Based on experience

Step 15, PRELIMINARY VALUE SCREEN. Most employee ideas will not ~~turn out to~~ have significant potential. This two-part evaluation step is designed to be a quick and low-cost process for sorting those which may have significant value from those which have little promise. The first question (Step 15-A, COMMERCIAL/ GOVERNMENT VALUE SEEN?) involves technological, economic, and managerial questions. The Government may anticipate using the ~~idea and need~~ defensive protection even if there does not appear to be any commercial potential. If there is reason to believe the idea or discovery may be of commercial value or of use to the Government, the second part (Step 15-B, PATENTIBLE?) should be performed by a patent attorney to provide advice on what type of patent protection may be obtainable. If this Preliminary Value Screen indicates the idea may have commercial potential or value to the Government and be patentable, the employee is considered to have made an invention.

AND

This step will involve the employee, the technology transfer officer, the person designated by the laboratory for conducting the screening process, individuals who may be members of a screening committee, a patent attorney, and perhaps others. ~~Significant~~ thought should go into how a laboratory will organize and conduct this step which should include the content and flow of invention reports, confidentiality agreements, and controls.

considerable

(Part 2c. Determining the Value of a Technology outlines factors and approaches to evaluating technology; page 14.)

Step 16, COORDINATE PUBLICATION WITH PATENTING. It may be desirable to publish a paper on the discovery or idea. Publication is entirely consistent with patenting, but done prematurely, publication can destroy the opportunity to obtain a patent. In addition, "publication" has a special meaning in patent law. The inventor should be advised on how to coordinate the timing of discussions of the technology and publications with domestic and perhaps foreign patent applications.

Step 17, WORK RELATED? Executive Order 10096 sets the policies and the rights of the Government and its employees to employee inventions. A test is whether the invention was work related or made in the course of regular assigned duties. If YES, the invention should be examined more extensively for possible commercial value.

Leave in

Step 18, DONATED BY EMPLOYEE? NO. (If YES, go to Step 20)

and

Step 19, LET EMPLOYEE KEEP. If the invention was not work related, and ~~not donated by the employee,~~ the Government has no interest in it, ~~and~~ the employee should allowed to keep it.

normally be

Step 20, SIGNIFICANT COMMERCIAL VALUE SEEN? YES. If the invention is work related or has been donated by the employee and

it has passed the Preliminary Value Screen, its commercial potential should be evaluated more extensively. Although a small step on the chart, determining commercial value can be a complex process. (If NO, go to Step 33.)

(See Part 2c, "Determining the Value of a Technology"; page 14.)

Step 21, APPLY FOR PATENT. The laboratory should apply for a patent on an idea or discovery of an employee to which the Government has rights, that appears to be patentable, and that appears to have significant commercial value. While the Government has obtained thousands of patents, few of them were obtained primarily for commercial use. The laboratory needs to ensure that the application is designed to produce a strong and licensable patent.

Step 22, ADDITIONAL DEVELOPMENT NEEDED? YES. The idea may need additional development, either to meet Government needs or to make it more attractive for promotion and licensing.

Step 23, COOPERATIVE DEVELOPMENT POTENTIAL? YES.

Step 24, SEEK LICENSEE/DEVELOPER. To be done if it appears that a cooperator might be found to help develop the invention. ~~In many cases, a cooperator with established market interests or understanding will want to amend the patent application and obtain a stronger patent.~~

(See Part 2a. Techniques for Finding R&D Cooperators and Licensees; page 10.)

Step 25, FIND LICENSEE/DEVELOPER? YES. If a licensee/developer is found, the logic of the chart flows back to Step 7 for creating a cooperative R&D project.

Step 26, LABORATORY WILL DEVELOP? YES. If the invention does not appear likely to interest a cooperator, or if one cannot be found, the lab must decide whether to continue development on its own, ~~or obtain a patent and try to license it~~. and continue seeking patent protection and licensees,

Step 27, LABORATORY DEVELOPS.

Step 28, OBTAIN PATENT. Regardless of whether or not the lab continues development, if the idea still appears to have commercial potential, the lab will continue to pursue a patent.

Step 29, FIND LICENSEE.

(See Part 2a. Techniques for Finding R&D Cooperators and Licensees; page 10.)

None

Step 30, RESOLVE CONFLICTS OF INTEREST. The degree of involvement that a laboratory employee inventor may have in the follow-on development and commercialization of an invention must be decided. This should be considered before the laboratory enters into negotiations with a potential licensee, recognizing that the licensee's wishes must also be considered. (

(See Part 2d. Conflicts of Interest; page 16.)

Step 31, NEGOTIATE AND EXECUTE LICENSE. Under the new law, laboratories may be delegated authority to negotiate their own licenses. Once the lab has decided to seek a patent, it should start looking for a licensee. If one is found before the patent is issued, the licensee may ~~want~~ wish to amend and the strengthen the patent application in relation to a specific product.

Step 32, HELP DEVELOP PER LICENSE. Extensive development is usually required to convert an invention into a marketable product, and often the inventor or the originating lab can make unique contributions. The new law allows laboratories to include in their licenses, provisions for the laboratory or the inventor to contribute to further development and commercialization of the invention. Although not shown on the chart, the license might actually be a cooperative R&D agreement which could lead to additional, follow-on inventions. In this case, the logic flow would be from Step 32 back to the cooperative agreement activities beginning at Step 7.

Step 33, EMPLOYEE WANTS? YES. The new law says that an employee will be allowed to keep his or her invention that the Government has a right to own, but has decided not to patent or commercialize. Since the employee may believe the invention has more value than the Government recognizes, this serves as a backstop to prevent destroying the invention's commercial value.

Step 34, GOVERNMENT PROTECTION NEEDED? YES. In the past, the Government obtained most of its patents to protect its royalty-free right to use inventions it had funded. The Government will continue to need this protection for many inventions regardless of their commercial value.

Step 35, LET EMPLOYEE KEEP. The employee should be allowed to keep the invention on the condition that the Government will retain a royalty free right of use.

Step 36, HELP PATENT WITH GOVT. USE LICENSE. Had the employee not wanted the invention, and had the Government decided to file a Statutory Invention Disclosure, (see Step 40) the Government would have incurred filing and attorney costs. Thus, it is equitable for the lab to help the employee obtain a patent where the Government retains a royalty-free use license. The help

would be flow Step 32 back to the cooperative agreement

could include actual filing of the patent for the employee or paying a fair share of the costs.

Step 37, LET THE EMPLOYEE KEEP. If the Government sees no use of its own to protect, the employee should be allowed to keep the invention without giving the Government a license.

Step 38, GOVERNMENT PROTECTION NEEDED? YES. If the employee does not want an invention that the Govenment does not intend to patent, then the Government should decide whether it needs to protect its royalty-free right of use. This is the same decision as Step 34, but the actions taken are different.

Step 39, PUBLICATION ADEQUATE? YES. Once an idea or discovery has been published, statutory bars to patenting take effect. After prescribed periods, the bars prevent anyone from obtaining a patent, and the idea or discovery can be used freely. Thus, publication may provide the use protection the Government needs, and where adequate, publication is also the cheapest form of protection.

Step 40, STATUTORY INVENTION REGISTRATION. P.L. 98-622 allows an inventor or the Government to register an invention with the Patent Office without obtaining a regular patent. By this process (called a SIR), the invention is put into the public domain for anyone to use freely. It serves the Government's purpose of protecting the right of free use. It takes effect sooner than a publication, which may be important for rapidly moving fields of technology. A SIR costs less than a patent but is more than a simple publication.

Step 41, PUBLISH.

PART 2

Part 2a. Techniques for Finding R&D Cooperators and Licensees

Close cooperation between a Federal laboratory and a commercial firm is a type of relationship that is foreign to the culture of most Government employees and managers. They have legitimate concerns that relationships with the private sector both be fair and appear fair. An attribute of the industrial culture, however, is to maintain secrecy around actions that may affect future products. Much of the trick in establishing cooperative R&D agreements and patent licenses is to bridge the two cultures. The way a laboratory decides whom to accept as cooperating party is important to both the appearance and actuality of fairness. This is particularly true where the industry partner will obtain a degree of exclusivity in the results. Labs will have to exercise some ingenuity in organizing their opening gambits, but here are a few ideas.

There are three primary avenues by which a laboratory and a private sector firm might be brought together in a cooperative R&D agreement. These are through:

- A firm's desire or willingness for the laboratory to aid in further development and commercialization of a laboratory invention.
- The laboratory's efforts to find a cooperator to participate in research or in developing a particular technology.
- A firm's request to establish a cooperative project for research or development of a particular technology.

A. If the cooperation stems from an existing laboratory invention, there are three major ways to ensure fairness are:

(1) Advertising the invention as available for licensing through NTIS publications, agency fliers, and industry contacts, or use of intermediaries, and other dissemination techniques that expose the invention to possible licensees.

