfer from Federal laboratories. The task force will report to the President on the progress of and problems with technology transfer from Federal laboratories.

(b) Specifically, the report shall include:

(1) a listing of current technology transfer programs and an assessment of the effectiveness of these programs;

(2) identification of new or creative approaches to technology transfer that might serve as model programs for Federal laboratories;

(3) criteria to assess the effectiveness and impact on the Nation's economy of planned or future technology transfer efforts; and

(4) a compilation and assessment of the Technology Share Program established in Section 2 and, where appropriate, related cooperative research and development venture programs.

Sec. 8. *Relation to Existing Law.* Nothing in this Order shall affect the continued applicability of any existing laws or regulations relating to the transfer of United States technology to other nations. The head of any Executive department or agency may exclude from consideration, under this Order, any technology that would be, if transferred, detrimental to the interests of national security.

Ronald Reagan

THE WHITE HOUSE,
April 10, 1987.

[FR Doc. 87-9270
Filed 4-21-87; 11:10 am]
Billing code 3195-01-M

Editorial note: For the President's statement of Apr. 10, on signing EO 12591, see the *Weekly Compilation of Presidential Documents* (vol. 23, no. 15).

(2) identification of new or creative approaches to technology transfer

DEPARTMENT OF THE ARMY
OFFICE OF THE ASSISTANT SECRETARY
WASHINGTON, D.C. 20310

29 APR 1987

General Louis C. Wagner, Jr.
Commander
U. S. Army Materiel Command
5001 Eisenhower Avenue
Alexandria, Virginia 22333-0001

Dear General Wagner:

The Federal Technology Transfer Act of 1986 (PL 99-502), which was signed into law on 20 October 1986, reflects the desire of Congress and the Administration to more actively promote the transfer of technology from Federal laboratories to the private sector. Technology Transfer constitutes a vital part of the President's competitiveness initiatives as mentioned in the State of the Union Address and amplified in the enclosed White House Fact Sheet (Enclosure 1).

I believe that Army laboratories should be encouraged to actively participate in technology transfer efforts, consistent with their respective missions. Since LABCOM has been delegated responsibility under AR 70-57 to provide centralized coordination, under the direction of the SARDA, for all Army technology transfer activities, you are requested to propose a technology transfer implementation plan for my approval.

Your plan should specify the necessary changes to AR 70-57, propose new regulations or amendments to existing regulations to implement the various requirements of the Act, identify organizations whose coordination may be required, outline LABCOM's role in relation to the Army laboratories, and request such delegation of authorities as you consider necessary.

An oral briefing of your proposed plan is requested within 45 days. Dr. Joseph Sattler is the POC for this action and can be reached on 695-7674.

Sincerely,

J. R. Sculley
Assistant Secretary of the Army
(Research, Development and Acquisition)

Enclosure

with their respective missions. Since LABCOM has been dele-

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Memorandum

Date

From The Secretary

Subject Implementation of the Federal Technology Transfer Act of 1986

To Assistant Secretary for Health

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 sectors. It offers new incentives to Government scientists and industry to participate in this process.

I am directing the Public Health Service, the sole Operating Division in HHS with research laboratories, to vigorously implement the new law by entering into collaborative arrangements with the private sector and arranging for the marketing of technological innovations made by PHS scientists. Accordingly, I am delegating to you authority to carry out the major provisions of the Act.

Under your leadership, I know that PHS scientists will respond enthusiastically to the purpose as well as the opportunity created by this important legislation. Please inform PHS personnel of my interest and apprise me periodically of your progress in carrying out the Act.

Otis R. Bowen, M.D.

OFFICE OF FEDERAL TECHNOLOGY COMMERCIALIZATION

SECTION 1. PURPOSE

.01 This Order prescribes the organization and the functions of the Office of Federal Technology Commercialization.

SECTION 2. STATUS AND LINE OF AUTHORITY

.01 The Office of Federal Technology Commercialization, a constituent operating unit of the Department, shall be headed by a Director, who for all matters of policy and program shall report to the Under Secretary for Economic Affairs. The Director shall be responsible to the Assistant Secretary for Productivity, Technology and Innovation for all other purposes.

SECTION 3. FUNCTIONS

The Office of Federal Technology Commercialization shall be the principal unit in the Department on issues and policies relating to technology developed in Federal laboratories, developed with Federal funding, or affected by Federal programs and activities. In carrying out these responsibilities, the Office shall:

a. Advise the Under Secretary for Economic Affairs and other Department officials on important policy questions and problems relating to private sector use of Federal technology.

b. Enhance the flow of Federally funded technologies to the private sector and minimize adverse affects of Federal programs on technology developed by the private sector.

c. Assist the Under Secretary for Economic Affairs in performing the lead agency functions delegated by the Secretary, concerning Federal technology management policy under Public Laws 96-480, 96-517, 98-620, 98-622, and 99-502 and Executive Order 10096 and the President's patent policy memorandum, including coordinating, monitoring, gathering relevant data, evaluating relevant programs and activities, developing uniform Government-wide standards for implementing Federal patent policy, preparing reports, disseminating information, making recommendations, and taking other actions necessary to assure maximium private sector opportunity for commercializing technology resulting from projects performed by Federal agencies or financed with Federal Government funds.

d. Review for the Under Secretary and advise on, all Commerce activities under the Stevenson-Wydler Technology Transfer Act of 1980 and the Federal Technology Transfer Act of 1986.

Department officials on [illegible]

e. Chair the Federal Coordinating Council on Science, Engineering, and Technology Committee on Intellectual Property for Technology Transfer.

f. Develop a Government-wide policy on technical data used or developed at Government expense.

g. Develop training materials and programs for helping Federal laboratories or Federally-funded laboratories evaluate the commercial value of their technologies and improve their technology transfer capabilities.

h. License Federally-owned inventions both within the custody of the Department of Commerce and other agencies.

i. Chair the Commerce Committee on Laboratory Technology Management, to coordinate implementation of authorities delegated to DOC laboratories under subsection 11(a); the awards program authorized by section 12 of P.L. 99-502 and the distribution of royalties under Section 13 of P.L. 99-502.

j. Prepare the reports from the Secretary to the President and Congress as required in P.L. 99-502.

SECTION 4. ORGANIZATION

.01 The Office of Federal Technology Commercialization shall consist of the Division of Federal Technology Management Policy and the Division of Federal Patent Licensing.

