announcement of the policy [illegible] inventors of existing licensed inventions would institutionalize this policy.

2. Residual share of royalties: The ~~contrary~~ incentive for laboratory managers is the residual royalties after paying the inventors' shares. If the HHS intent is to promote patenting and licensing, the best incentive will come from allowing each laboratory to receive all the royalties from its own employees' inventions. ~~Other use of royalties would dilute the incentive.~~ A decision could be made for two years, with perhaps the option kept open for changing the distribution policy in the future as the royalty flow increases. This option would be more palatible to lab directors if they are assured that they will participate in any decision to change the 100% return policy.

3. License administration: Today, NTIS administers the HHS licenses, a chore involving accounts receivable-like bookkeeping. An agreement should be reached for HHS to take over this function, or for NTIS to continue to perform it for existing licenses. Agreement on the NTIS payment or share of the royalties should be reached as soon as possible to avoid disputes. The agreement may or may not extend to inventions that HHS will license directly in the future. Some HHS inventions should probably be protected with foreign patents. NTIS does almost all of the Government's foreign filing, a factor to consider when deciding on which NTIS services HHS may continue to use. The Act provides that a laboratory may use its royalties to pay for technology transfer promotion ✓at the laboratory or elsewhere.

Blocks 29 and 31 on schematic

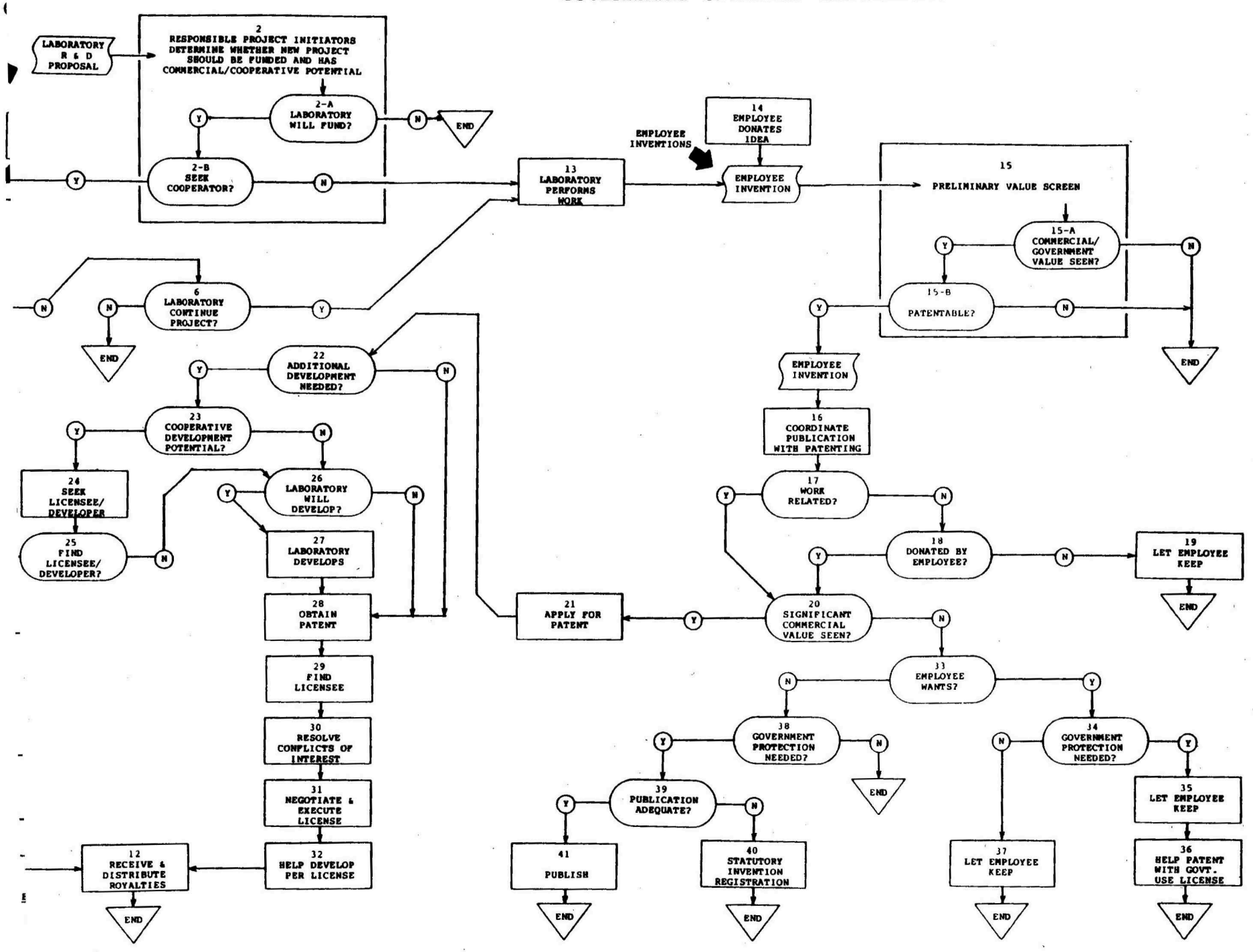
4. License promotion and negotiation: Delegation of authorities to promote and negotiate invention licenses will probably be easier to obtain if joined with an agreement on a higher organizational level to approve licenses.