(2) The Federal patent licensing regulation (37 C.F.R. Ch. IV based on 35 U.S.C.208), establishes a process for determining the best potential licensee for a Government-owned invention and includes a Federal Register publication requirement for exclusive and partially exclusive licenses. While cumbersome and at times self defeating, the regulation provides for a selection process that is perceived as fair.

(3) Use of a technology management intermediary (such as NTIS, Reseach Corporation, or for-profit technology brokers)

to approach industry for the laboratory. In general, these services work best for inventions that have an obvious market value and require relatively little additional development.

B. If the laboratory tries to find a collaborator to help conduct research or develop a technology for which no property rights have yet been established, there are several factors and approaches to consider.

(1) While procurement rules do not apply to cooperative R&D agreements, the feeling of need for an open process comes from the requirement for competitive procurements. There is, however, provision for sole source procurement of R&D that involves unique ideas and when it makes sense to deal directly with those who have the ideas. This view might guide [redacted] entering into cooperative R&D agreements but labs should be sure to have recorded justifications of their actions.

(2) A lab could publish notices that it is seeking a cooperating party. It could use the Federal Register as a formality, but scientific, professional, and trade journals and associations would probably be more effective.

(3) Depending on the structure of the industry, the lab could contact the firms it believes most likely to be interested and negotiate with those that respond.

(4) The lab could organize the project in conjunction with a university or unit of State or local government as a partner or intermediary. Allowing the partner or intermediary to select the company or companies could remove the choice from the laboratory. This may be useful where lower levels of government or universities are more able to establish relationships with industry that are closer than arms-length. The partner or intermediary may not, however, be able or willing to evaluate the technical capabilities of a potential R&D cooperator, however.

(5) The lab could list its search with the FLC, NTIS, and other intermediaries who could direct candidates to the lab.

C. Handling cases where a firm approaches the laboratory with a request to collaborate in research or in developing a technology on which the Government holds no patents, can be divided into two time periods.

o Requests received before the lab makes a general announcement of its willingness to enter into cooperative R&D agreements, and

[illegible]

o Requests received after the lab has made an announcement.

(1) It appears that a laboratory can announce its willingness to consider cooperative R&D agreement proposals in fields of science or technology, to be acted on at the lab's convenience. The announcement can provide for a first-come, first-considered selection process, or one that accumulates proposals for a while and then picks the most desirable. The announcement could offer confidentiality for the proposals and present the general agreement terms the lab would offer and require. Once a lab makes this sort of announcement, and follows a rational selection process, it would probably have met the requirements for both actual and apparent fairness. With the general announcement made in advance, no additional publication should be needed for a specific agreement.

(2) The problem may be greater if a proposal is received that leads to a cooperative R&D agreement before an announcement is made. This may be primarily a start-up problem, but it could occur any time a firm offers a proposal in a field not covered by a lab's announcement. It would be good if the company would agree to a public notice of the proposed agreement. But possibilities of delays, actions by competitors, and publicity may lead a company to reject the idea. Many labs have service for others programs that make lab facilities available to companies for proprietary work. The policies on deciding who can participate in these programs may be a useful and realistic precedent. It may also be possible to work though a university or local government intermediary to remove the selection onus from the laboratory. Finally, the view discussed above (2(a)), that R&D agreements don't fit the normal openness mold of procurement might be applied.

Part 2b. Types of R&D Cooperation

The range of different types of cooperative R&D projects, in order of increasing complexity includes the following.

A. Parallel Efforts. Probably the simplest type of cooperative R&D project that a laboratory may undertake would consist of parallel but separate work by the lab and the cooperator, with agreement to exchange results. This would not involve joint or shared management, mingling of resources, or the likelihood of inventions made jointly by laboratory employees and non-Federal co-inventors. Since the cooperator would not be a party to the work done by the lab, there would be no provision under existing law to restrict public access to the results produced by the lab. If restricted access is important to some aspects of the project, such as creation of computer software that the non-Federal party

desires to Copyright, the work should be divided so that the non-Federal party develops and controls those aspects.

B. Facilities Sharing. Either party might agree to provide the use of equipment or facilities to a joint project. For example, either party might provide an environment to test equipment developed by the other party under the agreement. Under such agreements, there would be minimal mingling of resources, but there may need to be provisions covering damage to and disposition of the shared facilities and the equipment being tested.

C. Personnel Sharing. Next ~~up~~ on the complexity scale, would be where either the laboratory or the cooperator would provide the services of personnel to pursue an agreed program of work, perhaps at the other's site. This could occur under a patent license where the lab agrees to allow the inventor to assist the licensee with advice or other types of assistance in transforming the invention into a product. Or, it could result from a company requesting the opportunity for one or more of its employees to assist a particular Federal laboratory employee in the conduct of a particular line of work. Under these situations, there would be little or no mingling of resources other than personnel time, but co-inventions involving the non-Federal employees might be a distinct possibility.

D. Industry Funding. A firm might be willing supplement the funding of work undertaken by the laboratory. In their simpler forms, these agreements would include an explicit and predetermined statement of work that is not likely to change, so there would be minimal sharing of decision-making responsibility. Industry funding agreements may require provisions listing the types of laboratory costs that will be allowable and how the costs will be reported. In laboratories whose accounting systems are slow to report, special records may have to be kept to track the use of non-Federal funds.

E. Shared Management. Probably the most complex type of cooperative R&D arrangement would involve a project with significant unknowns and where it is necessary to provide for mutual sharing of the project direction responsibilities. The agreements for these projects need to provide for the management and decision making process. Perhaps the best approach to developing such a project is for the lab and cooperator to work out in technical terms, the initial direction of work, the preliminary decision points, the possible alternatives that may be followed as a result of the decisions, and other significant anticipated or possible events. The formal agreement for the project would then be drafted after the strategy for conducting the project has been outlined.

Part 2c. Determining the Value of a Technology

This paper will not attempt to replicate the many books and articles in print and being written about evaluating technologies, but there are some points of particular relevance to Federal laboratories.

A. Basis for a Technology's Value. For our purposes, technology is knowledge resulting from R&D, of how to achieve a desired physical result. The value of the technology is basically the value of the result minus the cost of achieving the result.

Sometimes, the value of a technology is directly related to the number of people or firms who have access to it and can use it. To achieve its greatest value, such technology should be put into the public domain through publications, meetings, etc., and distributed through technology dissemination programs, consultants such as Agricultural Extension Agents, and education programs.

At the other extreme, the value of a technology may be inversely related to the number of people or firms that have access to it and can use it. This is often the case with an invention, where a significant capital investment is needed to bring the invention to market by the first firm to use it, but where other firms if allowed, might bring similar or improved products to market without having to repeat the investment. ~~The key is protecting~~ the first firm's capital investment by restricting other firms' ability to copy. Simply put, this is what a patent does.

Perhaps the clearest example is a ~~new medicine~~ potential therapeutic product, where millions of dollars must be spent by the developing firm on testing and obtaining pre-market approvals. A firm making a direct copy would be spared much of this investment, would have lower costs to recover, and could sell at a lower cost. Without confidence that copying would be restricted, no firm would make the initial investment, and the ~~medicine~~ therapeutic would not come to market. Thus if anyone were allowed to use the technology necessary to make the ~~medicine~~ therapeutic, the ~~medicine~~ therapeutic would never be made and its practical value to the public and the economy would be zero.

A body of technology might include elements with both types of value. This could occur, for example in a field of measurement, where an part of the technology consists of data that should be widely publicized. Another part of the technology might be needed to make special measurement equipment and would require a significant developmental investment before the equipment becomes available to those who need to make the actual measurements.

Finally, the value of a technology may stem primarily from its usefulness to the Government. In such cases, the Government may need to protect its right to use the technology it created

without having to pay royalties to others who may claim it as their invention. In the past, most Government patents were obtained to gain this protection.

Step 2 on the system chart requires a prediction of the value of the technology that a new project is most likely to produce. Step 15 requires a preliminary evaluation of a discovery or idea. In both steps, the distinctions just described must be applied to each particular case.

B. Intellectual Property. The way to protect the rights of one party to use a technology while controlling the opportunity for others to use it is through identifying and protecting the technology as intellectual property. Normally this is done today to protect an investment in developing the technology and bringing it to market. It is done primarily through:

- o Patents,
- o Copyrights, and
- o Technical data kept in confidence.

Conversely, the way to ensure that anyone including the Government can use a technology is to ~~deliberately~~ destroy any intellectual property value it might have by putting it in the public domain through publication or some other means. Unfortunately, it is easy to accidentially destroy the intellectual property value of a technology that should be protected. In part, Steps 2 and 15 should lead to a deliberate decision on protection, publication, or a combination of the two.