02. The Division of Federal Technology Management Policy shall:

a. Provide advice and assistance as requested by other Federal agencies on commercializing inventions, model agreements, and cooperative research and development projects as authorized by paragraph 10(g)(1) of P.L. 99-502.

b. Develop the biennial report required by subparagraph 10(g)(2) of P.L. 99-502 to the President and Congress on Government-wide use of the authorities provided in the Act.

c. Analyze, review and propose new legislation or other policies including Government-wide regulations on management of technology developed by the Government or with Government funding, including preparation of the report to Congress and the President required by paragraph 10(g)(3) of P.L. 99-502.

d. Draft Commerce regulations as may be necessary to comply with subsection 11(c) of P.L. 99-502.

e. Develop and administer policies for distributing royalty income within the Department of Commerce in accordance with subsection 13(a) of P.L. 99-502.

f. Issue, interpret, and maintain regulations under P.L. 96-517 and 98-620 on ownership of Government funded inventions (37 CFR Part 401) and licensing of Government-owned inventions (37 CFR Ch.IV).

g. Interpret and administer Government Employee Inventor Program under E.O. 10096, including recommendations for changing the Order if necessary to conform with new legislation.

h. Work with agencies to help take advantage of the Statutory Invention Recording process authorized by P.L. 98-622 and develop the required annual report.

i. Provide advice and assistance to the Director of the Office of Science and Technology Policy on matters related to managing technology developed by the Government or with Federal funding.

03. The Division of Federal Patent Licensing shall:

a. Negotiate agreements with Federal laboratories and/or agencies for provision of services related to licensing of laboratory or employee inventions.

b. Provide services to Federal laboratories and/or agencies in finding potential licensees, negotiating licenses, and administering licenses including collecting royalty payments.

c. At laboratory and/or agency request, file patent applications, particularly for overseas patents.

d. Provide training on a reimbursable basis to Federal agency and laboratory personnel in patent licensing.

From The Secretary

Subject: Implementation of the Federal Technology Transfer Act of 1986

To Assistant Secretary for Health

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 Government research labortories to develop new products with potential application in the private as well as public sectors. It offers new incentives to Government scientists, the laboratories, and industry to participate in this process.

I am directing you to have the new law implemented vigorously in the Public Health Service by entering into collaborative arrangements with the private sector and arranging for the marketing of inventions made by PHS employees. The PHS is the sole operating division in HHS with research laboratories, and this assignment is consistent with your current responsibilities for Department patent activities as set forth in Chapter 1-901 of the Department's Organization Manual. Accordingly, I am delegating to you authority to carry out the major provisions of the Act.

Under your leadership, I know that PHS scientists will respond enthuiastically to the purpose as well as the opportunities created by this important legislation. Please inform PHS personnel of my interest and apprise me peridocially of your progress in carrying out this Act.

Otis R. Bowen, M.D.

responsibilities for Department patent activities as set forth in

NCTR TELECOPIER TRANSMISSION RECORD

TO: (NAME, ORGANIZATION & PHONE NO., IF KNOWN)

Dr. Norm Kerber

301-443-4179

FROM: [illegible] (National Center for Toxicological Research)
Jefferson, Arkansas 72079

Lynn Hart

~~501/543-4542~~

501/543-3431 (1-time #)

DATE: 2/1/91 COMMENTS:

NO. OF PAGES: 5 (following cover sheet)

NCTR'S AUTOMATIC TELECOPIER NUMBER IS FTS 790-4576; COMMERCIAL 501/541-4576
(a BURROUGHS/UNISYS 2100)

FOR VERIFICATION, CALL: FTS 790-4516; COMMERCIAL 501/541-4516.

(1)

FROM: Assistant Secretary for Health

SUBJECT: Implementation of the Technology Transfer Act of 1986

TO: Under Secretary

The purpose of this memorandum is to provide the PHS proposed plan for the implementation of the Technology Transfer Act (TTA) of 1986. We request your endorsement and transmittal of this document to the Secretary. The plan includes a public statement to be issued by the Secretary and a delegation of authority from the Secretary to the ASH.

BACKGROUND

The Technology Transfer Act of 1986

Under the terms of the Act, each Federal agency may permit the director of its Government-operated Federal laboratories to enter into cooperative research and development agreements with Federal agencies, industrial organizations, public and private foundations or other "persons". The law seeks to provide opportunities and incentives for the commercialization of technology at such laboratories. The law also makes it the responsibility of each technical employee in the management structure to develop opportunities for the transfer of technology out of the Federal laboratories.

The Executive Order

On April 10, 1987, the President issued Executive Order No. 12591 which directed Federal agencies to implement the Act by delegating authority to government-owned, government-operated Federal laboratories to enter into cooperative research and development agreements and to license inventions produced by the laboratories.

Departmental Impact

In order for the Department to vigorously implement the Act: 1) delegations of authority to the level that will provide for the most effective implementation must be accomplished as quickly as possible; and 2) [illegible]s must be established which a) protect the public interest yet fully realize this "new way of thinking", b) strongly encourage the development of cooperative research and development agreements, patents and licenses, and c) provide guidelines which the laboratories and their scientists find helpful in accomplishing their new responsibilities.

Current Procedures

Under Chapter 1-901, "Department Patent Activities", of the Department's Organization Manual, I have Department-wide responsibility to evaluate current patent policy, develop policies to meet changing needs, and to make determination of the rights in inventions and patents involving important policy considerations. My office is experienced in the area of patent policy since we have actively developed all Department invention and patent policies since 1969. PHS is the sole operating division in HHS with research laboratories which would be involved in the type of collaboration addressed by the Act.

We are prepared and eager to assimilate changes created by this new Act, which primarily requires more direct laboratory/industry technical collaboration and calls for delegating the necessary authorities to effect these changes by laboratory directors. The primary challenge will be to reserve enough oversight to prevent major problems yet not hinder the processes leading to successful collaborative and licensing agreements.

THE PROPOSED PLAN

As a first initiative under the delegation, I will identify all the salient decisions and actions that must be addressed in the management processes to:

- Embody the spirit of the Act through seeking cooperative support for research projects funded by HHS laboratories that have been identified as having the potential to create new commercial products, and
- Identify, evaluate, protect and license other new technologies that have been created by HHS laboratories.

In all of our activities, I intend to provide leadership so that our employees do not lose sight of the fact that our laboratory employees and our entire management staff must adopt an institutionally new way of viewing our role in transfer of technology. I intend to see that all of our employees understand the major national importance of entirely new approaches and thought patterns. While focusing constantly on the end objectives and not impeding the effort, a number of new decisions and responsibilities must be identified within the context of these processes before they can be assigned within the Department. For instance, in the new management process of obtaining cooperative support from the private sector, it will be necessary for the Department to [illegible] the following activities:

- Identify those research projects and facilities which might attract private sector support
- Develop a conduit for transfer of this information to the private sector
- Establish support from the private sector through this conduit
- Identify and resolve conflicts of interest or moral issues which might be associated with the private support
- Negotiate and approve the cooperative research and development agreements
- Execute the agreements
- Conduct and monitor the cooperative program
- Report new technologies created under cooperative agreements
- Receive and distribute royalties based upon commercialization of new products.

