The Honorable James T. Lynn
Director, Office of Management
and Budget
Washington, D. C. 20503

SEP 17 1976

Dear Mr. Lynn:

This is in response to your request for a report on the Department of Commerce's draft bill "To establish a uniform Federal policy for intellectual property arising from Federally-sponsored research and development; to protect and encourage utilization of such technology and to further the public interest of the United States domestically and abroad; and for other related purposes."

In summary, we support the draft bill because we believe it would allocate rights to inventions resulting from federally supported research and development between Federal agencies and their contractors or employees under uniform principles which recognize each party's equities while preserving the incentive for technological innovation and commercial application. We also enclose some suggested amendments to improve the draft bill.

In general, the draft bill provides for the first time a clear Government-wide legislative foundation based on uniform principles for the allocation of rights to inventions resulting from federally supported research and development. To date, allocation of such rights has been based on a number of statutes covering individual agencies and research programs, executive orders, presidential statements, and regulations. These authorities allow for differing allocation of invention rights in similar situations. Further, to the extent that a research program is now governed only by executive order, presidential statement, or regulation, as is the case in this Department, there is a question raised by litigation, not yet resolved, as to whether such a program has the authority to dispose of invention rights without statutory authority.

The draft bill would establish a single patent rights clause which is to be normally used in all federally sponsored research and development contracts (including research grants) with certain specified exceptions. The single patent rights clause provides to the contractor the first option to all inventions resulting from such contracts, subject to provisions requiring the contractor to license competitors upon a determination that (1) the contractor is not effectively pursuing utilization, or (2) it is necessary to meet important and imminent public needs, or (3) the contractor's position has "tended substantially to lessen competition", or (4) the contractor's prescribed exclusive period of ownership has ended and it is equitable to require such licensing.

We anticipate that the single patent rights clause will encourage participation of the most qualified and competent contractors in federally sponsored research and development, foster competition, promote the widespread utilization of inventions resulting from such research and development, and reduce administrative burdens for both Federal agencies and their contractors.

The draft bill provides in general for Federal ownership of employee inventions. The draft bill further provides for an incentive awards and/or royalty-sharing program which is intended to monetarily reward or recognize employees, stimulate inventive creativeness, and encourage disclosure of inventions.

The Federal licensing program established by the draft bill should enhance the possibility of private development and utilization of employee inventions and inventions that contractors have assigned to the Federal agencies under the provisions of the draft bill due to contractor disinterest or failure to diligently pursue utilization.

The draft bill's most important effect on this Department, in addition to resolving the question of authority, will be on the Department's dealings with for-profit contractors. Under the draft bill, such contractors will have the first

option to ownership of resulting inventions, whereas presently the Department retains that option in substantially all contracts. The contractor presently can obtain ownership rights only on submission of a petition after identification of an invention. Since over 90 percent of such petitions have been granted, the draft bill would end an unnecessary administrative burden, while probably encouraging greater participation of more qualified contractors in the Department's research and development programs and expediting private development and utilization of inventions.

The allocation of invention rights under the single patent rights clause substantially parallels the allocation made under the Department's institutional patent agreement program for nonprofit institutions. Under this program, 64 nonprofit institutions with identified technology transfer capabilities have a first option to inventions resulting from Department-sponsored grant research, subject to compulsory licensing provisions similar to those in the draft bill. Accordingly, use of the single patent rights clause will, in effect, expand the concept of first option in the contractor to those nonprofit institutions not now covered by the Department's institutional patent agreement program. Since the 64 institutions having agreements are now the recipients of a substantial majority of departmental research and development funds available to nonprofit institutions, the effect of the change should be modest.

Passage of the draft bill should have little effect on Department allocation of employee inventions. However, implementation of the incentive awards and/or royalty-sharing program should increase invention reporting. Increased reporting plus the legislated authority to grant exclusive licenses should result in increased utilization of Department-owned inventions.

While we support the draft bill, we believe it would be enhanced if amended as suggested in the technical attachment. We are particularly concerned with the need to provide to

the head of a Federal agency the authority to deviate on a class basis from the single patent rights clause if necessary to expedite resolution of an imminent public health problem.

We therefore recommend that the draft bill incorporate our suggested amendments and be submitted to the Congress.