C. Commodities vs. Differentiated Products The goods traded by the world's economies tend to be either commodities or differentiated products. The markets for commodities (e.g. iron, wheat, and oil) are usually very competitive and there is little a single producer can do to increase his profitability. The markets for differentiated products (e.g. ~~medicines~~, special devices, and computer programs) allow a single producer much more opportunity to influence his profitability.

Technology is used by producers of both commodities and differentiated products. However, technology in the form of intellectual property is often the basic ingredient necessary to create a differentiated product. If many producers could use a new technology, the product would soon become a commodity.

This distinction is important when evaluating a technology. An objective of most nations that have or aspire to have modern industrial economies is to increase the portion of their economy dedicated to differentiated products, while reducing dependence on commodities.

D. The Evaluation Process. Evaluating an idea or discovery can be time consuming and costly. A laboratory can conserve its resources by using a multi-step evaluation process, highlighted on the system chart as Steps 15 and 20. Step 15, the PRELIMINARY VALUE SCREEN, is intended to be a weeding process to reduce the number of ideas under consideration to those which appear to have the best potential. The three primary purposes of ~~the~~ this Step are to obtain preliminary indications of:

- What the technology will actually do and how well it will do it from a technical standpoint,
- Identify what the market or markets may be for the technology, including its ability to meet a Government need, and
- Whether it can and should be protected as intellectual property.

If ~~the~~ all three indications are positive, then the lab is justified in spending more resources for additional evaluation. This is what Step 20 is to indicate. The continuing evaluation may be analytical or it may be done by an actual market test.

If the invention will be used in a commercial product, the sooner a firm is involved in the development process, the more likely the chances of ultimate success. Once a patent application has been filed, the lab can start to seek a licensee. This is the market test approach. The analytical approach is needed if the lab has to do preliminary market and cost projections to interest a potential licensee.

The point is to work gradually into the evaluation process, committing or not committing additional resources on a controlled basis as knowledge is gained.

Part 2d. Conflict of Interest

Conflict of interest is often mentioned in conjunction with technology management by laboratories. While this paper is not to provide legal advice, there are indications that the term is frequently used incorrectly. Three different situations are often confused, but need to be recognized and handled separately:

A. Conflict of interest. A legal conflict of interest situation is probably one that:

- Is prohibited by Federal statute,
- Allows a Federal employee to commit the Government or Government resources including the employee's work time,

without prior approval or subsequent management review, and

o May lead to personal benefit for the employee.

Most conflict of interest statutes were written before enactment of the Federal Technology Transfer Act and were based on the concepts that a Federal/industry relationship should be arm's-length and a Federal employee could serve only one master. These statutes must be applied in light of the new relationships Congress intended under the Act.

Agency regulations written before the Act that do not provide for Federal employees having relationships with more than one organization may need to be revised. While unheard of in most agencies, such arrangements have long been accepted and promoted by ~~at least two~~. In addition, implementation of the Act requires agency regulations to accommodate the technological innovation process as it is used in the United States economy. This means that the public good may best be served by special treatment for innovating firms and restricted access to the technology on which a new product is based.

B. Congruence of interest, is a situation anticipated by the Act, where, for example, a laboratory employee inventor is allowed to contribute to and directly benefit from the commercialization of the invention where the employee can make a unique contribution that is in the interest of both the laboratory and a private firm. Patent licenses, cooperative R&D agreements, and employee ownership of inventions not managed by the laboratory are types of hand-in-hand congruence of interest situations which are fundamentally different from the arms-length relationships toward which the conflict-of-interest statutes were directed.

Congruence of interest situations are more like partnerships than typical Government/private sector, arms-length relationships, and the agreements establishing them should be similar to partnership agreements. In many cases, relationships between firms and laboratory employees that would result in conflict of interest situations if the employees acted on their own, can become congruence of interest through agreements between the laboratories and the firms.

C. Conflict of committment, or the competing demands for resources. This can arise, for example, when the services of an investigator are desired both to aid commercialization of a technology and to perform other laboratory work. If it arises, it is a management problem, not a legal conflict of interest issue. It should be solved on the basis of the laboratory's priorities, including its mission committments, commercialization objectives, desires to accommodate its staff, and the value of the technology.

The most difficult aspect of this for many to accept will probably be the fundamentally new types of relationships the Act permits. The Act was designed to bridge between what have formerly been two entirely separate cultures--industry and Government research. The bridge may involve co-work, co-management, co-acceptance of risks, and co-enjoyment of rewards. While some employees of a few agencies, particularly Agriculture and the VA have experience in these types of relationships, for most Government people, ~~it~~ they will be entirely new. As such, the Act is plastic and waiting to be molded in the wisest and most imaginative ways that can be created.

One way an agency could approach this gradually, would be to develop preliminary policies or a statement of intent for the basic types of inventor participation in commercialization that the agency will normally allow. It could establish a review and approval process for proposals of types of participation that go beyond. The organizational levels that could approve more extensive participation should probably correspond with those that make or approve research project funding decisions for a laboratory. These levels will probably also be involved with decisions to approve cooperative R&D projects.

CSIS

Center for Strategic & International Studies
Washington, DC

August 13, 1987

Dr. John C. Williams
Staff Director, Productivity, Technology and Innovation
Dept. of Commerce
15th and Constitution AVe., NW
Washington, DC 20230

Dear Dr. Williams:

CSIS is pleased to invite you to attend a conference on "Technical Change and the Politics of Energy." The conference will be held on 9 September at the International Club of Washington, 1800 K Street, N.W.

This conference is sponsored by Los Alamos National Laboratory and addresses a number of technologies and technology issues that potentially impact on the energy future. The subject is timely as U.S. dependency on oil imports continues to grow.

Enclosed is the proposed agenda for the conference. Please indicate whether or not you plan to attend by returning the enclosed reply form to Mrs. Mary Park at CSIS before 4 September. You may also RSVP by phone to Mrs. Mary Park at (202) 775-3102.

We look forward to seeing you on the 9th of September.

Sincerely,

Reginald J. Brown
Senior Fellow

Enclosures

Proposed Agenda (8/7/87)

TECHNICAL CHANGE
AND
THE POLITICS OF ENERGY
CSIS, INC.

SEPTEMBER 9, 1987

8:45 - 9:00 a.m.	Registration Abshire Room, 3rd Floor International Club 1800 K Street, N.W. Washington, D.C.
9:00 - 9:10 a.m.	Welcome - W. J. Taylor, Jr. Executive Vice President Chief Operating Officer CSIS
9:10 - 11:30 a.m.	Morning Session Chair: Charles K. Ebinger Senior Consultant, Putnam, Hayes & Bartlett Adjunct Fellow in Energy Studies, CSIS
9:15 - 9:35 a.m.	**Technical Change In Industry-Economic** - Charles D. Kolstad University of Illinois
9:35 - 9:55 a.m.	Discussion Break
10:00 - 10:20 a.m.	**Technical Change In Industry - History** - Mark P. Mills Science Concepts, Inc.
10:20 - 10:40 a.m.	Discussion Break
10:50 - 11:10 a.m.	**Technology & Structural Change** - Ahmed Faruqui Battelle Memorial Institute
11:10 - 11:30 a.m.	Discussion

11:30 - 11:50 a.m. **Electricity Production & Deregulation**

- Richard Schuler
  Cornell University

11:50 - 12:10 p.m. Discussion

12:15 - 1:30 p.m. Lunch: Mediterranean Room

1:30 - 5:15 p.m. Afternoon Session

Chair: Ron Smith
Los Alamos National Laboratory

1:30 - 1:50 p.m. **Motor Vehicles & Motor Vehicle Fuels**

- Al Sobey
  General Motors Corp.

1:50 - 2:10 p.m. Discussion

2:15 - 2:35 p.m. **Air Transport & Aviation Fuels**

- William Alley
  Aviation Consultant

2:35 - 2:55 p.m. Discussion

3:00 - 3.20 p.m. **Clean Coal Technologies**

- Peter Blair
  Office of Technology Assessment
  U.S. Congress

3:20 - 3:40 p.m. Discussion

3:50 - 4:00 p.m. **Natural Gas Technologies**

- Robert Kelly
  Gas Research Institute

4:10 - 4:30 p.m. Discussion

4:30 - 4:50 p.m. **Petroleum Finding & Production**

- Frank Finch
  Los Alamos National Laboratory

4:50 - 5:10 p.m. Discussion

5:15 p.m. Adjourn

4:10 - 4:30 p.m. Discussion

TECHNICAL CHANGE AND THE POLITICS OF ENERGY

September 9, 1987

[ ] I will attend [ ] Sorry, I am unable to attend

I will attend the following (Refer to tentative agenda):

[ ] Morning Session

[ ] Lunch

[ ] Afternoon Session

Name_____

Title_____

Organization_____

Address_____

_____

Phones (Business)_____(Home)_____

Dietary Restrictions: Please indicate_____

AUG - 5 1987

Assistant Secretary for Health

DRAFT

Federal Technology Transfer Act (FTTA) of 1986

PHS Agency Heads

The Secretary has delegated to me authority to carry out all provisions of the subject act and has requested me to prepare an implementation plan for his review by the end of September. The purposes of this memorandum are: (1) to ask for your agency's participation on a PHS Technology Transfer Advisory Board to develop a PHS implementation plan and adequate and effective policies, procedures, and reporting relationships necessary to govern the administration of the Act; and (2) to set forth some policies that should govern your agency's activities in the interim.