Although within the PHS, we have a management process to identify, evaluate, protect and license new technologies created by our laboratories, the Executive Order requires consideration of decentralizing these responsibilities. The Act and the Executive Order also create new decisions in the process which must be identified and assigned. It is my intention to guard against the tendency to centralize these responsibilities because as was made clear in the deliberative process by the Congress, negotiations must be based

on trust established between the technically knowledgeable individuals.

In light of the high priority that the White House has given the implementation of the Act, I intend to share the identified management processes within four weeks of the Secretary's acceptance of our recommendation.

I also intend to create an HHS committee of all interested and appropriate units to assist in implementing the Act. I will provide periodic progress reports to your office during implementation to assure open communications with you and the OS staff offices.

The identified management processes will require those elements of the Department seeking delegations of authority to focus on the resources necessary to undertake decision making. This exercise will more clearly determine where and under what terms assignments of responsibility should be made, including oversight.

It is clear that in addition to utilizing the management processes as a means of identifying resources and recommending subdelegations, it will also be necessary to identify and develop policies to guide those management processes. The committee will identify and assist in developing these policies. For example, policy guidance may be needed to address:

- Whether the inventor's royalty share should be higher than the 15% mandated by the Act
- How the residual share of royalties should be distributed
- Under what circumstances the use of other departments' or the private sector's management services should be utilized
- Guidelines for defining conflicts of interest
- Guidelines for use in locating cooperative agreement partners

In addition to the activities identified above, my office will proceed to develop administrative tools to facilitate the management processes. For instance it will be necessary to develop a model cooperative research and development agreement tailored to use by HHS laboratories and an invention awareness in technology management training program for laboratory scientists and their managers.

Other issues such as the need for a data system are not yet clear and need the review of the committee after responsibilities are affixed. Until they are determined, it will be unrealistic to attempt a definition of the needs for such a system. It will be of utmost importance that we do not delay implementation of the Act while waiting for the data systems development. After some experience, we will be better able to define our data systems needs.

My office will work very closely with the Department of Commerce which as assigned by the Act, is assisting others and coordinating the development of cooperative agreements and training programs. We will assure proper coordination with other agencies through a close relationship with the Department of Commerce.

SUMMARY

Your memorandum of March 20, 1987 asked the Deputy ASH and the Deputy Under

(4)

Secretary to identify and present options for issues of concern to you and the Policy Council. A number of these issues will have to be developed by a committee which I will appoint upon approval of this proposal and whose deliberations will be accomplished within 30 days. I share the concern of the Policy Council over the need for a well- considered set of policies. I am also greatly concerned about the practical barriers to studying each policy option at length prior to any implementation. I believe such an approach would be contrary to the intent of the Administration and the Congress.

Due to the urgency of proceeding, upon your approval, I will ask each OPDIV to prepare all proposed agreements they have ready, as well as areas and details of potential agreements not yet ready, for review by the committee. I do not want to delay the approval of proposed agreements unless absolutely necessary. Also, I believe that such a review will be instructive to the committee in defining the guidelines within which the laboratories will be able to operate. I believe there is minimal risk in this approach, and failure to do so could be viewed by many as being unresponsive to both the Executive Order and the will of Congress.

If you approve this proposed plan, please transmit the Secretarial statement and the Delegations of Authority to the Secretary for his signature. I will ask the Deputy Assistant Secretary for Health to undertake implementation immediately.

Robert E. Windom, M.D.

(5)

Items expanded in the Under Secretary's March 26 memorandum and the plan's response:

1.	management structure	Under the guidance of the ASH and to be fleshed out by a committee
2.	OS involvement	Participation on committee and through periodic reports
3.	degree of centralization	To be determined by committee
4.	procedures for licensing, patents and cooperative agreements	To be determined by committee
5.	negotiating agreements	To be determined by committee
6.	provide due process for industry	To be determined by committee
7.	protection of Federal interests	To be determined by committee
8.	allocation of royalty proceeds	To be determined by committee
9.	necessary coordination steps	To be determined by committee
10.	achieving uniformity of policy with other agencies	To be determined by committee
11.	compatibility of data systems	To be delayed pending other decisions by the committee and then determined by the committee
12.	provide simple, flexible procedures for the private sector	To be determined by committee
13.	provide options for the above	The only option is to approve or disapprove the entire proposal. This is only reasonable since the proposal is to use a committee. The danger of that is the appearance of delay caused by assigning any set of tasks to a committee. This is countered by the proposal to implement prior to fleshing out all options and getting some on the job training.

THE UNDER SECRETARY OF HEALTH AND HUMAN SERVICES

WASHINGTON, D.C. 20201

MAR 20 1987

MEMORANDUM FOR: Lowell Harmison
Bob Raclin

FROM: Don Newman
Under Secretary

SUBJECT: Follow-up of March 17 Policy Council Meeting

As a follow-on of the March 17 Policy Council meeting on implementing the Technology Transfer Act, I would like you to initiate the planning to implement that Act, working closely with the General Counsel, Assistant Secretary for Management and Budget, Inspector General and Assistant Secretary for Planning and Evaluation.

Specifically, you should develop a plan that addresses such things as the management structure and OS involvement; degree of centralization or decentralization; procedures for licensing, patent and cooperative agreements, and negotiating these with industry; how to ensure that these procedures provide the necessary due process for industry, and protection of the Federal Government's interest; guidelines for allocation of royalty proceeds within HHS, etc.

In your planning, please consider:

(1) the necessary coordination steps both within and outside the Department;

(2) ways to achieve uniformity of policy with other Federal agencies, including consultation during the development of your plan;

(3) compatibility of whatever data systems are appropriate; and

(4) ways to ensure procedures provide the flexibility and simplicity for the private sector to work with HHS.

Given the discussion at the Policy Council, clearly there are a variety of issues that need to be resolved. Please identify these and options to address them.

I would like to review your plan and related issues with the Policy Council on April 15. So that we can focus on the most important issues, please discuss your draft plan and issues/options with the General Counsel, Inspector General, and Assistant Secretaries for Health, Management and Budget and Planning and Evaluation prior to our meeting.

Thanks.

cc: Bob Helms
Tony McCann
Dick Kusserow
Ron Robertson
Bob Windom

95463

Assistant Secretary for Health

Impact of the Technology Transfer Act of 1986 on PHS Cooperative Research and Development Agreement, Patent, and Licensing Activities

Under Secretary

The purpose of this memorandum is to provide you with PHS' proposed plan for the implementation of the Technology Transfer Act (TTA) of 1986, and to review for you the optional approaches for future conduct of licensing activities, that PHS considered in the development of that plan.

This plan also requests your endorsement and transmittal to the Secretary of a public statement for the Secretary to issue and of a delegation of authority from the Secretary to the ASH.

BACKGROUND

The Technology Transfer Act of 1986

Under the terms of the TTA of 1986, each Federal agency may permit the director of any of its Government-operated Federal laboratories to enter into cooperative research and development agreements (CRDAs) with Federal agencies, industrial organizations, public and private foundations or other "persons."

