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STATEMENT ON BEHALF OF THE
NATIONAL ASSOCIATION OF COLLEGE AND
UNIVERSITY BUSINESS OFFICERS

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BEFORE THE NATIONAL COMMISSION FOR THE
PROTECTION OF HUMAN SUBJECTS OF
BIOMEDICAL AND BEHAVIORAL RESEARCH

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Mr. Chairman and Members of the Commission:

My name is Howard Bremer and I appear before you this morning as a representative of the National Association of College and University Business Officers which association represents 102 institutions of higher education. The members of this Association include many of the major educational institutions in this country and all have on-going research functions which are funded through Federal agency grants. I have been engaged in the transfer of technology from the University environment to the public sector for over 16 years as Patent Counsel for the Wisconsin Alumni Research Foundation and have drawn upon that experience for some of the facts which I will present to you.

The charge to your Commission by Congress is amply and fully stated on page 5 of the memorandum to the Commission authored by Messrs. Wallace and Arthur.

Although the interest and experience of the National Association of College and University Business Officers flow to all of the items in the Congressional charge to the Commission I will consider primarily the effect of premature disclosure of research protocols on the proprietary interests of the researcher, the destructive effect such disclosure will have on potential patent protection relative to such rights, and the serious impact on the public of the loss of such proprietary rights. I will present some statistics which I believe are enlightening and which will serve to show the adverse impact premature disclosure can have.

At the outset it must be presumed that Federal research dollars are made available in the expectation of not only developing basic knowledge but also in the expectation that the funded research will lead to products, processes and techniques which will be useful and acceptable in all or parts of our society to improve the well being of the society in general. More specifically, and under the Department of Health, Education, and Welfare auspices to which the Congressional charge is directly pointed, the expectation is that the research results will benefit the public in the health-care area. In the face of this presumption, full and careful consideration must be given to the making of any policy which affects the entire process of the transfer of the technology generated by Federally funded research.

Since a major consideration leading to the Congressional charge is the Sunshine Act a portion of that Act which is quoted on page 17 of the

Commission Memorandum is also significant to my remarks. At page 17 the Commission Memorandum states that the Act's purposes is "to provide the public with such information while protecting the rights of individuals and the ability of the Government to carry out its responsibilities." In the application of this basic tenet of the Sunshine Act the Commission Memorandum has emphasized the protection of the rights of individuals as a general class but has ignored the proprietary rights of individuals in the scientific community and perhaps, of even greater importance, of protecting the ability of the Government to carry out its responsibilities.

It is firmly believed that one such major responsibility is that the Government use its best efforts to transfer as much as possible of the technology which is generated by Federally supported research, and in particular that technology which relates to the health-care field, to the public sector. To aid in accomplishing such transfer the Government has sought the cooperation of private enterprise and the expenditure of private funds as a desirable and necessary element of transferring the fruits of basic research funded by the Government from the academic environment into the marketplace for the benefit of the public. In our experience the patent system has provided and continues to provide the most viable vehicle for accomplishing such end since it provides the incentive necessary to the commitment of private funds to such an effort.

Since premature disclosure will destroy the patent base there is little question in our minds that through operation of the legislation

discussed in the Commission Memorandum public access to research proposals and an open peer review system will practically stifle the ability of the Government to carry out its responsibility to secure the transfer of technology generated by its funded research programs. (Note the comments in the Commission Memorandum at Page 41, last full sentence and page 42.)

The preservation of the proprietary rights of individuals in the contents of their research proposals is another major concern. Such proposals contain the stock in trade, or, if you will, the trade secrets, of scientists and investigators and should be afforded the full protection which is guaranteed under the Constitution. That there is a concern about this situation is evidenced by the remarks at page 49 of the Commission Memorandum which says "the real danger to proprietary rights comes in the case where a patentable idea is developed in the course of a project which was originally intended to be basic research. There is an obvious unfairness in jeopardizing the patent rights of a scientist whose application may have been disclosed before anyone was aware that ideas of potential commercial value were involved." Yet the memorandum suggests nothing to assuage this situation.

