COMMENTS ON THE IMPACT OF PUBLIC DISCLOSURE ON THE PROPRIETARY INTERESTS OR PATENT RIGHTS IN INFORMATION CONTAINED IN RESEARCH PROTOCOLS, HYPOTHESES, OR DESIGNS SUBMITTED BY UNIVERSITIES OR OTHER NON-PROFIT ORGANIZATIONS TO DHEW AS PART OF A GRANT OR CONTRACT PROPOSAL OR APPLICATION.

1. DHEW Patent Policy and Technology Transfer.

The most obvious problem affecting ultimate utilization of an innovation depicted in a research protocol, hypotheses, or design eventually enhanced or corroborated in performance of DHEW funded research at the university or other non-profit organization laboratory initiating such protocol, hypotheses, or design is the fact that these organizations (hereinafter referred to as universities) do not engage in the direct manufacture of commercial embodiments, and it is industry which must bring such innovation to the marketplace.

A fundamental premise of DHEW patent policy and practice is the understanding that inherent to the transfer of the innovative results of the research conducted in university laboratories to industrial developers is a decision on the part of the developer that the intellectual property rights in the innovation being offered for development are sufficient to protect its risk investment. Of course, not all transfers of potentially marketable innovations from such laboratories require an exchange of intellectual property rights in the innovation, but it is unpredictable in which transfers the entrepreneur will demand an exchange to guarantee its collaborative aid. Notwithstanding, where substantial risk investment is involved, such as required for pre-market clearance of potential therapeutic agents, and before long some medical

devices, there is an identified likelihood that transfer will not occur if the entrepreneur is not afforded some property protection in the innovation offered for development. This point was made with some force to DHEW in the 1968 GAO Report No. B-164031(2) on "Problem Areas Affecting Usefulness of Results of Government-Sponsored Research in Medicinal Chemistry," copy attached as Item A.

Since 1968 the DHEW patent program has consciously made efforts to close the identified gap between the fundamental innovators the Department supports and the private industrial developers who may be necessary to the delivery of end items to the marketplace. The main thrust of Department patent policy as applied to universities has been directed toward:

1. Establishment of a patent management focal point in the innovating organization trained to elicit invention reports and establish rights in intellectual property on a timely basis for possible licensing of industrial developers, and
2. Assurance that the innvoating group has the right to convey whatever intellectual property rights are necessary to accomplish a transfer.

DHEW has carefully circumscribed the conditions of licensing within which university patent management groups must function. These conditions have become well known to industrial developers and have been gradually accepted in licensing arrangements by a widening circle of such

developers. This compares to the virtual boycott of development of NIH generated drug leads by industry reported by GAO during the 1962-1968 period covered by their report.

Since 1969 through the Fall of 1974 the Department estimates that the intellectual property rights to 329 innovations either initially generated, enhanced or corroborated in performance of HEW funded research were in the hands of universities' patent management organizations for the purpose of soliciting further industrial development support. The Department has been advised that during the 1969-1974 period these organizations had negotiated 44 non-exclusive and 78 exclusive licenses under patent applications filed on the 329 innovations. The Department understands that the 122 licenses negotiated have generated commitments in the area of 100 million dollars of private risk capital. Two licenses have resulted in the marketing of a corresponding number of drugs, while a number of other licenses cover potential therapeutic agents in various stages of pre-market clearance.

In the above context it is apparent that the existence of a licensable patent right may be a primary factor in the successful transfer of a university innovation to industry and the marketplace, and failure to protect such right may fatally affect a transfer of a major health innovation.

II. Publication Within the Patent Laws and its Effect on Patent Protection.

Publication within the patent laws has been broadly defined as any unconditioned disclosure by its owner of information on an innovation

of interest. Thus, a thesis available on the shelves of a university library but not necessarily reviewed by any researcher has been deemed a publication within the patent laws of the innovation disclosed therein.

Both the United States and foreign patent laws are drafted against the interest of those parties making or permitting publication of their invention prior to the filing of a patent application. Accordingly, in the United States publication of an invention prior to the filing of a patent application initiates a one-year statutory period in which one must file a United States patent application on the invention disclosed if valid patent protection is to be established. Further, the laws of most foreign countries preclude on the day of disclosure obtaining valid protection on an invention disclosed if a patent application had not been filed prior to the disclosure date.

All university patent management organizations can be expected to understand these basic principles of patent law and, therefore, will, unless otherwise constrained, preclude publication (including unconditional access to), information which might disclose an innovation of interest prior to the appropriate time to file a patent application. Any publication of an invention made prior to generating clinical or other corroborating data necessary to support a patent claim would, of course, be deemed premature since the filing of a patent application without such data, <u>if at all possible</u>, would need to be made on the uneconomic, speculative basis of possible future positive findings.