The act provides the following definition for the term "Federal laboratory":

> "...a facility or group of facilities owned, leased, or otherwise used by a Federal agency, a substantial purpose of which is the performance of research, development, or engineering..."

This definition is broad enough to allow application of the term "laboratory" to organizations at varying levels of the PHS hierarchy, ranging from agencies (those with substantial laboratory related activities); to bureaus, institutes and centers; to research divisions or laboratories and branches within bureaus, institutes and centers.

Under such agreements "a Government-operated laboratory may...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...and/or waive...in advance, in whole or in part, any right of ownership which the Federal Government may have to any subject invention made under the agreement by a collaborating party or employee of a collaborating party..."

The Act provides that royalties or other income received by a Federal agency from the licensing or assignment of inventions under agreements shall be retained by the agency (heretofore it went to Treasury). The income is then to be transferred to its Government-operated laboratories to be used or obligated by that laboratory for such activities as education and training of employees, monetary rewards, administration and licensing of inventions, etc.. However, at least 15 percent of the royalties received (not to exceed $100,000 annually, per person) must be paid to the inventor (or co-inventors) if the inventor was an employee of the agency at the time the invention was made.

Under the Act, each Federal agency may permit the Director of any of an agency's Government-operated Federal laboratories to negotiate licensing agreements (including royalty income) for Government-owned inventions made at the laboratory (and other inventions of Federal employees) not previously included or dealt with in the terms of cooperative R&D agreements.

Another provision of the Act is the establishment of a Federal Laboratory Consortium for Technology Transfer (administratively supported by the National Bureau of Standards) to provide training, promotion, and awareness, in both the Federal and private sectors, of the commercial potential of laboratory technology and innovations.

Within HHS, PHS has been and continues to be the only OPDIV involved in those activities of the Act relating to cooperative research and development agreements and the promotion and administration of licenses for patents developed by Federal inventors within HHS. (In fact, PHS has the preponderance of non-military related patents throughout the Government.) The focus of this memorandum is on these activities.

The Draft Executive Order

Of particular significance to the plan to implement the Act, the draft Executive Order, which we are told will soon be issued, says in Section 1:

> "In particular, the head of each Executive department and agency shall, within overall funding allocations and to the fullest extent and in the manner permitted by law,... delegate authority to its Government-owned laboratories...to enter into cooperative research and development agreements with other Federal laboratories, State and local governments, universities and the private sector..."

Description of Current Activities

Attached at Tab A is a description of the current process for developing CRDAs in the PHS agencies and of related issues concerning the Act.

Tab B describes the process for obtaining patents for PHS inventions when an inventor's activities have not been previously negotiated under a CRDA.

Tab C contains a description of the licensing processes that currently exist, including what the National Technical Information Service (NTIS), our agent for the administration and promotion of licenses for PHS inventions, does for us, their organization and resources devoted to these activities, and the interrelationships that currently exist.

Tab D contains a discussion of optional approaches for carrying out future PHS licensing activities for PHS.

THE PHS PROPOSED PLAN

We recommend that the Secretary issue a policy statement calling for the vigorous implementation of the Act. This would show support for the legislation and responsiveness to the intent of the Executive Order being drafted by OMB. This statement should be publicized, and distributed throughout the PHS scientific community. (A proposed statement for Secretarial signature is attached at Tab E.)

Because PHS is the only OPDIV within HHS that carries on activities directly affected by this Act, I am asking that the Secretary delegate to me the authorities necessary to implement the Act. I plan to report to him periodically on PHS activities related to the Act. The necessary delegation papers (the same as those originally transmitted to OS) are attached to this memo (Tab F) for you to transmit to the Secretary for his signature if you approve of the plan I am proposing below:

1. I will establish within my own office, reporting to the Deputy Assistant Secretary for Health, the position of Technology Transfer Advisor to oversee the activities of the agencies with regard to this Act. The incumbent will also review and make recommendations to me, through the Deputy ASH, concerning approval of exclusive agreements and licenses, serve as my representative in the license negotiation process, collect information and report to me on CRDA's, patents and licensing activities of the PHS agencies and coordinate the drafting of the report required by the Act to be submitted by the Secretary to the Congress on income received and expenditures made.

2. I plan to appoint a task force to develop and recommend to me policy/procedures/guidelines implementing the CRDA section of the Act. The Deputy ASH would chair the group. Membership would include up to two senior representatives from each of the PHS agencies, chosen by the agency heads from their immediate office staffs, a member of the General Counsel's office, a representative of OS, and of the Offices of Resource Management, Organization and Management Systems and Personnel Management/OM/PHS. The Science Technology Specialist, now reporting to the Deputy ASH, and the Office of Management would provide staff support. The task force will be asked to coordinate with the other Departments and Agencies which are heavily involved in technology transfer issues to ensure that the approaches to implementing the Act are complementary.

The policies and procedures developed by the group will deal with issues such as:

--how to define "laboratory" as used in the Act. The Act does not do this. Our recommendation would be to define it as broadly as possible, e.g. to consider all NIH intramural research as a single "laboratory". A definition is critical because it will influence the loci of responsibility for a number of the areas described below,

--how to guard against conflict of interest both within and between agencies as this Act is implemented,

--how to ensure that the basic research mission of PHS agencies is not diverted by the new incentives for patentable applied research,

--how and by whom the decision will be made as to whether or not the objective of a proposed agreement is desirable to pursue,

--what should be the process for determining patentability of an invention and who should do it,

--whether and how competition and/or peer review should be involved in the negotiation and execution of CRDAs, to maintain fairness among interested parties,

--who should have the authority to negotiate such agreements,

--how and when the ASH or his office should be involved in the approval of these agreements,

--who should have responsibility to negotiate and administer licenses resulting from these CRDAs,

--how the cash awards program called for in the Act should work,

--how net royalty income should be distributed,

--how science information concerning PHS research activities should be transmitted to parties potentially interested in CRDAs in order to "market" them more vigorously without jeopardizing or distorting the research mission of the PHS agencies,

--who should represent the agency on the Federal Laboratory Consortium for Technology Transfer, established by the Act.

The procedures drafted by this task force will be sent to the agencies for review and comment. I have set a target date of two months from the date of the assignment for the task force to submit its recommendations to me for approval and promulgation.

3. I will direct all agencies to develop written internal policies and procedures to conform with those promulgated by the ASH and to charge a central office within the immediate office of the agency head with the responsibility of tracking and of reviewing and approving all such agreements that do not need a higher level of approval.

4. I plan to rely on the Deputy Under Secretary to promote outside contacts with investors and other members of the private sector who might participate in technology transfer activities.