In our estimation, and based upon experience, the unfairness is not limited to the situation described, since at the proposal stage most investigators do not and cannot know what the commercial potential or commercial application of their research results may be. It must be

remembered that disclosure of the research proposal will immediately prohibit filing of patent applications in most foreign countries and will start the 12-month statutory bar running in the United States. Thus, the basic advance which might have been patentable after the research program under the proposal had progressed would in most cases be unpatentable and any patentability of improvement inventions would have been severely jeopardized.

Premature disclosure would also permit anyone to garner valuable research ideas and protocols which could then be applied for selfish purposes. For example, a commercial company, either domestic and foreign, could take such ideas and then develop them internally for its own particular use. In such a situation it is not only conceivable but highly probable that a private commercial interest, with concentrated effort, and without any external indication of that effort, could have moved to acquire a strong position relative to a research idea and protocol even before it is funded by a Federal agency. The investigator would have literally transferred his birthright for a mess of pottage.

Let me give you some examples of what, as a practical matter, the impact of premature disclosure can have upon the public. Since this Commission is operating under the auspices of the Department of Health, Education, and Welfare the experience at the University of Wisconsin under the Institutional Patent Agreement with the Department is probably the most significant. Under that Agreement, which became effective December 1, 1968, the Wisconsin Alumni Research Foundation, on behalf

of the University of Wisconsin, has filed 53 patent applications from which 31 patents have matured to date. Under those patent applications and issued patents there are now 17 licensees who are spending substantial sums of money in the development of the inventions for the market. Many of the inventions involved are health related and, therefore, require the expenditure of inordinately large amounts of money to meet the criteria established by the Food and Drug Administration and other regulatory agencies before the inventions can be placed in the market. One of these inventions is now being actively marketed in France and is earning royalties but, more importantly, is being used in the treatment of a multiple number of disease states. Moreover, other of the licensees are expected to shortly introduce different one of these inventions into the market in other parts of the world, including the United States. Had the research proposals which ultimately led to these inventions been publicly available there would have been little likelihood that any of these licensees would have been willing to embark on the necessary development program. Patenting would have been precluded by early disclosure and the incentive supplied by the patent system would not have been available to motivate the development efforts.

In another situation where the invention has been licensed we are relying upon the disclosure in a research proposal to establish the date of conception of the invention. From the date of the proposal to the actual reduction to practice of the invention a period of almost three years elapsed while constant research effort was being put forth. Since both conception and reduction to practice are necessary to patentability and

a patent is necessary to a license, in that situation disclosure through the public availability of the research proposal would have precluded any patent coverage.

In a broader aspect, over its 51 year history the Wisconsin Alumni Research Foundation has been successful in licensing a high percentage (over 20%) of the inventions which were brought to it. By back calculating from the royalties paid it can be estimated that all of WARF's licensees have collectively enjoyed close to two billion dollars of sales under license while the royalties were being utilized for additional research at the University of Wisconsin. More importantly, these inventions included some which had a world-wide impact. Among such inventions are: the warfarin rodenticides, which have for many years been the rodenticides of choice throughout the world - the benefit to the public from the use of these rodenticides in savings of food crops and reducing the spread of disease is incalculable; the use of warfarin as a life-saving drug used extensively as a blood anticoagulant in humans throughout the world; a particular combination of urea and dextrose which reduces intracranial pressure. (That this invention found its way into medical application only because of the ability to license under the patent system is documentable.)

The foregoing are only a few examples of technology at the University of Wisconsin which has been transferred from the academic environment into the public sector via the patent system. With any of

these inventions, premature disclosure, as through availability of research proposals, would have precluded patenting and, therefore, the transfer of this desirable and life-saving technology to the public. Based upon the many years of experience with the technology transfer mechanism we believe we can summarily state that a completely open technological system will become a technologically stagnant system.

We believe that it is imperative that some action be taken to amend the Public Health Service Act to protect the proprietary rights of investigators and the public from the adverse consequences of premature disclosure.

As a final point, the scope of this statement, because of the time allotted for its presentation is inadequate to consider all of the elements which must be addressed. If the Commission is to be responsive to the charge given it by Congress it should also obtain, in full and fair hearings, the views of researchers on the "open" vs. "closed" peer review system, what is meant by the free exchange of scientific information, the impossibility of separating a basic idea from other material in a research proposal and the existing multilayer protection afforded human subjects in the system as it exists today.