ESTABLISHING A PHS TECHNOLOGY TRANSFER ADVISORY BOARD AND DEVELOPING A PLAN

I plan to have Dr. Lowell Harmison convene and chair a PHS Technology Transfer Advisory Board to develop an implementation plan, to consider the issues described below, and to make recommendations to me on their resolution. I would like each agency to be represented on the Board by two participants: your deputy, who will represent you personally, and another principal official who has been involved in technology

transfer. The first meeting of the Board will be on August 14. An agenda and list of participants will be provided before hand. Please send your nominees to Wilford Forbush by August 7.

By late September, procedures and policies must be planned or in place throughout PHS, and incorporated in the implementation plan requested by the Secretary. At the time these are in place, I will make appropriate delegation of authority to you for carrying out the Act's provisions.

Listed below are several areas of concern to the Secretary and me that must be addressed in the PHS implementation plan:

- o the structure and procedures necessary to manage effective implementation and operation of the Act, particularly certain common procedures and data systems, conduits for transfer of information to and encouraging support from the private sector, and relationships with other Federal Agencies;

- o how cooperative research and development agreements should be negotiated and approved;

- o the degree of decentralization and roles of OS, OASH and PHS Agencies;

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

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

- guidelines necessary for defining conflicts of interest both within and between Federal Agencies;

- how to ensure that public benefits are given proper weight in matters involving potential commercial gain by Government agencies and by private sector organizations;

- whether and how peer review and advisory mechanisms can be involved at some stage of development and approval of cooperative research and development agreements to maintain objectivity; and

- policies regarding uses agencies will make of royalties and other income.

INTERIM POLICY

Outlined below are several steps that you should take immediately within your agency to govern the administration of FTTA activities while longer range policies are being developed.

Cooperative Research and Development Agreements - Henceforth, all agreements must be in writing. In addition, the parties involved in the development of agreements, as well as in their review and approval, should be made a matter of record.

At a minimum, until our policies and procedures are more fully developed, you should be sure that each new agreement is reviewed for:

- possible conflicts of interest or ethical improprieties, even though formal guidelines have yet to be established; and

- whether a laboratory's basic research/regulatory mission could be impaired by the proposed agreement.

You should also be aware that the law requires that your review, or that of your designee must be completed within 30 days of the date the agreement is presented to you or your designee by the head of the laboratory concerned. I request that you send to

me for my review and approval:

- o all agreements providing exclusive licenses or waiving government patent rights, and

- o all cooperative agreements dealing with research activities related directly to AIDS.

Reports and Data Collection - Of immediate concern to me is the FY 87 report on FTTA activities that must be made to the Secretary and to the Congress. I would like you to assign an agency-level organization responsibility for collection, analysis, and maintenance of FTTA-related data relevant to your agency. Until PHS has established formally the data collection and reporting requirements necessary to respond to the Secretary's needs and Congressional requirements, the preliminary information requirements listed in Attachment A must be collected by each agency.

Robert E. Windom, M.D.

Attachments

Attachment A

Preliminary Information Required for the Development of a Report to the Secretary (and Congress) on Implementation of the Federal Technology Transfer Act of 1986

Cooperative Research and Development Agreements (for each Institute/Center)

-- The number of cooperative research and development agreements in effect.

-- The number put in place in FY 88.

-- A brief explanation of each of the more significant agreements.

-- The number of cooperative research and development agreements under development, including a brief explanation of the nature of the more significant of these agreements.

Patents and Licenses (for each Institute/Center) 1/

-- The number of government-owned U.S. and foreign patents in effect, including brief explanations of the nature of the patent and government inventors of record (and current license status) for the more significant of these).

agreements

-- A summary list of significant U.S. and foreign patents owned by our collaborators, government employees, contractors and grantees resulting from activities funded in whole or in part by PHS.

-- A summary list of patent applications pending, including brief explanation of the nature of the patent, date of filing, and inventors of record.

1/ In order to maintain reporting and nomenclature consistency and continuity, each Institute/Center is to take steps to establish registries of cooperative agreement titles and of patent titles which will be the basis for all FFTA reports.

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

JUN 23 1987

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

SUBJECT: Implementation of the Federal Technology Transfer Act of 1986

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

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

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

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

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

- recommendations concerning royalty sharing and a cash awards program;

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

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

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

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

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

Otis R. Bowen, M.D.
Secretary

cc:
OPDIV Heads
STAFFDIV Heads

Topics on Implementing the Technology Transfer Act

I. Internal Government Actions

A. Who has agency lead?
B. Define "laboratory"
C. Develop guidelines for conflict of interest rules
D. Prepare executive summary of laws
E. Create guidance for awards system
F. Develop guidance for items reportable to Congress
G. Develop procedures for the "30-day" review
H. Develop on-line "bulletin board" for CRDA's
I. Propose identification of the "deal maker" at the lab level
J. Circulate a model CRDA
K. Executive briefing for functional units, eg, FoIA, Conflict of Interest, procurement, political appointees/public affairs/Congressional affairs, finance
L. Propose that each agency establish a "Lab Directors Council"

II. Implementation/Laboratory Resources

A. Training laboratory personnel
   -screening projects for commercial potential/development
   -protection of intellectual property
   -relationship of patents to publication
   -licensing negotiations
   -types of cooperation posssible
      o co-venturing
      o through universities (royalties too)
   -external work by lab staff
   -managing technology produced through cooperative ventures
B. Granting rights to inventor if lab unwilling to commercialize
C. Inventorying resources and providing access
D. Rewards for personnel other than inventor
E. Methods of advertising availability of opportunites
F. Interacting with other labs and universities
G. Science entrepreneur/broker
H. Role for state and local governments

III. Actualization

A. Preparation of business and technical proposals
   -Internal--existing technology
   -External--cooperative R&D
   -Internal--cooperative R&D
B. How (and should) we select and use brokers
   -State and local government bodies
   -Contractors
   -Self (electronic systems)
   -Professional brokers

*C. Capitalization procedures
D. Sharing existing facilities not directly involved in cooperative R&D and developing costing procedures
E. How is lab compensated in equivalence for employee compensation
*F. How and who manages a lab's equity portfolio

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Office of the Assistant Secretary
for Health
Washington DC 20201

August 4, 1987

NOTE TO DR. WINDOM:

Attached is my recommendation for restructuring the AIDS activity within the Public Health Service. As noted in the draft, the formulation of policy, its implementation and advisory input is crucial to success in meeting the challenge posed by AIDS. As the budget exceeds the size of some agencies (approximately $1 billion), the structure will permit prioritization of critical efforts, the effective use of the PHS budget, and the application of all PHS resources to the urgent demands of AIDS and the people affected by the disease. Further, it will provide you and the Secretary with the needed capacity to manage the problem of AIDS by being able to be responsive to research opportunities, to be sensitive to the needs of AIDS patients and the health care delivery system, and to assure the Administration and Congress of management effectiveness on the part of the PHS, and sound stewardship of the funds being committed to AIDS. We must act now to strengthen and to provide the leadership in the struggle against AIDS.

Lowell P. Harmison, Ph.D.
Deputy Assistant Secretary for Health

Attachment

Suggested Executive Task Force Composition

Under Secretary or designate: chair
Assistant Secretary for Health
Assistant Secretary for Legislation
Assistant Secretary for Management and Budget
Assistant Secretary for Planning and Evaluation
Assistant Secretary for Personnel
Assistant Secretary for Public Affairs
General Counsel
Representative Laboratory Director
Representative Laboratory Director
Chief of Staff
Chairs of task forces

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

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.