5. A management information system that provides data needed at each organizational level in PHS and OS will be developed. Data elements, definitions, and reporting protocols should be identified and/or developed for items such as cooperative agreements, patent applications, patents, and licenses. Appropriate off-the-shelf software and hardware should then be selected to support processing of this information. By using a distributed database and by selecting compatible equipment and common software, summary data may be electronically collected and reported at the ASH level. I plan to ask NIH to take the leadership in developing such a system, since approximately 90 percent of the activity within PHS is within NIH. The members of the Task Force and staff from ASMB would review and approve the final system proposal.

6. The current arrangements with NTIS referred to in Tab C re patent licensing should be modified so as to ensure that PHS has the opportunity and the flexibility to involve itself substantially, and on a case-by-case basis, in licensing activities and in decisions concerning whether or not to seek foreign patents. After considering various options, I have

concluded that continuing to rely on the service provided by NTIS would enable PHS to have the best of both worlds -- direct involvement, when we deem necessary, at the critical part of the patent and licensing process, no responsibility for complicated direct operations, a flexible arrangement with an effective and experienced organization, no requirement to come up with scarce FTE to run the activity, and a relatively risk free budget arrangement. This approach allows us to establish priorities for focussing the efforts of our staff on the most important activities that we are concerned about.

Since the memorandum of agreement drafted by NTIS allows for its termination with 90 days written notice, such a decision would not be irrevocable. In the event that NTIS failed to perform, PHS could at that time establish an office to take over the NTIS activities.

If you approve of this proposed plan, please transmit the Secretarial statement and Delegation of Authority to the Secretary for his signature. I will ask the Deputy Assistant Secretary for Health to undertake its implementation immediately.

Robert E. Windom, M.D.

DEVELOPMENT OF COOPERATIVE RESEARCH AND DEVELOPMENT AGREEMENTS

A number of terms are in use by those involved to deal with the concept set forth in the Act. These include: "cooperative agreement", "collaborative agreement", "joint endeavor", "joint funding agreement", etc. This situation is further confused by the fact that the legal definition of the term "cooperative agreement" differs, depending on whether one is referring to the TTA or to the Federal Grant and Cooperative Agreement Act of 1977.1/ The TTA definition of "cooperative research and development agreement" (CRDA), and the one to which the rest of this paper refers, is:

> "any agreement between one or more Federal laboratories and one or more non-Federal parties under which the Government, through its laboratories, provides personnel, services, facilities, equipment, or other resources with or without reimbursement (but not funds to non-Federal parties) and the non-Federal parties provide funds, personnel, services, facilities, equipment, or other resources toward the conduct of specified research or development efforts which are consistent with the missions of the laboratory; except that such term does not include a procurement contract or cooperative agreement as those terms are used in...(The Federal Grant and Cooperative Agreement Act)."

The only clear "policy" that is understood with respect to CRDA's, despite the fact that it is not in writing, is that ASH approval is required on those collaborative agreements which propose license "exclusivity" or waiver of the Government's patent rights. In the past, such proposals were transmitted to OASH, where they were staffed out by the former Science Advisor and sent to the ASH for signature. There is no public notice required of ASH's decision on these agreements. (An estimated 12 or fewer CRDAs were sent by NIH to the ASH for approval in 1986. Exact figures are not available since central records were not

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1/ In fact, PHS regulations implementing the 1977 act drastically contradict the purposes of the TTA.

> "Cooperative agreements have been established not to encourage more involvement in assistance activities, but rather to provide a formal instrument for those assistance activities which do require substantial involvement. Except where there is a demonstrated need for the involvement of programmatic staff during the performance of a sponsored activity, awarding offices should continue to implement existing assistance programs through the grant mechanism."

maintained prior to November, 1986. Ten proposed subjects for agreements were submitted directly to the Deputy ASH in response to an RFP published last summer. These are awaiting his review and will require the development of formal CRDAs. The number of CRDA's that will be sent to the ASH for approval is expected to be greater in 1987 than in 1986.)

Otherwise, there is no written, official HHS or PHS or agency policy regarding 1) the process or procedures by which CRDAs are developed, reviewed, and decisions made regarding their merit, or 2) the language or terms to be included in such agreements, or even the stipulation that they must be in writing. No mandate exists that these agreements deal uniformly, or at all, with the subject of patenting and licensing of inventions that may result. No organized system exists in any PHS agency to keep track of CRDAs and their results.

Discussions with agency officials about the Act raise a series of concerns about its potential impact. For example, FDA is studying the impact of increased CRDAs with the private sector in terms of potential conflicts of interest that may arise, given its regulatory mission. Some NIH officials are concerned that the incentives for scientists to do basic research may be changed by the potential monetary rewards that could come from a shift to applied research. How to deal with the exchange of scientific information, so necessary for scientific advancement, when that exchange might result in the loss of considerable income, is another issue. How to distribute royalty income to people and organizations other than the inventor needs to be decided. This question has a great many personnel and labor relations ramifications. These and many other issues will need to be worked out over the coming months.

The CRDA/joint endeavor process has been working as follows: rough drafts of proposed agreements and related protocols concerning collaborative efforts are worked out by the Federal researchers and the outside organizations and are then provided to the concerned Institute or Center management by the Federal researcher. For those thought by the scientist to be of significance, and for those requiring ASH approval of exclusive licensing arrangements, the Institute/Center requests either the NIH Branch or the Patent Branch of the General Counsel's (GC) Office to review the proposal, especially the sections that relate to patents and licenses. The GC reviews the agreement to assure conformance with legal policy and procedures, and may provide recommendations of new or better language.

In 1985, then-Deputy Director of NIH, Dr. Tom Malone directed that a study be undertaken and that data be gathered concerning "joint endeavors". The outcome of that study was information (available centrally for the first time) on such

activities, and a recommendation that the data gathering process continue. The data gathered as a result of the study showed that during FY 1985 NIH had approximately 225 such "joint endeavors" in effect. None of these has resulted in a patent thus far. A review of NIH files showed that most of these were short term agreements with non-government organizations to share resources to accomplish some specific goal or perform a task. Only two appeared to include provisions for licenses and patents. NIH is in the process of gathering comparable information for FY 1986. FDA currently has 6 agreements outstanding, none of which appear to have patent and licensing provisions. Other PHS agencies have reported no agreements.

OBTAINING PATENTS

The responsibility for obtaining domestic patents lies primarily with the HHS Office of the General Counsel in the Patent Branch of the Business and Administrative Law Division. A total of 6 FTE perform the work involved. Contracts exist with 3 law firms to "prosecute" HHS patents (i.e. to shepherd the applications through the U.S. Patent Office and obtain issuance of the patents). The cost of these contracts in 1986 was approximately $335,000. Foreign patents are obtained by NTIS, which carries this out primarily through contractors. Foreign patents are filed on a very limited basis, however, based on scientific and economic importance, and on the advice of PHS. (37 CFR Part 100 gives the Department of Commerce (DoC) responsibility for coordinating foreign patent filing throughout the government.)