5. Invention management: Five initial steps to establish a practical invention management system in a laboratory include:

Block 15 on schematic →

(a) Each laboratory receiving a delegation should establish a preliminary value screen process to separate employee inventions which the lab intends to commercialize from those that do not appear to have significant commercial potential. Invention reports should be submitted directly to a management-selected point in each laboratory that is neither the employee's supervisor nor the patent counsel. Advice on patentability from the patent counsel should be included in the screening process. As a backstop to the process, inventors are allowed by law to own inventions that the laboratory does not intend to commercialize.

MANAGING TECHNOLOGY IN A GOVERNMENT-OPERATED LABORATORY



5/6/87

DRAFT

PHS: RESTRUCTURING THE AIDS MANAGEMENT AND ADVISORY PROCESS

The PHS's management of AIDS has undergone regular assessment and change by each Assistant Secretary for Health since 1981 to meet the requirements posed by the dreaded disease AIDS. The dimensions of the disease continue to grow on every level of pursuit; and especially on the research, services, patient and resource levels. Given the expanded scope and budget changes, I am setting forth a revised structure to manage AIDS within the Public Health Service, to obtain the needed science and health advice to operate the PHS programs on AIDS, and to be able to advise the Secretary on health issues related to AIDS.

The restructuring consists of two parts: (1) policy formulation and implementation functions within the PHS; and (2) on AIDS advisory structure to obtain the needed input from the health and scientific communities and the public.

First, concerning the policy and implementing functions within the PHS, I am establishing an AIDS Executive Policy Board within OASH, consisting essentially of the Agency Heads and other vital policy persons, and a focus for the overview and coordination of the AIDS effort. Accordingly, an AIDS Program Office is to be established in OASH and the Director of this program will report to me. The office will advise on the development of policy, the setting of priorities, and the guidance of implementation with respect to the prevention, diagnostics, treatment, and health care features of AIDS and its future implications on our health care system (see Attachment 1). I am creating within the office four AIDS coordinators instead of one on the critical AIDS issues to meet our increasing challenge and need for responsiveness to AIDS. In addition, I am designating the Surgeon General of the PHS as a senior advisor on AIDS. I am asking that each Agency within PHS establish a focus for AIDS coordination through designating a Deputy or Associate Agency Head.

Secondly, concerning the improvement of our advisory input to the PHS and its operating agencies, I want to establish a PHS AIDS Advisory Committee that will provide us the needed assessments and guidance on programs and the needs and problems of the scientific and health communities as well as those of the public. Attachment 2 outlines the structure for this advisory input. I am moving to increase the sensitivity of the advisory input to each of the operating agencies by asking that a specific committee that looks at the effectiveness of agency programs and needs and the needs and problems of the agencies' constituents be put in place. Further, I want the Chairperson of each Agency Advisory Committee to sit on the PHS Advisory Committee. This will give the appropriate structure for systematically obtaining and blending the important advisory inputs. This effort is designed to ensure that we are concerned about the outreach of our research and services and that we listen at all appropriate levels to the needs of the health community.