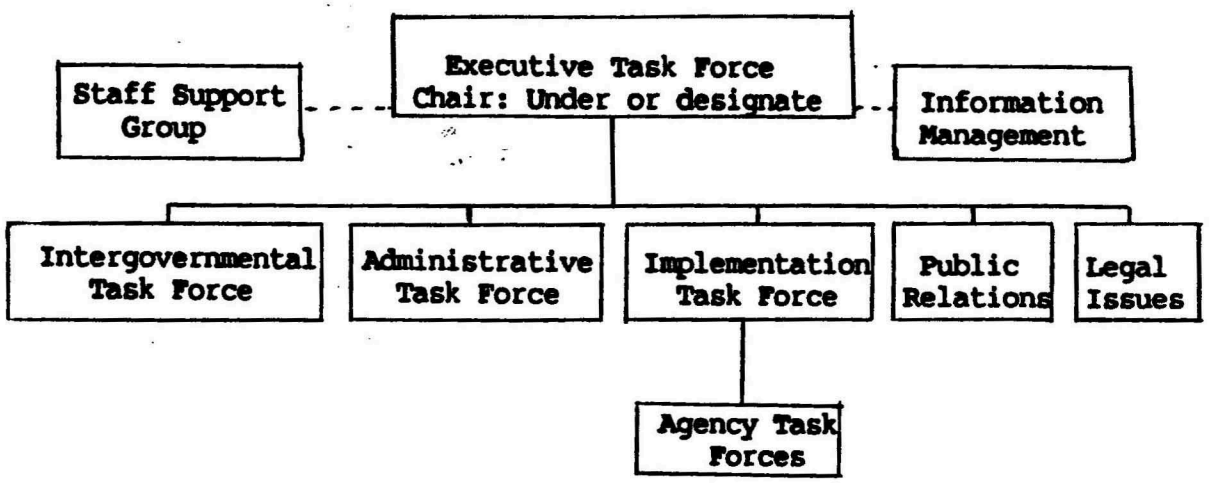
I would like to review your plan and related issues with the Policy Council on April 15. So that we can focus on the most important issues, please discuss your draft plan and issues/options with the General Counsel, Inspector General, and Assistant Secretaries for Health, Management and Budget and Planning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

Thanks.

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

TLO
95683

ORGANIZATIONAL SCHEMATIC



From: Deputy Under Secretary

Subject: Facilitating Access to Science and Technology

To: The Under Secretary

ISSUE

On Tuesday, March 3, 1987, the Department received a draft Executive order entitled "Facilitating Access to Science and Technology" from OMB requesting comments by March 2. I called the author of the transmittal letter, John Carley, who agreed to allow us until Friday, March 6, to provide our comments.

DISCUSSION

The Executive order stresses the importance of fully implementing the Federal Technology Transfer Act of 1986 which we have discussed. It is a strong statement of support for technology transfer, requiring :

- o procedures to facilitate the transfer of technologies from Federal laboratories,
- o establishment of the Technology Share Program between laboratories in Agriculture, Commerce, Energy, NASA and HHS,
- o technology exchange involving scientists and engineers,
- o procedures to ensure that the United States benefits from technology developed abroad,
- o procedures to facilitate technology transfer from the Department of Defense,
- o procedures to facilitate technology transfer from universities, and
- o an annual report coordinated by OSTP.

Considering the importance of this issue to the Department, I believe it would be important to respond on Friday with a vigorous reply that shares our implementation plan with them. I have attached a copy of the draft Executive order as well as the implementation plan to this memorandum for your review.

DEPARTMENT OF HEALTH & HUMAN SERVICES — Public Health Service

Memorandum

Date NOV 24 1987

From Assistant Secretary for Health

Subject Implementation of the Technology Transfer Act

To Heads of PHS Agencies, Center and Institutes
(Delegatees of Technology Transfer Act of 1986)

In followup to the first meeting of the PHS Technology Management Advisory Board, I am providing additional information and guidance to be followed in implementing the Act. This memorandum contains:

(1) Additional information on actions that may be taken under the delegation of October 14, 1987 memorandum and points to be addressed in cooperative research and development agreements (Attachment I Part A and B).

(2) Attachment II presents Draft Model Agreements for cooperative/collaborative research and development agreements and Draft License Agreements:

- o Agreement A--Department of Commerce Model R&D Agreement;
- o Agreement B--PHS Model R&D Agreement;
- o Agreement C--Department of Commerce License Agreement; and
- o Agreement D--PHS License Agreement.

These documents provide a basic guidance that institutes or centers can utilize to shape precise agreements to accomplish the specific tasks of collaboration with other organizations or in licensing of technologies.

(3) Identification of three working groups to support the work of the PHS Technology Management Advisory Board.

A. Implementation Group. This group is to assist, review and facilitate the PHS agencies, centers and institutes in their development of implementation plans required by ASH's October 14 delegation. Further, the group is to establish

appropriate guidelines and procedures for carrying out the Act which includes developing reports, information and data needs and other operational procedures pertinent to the Advisory Board. This group will be chaired by Dr. Ronald Hart, Director NCTR.

B. Operations Group. This group will develop collaborative R/D, licensing and other instruments for carrying out the purposes of the Act. It will provide descriptions of, and access to, tools available to the institutes and centers. As a first agenda item, this group will be responsible for reviewing cooperative research and development and licensing agreement for use by the institutes and centers (see Attachment II above). This group is to be chaired by Dr. Vince DeVita, Director, NCI.

C. Legal Support Group. This group is responsible for assisting the Implementation and Operations Group and in providing legal assistance of issues related to conflict of interest, confidentiality, patent and license agreements, and other support material as requested. It is to chaired by Mr. Robert Lanman, NIH General Counsel.

Full consideration of other cross-cutting issues shall be folded into the work of each group on a best-fit or case-by-case basis as they arise. I will leave selection of the membership of the three working groups to the Chairperson. Further, I would request that those of you who have interest in one or more of these areas contact Chairperson and indicate that interest.

(4) For you information, I am attaching a memo entitled "Preparation of Materials Explaining the Application of the Employee Standards of Conduct to Activities Under the Technology Transfer Act of 1986" by Robert Ortner, Under Secretary for Economic Affair at Department of Commerce, see Attachment III.

Robert E. Windom, M.D.

DRAFT AGREEMENT A.

Introduction

This proposed model cooperative research and development agreement (CRDA) is presented in accordance with Section 5 of the Technology Transfer Act of 1986 (15 United States Code (USC) Sec. 3710(g)(1)(B)). In providing this model agreement our intention is to furnish advice and assistance for a generic model from which parties can add to or substract as they think is appropriate for their particular situation. The definition of cooperative agreement in the Act (15 USC 3710a(d)) excludes a procurement contract, grant, or cooperative agreement. Consequently, the CRDA does not include all the terms and conditions used in these legal instruments nor the required clauses in the Federal Acquisition Regulation (FAR). Of course, an agency or laboratory has the discretion to insert wording from selected clauses of the FAR or may paraphrase such clauses for use in the CRDA. We are available to assist you in any way relating to this matter.

Model Cooperative Research and Development Agreement

This Cooperative Research and Development Agreement ("CRDA"), dated as of _____, is entered into by and between the ABX Company, Inc., a New York Corporation ("ABX"). and the XYZ Center, a laboratory of the X Agency ("XYZ").

A. Whereas, the Congress in enacting the Federal Technology Transfer Act of 1986, Public Law No. 99-502, October 20, 1986, has found that Federal laboratories'

D. Whereas, XYZ possesses certain advanced scientific skills, facilities, special equipment, information, computer software, and know-how pertaining to the Technology;

E. Whereas, XYZ desires to pursue the development of the Technology with the objective of developing {For example, cancer therapeutic reagents consisting of specific monoclonal antibodies coupled to specific radionuclides with cell killing potential};

F. Whereas, ABX is interested in the further development of the Technology and its utilization by private and public {For example, medical institutions};

G. Whereas, ABX desires to provide resources for XYZ's further development of the Technology and subsequently, upon the successful completion of development, carry out a plan for marketing of the {For example, reagents leading to the widespread commercial availability of such reagents};

H. Whereas, XYZ views its collaboration with ABX to develop the Technology and the commitment of ABX to undertake its marketing plan to be in the furtherance of the public interest;

Now, therefore, the parties hereto agree as follows:

Article 1. Definitions

As used in this Agreement, the following terms shall have the following meanings and such meanings should be equally applicable to both the singular and plural forms of the terms defined:

1.1 Cooperative research and development agreement (CRDA) means this agreements as used herein.

1.2 "Invention" means any invention or discovery which is or may be patentable under Title 35 of the United States Code or any novel variety of plant which is or may be protectable under the Plant Variety Protection Act (7 U.S.C. 7321 et seq.).

1.3 "Made" in relation to any invention means the conception or first actual reduction to practice of such invention.

1.4 "Proprietary Information" means information which embodies trade secrets developed at private expense or which is confidential business or financial information provided that such information:

(i) Is not generally known or available from other sources without obligations concerning its confidentiality;

(ii) Has not been made available by the owners to others without obligation concerning its confidentiality; and

(iii) Is not already available to the Government without obligation concerning its confidentiality.

1.5 "Subject Data" means all recorded information first produced in the performance of this Agreement.

1.6 "Subject Invention" means any invention conceived or first actually reduced to practice in the performance of work under this Agreement.