Approximately 250 patent applications for PHS inventions were filed with DoC and sent to NTIS for licensing during the period 1982 through 1986. All but 17 of these were for NIH scientists' inventions. FDA accounted for 16 of these. There are 188 PHS employee patent applications currently pending.

The Process - All employees are required to report to the ASH every invention made by them in the course of their official duties, according to 45 CFR Section 7.1. (It would appear, however, that most scientists are not aware of this requirement.) These reports are filed with the OGC Patent Branch, which evaluates the reports for possible patenting. The Patent Branch first asks NIH/Office of Medical Applications of Research (OMAR) for technical evaluation of the invention in terms of its scientific significance and whether it appears to be worth patenting. The Patent Branch then searches the scientific literature and existing patents (on its own or by using contractors) to determine if the invention appears to be patentable. If so, the Branch has a patent application prepared and filed in the Patent and Trademark Office of the Department of Commerce (DoC). This is done by contractors working under the supervision of the Patent Branch. Following filing, the Branch provides a copy of the patent application to the NTIS/DoC.

Under the terms of an Inter-Agency Agreement of January 20, 1975 titled "To obtain patents in foreign countries on selected inventions in the custody of the Secretary of Health, Education and Welfare" (IA-75-046), NTIS under the direction of the Patent Branch, files selectively for foreign patents to protect U.S. interests abroad. This is done for NTIS by contractors. The total cost of this activity by NTIS on PHS' behalf in FY 1986 was $206,000.

[illegible] employees are required to report to the ASH

PROMOTION, NEGOTIATION AND ADMINISTRATION OF PATENT LICENSING BY NTIS

The NTIS, located organizationally in the Department of Commerce, is the central source for the public sale of U.S. Government-sponsored research, development, and engineering reports, as well as foreign technical reports and other analyses prepared by national and local government agencies, their contractors, or grantees.

The Office of Federal Patent Licensing (OFPL) in NTIS' Center for Utilization of Federal Technology (CUFT) handles the licensing of inventions developed by Government employees at the Departments of Health and Human Services, Agriculture, Commerce, Interior, the Environmental Protection Agency, and the Veterans Administration.

Total staffing for the licensing operation, including CUFT's Director, licensing specialists and clerks, and staff allocated from other organizations for accounting, Freedom of Information Act (FOIA), and legal support from DoC headquarters, has totaled about 9.5 FTE. In addition, the General Counsel's office at DoC does all the staff work concerning protests of exclusive licenses. As the number of protests increases, so does the FTE allocation of this office.

The Patent Licensing Program planned budget for FY 87 is $1.1 million, including an estimated $330,000 for foreign patent filing costs and $120,000 for inventor awards. HHS activity normally accounts for approximately 70 percent of this, or about $770,000. Of this HHS total, NIH accounts for approximately 90 percent.

OFPL serves as the principal marketing/promotion agent for the licensing of patents of Government scientists' inventions. It also negotiates the terms of licenses and size of royalties to be paid for patents, and receives and administers royalty income. It does this in accord with 37 CFR Chapter IV; Part 404 - "Licensing of Government-Owned Inventions".

For PHS, the terms of an HHS/NTIS Inter-Agency Agreement which deal with licensing of foreign patents have been applied on an informal basis to the licensing of domestic patents. In other words, although NTIS has been doing this for a number of years, there is no formal agreement underlying their activities. However, NTIS has recently drafted such an agreement, given the new law, and has begun discussing it with PHS agencies.

Volume of NTIS Activity

1982 - 1986

	FDA	CDC	HRSA	NIH	TOTAL HHS
New HHS Patent Applications Forwarded to NTIS	17	0	1	232	250
Licenses Issued by NTIS on HHS Patent Properties	13	0	0	124	137*

*A Total of 197 Licenses for all Federal Agencies were Issued by NTIS During this Period. Thus 70% of NTIS "business" is HHS. Of this, nearly 90% is NIH.

Fee and Royalty Income from HHS Licenses

($ in millions)

Total Income, 1982-1986..... $6.1

	1986	1987 (est.)	1988 (est.)
Income			
AIDS Anti-body test	$3.5	$0.8 a/	$0.8 a/
Hepatitis	1.0	.8 b/	.7 b/
All Other c/	.3	.4	.4
Total Income	4.8	2.0	1.9
Payments			
Royalties to scientists	.05	.1	.3 d/ e/
Foreign filing charges	.2	.3	.3
Total Payments	.3	.4	.6
Net Income	$4.5	$1.6	$1.3

a) Assumes income will decline because of Franco-American agreement.

b) Assumes hepatitis royalties will soon decline because of a non-government invented replacement. Could decline further if new product is marketed more heavily.

c) Includes fees from licensees.

d) Awards are made based on the prior year income. 1988 awards reflect the TTA enactment. Of the total, $200,000 is for the inventors of the AIDS test.

e) Does not include funds for the cash awards program.

NTIS Promotion Activities - NTIS serves as a national technical information clearinghouse for information on the products of U.S. Government sponsored research, development and engineering. As part of its efforts to promote licensing of Government-owned inventions, it produces a series of products, which it sells. These include:

- o Government Inventions for Licensing Abstract Newsletter (weekly).
- o Catalog of Government Patents (annual).
- o Federal Applied Technology Database (electronic and online).
- o Published Search Catalog (annual).
- o Directory of Federal Laboratory and Technology Resource - A Guide to Services, Facilities, and Expertise (annual).
- o Brochures and pamphlets.

In addition to these ongoing information activities, OFPL/NTIS promotes PHS patents by writing letters to selected market sources likely to have interest in particular patents.

When NTIS receives an expression of interest in a patent from a potential licensee, it requests a "transfer of custody" of that patent from OGC/HHS. (Such interest is usually manifested within two years of filing.) OGC queries the PHS agency involved to determine if it has any problems with the terms offered and, if not, drafts and signs a document assigning custody to NTIS.

Negotiation Activities - OFPL/NTIS negotiates the terms of licenses (including size of royalty) for all PHS patents, unless they have been pre-arranged in a cooperative agreement. Royalty rates are negotiated on a case-by-case basis, using net sales price, primarily, as a basis for running royalty calculations. The usual range of rates is 5 percent to 10 percent for exclusive licenses, and 2 - 8 percent for non-exclusive licenses. In recent years, NTIS has had a bias toward issuance of exclusive licenses as the best way of fostering commercialization of Government inventions. When it does choose to grant an exclusive or partially exclusive license, it must publish notice of its intent in the Federal Register three months prior to the final approval of the license. In any case, OFPL/NTIS, as a matter of practice, discusses with HHS the terms of licenses prior to final negotiation with potential licensees even though responsibility to make that decision rests with NTIS. The sole exception to this, as discussed above, is where an exclusive license was a part of a cooperative agreement and was approved by the ASH.

