Ms. Kathen

MEMORANDUM

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
Public Health Service

Comments on 2nd Report background

TO : Mr. James Hinchman
Associate General Counsel

DATE: February 17, 1978

PATENT BRANCH, OGC
DHEW

MAR 20 1978

FROM : Science Advisor
Office of Health Policy, Research, and Statistics

SUBJECT: Comments on Draft Report Entitled "HEW Patent Policy"

The following is in response to your request for review and comments on the report developed by your office.

The report identifies several of the key problems and issues that exist in the patent area and identifies four alternatives. I do not believe that the background information and issues of operating programs are adequately reflected in the discussions to provide a comprehensive base for adequate consideration of the alternatives. With the benefit of the experience in achieving technology transfer from the operating programs, it may be possible to construct additional or modified alternatives that more clearly identify the critical choices. The basic concern is the need for maintaining and improving an approach that results in effective transfer of the benefits of research to the public. An important element of this process is the recognition that patent policy plays an important role in the transfer of these benefits to the public which requires that they be commercizlized through the marketplace. The key issues affected by our patent policy are: (1) technology transfer; (2) involvement of the best researchers and organizations in the work sought by grantees and contractors and in the transfer process regardless of their profit or non-profit status; and (3) minimizing Departmental resources in achieving the effective transfer to the public, i.e. dollars, manpower (administration), and the time for transfer. The discussion leading to consideration of alternatives should reflect thorough consideration of the following points:

1. The incentive for the widest competition for our grant and contract requests to assure that we have the best contractors interested in performing the variety of biomedical research and development or health service activities that we seek to conduct through these mechanisms;

2. Increased incentives for the private sector to invest in carrying forward the knowledge and inventions that are produced under government research and development efforts in a cost-effective manner thus enhancing the investment in further development of any invention and reducing the amount of Federal expenditures needed;

3. The proper stimulus for timely development and diffusion of the technology and to achieve early evaluation of the technology for an equally timely acceptance or rejection of the technology; and

4. A mechanism for allocating patent rights that will avoid additional complexities and burdens in negotiating and administering our grants or contracts. (It is a difficult task, if not an impossible one, to definitively separate inventions made under research efforts sponsored where similar work is sponsored by different agencies. This would be made more complex and burdensome if different sponsors had varying methods for allocating patent rights to the respective grantee or contractor.)

These points are of particular concern in addressing the development and transfer of high risk, low payoff research endeavors where the research and needed therapeutic benefits from a health standpoint are key to alleviating the effects of a particular disease. Under these conditions the ability to provide for exclusivity is essential for attracting the participation of all parties needed to transfer the benefits of the research from the laboratory to the patient.

My comments on the report are to identify areas of concern which I hope will be helpful in the preparation of a report for circulation that will consider the framework that I have outlined above. It is important that the policy set forth the flexibility to build and maintain the progress that has been achieved through the existing HEW patent policy. Over the years, the patent policy has stimulated interest and generated an initiative within the university and academic communities, other non-profit sectors and the developing

industry to develop mechanisms for transfer of research achievements from the laboratory to the marketplace. Specifically, the Institutional Patent Agreements (IPA's) have played a critical role in bringing about interest within these sectors for transfer of ideas that would have otherwise not been brought to the health care community. We need to build on this progress and to establish a clear policy that will increase the interests for effective transfer and achieve greater stability within the university and industrial sector that must come together in effective arrangements for achieving the flow of ideas and technology to the public. The need is much greater now than in the past for an effective and stabilizing policy with regard to patents because of the declining R&D budget.

The points that I would like to highlight in review of the report are identified below.

1. The report seems to present a strong bias toward ultimate amendment of Departmental patent policy to permit ownership and licensing of innovations generated by non-profit organizations only after identification and petition followed by case-by-case review and waiver by the Department under criteria to be developed by a technology management office. This conclusion is based on the draft recommendation that the Secretary: "Announce intent to consider termination of the IPA's (Institutional Patent Agreements which provide conditional ownership of inventions made by 72 non-profit organizations having a patent management capability) and seek (public) comments." See pg. 24. (Parenthetical clauses added.)

The support that is developed for this recommendation within other comments on pages 17 through 23 is questionable and may be in conflict with its own conclusion that: "The National Science Foundation also makes wide use of these agreements. There is widespread support for these agreements, both within HEW and outside the Department, in other agencies and among research institutions. GSA has just promulgated a regulation (Federal Procurement Regulation) allowing agencies to use such agreements with non-profit institutions to cover inventions made under research and development contracts (and grants)." This conclusion is supported by several documents from PHS agencies on Department patent policy.

2. The report attempts in pages 16 through 23 to specify the reasons why a case-by-case approach is utilized when the Department deals directly with profit-making organizations as opposed to the IPA approach when dealing with the non-profit sector and concludes that: "These reasons for the distinction between the non-profit institutions and profit-makers are not particularly strong." See pg. 20.

At no point does the report recognize that the non-profit sector by definition does not engage in development and delivery of innovations to the public as do profit makers. This basic fact is the primary factor in the problem of "technology transfer" from the laboratory to the marketplace and was the reason for the Federal Council for Science and Technology's (FCST's) recommendation to extend an amended HEW IPA policy to the other agencies of the Executive Branch through the regulations noted by the report. All of the arguments made by the report (and many others) equating non-profit organizations to profit makers were considered in the interagency report submitted to FCST and rejected.

3. A basic problem with the report is the acceptance of the concept that the Department patent policy can be utilized effectively as part of an office of technology management for intervention or stimulation purposes (to speed up or slow down transfer). See pgs. 9 and 10. This indicates a fundamental conflict because the two processes are in general mutually exclusive. The judgment on "how" to best create incentives for technology transfer and when intervention is appropriate for the most part occur at different times in the development of a specific technology. It seems clear that the method of promoting transfer involves the creating of incentives in the innovating organization prior to the time that assessment for the purpose of intervention can be made. A decision on who should own an innovation cannot ordinarly be delayed pending a definitive assessment on its negative impact on society if there is an expectation that the owner is to continue pressing for its development.

Further, it appears to be a major error to equate technology transfer and intervention problems on an equal basis since it is likely if the incentives for transfer are not in place prior to judgments on intervention there may well be nothing to assess for intervention purposes.

4. The report suggests that a case-by-case policy will give the Department the opportunity to assure that inventions where there is a high commercial potential will be retained by the Department for licensing or dedication at its discretion. (This presumes that criteria to make such a distinction can be successfully developed without marketplace evaluation.) See pgs. 9 and 10. Technology transfer experts (many who are the institution managers of our IPA's) will immediately detect that the Department intends to keep everything that can be in anyway identified as valuable and leave the non-profit sector the leftover or "junk." Any suggestion that the non-profit sector will cooperate in the difficult task of technology transfer by identifying, reporting and seeking and cooperating with potential commercial developers under such circumstances with any degree of vigor is highly questionable and contrary to existing experience.

5. The report indicates a need to substantially increase our staffing in order to handle inventions now managed by IPA holders. See page 22. This, along with other suggestions, i.e. case by case approach, would create an unnecessary drain on DHEW resources (money, staff, time and expertise).

Thank you for the opportunity to comment on this report.

Lowell T. Harmison, Ph.D.