Article 2. Cooperative Research *

2.1 Statement of Work. Cooperative research performed under this Agreement shall be performed in accordance with the Statement of Work ("SOW") attached hereto as Appendix A. XYZ agrees to perform the cooperative research and to utilize such personnel resources, facilities, equipment, skills, know-how and information as it considers necessary, consistent with its own policies, missions and requirements.

2.2 Review of Work. Periodic conferences shall be held between XYZ and ABX, personnel for the purpose of reviewing the progress of work; however, XYZ shall have exclusive control and supervision over the conduct of all cooperative research. It is understood that the nature of this cooperative research is such that completion within the period of performance specified, or within the limits of financial support allocated, cannot be guaranteed. Accordingly, it is agreed that all cooperative research is to be performed on a best efforts basis.

2.3 Principal Investigation. XYZ agrees to assign a substantial portion of the work to be performed pursuant to the SOW to the "W" Branch. The work will be performed under the supervision of Dr. _____ who as principal investigator has the responsibility for the scientific and technical conduct of this project.

2.4 Scope Change. If at any time Dr. _____ determines that the research data justifies a substantial change

in the direction of the work, XYZ shall promptly notify ABX and the parties shall make a good faith effort to agree on any necessary change to the SOW.

2.5 "An alternative" {To the extent that the conduct of sponsored research may require a joint technical effort of ABX and XYZ, the parties agree to establish a joint research and development team (the "Team") which shall conduct sponsored research in accordance with the SOW. Each party shall make available to the Team such unique resources, facilities, equipment, skills, know-how and information as it considers necessary and appropriate. Both parties pledge to support the Team in a mutually cooperative manner, on a best efforts basis, consistent with their respective policies, missions and requirements. The Team shall prepare and submit written reports to both parties, on a periodic basis, setting forth the technical progress made, identifying such problems as may have been encountered, and establishing goals and objectives requiring further effort. The Team's progress shall be prepared as an unwritten amendment to this Agreement and subsequently subject to the joint supervision of the parties, each of whom shall make their own independent judgment regarding the Team's progress and direction. Either party may suggest changes to the SOW or to the scope and direction of the effort which, if agreed to by the other party, shall be implemented by the Team. Although the members of the Team shall be considered as having been delegated to the Team, they shall continue to remain employed by their respective employers with full benefits and salary}.

Article 3. Reports

3.1 Quarterly Reports. Commencing three months after the expiration date, XYZ shall submit quarterly written reports to ABX during the term of this Agreement on the progress of its work and the results being obtained and shall make available to ABX, to the extent reasonably requested, other project information in sufficient detail to explain the progress of the work.

3.2 Final Reports. XYZ shall submit a final report of its results within four months after completing the SOW.

Article 4. Financial Obligation

4.1 Advance Payment. The performance of research by XYZ under this Agreement is conditioned on the advance payment by ABX of XYZ's full cost for the performance of such research. (Use this clause only if agency desires advance payment).

4.2 Deposit Account. ABX shall pay ${X} to XYZ for the performance of the research specified by Article 2. Such funds shall be deposited in {Department of Treasury, Special Collaborative Agreement Account No. _____} as follows:

${.4X} to be deposited upon the execution of this Agreement;

${.2%} to be deposited 30 days prior to the beginning of the second budget period;

${.2X} to be deposited 30 days prior to the beginning of the third budget period; and,

${.2X} to be deposited 30 days prior to the beginning of the fourth budget period.

XYZ shall not be obligated to perform any of the research specified herein or to take any other action required by this Agreement if the agreed to funds are not deposited as required by this Article. (An alternate clause establishing an Agency rather than a Treasury deposit account may be used).

4.3 Insufficient and Excess Funds. XYZ shall not be required to continue its research and development activities under this Agreement if the funds provided by ABX are insufficient to cover XYZ's full cost for such continued activities. Funds not expended by XYZ shall be returned to ABX upon XYZ's submission of a final fiscal report to ABX.

4.4 Accounting Records. XYZ shall maintain separate and distinct current accounts, records, and other evidence supporting all its expenditures under this Agreement. XYZ shall provide ABX a semi-annual report accounting for the use of ABX's funds and a final fiscal report within _____ months after completing the SOW or ending its research activities under this Agreement and the completion of the research work. These accounts and records of XYZ shall be available for reasonable inspection and copying by ABX and its authorized representative.

Article 5. Title to Property

5.1 Capital Equipment. All capital equipment developed or acquired under this Agreement shall be the property of XYZ,

except that title to the following items of capital equipment provided to XYZ by ABX or acquired by XYZ with funds supplied by ABX shall remain or vest in ABX:_____ Upon completion of the research by XYZ, ABX shall be responsible for all costs attendant to the maintenance, removal, storage and shipping of the above identified capital equipment to ABX.

5.2 Disposal of Toxic or Other Waste (A clause may be necessary to govern the disposal of toxic and other waste resulting from this agreement).

Article 6. Patent Rights

6.1 Reporting. XYZ shall promptly report to ABX each Subject Invention reported to XYZ by its employees. ABX shall promptly report to XYZ each Subject Invention reported to ABX by any of its employees.

6.2 ABX Employee Inventions. XYZ, on behalf of the U.S. Government, waives any ownership rights the U.S. Government may have in Subject Inventions made by ABX employees and agrees that ABX shall have the option to retain title to any such employee Subject Invention. ABX shall notify XYZ promptly upon making this election and agrees to timely file patent applications on such Subject Invention at its own expense. ABX agrees to grant to the U.S. Government on its employee's Subject Inventions a nonexclusive, irrevocable, paid-up license in the patents covering a Subject Inventions to practice or have practiced, throughout the world by, or on behalf of the U.S. Government, and

such other rights as we specified in Article _____. Such nonexclusive license shall be evidenced by a confirmatory license agreement prepared by ABX in a form satisfactory to XYZ. ABX may release the rights provided for by this paragraph to employee inventors subject to a license in XYZ. (See paragraph 6.4)

6.3 XYZ Employee Invention. (Note: The parties may agree to allow ABX the option of obtaining title to subject invention subject to a paid-up, nonexclusive, irrovacable license in the government. In this event paragraph 6.6 will need to be deleted). XYZ, on behalf of the U.S. Government shall have the initial option to retain title to each Subject Invention Made by its employees and in each Subject Invention Made jointly by an ABX and XYZ employee. In the event that the XYZ informs ABX that it elects to retain title to such joint Subject Invention, ABX agrees to assign whatever right, title and interest ABX has in and to such joint Subject Invention.

6.4 Filing of Patent Applications. The party having the right to retain title and file patent applications on a specific Subject Invention may elect not to file patent applications thereon provided it so advises the other party within 90 days from the date it reports the Subject Invention to the other party. Thereafter, the other party may elect to file patent applications on such Subject Invention and the party initially reporting such Subject Invention agrees to assign its right title and interest in such Subject Invention to the other party and cooperate with such party in the preparation and filing of patent

applications thereon. The assignment of the entire right title and interest to the other party pursuant to this paragraph shall be subject to the retention by the party assigning title of a nonexclusive, irrevocable, paid-up license to practice, or have practiced, the Subject Invention throughout the world. In the event neither of the parties to this agreement elect to file a patent application on subject invention, either or both (if a joint invention) may, at their sole discretion and subject to reasonable conditions, release the right to file to the inventor(s) with a license in each party of the same scope as set forth in the immediate preceeding sentence.

6.5 Patent Expenses. The expenses attendant to the filing of patent applications as specified in 6.4 above, shall be borne by the party filing the patent application. Each party shall provide the other party with copies of the patent applications it files on any Subject Invention along with the power to inspect and make copies of all documents retained in the official patent application files by the applicable patent office.

6.6 Exclusive License

6.6.1 Grants. XYZ, on behalf of the Government, hereby agrees to grant to ABX an exclusive license in each U.S. patent application, and patents issued thereon, covering a Subject Invention, which is filed by XYZ on behalf of the U.S. Government subject to the reservation of an irrevocable, royalty-free license to practice and have practiced the Subject Invention on

behalf of the U.S. Government, and such other terms and conditions as are specified by XYZ in such exclusive license.