License Administration - OFPL/NTIS administers domestic and foreign patents for HHS. This includes the collection and handling of, and accounting for fees, royalties, and other income from licenses under PHS patent properties in the custody of NTIS. The Office also keeps track of the number of patent applications received and the number of exclusive and nonexclusive licenses issued by NTIS for its clients. NTIS also has traditionally made small cash awards to inventors through an awards ceremony held by the DoC. Under the new Act, it plans to make royalty payments to inventors and could also allocate other funds in accord with policy decisions made by PHS.

NTIS Charges to PHS - For FY 1988 NTIS has proposed charging PHS a flat fee, sufficient to cover only approximately 3 FTE, plus a share of the royalties and fees received, assessed on a sliding scale. Total estimated charges are $727,000.1/ Because NTIS must recover all its costs, NTIS officials believe that this approach provides the best incentive to OFPL staff to promote licenses. If its costs exceed income at any point, it uses monies from the sale of documents that are in a no-year "trust fund" to cover unanticipated expenses in the patent licensing program.

1/ In FY 1987, charges to PHS will be approximately $472,000. The remaining cost of running the operation will be covered by appropriated funds which will not be available in FY 1988.

OPTIONAL APPROACHES TO THE PROMOTION OF PATENTS AND ADMINISTRATION OF LICENSES -

1. Continue the Existing Process. Make the Minimum Changes Required by Law.

The NTIS arrangement could be formalized with a new memorandum of understanding (which NTIS has already begun to draft). Any outstanding issues, such as whether PHS should have the right to review and approve each licensing agreement, would be resolved in that context. Policies developed within PHS re the allocation of royalty income could be implemented by NTIS as part of their license administration activities.

Pros

- NTIS already has an operation in place, well supported by accounting, publication and other overhead staffs to promote patents to prospective licensees, to negotiate and to execute licenses and administer them. It would take PHS considerable time to develop these support functions and run its own licensing operation.

- NTIS has a network of contractors to carry out their foreign patent activities, and a network of contacts for marketing and promoting domestic licenses. In short, they know their business.

- An independent contract study of NTIS/CUFT technology transfer activities concluded that NTIS' performance compared well with private sector technology transfer programs in universities and non-profit institutions.

- The Congressional Conference Committee report indicated the conferees "value the licensing activities that have been performed by NTIS for other agencies..."

- PHS does not currently have the FTEs or funds to support the start up and operating costs of such an operation. The income from the licenses that support the costs of the NTIS operation have just been drastically reduced.

- NTIS has demonstrated a willingness to accommodate PHS needs in terms of adjustments to NTIS' operations either in general or on a case-by-case basis. Because it is administered like a business, it can more easily "buy" additional services it may need, or, likewise, shrink its effort.

Cons

- OFPL's future may be jeopardized by OMB's desire to contract out NTIS current activities. The OMB proposal may result in staff departures that could cripple NTIS' operations. (Congressional hearings on contracting out NTIS functions suggest, however, that Congress may not accept the OMB proposal, and that this issue may be moot within a couple of months.)

- Some allege that NTIS has not always acted vigorously in the promotion of PHS patents and if PHS ran its own licensing operation, it could be a great deal more active.

- Some argue that a PHS-run organization could do what NTIS does for us more efficiently and effectively.

- PHS would not have total control, and would not have the flexibility to deviate from fixed arrangements with NTIS.

2. Set Up an Organization Within OASH to Carry out NTIS Functions Plus Other Activities to Vigorously Administer the Act

Establish a position of Technology Transfer Advisor reporting to the Deputy ASH to serve as the head of not only a new organization to carry out NTIS licensing functions, but also to oversee the activities of the agencies with regard to the Act. This Advisor would also be assigned the responsibility to review and make recommendations through the Deputy ASH to the Assistant Secretary for Health, concerning approval of exclusive agreements and licenses; collect information and report to him on CRDAs, patents and licensing activities of the PHS agencies; and coordinate the drafting of the report required by the Act to be submitted by the Secretary to the Congress on income received and expenditures made.

Pros

- Responsibility for all PHS activities relating to administering the Act would be focused in one place. PHS would be firmly in control.

- Negotiation of important, complex or unusual licensing agreements could be accomplished more expeditiously and with greater regard to health policy issues.

- A potential director for such a staff is already in PHS employ. He is highly experienced in all aspects of patent licensing.

Cons

- Staffing such an office would require initially approximately 6 FTEs in the office itself, plus additional FTE for the establishment and operation of an accounting system, and for FOIA responses. Additional GC support to handle appeals of exclusive license awards and other related legal issues, as well as the foreign patent operation, would probably require about 2 FTEs. These FTEs are not now available in OASH, and would therefore require commensurate reductions in other areas of OASH or unpopular taps of PHS agency FTEs. Futhermore, this staffing level does not take into account the probable increase in activity that will come about as a result of the implementation of the new act.

- PHS could not easily increase or shrink staff resources to accommodate variations in workload.

- Such a function would cost nearly $700,000, per year excluding foreign filing fees and payments to inventors. This is the same as what NTIS would charge us. Thus we would save no money by this approach.

- It would not be possible for PHS to establish an incentive approach to funding this organization the way NTIS has proposed. There are no other "customers" to share the risk.

- Because of the recent Franco-American agreement on the patent for the AIDS tests, income from the largest income producing license has been drastically reduced. Futhermore, royalties from the hepatitis vaccine are expected to decline given the expected marketing of a new, non-governmental invented vaccine. Thus it is questionable whether such an office could be self-supporting until such time as other major income producing licenses could be negotiated. Start-up funds for such an office are not currently available in the OASH budget.

- OMB is not likely to look favorably on such a proposal, given its desire to contract out the existing NTIS activity. PHS represents the preponderance of the business of OFPL. Were we to propose pulling out, the contract to do the residual OFPL licensing work would not really be saleable.

- OASH does not currently have in place the systems necessary to support such an operation. Accounting and FOIA systems and procedures would have to be established, data systems would have to be set up, etc. Considerable time and effort would be involved.

- PHS would have to focus on all patent and licensing activities, low as well as high priority.

3. Modify the Arrangement with NTIS to Provide Opportunity for More Direct Involvement of PHS in Licensing Activities. Set Up an Organization Within OASH to Administer Other Activities Under the Act.

Include a provision in the memorandum of understanding that would ensure that PHS staff can participate, as they determine necessary, in the negotiations of licenses, and in decisions regarding which patents will or will not be filed in foreign countries. Require NTIS to provide regular reports on their activities.

Establish a position of Technology Transfer Advisor reporting to the Deputy ASH. The incumbent would have the same oversight responsibilities described in option 2, above. However, instead of managing an office carrying out all patent licensing and foreign patent activities, he would serve as PHS representative in the NTIS license negotiation process.

