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MEMORANDUM

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
OFFICE OF THE SECRETARY

TO : Dr. Lowell T. Harmison
Special Assistant to Assistant Secretary
for Health

DATE: September 1, 1976

FROM : Patent Counsel
OS/GCB

SUBJECT: Comments on the Proposal to Enact the "Federal Intellectual Property Act of 1976."

The "Statement of Purpose and Need" is identified as highlighting the history leading to the development of the 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 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," by a number of intensive reviews, is now being abandoned for the new direction of the 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. I recommend that the "Statement" be redrafted to more properly reflect administration support of the Bill.

As to the Bill itself, I believe that it will accomplish its stated purposes to a greater extent than any other suggested program for allocating invention rights. However, I believe the Bill would be enhanced if amended as follows:

1) Add the following new sec. 312 (c) (2):

> (2) The Head of a Federal agency may deviate on a class basis if necessary to expedite resolution of an imminent public health problem.

2) On page 13 line 3 change (2) to (3) (only if 1) is acceptable).

3) On page 14 line 9 change (3) to (4) (only if 1) is acceptable).

I believe that this authority is necessary to enable this 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.

Public health, safety or welfare is the only mission identified as affecting allocation of invention rights in the Bill. Thus, section 312 (b) (2) (D) (i) requires licensing of an invention after it has been made if necessary to resolve an imminent public health, safety or welfare problem.

Further, section 312 (b) (7) lists public health, safety or welfare as one of the 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. It seems clear and consistent that 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.

4) 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.

5) On page 15 line 16 after the words "subsection (c)," add "and (e)" (only if 4) is acceptable).

Unfortunately, the Drafting Committee of the 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. HEW 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, I fear that Government employees will be denied involvement in some useful collaborative programs.

I consider this a serious oversight on the part of the drafters and should be remedied prior to submission of the Bill to Congress.

Norman J. Latker

cc: Neil Lawson/Greg Ferris - VA