The existing PHS Executive Task Force will continue unchanged to function in raising key issues, i.e. problems, needs, accomplishments, crosscutting PHS matters and other related issues; to disseminate information across the PHS and its agencies; to obtain consensus for implementation; and to formulate and surface policy issues to the Executive Policy Board. Further, the Federal Coordinating Committee on AIDS will continue its meetings to fundamentally achieve the same results across the Departments and Agencies of the Federal Government as the PHS Executive Task Force achieves within the PHS.

These changes in the structure within the PHS should strengthen our capacity to manage the AIDS program, to advise the Secretary and to assure the sound stewardship of the resources at our command for AIDS.

(Operating structure)

DHHS

AIDS Executive Policy Board

Dr. Windom (Chair)
Dr. Harmison (Co-Chair)
Dr. Koop
Dr. Mason
Dr. Sundwall
Dr. Young
Dr. Macdonald
Dr. Wyngaarden

Other Participants

Dr. Roper (HCFA)
PHS General Counsel
AIDS Coordinators

ASSISTANT SECRETARY FOR HEALTH

Federal Coordinating Committee on AIDS Information/Education/ Risk Reduction

Dept. of Agriculture
Dept. of Defense
Dept. of Education
Environmental Protection Agency
Dept. of Housing and Urban Development
Dept. of Justice
Dept. of Labor
State Dept.
Action
Office of Personnel Management
U.S. Information Agency
Veterans Administration
Domestic Policy Council
Office of Science and Tech. Policy
OMB

National AIDS Program Office
Director/Deputy Director

AIDS Research Coordinator
AIDS Health Care Coordinator
AIDS Prevention Coordinator
AIDS Regulatory Coordinator
(AIDS Financing Coordinator-HCFA)
(Public Affairs/Budget/Legislative Planning/Evaluation Officers)

PHS AIDS Executive Task Force

(Current PHS Executive Task Force--See Subgroup under each Agency)

NATIONAL INSTITUTES OF HEALTH
(Designate Deputy or Associate Director for A
Vaccine Research and Development Subgroup
Therapeutic Intervention Subgroup

FOOD AND DRUG ADMINISTRATION
(Designate Deputy or Associate Commissioner f
Blood and Blood Products Subgroup

CENTERS FOR DISEASE CONTROL
Deputy Director for AIDS
Epidemiology and Prevention Subgroup
Information and Education and Risk Reductio
Subgroup

HEALTH RESOURCES AND SERVICES ADMINISTRATION
(Designate Deputy or Associate Administrator
Patient Care and Health Services Delivery
Subgroup

ALCOHOL, DRUG ABUSE AND MENTAL HEALTH ADMINIST
(Designate Deputy or Associate Administrator f
Neutroscience and Behavior Subgroup
Addiction and Behavior Subgroup

07-14-86
REVISED

AIDS
Proposal for
A Franco-American Agreement

Due to an unfortunate concatenation of circumstances, misunderstandings have arisen among teams of scientists in France and the United States as to the antecedents with respect to the discovery of the causes of AIDS. Nevertheless, the convergent efforts of these scientists have led to the development in both countries of blood tests for the diagnosis of AIDS virus infection which now permit the implementation of strategies for the avoidance of transfusion-transmitted infection. There is a continuing need for additional means to contain the viruses of AIDS.

The scientists of both countries acknowledge the important contributions that have been made in each country, and in a conciliatory spirit their respective institutions, the Institut Pasteur ("IP") and the National Institutes of Health/National Cancer Institute ("NIH/NCI"), have agreed to integrate their rights or claims to royalties from patents for sero-diagnostic kits. In the same spirit, they have agreed to place these royalties into a foundation to be established for furthering research in prevention and treatment of AIDS. This foundation will be called the Franco-American AIDS Foundation ("FAAF"), the Board of which will include equal numbers of French and American directors.

The basic principles have been agreed upon, and the details of the plans and programs will in due course be announced with respect to:

1. Satisfactory resolution of rights or claims to patents,
2. Creation of a joint fund with royalties,
3. Establishment of a foundation,
4. Utilization of foundation funds.