6.6.2 Exclusive License Terms. Upon filing of a patent application on a Subject Invention by XYZ, ABX shall have the option to acquire a limited term exclusive license in the resulting patents at reasonable royalty rates upon the execution of an exclusive license agreement containing the terms and conditions and substantially in the form specified in Exhibit A. The specific royalty rate and term of exclusivity shall be negotiated promptly after the Subject Invention is filed in the U.S. Patent and Trademark Office, provided however, that this option must be exercised by ABX by written notice to XYZ within ____ months from the date the U.S. Patent Application is so filed. {The reasonable royalty rate for each exclusive license shall be based upon a portion of the selling price of the {item} attributable to the presence of claimed subject matter where such {item} is a machine, article of manufacture, product made by a process, or composition of matter as defined by the claims of the patents. Where the claimed subject matter relates to a process or method to be practiced under the claims of the patent, the royalty will be based upon the net savings attributable to the implementation of said process or method.}

6.6.3 Extension of Exclusive Licenses. The term for each exclusive license acquired by ABX pursuant to 6.6.2 above shall extend from the issuance date of the U.S. patent on the Subject Invention. Requests by ABX for extensions of an exclusive

license may be filed at any time prior to the expiration of the exclusive license and must be supported by a factual showing that such a renewal is necessary to permit ABX to recapture its investment and make a reasonable profit. The decision to extend an exclusive license shall be within the sole discretion of XYZ. (Note: If premarketing approval is required by a federal agency, the extended term time period for the patent grant should be taken into consideration by providing for an extension by the period of exclusivity).

Article 7. Data and Publication

7.1 Rights. Subject to the provisions of paragraph 7.3, subject data which is required to be delivered to ABX under this Agreement shall be the property of ABX. ABX shall, upon request, have the right to review all Subject Data first produced under this Agreement which has not been delivered to ABX, except to the extent that such Subject Data is subject to a claim of confidence or privilege by a third party.

7.2 Proprietary Information. ABX shall place a Proprietary notice on all information it delivers to XYZ under this Agreement which it asserts is proprietary. XYZ agrees that any information designated as proprietary which is furnished by ABX to XYZ under this agreement, or in contemplation of this agreement, shall be used by XYZ only for the purpose of carrying out this agreement. Information designated as proprietary shall not be disclosed, copied, reproduced or otherwise made available in any form whatsoever to any other person, firm, corporation, partnership,

association or other entity without the consent of ABX except as such information may be subject to disclosure under the Freedom of Information Act (5 U.S.C. 552). XYZ agrees to use its best efforts to protect information designated as proprietary from unauthorized disclosure. ABX agrees that XYZ is not liable for the disclosure of information designated as proprietary which, after notice to and consultation with ABX, XYZ determines may not lawfully be withheld or which a court of competent jurisdiction requires disclosed.

7.3 Release Restrictions. XYZ shall have the right to use all Subject Data for any Governmental purpose, but shall not release such Subject Data publicly except: (i) XYZ when reporting on the results of sponsored research may publish Subject Data, subject to the provisions of paragraph 7.4 below, and provided ABX is given a ninety (90) day opportunity to review the manuscript and provide suggestions before publication; and (ii) XYZ may release such Subject Data where such release is required pursuant to a request under the Freedom of Information Act (5 U.S.C. Section 552); provided, however, that such data shall not be released to the public if a patent application is to be filed (35 U.S.C. Section 205) until the party having the right to file has had a reasonable time to file.

7.4 Publication. XYZ and ABX agree to confer and consult prior to the publication of Subject Data to assure that no Proprietary Information is released and that patent rights are not jeopardized. Prior to submitting a manuscript for review which

XYZ intends to publish sponsored research may publish Subject Data

contains the results of the research under this Agreement, or prior to publication if no such review is made, each party shall be offered an ample opportunity to review such proposed publication and to file patent applications in a timely manner, if it is so entitled under this Agreement.

Article 8. Representations and Warranties

8.1 Representations and Warranties of XYZ. XYZ hereby represents and warrants to ABX as follows:

8.1.1 Organization. XYZ is a Federal laboratory of the X Agency and is wholly owned {or leased} by the U.S. Government of the United States whose substantial purpose is the performance of research, development, or engineering by employees of said Government;

8.1.2 Mission. The performance of the activities specified by this Agreement are consistent with the mission of XYZ.

8.1.3 Authority. 8.2.1 (1) All prior reviews and approvals required by regulations or law have been obtained by XYZ prior to the execution of this Agreement. The XYZ official executing this Agreement has the requisite authority to do so.

8.1.4 Statutory Compliance. XYZ's Laboratory Director, prior to entering into this Agreement, has given special consideration to the entering into CRDAs with small business firms and consortia involving small business firms.

8.2 Representations and Warranties of ABX. ABX hereby represents and warrants to XYZ as follows:

8.2.1 Corporate Organization. ABX, as of the date hereof, is a corporation duly organized, validly existing and in good standing under the laws of the State of {New York}, and (if applicable) is a wholly owned subsidiary of Y, Inc., a Delaware corporation.

8.2.2 Power and Authority. ABX has the requisite power and authority to enter into this Agreement and to perform according to the terms thereof.

8.2.3 Due Authorization. The Board of Directors and stockholders of ABX have taken all actions required to be taken by law, ABX's Certificate or Articles of Incorporation, its bylaws or otherwise, to authorize the execution and delivery of this Agreement.

8.2.4 No Violation. The execution and delivery of this Agreement does not contravene any material provision of, or constitute a material default under any material agreement binding on ABX or any valid order of any court, or any regulatory agency or other body having authority to which ABX is subject.

Article 9. Termination

9.1 Termination by Mutual Consent. ABX and XYZ may elect to terminate this Agreement, or portions thereof, at any time by mutual consent. In such event the parties shall specify the

disposition of all property, patents and other results of work accomplished or in progress, arising from or performed under this Agreement. Upon a termination by mutual consent, XYZ shall not make any new commitments and shall, to the extent feasible, cancel all outstanding commitments that relate to this Agreement or portions thereof mutually terminated, by the termination date, or as soon thereafter as feasible.

9.2 Termination by Unilateral Action

9.2.1 Written Notice. Either party may unilaterally terminate this entire Agreement at any time by giving the other party written notice, not less than 30 days prior to the desired termination date. If ABX unilaterally terminates this Agreement, any exclusive license entered into by the parties shall be simultaneously terminated unless the parties agree to retain such exclusive license.

9.2.2 New Commitments. XYZ shall make no new commitments after receipt of a written termination notice from ABX and shall, to the extent feasible, cancel all outstanding commitments and contracts by the termination date.

9.3 Termination Costs. Within 90 days following termination of this Agreement, XYZ shall submit a statement of all costs incurred prior to the date of termination and for all termination costs for removal of abandoned property. Any unspent funds provided to XYZ by ABX shall be used to fund termination costs. In the event such funds are insufficient to cover all the

any exclusive license entered into by the parties shall be

termination costs, ABX agrees to promptly meet with XYZ to reach a settlement agreement regarding the payment of the remaining termination costs.

Article 10. Disputes

10.1 Settlement. Any dispute arising under this Agreement which is not disposed of by agreement of the { } shall be submitted jointly to the signatories of this Agreement. A joint decision of the signatories or their designees shall be the disposition of such dispute.

10.2 If the signatories are unable to jointly receive a dispute within a reasonable period of time after submission of the dispute for resolution, the matter shall be submitted to the head of the agency or his designee for resolution.

10.3 Continuation of Work. Pending the resolution of any dispute or claim pursuant to this Article, the parties agree that performance of all obligations shall be pursued diligently in accordance with the direction of the XYZ signatory.

Article 11. Liability

11.1 Property. The U.S. Government shall not be responsible for damages to any property of ABX provided to XYZ or acquired by XYZ pursuant to this Agreement.

11.2 Sponsor's Employees. ABX agrees to idemnify and hold harmless the U.S. Government for any loss, claim, damage, or liability of any kind involving an employee of ABX arising in

connection with this Agreement, except to the extent that such loss, claim, damage or liability arises from the negligence of XYZ or its employees. XYZ shall be solely responsible for the payment of all claims for the loss of property, personal injury or death, or otherwise arising out of any negligent act or omission of its employees in connection with the performance of work under this Agreement.

11.3 No Warranty. Except as specifically stated in Article 8, XYZ makes no express or implied warranty as to any matter whatsoever, including the conditions of the research or any invention or product, whether tangible or intangible, made, or developed under this Agreement, or the ownership, merchantability, or fitness for a particular purpose of the research or any invention or product.

11.4 Indemnification. ABX holds the U.S. Government harmless and indemnifies the Government for all liabilities, demands, damages, expenses and losses arising out of the use by ABX, or any party acting on its behalf or under its authorization, of XYZ's research and technical developments or out of any use, sale or other disposition by ABX, or others acting on its behalf or with its authorization, of products made by the use of XYZ's technical developments. This provision shall survive termination of this Agreement.

11.5 Force Majeure. Neither party shall be liable for any unforeseeable event beyond its reasonable control not caused by the fault or negligence of such party, which causes such party to

be unable to perform its obligations under this Agreement (and which it has been unable to overcome by the exercise of due diligence), including, but not limited to, flood, drought, earthquake, storm, fire, pestilence, lightning and other natural catastrophes, epidemic, war, riot, civic disturbance or disobedience, strikes, labor dispute, or failure, threat of failure, or sabotage of the XYZ facilities, or any order or injunction made by a court or public agency. In the event of the occurrence of such a force majeure event, the party unable to perform shall promptly notify the other party. It shall further use its best efforts to resume performance as quickly as possible and shall suspend performance only for such period of time as is necessary as a result of the force majeure event.