Pros and Cons

- All of the other pros listed under option 1, above, would still pertain. The cons would be alleviated except with regard to OMB interests in contracting out the NTIS operation. This option would have the following additional advantages:

  -- The major objectives of taking over the current OFPL activities would be achieved without PHS having to get involved in developing, staffing and operating the entire administrative operation.

  -- No financial/budgetary risk for PHS would be involved. This approach would not require additional PHS FTEs.

  -- With PHS participating in the NTIS licensing process, negotiation of important, complex or unusual licensing agreements could be accomplished more expeditiously and with greater regard to health policy issues.

  -- PHS staff would have the opportunity to determine, on a case by case basis, priority for and the intensity of their involvement in terms of questions, issues, or special interests, related to individual patents.

TAB F

DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary

Washington, D.C. 20201

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, excluding the authority to promulgate regulations and to submit reports to the Congress. This authority may be redelegated.

This delegation is effective upon the date of signature.

Otis R. Bowen, M.D.

BILLING CODE: 4160-17

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Stevenson-Wydler Technology Innovation Act of 1980
As Amended by the Federal Transfer Technology Act of 1986

Notice is hereby given that on the Secretary of Health and Human Services delegated to the Assistant Secretary for health, with authority to redelegate, all the authorities vested in the Secretary under the Stevenson-Wydler Technology Innovation Act of 1980 (15 U.S.C. 3701 et seq.), as amended by the Federal Transfer Technology Act of 1986, P.L. 99-502, including the authority to promulgate regulations and to submit reports to the Congress.

This delegation was effective on .

Date

James B. Wyngaarden, M.D.
Secretary

DHEW
Patent Counsel
Westwood Bldg
Room 5A03
5333 Westbard Ave
Bethesda, Md
20014

PATENT BRANCH, OGC
DHEW

MAY 1 9 1978

JUN 29 1978

MEETING OF 5/18/78 ON INTELLECTUAL PROPERTY AND INFORMATION

John M. Deutch, Director
Office of Energy Research

Distribution:
1. Addressee
2. Chrono.
3. GC Read File
4. Yohalem, GC
5. FCCSET: Cpyrt.Workg.Grp. (COGPP)
6. Commerce Draft Bill on Fed. IP - dm
7. Gov't PAT Policy - jed

Congratulations! You picked "the meeting of the month" to be absent from.

Jordan spent two hours guiding a discussion of what the different agencies considered to be appropriate patent policies, the practices followed by the agencies, and in general their theories on why they selected the policies they followed. The last half-hour was devoted to a discussion of the proposed copyright policy which my Executive Subcommittee drafted, which the Copyright Office objected to on questionable legal grounds, and which the Department of Justice vetoed for the expressly stated purpose that they did not know what the policy statement was all about.

The overall effect of the meeting was, in my mind, a major step backward in arriving at government-wide resolutions of these issues.

original signed by

James E. Denny
Acting Assistant General
Counsel for Patents

Enclosure:
cc of ltr. to J. Baruch
w/o encls.

cc: H. Yohalem w/encl.
(did not encl. ERDA 76-16
or cc of PAT Regs.)

PAT

JEDenny:dm
5/19/78

MAY 19 1978

Dr. Jordan J. Baruch
Assistant Secretary for
Science and Technology
U.S. Department of Commerce
Washington, D.C. 20230

Dear Jordan:

Enclosed is a copy of our Patent, Data and Copyright policy which was issued under ERDA on July 13, 1977, and which we are currently utilizing as DOE patent policy. Our provisions regarding waivers begin in §9-9.109-6 on page 23. Paragraph (a) sets forth four objectives of our waiver policy which come directly from our statute. In addition, paragraph (b) sets forth 13 factors to be considered in making advance waiver determinations--12 of which come from our Nonnuclear Act and one which comes from the Atomic Energy Act. Finally, subparagraph (c) on page 24 sets forth 12 factors to be considered in making waiver determinations on individually identified inventions.

For universities, we approve technical transfer capabilities and programs of educational institutions in the same manner as HEW and NSF under their Institutional Patent Agreement (IPA) program; however, we do not utilize IPA's. Instead, we equate approved programs with the equivalent of manufacturing and marketing capabilities for purposes of advance waivers; and for individual waivers, we reverse the presumption in favor of granting the waiver to the universities with approved programs. These provisions start with subsection (h) on page 26 and specifically note paragraphs (4) and (5) on page 27.

Also enclosed is a copy of our domestic and foreign patent licensing procedures which have not been modified subsequent to the existence of AEC. We have a revision underway, but the regulations will be substantially unchanged.

If you have not done so to date, I would recommend that you or David give some careful study to the details of the first Harbridge House study which provides a substantial amount of factual information of the type being discussed in yesterday's meeting. It took a rather large sampling of government-supported inventions, reviewed their utilization and reasons for nonutilization, compared their effects on competition, searched for the existence of "windfall," identified the amount of

investment in further development and marketing of the inventions, and accumulated considerable other data which everyone seems to assume does not exist. This was an expensive and thorough study, which was monitored by the Department of Justice; and Dr. F. M. Scherer was the consulting economist on both conducting the study and analyzing the results. I do not believe anything equivalent to this study will be supported again, as to do so would cost approximately $1 million. Therefore, I highly recommend it to you.

In addition, DOE is presently supporting a second Harbridge House study in the area of compulsory licensing. Under this study, Harbridge House is looking into the effects of the two present compulsory licensing statutes (Atomic Energy Act and the Clean Air Act), reviewing the effects of antitrust compulsory licensing decrees and of injunctive enforcement of patents, and examining the compulsory licensing experience in several foreign countries. All of the preliminary results of this study are available to you through the Commerce representative on our task force, Barry Grossman of the PTO.

Barry also has access to the transcript of the public colloquium through which DOE supported the writing, presentation and discussions of six papers on the issue of compulsory licensing authored by economists (F. M. Scherer and Jesse W. Markham), the legal profession (Marcus B. Finnegan and James B. Gambrell), and the business community (Dayton H. Clewell and Dr. Nat C. Robertson). This effort was an attempt to assess expert opinion in this area in order to parallel the factual information which we hope to obtain through the second Harbridge House study.

Finally, I have enclosed an initial report that ERDA prepared for the President and Congress as required under §9(n) of P.L. 93-577. This report provides the historical development of Government patent policy, a review of legislative enactments, and a detailed summary of the development of ERDA's nonnuclear patent legislation. Of particular interest is the transcript of the public hearings that were held in regard to Government patent policy and compulsory licensing, and the comments that were received on this subject.

It is because of the information enclosed and referred to above that I keep stating the position that we probably have before us as much information on this topic as we are going to get. The problem is that, after digestion of the information, all parties concerned with the issue have not been led to the same policy decision. In my opinion, this is not