The principles that have been agreed upon are:

A. The parties have recognized that under the 1883 Paris Convention for the Protection of Industrial Property and the U.S. patent laws neither the NIH nor IP patent is prior art against the other and therefore, assuming PTO agreement, both patents can issue and coexist; the FAAF will own both patents.

B. The IP and the NIH/NCI will each receive annually from the FAAF, for continued support of research, an amount equal to one-third of the royalties received, the remaining one-third to be used for collaborative research on AIDS control and prevention, primarily directed to the specific needs of the developing countries.

C. A scientific advisory committee will be created by the Board of FAAF to consider and suggest collaborative research strategies supplementary to efforts which are supported from other sources, as well as to advise the Board on the allocation of the remaining one-third of the royalties.

D. This committee will also [illegible] directors
financial

EXECUTIVE ORDER NO. 12591

THE WHITE HOUSE

Office of the Press Secretary
(Los Angeles, California)

For Immediate Release April 10, 1987

EXECUTIVE ORDER

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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

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

(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

(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.

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THE WHITE HOUSE

Office of the Press Secretary
(Los Angeles, California)

For Immediate Release April 10, 1987

FACT SHEET

"Facilitating Access to Science and Technology"

The Executive Order on Facilitating Access to Science and Technology initiates a number of steps designed to promote cooperation between the Federal Government, State and local governments, industry and academia in cooperative research and the commercialization of research. These steps will:

1. Direct Federal departments and agencies to improve the transfer of federally developed technology and technical information to the marketplace by:

   -- encouraging Federal laboratories to collaborate with State and local governments, universities and business, particularly small business, through cooperative research and development agreements;

   -- licensing intellectual property developed through the cooperative research and development agreements or by individual Federal laboratories;

   -- encouraging "science entrepreneurs" to act as conduits between Federal laboratories, universities, and the private sector;

   -- implementing royalty-sharing programs for Federal inventors; and

   -- developing a uniform Federal policy permitting Federal contractors to retain rights to software, engineering drawings, and other federally generated technical data, in exchange for royalty-free use by the government.

2. Direct the Secretaries of Agriculture, Commerce, Energy, and Health and Human Services and the Administrator of the National Aeronautics and Space Administration to select one or more of their laboratories to participate in the "Technology Share Program," involving multi-year joint basic and applied research with consortia of U.S. firms and universities.

3. Direct the President's Commission on Executive Exchange to assist Federal agencies in 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

United States Trade Representative to whether the country: offers comparable research and development and licensing opportunities for U.S. nationals and companies and protects U.S. intellectual property rights;

b. the Secretary of State to develop a recruitment policy encouraging scientists and engineers from across the Federal Government, academia, and industry to serve in U.S. embassy assignments abroad; and

c. the Secretaries of State and Commerce and the Director of the National Science Foundation to 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.

5. Direct the Secretary of Defense to identify within 6 months a list of funded technologies that would be potentially useful to U.S. industries and universities and to then accelerate efforts to make these technologies more readily available.

6. Direct Federal agencies to examine the potential for including the establishment of university-based research centers in engineering, science, or technology in the strategy and planning for any future R&D programs. Such centers would be jointly funded by the Federal Government, the private sector, and, where appropriate, the States and would 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.

7. Direct the Director of the Office of Science and Technology Policy to convene within 1 year an interagency task force of Federal research agencies and their laboratories to assess the progress in transferring technologies from Federal laboratories and to develop and disseminate additional creative approaches to technology transfer.

The President's intention to issue an Executive order was announced in January as part of his 43-point Competitiveness Initiative.

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THE WHITE HOUSE

Office of the Press Secretary
(Los Angeles, California)

For Immediate Release April 10, 1987

STATEMENT BY THE PRESIDENT

I believe a vigorous science and technology enterprise involving the private sector is essential to our economic and national security as we approach the 21st century. Accordingly, I have today issued an Executive Order "Facilitating Access to Science and Technology."