Article 12. Miscellaneous

12.1 No Benefits. No member of, or delegate to the United States Congress, or resident commissioner, shall be admitted to any share or part of this Agreement, nor to any benefit that may arise therefrom; but this provision shall not be construed to extend to this Agreement if made with a corporation for its general benefit.

12.2 Governing Law. The construction validity, performance and effect of this Agreement for all purposes shall be governed by the laws applicable to the Government of the United States.

12.3 Entire Agreement. This Agreement constitutes the entire agreement between the parties concerning the subject matter

hereof and supersedes any prior understanding or written or oral agreement relative to said matter.

12.4 Headings. Titles and headings of the Sections and Subsections of this Agreement are for the convenience of references only and do not form a part of this Agreement and shall in no way affect the interpretation thereof.

12.5 Waivers. None of the provisions of this Agreement shall be considered waived by any party hereto unless such waiver is given in writing to all other parties. The failure of any party to insist upon strict performance of any of the terms and conditions hereof, or failure or delay to exercise any rights provided herein or by law, shall not be deemed a waiver of any rights of any party hereto.

12.6 Severability. The illegality or invalidity of any provisions of this Agreement shall not impair, affect or invalidate the other provisions of this Agreement.

12.7 Amendments. If either party desires a modification in this Agreement, the parties shall, upon reasonable notice of the proposed modification by the party desiring the change, confer in good faith to determine the desirability of such modification. Such modification shall not be effective until a written amendment is signed by all the parties hereto by their representatives duly authorized to execute such amendment.

12.8 Assignment. Neither this Agreement nor any rights or obligations of any party hereunder shall be assigned or otherwise

transferred by either party without the prior written consent of the other party except that ABX may assign this Agreement to the successors or assignees of a substantial portion of ABX's business interests to which this Agreement directly pertains.

12.9 Notices. All notices pertaining to or required by this Agreement shall be in writing and shall be signed by an authorized representative and shall be delivered by hand or sent by certified mail, return receipt requested, with postage prepaid, addressed as follows:

If to ABX: Mr.
Vice President
ABX Company, Inc.
New York, New York

If to XYZ: Dr. John Doe
Laboratory Director
XYZ Center
X Agency
Washington, D. C.

Any party may change such address by notice given to the other party in the manner set forth above.

12.10 Independent Contractors. The relationship of the parties to this Agreement is that of independent contractors and not as agents of each other or as joint venturers or partners. XYZ shall maintain sole and exclusive control over its personnel and operations.

12.11 Use of Name or Endorsements. (a) ABX shall not use the name of the XYZ or X Agency on any product or service which is directly or indirectly related to either this Agreement or any patent license or assignment agreement which implements this Agreement without the prior approval of XYZ. (b) By entering into this Agreement XYZ does not directly or indirectly endorse any product or service provided, or to be provided, by ABX, its successors, assignees, or licensees. ABX shall not in any way imply that this Agreement is an endorsement of any such product or service.

Article 13. Duration of Agreement and Effective Date

13.1 It is mutually recognized that the development program, cannot be rigidly defined in advance, and that the contemplated time periods for completion of each phase are good faith guidelines subject to adjustment by mutual agreement, to fit circumstances as the development program proceeds. In no case will this Agreement extend beyond , unless it is revised in accordance with Article 12 of this Agreement.

The provisions of Article 6, _____ shall survive the termination of this Agreement.

13.2 Effective Date.

This Agreement shall enter into force as of the date of the last signature of the parties.

IN WITNESS WHEREOF, the Parties have caused this Agreement to be executed by their duly authorized representatives as follows:

For the Company: _____

_____ _____

Date

For the U.S. Government _____

_____

_____

_____

_____ _____

Date

Appendix A

Statement of Work

ATTACHMEMT I PART A

ACTIONS THAT HEADS OF PHS AGENCIES, CENTERS, AND INSTITUTES MAY TAKE UNDER THE OCTOBER 14, 1987 DELEGATION OF AUTHORITY UNDER THE FEDERAL TECHNOLOGY TRANSFER ACT

The Head of a PHS Agency, Center or Institute may:

- Negotiate licensing agreements for Government-owned inventions made within the respective Center, Institute or PHS Agency, or other inventions of Federal employees that may be voluntarily assigned to the government.

- Negotiate and enter into, subject to the approval of the appropriate PHS Agency Head, cooperative research and development agreements, under which the PHS components may accept, retain and use funds, personnel, services, and property and, in exchange, provide personnel, services and property, but not funds.

  Under these agreements, the Institute, Center or Agency may waive the Federal Government's right of ownership to any invention made under the agreement by collaborating party or employee of a collaborating party, subject to reservation by the Government of a nonexclusive, irrevocable, paid-up license to practice the invention, or have the invention practiced throughout the world by or on behalf of the Government.

  In addition, a collaborating party may be granted a patent license (exclusive or nonexclusive) or assignment, or option thereto, in any invention made in whole or in part by a Federal employee under the agreement, retaining for the Government a nonexclusive, nontransferable, irrevocable, paid-up license to practice the invention or have the invention practiced throughout the world by or on behalf of the Government.

- Identify, evaluate and file patent applications on inventions made by employees of the respective Agency, Center or Institute. These activities may be undertaken through the use of distributed royalties or other income.

- Subject to approval by the Assistant Secretary for Health, enter into agreements for the services of other agencies, persons or organizations for invention management and licensing services. The purpose of these services is to facilitate direct support to carry out the work of the institute and center in transferring technology to bring the result of research to the marketplace and patient.

nonexclusive, irrevocable, paid-up license to practice

- Use royalty income distributed to the PHS component to reward scientific, engineering and technical employees of the laboratory, for payment of expenses incidental to the administration and licensing of inventions, to further scientific exchange among the Government-operated laboratories, and for education and training of employees consistent with the research and development mission of the Agency, and for other activities that increase the potential for transfer of technology.

- Heads of the PHS agencies shall receive all royalty or other income produced under cooperative research and development and license agreements for distribution to their respective Centers and Institutes. After paying the inventor's share, the majority share of royalties and income shall be returned and utilized by the Center or Institute where the invention occurred. Any remaining amount shall be used as directed by the Agency, either at the Agency or at the Agency's other Centers and Institutes, in accordance with the requirements of the Act.

- Institutes and Centers may enter into Cooperative Research and Development Agreements negotiated by the Centers and Institutes. Part B of Attachment I identifies points to be considered in negotiating and finalizing such agreements. It should be noted that the PHS Agency Head has thirty (30) days to review and disapprove in writing to the Institute or Center Director.

- Institutes and Centers may enter into Cooperative

Topics to be Addressed in Cooperative Research and Development Agreements

A Cooperative Research and Development Agreement should contain provisions addressing the following subjects:

1. The effective date.

2. Principal investigator(s) for the Government and for the collaborating party.

3. Funds, personnel, services and property to be provided by the collaborating party.

4. Personnel, services and property to be provided by the Government.

5. Retention and ownership of property in the event of termination.

6. Delineation of the research encompassed by the agreement.

7. Procedures for interaction between the collaborating parties.

8. Provisions protecting the Government's right to publish research results while giving the collaborating party an opportunity to protect its proprietary information.

9. Provisions for the protection of proprietary information, including appropriate references to the Freedom of Information Act. Such provisions should reference 35 U.S.C. which authorizes federal agencies to withhold from disclosure to the public information disclosing any invention in which the Federal Government owns or may own a right, title or interest (including a nonexclusive license) for a reasonable time in order for a patent application to be filed.

10. Patent rights clauses, which may include the granting to the collaborating party of an exclusive or nonexclusive license to inventions made in whole or impart by a Federal employee and a waiver of any Government rights to an invention made in whole or impart by a collaborating party or an employee of a collaborating party. Both of the foregoing are subject

to retention by the government of a nonexclusive, nontransferable, irrevocable, paid-up license to practice the invention or have the invention practiced throughout the world by or on behalf of the government.

11. A disputes resolution clause, providing that disputes which cannot be resolved by the parties are to be resolved by the Head of the Agency.

12. A clause addressing identification. The Government cannot agree to identify the collaborating party for damages, nor may the Government agree to pay attorney's fees or waive any of its rights in litigation that might arise regarding the agreement but may permit a collaborating party to assume responsibility to pursue of patents licensed by government.

13. The term of the agreement.

14. Procedures for termination of the agreement and a statement of what rights survive termination.

15. A statement as to what law governs the validity and effect of the agreement. Federal law must control, but in the absence of any conflicting Federal law, State law may control.