Sincerely,

/s/ Marjorie Lynch

Under Secretary

Enclosures

TECHNICAL ATTACHMENT

1. The Statement of Purpose and Need is identified as highlighting the history leading to the development of the draft bill and the reasons legislation is being sought. In the nine pages of the statement only the next to last sentence attempts to explain the basis for the draft bill:

> In later meetings, after considering several proposals, the Committee unanimously agreed that the policy concepts of the so-called "Alternate Approach" set forth in the Commission's report should provide the basis for such legislation.

This sentence does little to explain why the philosophy of the President's Statement on Patent Policy, affirmed, as noted by the Statement of Purpose and Need, by a number of intensive reviews, is now being abandoned for the new direction of the draft bill. In fact, the disproportionate attention given to the affirmation of the President's Statement on Patent Policy leads one to ask why any change is necessary. It is recommended that the Statement of Purpose and Need be redrafted to more properly reflect administration support of the draft bill.

2. Add the following new section 312(c)(2):

> (2) The head of a Federal agency may deviate on a class basis from the single patent rights clause normally used provided that such deviation is necessary to expedite resolution of an imminent public health problem.

On page 13, line 31, change (2) to (3).

On page 14, line 9, change (3) to (4).

This authority is necessary to enable the Department to properly manage its research and development program on a timely basis. The need for this authority was recently dramatized by public reaction to the possibility of the swine flu epidemic and continued research on recombinant DNA.

In any future cases similar to the swine flu situation, it is anticipated that research and development contracts will need to be negotiated with a number of pharmaceutical companies in order to

accomplish expeditious delivery of the necessary therapeutic agent. The Department may need to control ownership of any invention made by such a company in performance of its contract in order to assure its availability to all the other companies in the delivery program.

In any future case similar to the recombinant DNA situation, it is anticipated that research and development contractors may need to be controlled in a manner which would assure public safety. Such control may require Department ownership of inventions that are made with its support.

Health, safety, or welfare are the only purposes identified as affecting allocation of invention rights in the draft bill. Thus, section 311(b)(2)(D)(i) requires licensing of an invention if necessary to resolve a health, safety, or welfare problem. Further, section 312(b)(7) lists public health, safety, or welfare as factors to be considered by the Board in determining whether licensing should be required after the expiration of the normal five and ten year exclusive control period.

If the Department can regain control of an invention after it has been made on the basis of public health considerations, it should also have the ability to deny ownership prior to the making of an invention if it has identified an imminent public health problem.

3. Add the following new section 322(e):

> (e) Notwithstanding (a) of this subsection, a Federal agency may enter into agreements with other public or private parties wherein future or identified inventions falling within the criteria of (a) and made in performance of co-sponsored, cost-sharing or joint venture research involving a substantial contribution of funds, facilities, equipment or employees by such parties, may be allocated in a manner satisfying the contribution of such parties.

On page 15, line 16, after the words "subsection (c)," add "and (e)."

Unfortunately, the Drafting Committee of the draft bill failed to take into consideration the fairly common situation in which a Federal employee is joined to a research program that is substantially funded by someone other than his own agency. The Department has had a number of situations in which its employees have made inventions

while collaborating with researchers funded by other sources. The Veterans Administration has serious problems in this area, since most VA hospitals are built contiguous to universities with the thought of encouraging exactly this type of relationship.

In the past, when an employee invention arose from such situation, the Department, after obtaining title as required by E. O. 10096, has attempted to meet the equities of the co-sponsor through the grant of a limited exclusive license. This is not an entirely satisfactory resolution due to the administrative problems in granting such a license, plus the fact that such a license could be granted only after the identification of an invention. There are presently no means at the time such research programs are initiated of assuring a prospective collaborator to rights in Federal employee inventions where the collaborator will make substantial contributions of funds, facilities, equipment, or employees to the program. If the agencies are not provided the flexibility of meeting the needs of a collaborative organization, Government employees may be denied involvement in collaborative programs which could enhance their professional capabilities.

4. It is suggested that the Act's coverage of grant-sponsored research (by defining contracts as including grants) be given more visibility by including defintiions near the beginning of the bill.

5. Add the following new sections 326(d)(4) and 326 (d)(5):

(4) for members of the Commissioned Corps of the United States Public Health Service with the approval of the Secretary of Health, Education, and Welfare.

(5) for members of the Commissioned Corps of the National Oceanic and Atmospheric Administration, with the approval of the Secretary of Commerce.

On page 19, line 5, delete the word "and."

Section 326, as drafted, does not include the Commissioned Corps of the Public Health Service or of the National Oceanic and Atmospheric Administration.