It is important not only to ensure that we maintain American preeminence in generating new knowledge and know-how in advanced technologies, but also that we encourage the swiftest possible transfer of federally developed science and technology to the private sector. All of the provisions of this Executive order are designed to keep the United States on the leading edge of international competition.

# # #

than being predicated on the arms-length relationship of procurement and assistance, these agreements should provide for the trusting, hand-in-hand partnerships where joint efforts, evaluation, decision making, and even project redirection, will be necessary and normal. Commerce is developing a preliminary model cooperativ R&D agreement.

4. Communicating and Transferring R&D Results: When each R&D project is undertaken, there should be an understanding on how the results will most likely be transmitted to the sponsor, other researchers, industry, and the public. At the project initiation stage, each laboratory authorized to enter into cooperative R&D agreements should determine whether the project as defined, or perhaps as expanded, may be the basis for industry or university cooperation. If so, the lab should seek a partner. In order to both be fair and appear to be fair, HHS should write guidelines on how to find cooperative R&D partner. These guidelines could provide for general public notices by laboratories of the fields in which they wish to explore the possibilities of cooperative R&D agreements, lab initiated contacts with industry, working through intermediaries of various types, and responding to unsolicited industry approaches. While they don't have to be complicated, these guidelines will allay many management and staff concerns. It may be necessary to build a bridge between the processes for obtaining industry partners and the peer review process.

5. Managing cooperative R&D projects: Over time, a laboratory will have to develop procedures for:

- Identifying the decision points and rights of each party to participate in decisions
- Accounting for funds, property, and effort
- Protecting technical data
- Protecting the rights to publish
- Ensuring performance of both parties to the agreement

These need not be undertaken in advance, if it is understood that each cooperativ R&D project must provide specifically for such management processes until they become routine.

6. Delegation sequence: The Secretary can delegate authorities to intermediate levels above the laboratories, with instructions to proceed with sub-delegations in conjunction with developing the laboratories' capacities needed to exercise sub-delegations.

7. In the interim: The policy decisions and delegations will take time to make. In the interim, the Department can benefit from actual experience by encouraging laboratories to seek cooperative R&D projects, negotiate them, and present them for case-by-case approval by the appropriate intermediate level just discussed.

(b) Preliminary policies or statements of intent should be developed for inventor participation in commercialization that HHS will normally allow. A review and approval process should be prescribed for levels of participation that go beyond. The levels of approval for extensive involvement should probably correspond with those that make or approve research project funding decisions. These levels will also be involved with decisions to approve cooperative R&D projects.

Blocks 7 and 30 on schematic

(c) HHS conflict regulations should be reviewed for their affect on license and commercialization agreements that may be approved by laboratories.

(d) An invention awareness and technology management training program should be conducted for laboratory scienists and their managers. This is to help staff identify when an invention may have been made, consider the legal and financial aspects of identifying ideas that may be inventions, and coordinate publications with patenting. Commerce is developing materials for use in such a program.

Block 20 on schematic

(e) Laboratories should work toward developing an intensive invention evaluation process to be used for inventions that pass the preliminary value screen. Developing and improving this evaluation process which can use technology and market analysis and/or market test techniques will be a continuing and evolutionary effort. Commerce is developing techniques and materials which agencies may use in the intensive evaluation process.

Cooperative Research and Development Agreements

1. Where should the delegations go? The laboratories, and programs in laboratories should be identified where cooperative R&D is

(i) generally appropriate,
(ii) appropriate in certain circumstances, or
(iii) not appropriate at all,

at least on a preliminary basis. This identification would guide the cooperative R&D agreement delegations and would resolve the most important concerns about improper relationships related to pre-market clearences or other regulatory activities. Category (ii) might, for example, include cooperative R&D between a lab primarily involved in regulation and a manufacturer of test equipment that is not in the industries the lab is to help regulate. The initial decisions could be conservative, with provision for review and relaxation after HHS has more experience with cooperative R&D agreements.

2. Scope of delegated authorities: Cooperative R&D agreements could be stratified, with immediate delegation for those involving less than a threshhold dollar or person/time level (e.g. $75,000 or one person/year). If this approach is taken, several levels could be established to negotiate agreements and to approve them. Some cooperative R&D may result from the