III. The Freedom of Information Act (FOIA) and Court Interpretations.

The promulgation of the Freedom of Information Act and the court interpretations of that Act have seriously impacted on university control over premature access to information in HEW hands which may disclose innovations which are in the process of being corroborated or enhanced in performance of HEW funded grants or contracts. This will be discussed further below. However, to date but under continued attack, the courts have supported HEW's contention that unfunded research proposals and applications and their supporting documentation are generally unavailable to third party requesters under the fifth exemption of the FOIA.

The FOIA generally requires disclosure of all Government records upon request. There are a number of exemptions to required disclosure. Of these exemptions, the question posed in Title III of the Health Research and Health Services Amendments of 1976 narrows our need to comment primarily to exemption 4 which was intended to deny access to "trade secrets and commercial and financial information which is privileged or confidential."

The leading case on the fourth exemption, National Parks and Conservation Association v. Morton, 498 Fed. 765 (1974), D.C. Circuit Court, states that the fourth exemption applies if it could be shown that disclosure was either likely, first, to impair the Government's ability to obtain necessary information or second, to cause substantial harm to a competitive position of a person providing the information.

The Court toughened these tests in Petkas v. Staats, 501 F. 2nd 887 (1974) when it held that a Government assurance and a Corporation's respective submission of information conditioned on confidentiality were not determinative, and remanded the case for disposition in accordance with the test of the National Parks case. Thus, a promise of confidentiality by the Government in and of itself may not prevent disclosure.

The Office of Legal Counsel of the Justice Department has advised that as a result of the above cases, Government protection of intellectual property and its withholding under the fourth exemption under a FOIA suit is very unpredictable, at best.

Further, 18 U.S.C. 1905 does not appear to have any effect in a FOIA suit. This statute, if applicable, would impose criminal penalties on Government officials who disclose proprietary information in the possession of the Government. At best, then, it is a deterrent to unauthorized disclosure, but it only takes effect after the disclosure and the damage to the owner. 18 U.S.C. 1905 has been virtually ignored by the courts in FOIA suits because of a general exemption contained in the statute, "unless otherwise provided by law." Courts generally have interpreted the quoted passage as exempting disclosure under the FOIA. Section 1905's penalties, therefore, would not be applied to an official who disclosed proprietary information in response to a freedom of information suit.

Even though commercial concerns might with predictable difficulty meet the "substantial harm to a competitive position" test of the National Parks case, universities and non-profit organizations wishing to deny access to their research proposals or applications appear to have little hope of meeting this test in light of Washington Research Project v. Weinberger, No. 74-1027 United States Court of Appeals for the District of Columbia Circuit. In that case, Washington Research Project sought access to a number of research proposals from different universities and non-profit organizations in order to investigate the ethics of the experiments in question, most of which dealt with the treatment of hyperactive children. Washington Research supported its claim to access with indications that "it is essential for researchers to be held accountable, and the research process has to be something other than the closed society which it is now." The court indicated, in denying the use of the fourth exemption, that:

> "It is clear enough that a noncommercial scientist's research design is not literally a trade secret or item of commercial information, for it defies common sense to pretend that the scientist is engaged in trade or commerce. This is not to say that the scientist may not have a preference for or an interest in nondisclosure of this research design, only that it is not a trade or commercial interest ..."

Notwithstanding the apparent inaccuracy of the Court's premise for denying the use of the fourth exemption in this case in light of

the University-Industry interface necessary to successful technology transfer as exemplified by the 122 licenses noted above and the estimated 100 million dollars of risk development generated thereunder, the FOIA and present court interpretation appear to be severely imbalanced toward prompting Federal Administrators to release information disclosing intellectual property whether arguable within the fourth exemption or not rather than undertake the burden of proof of denial. This burden is made even more severe due to the Act's requirement that the Federal Administrator provide a "yes" or "no" answer to a requester within ten days of the request or be subject to personal financial penalties.

IV. Prior Congressional Investigation of Problems of Protecting Proprietary Information under the Fourth Exemption of FOIA.

The unpredictability of protection of proprietary information under the fourth exemption of FOIA suggested above was discussed at length during consideration of the amendments to H.R. 3474, the ERDA Authorization Bill for Fiscal Year 1976. A copy of the Congressional Record covering this debate is attached as Item B. Of special importance is the agreement arrived at between Congressmen Goldwater and Moss set out on page H 12379 the essence of which appears in paragraph 6 which states:

> "We agreed that, in light of the apparent state of unpredictability of protection of proprietary information under exemption (b)(4) and the need for ERDA to provide such predictable protection in order to ensure the full cooperation

and participation of the private sector, Congress could conclude that there was a legitimate national interest in ERDA's having the specific authority to predictably protect proprietary information. Further, Congress could strike a reasonable and acceptable balance of that national interest and the national interest in freedom of information and create a (b)(3) exemption for ERDA for that purpose."

Also attached as Item C is the "(b)(3) exemption for ERDA" ultimately passed by the Congress as Section 307 of H.R. 3474.

This action would appear to establish a precedent for similar exemptions for other research and development programs needing authority to predictably protect proprietary information.

V. Example of the Procedure of Handling a Request for Release of a Research Proposal or Application.

As already noted HEW can, although under attack, predictably deny access to unfunded research proposals on applications under the fifth exemption of FOIA on the basis that such proposals on applications are "Interagency records." However, the Washington Research Project case clearly precludes the use of the fifth exemption as a means of denying access to funded research proposals on applications and leaves only the possibility of supporting a case for denial under the present court tests for the fourth exemption after case-by-case review.

To say "no" to a request for a funded research proposal requires the Federal Adminstrator handling the request to apply the National

Parks test to the situation and provide a written prima facie case to the Department Public Information Officer recommending denial. (The case would need to include arguments on how a non-profit organization could have a competitive position in order to overcome the general negation of such possibility in the Washington Research Case.) If the information the Federal Administrator believes should be denied involves a disclosure of an idea, invention, trade secret, etc., a prior art review indicating that such idea, etc. is in fact novel in comparison to the prior art would need to be conducted before a prima facie case could be made. If novelty cannot be shown it seems clear that the Government could not prevail in a suit to show that there will be "substantial harm to the owner's competitive position."

It appears appropriate at this point to ask whether a Federal Administrator, even with the aid of the university, can show during the early stages of funded research that a research protocol, hypotheses, or design is novel compared to the prior art. This would appear to be the primary purpose of conducting the research. Further, should the university and the public be placed in a position of being penalized because the Administrator makes a poor case to the Public Information Officer?

In those few situations where "novel" information can be decisively identified and a denial considered justifiable, the Act further requires

that the information to be denied be excised from the documents requested and the resulting "swiss cheese" document forwarded to the requester. Multiplication of this procedure by the estimated 200 research proposals Washington Research Projects requested shortly after prevailing in their first suit for access raises the strong possibility that a great number of intellectual properties can be destroyed by a few requests for a large number of research proposals since there is little likelihood that the Agency could meet the administrative burden posed by a need to process a large number of denials. It appears more likely that the Agency will tend to avoid the denial route in other than situations where the equities of the university are immediately and dramatically apparent, especially since release merely requires Xerox copies to the requester with no threat of penalty under 18 U.S.C. 1905 or enjoinment by the litigation-shy university sector. Such a result seriously jeopardizes technology transfers which at a later date may turn on the exchange of intellectual property.

VI. Comparison of Benefits Between Unconditioned Access to Research Protocols, Hypotheses, and Designs by the Public and Control of Access to Such Information by University Management and Investigators.

Although requesters need not identify the purpose of the request for access to a research proposal, volunteered information in addition to their organizational identification seems to place requesters in two broad but identifiable categories:

(1) Commercial concerns and other research investigators wishing to capitalize on the potential innovations disclosed.

(2) Public interest groups pursuing the possibility that research investigators are in some way abusing the public interest in the course of their research.

The requester in the first category can ordinarily be identified as having an investment in the same field of research as the research proposal sought. It is perceived that the information obtained by this category of requester will be used to

(1) determine the degree to which an investigator is moving the state of the art ahead, or

(2) generate a format for the requester's own grant or contract proposal.

At this point it should be noted that the controvery over release of research proposals is not <u>whether</u> the information therein will be released but <u>when</u> it will be released. It is historically evident that investigators are anxious to publish the results of their research for the scrutiny and critique of the entire profession <u>after</u> they believe it has moved to some reportable conclusion.

Accordingly, it would seem that the needs of the first category of requesters would be ordinarily, though delayed, satisfied by ultimate publication by the investigator, while the need of university management to successfully transfer technology and the investigator's need for

a period in which he is not subjected to premature competition to demonstrate his idea are preserved.

The more serious question attaches to access to research proposals by public interest groups. It is anticipated by the number of requests already made by the two identified categories, that the public interest groups will request access to the greatest number, since these groups believe unconditioned access to a large number of research proposals is necessary in order to establish patterns of investigator abuse. Of course, as discussed, such unconditioned access to these proposals will result in the loss of large numbers of intellectual property rights which must ultimately negatively effect technology transfer. Such loss appears to be justifiable only if the additional surveillance of public interests groups appears to be a necessary supplement to already existing Department clearance and surveillance procedures in areas such as human subjects, risk versus benefit, etc., and the need to correct abuses by such additional surveillance outweighs the need to optimize technology transfer.