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THE UNIVERSITY OF ROCHESTER

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OFFICE OF RESEARCH & PROJECT ADMINISTRATION
AREA CODE 716 TEL.: 275-4034

October 21, 1977

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The Monorable Joseph A. Califano, Jr. Secretary Department of Mealth, Education, and Welfare Washington, D. C. 20201

Dear Mr. Califano:

Re: Operation Common Sense

With reference to your letter of 19 September 1977 and after brief consultation with other members of the Association of American Universities, we have been asked to comment briefly on what DHEW might do to relieve the paperwork and administrative entanglements resulting from the HEW patent and copyright regulations.

It is pleasant, for a change, to be able to respond in a positive fashion, since the DHEW policies in these area have evolved rather smoothly over a number of years. These policies are believed to present a minimum of difficulty for the major research institutions. The manner in which they were developed might well serve as a model for future DHEW rule making rather than be viewed as two areas which should have top priority for Operation Common Sense. The following comments, however, should be considered in light of recent and pending legislation.

Thanks largely to the devoted efforts of one government employee, the DHEW was the first agency that we know of to enter into Institutional Patent Agreements (IPAs) whereby institutions might retain title and limited rights to all inventions developed under any form of DHEW support. As we understand it, an interagency group has recommended to CSA the use of a government-wide IPA. We strongly endorse this concept! Such an agreement would be of great advantage to research institutions because it would tend to do away with concerns they have over the differing requirements of the various agencies - even under existing IPAs. particular, we would hope that DHEW would continue to spearhead the effort to have GBA make it mandatory for the agencies to make full use of such agreements and, further, to encourage the single cognizant or lead agency concept as recommended in the 139 April 1977 Report of the Commission on Federal Eaperwork (recommondation (10. 9, pg. 41).

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- 2. Proposed legislation introduced by Representative
 Ray Thornton, the Uniform Federal Research & Development Utilization Act of 1977, (N.R. 8596) deserves
 the full support of the Department and of the major
 research institutions. This bill provides, among other
 things, that title to inventions resulting from
 federally-funded research shall be vested in the
 institution (with certain rights to the government)
 unless the institution elects not to file a patent
 application.
- 3. In implementing the so-called "Sunshine Act", the DHEW should continue to support the concept that unfunded proposals may contain intellectual property or disclose possible inventions that should not be made prematurely available to the public in order to protect the property rights of an individual or an institution.
- 4. On a related matter in the areas of Rights in Data, and the implementation of the new Copyright Law of 1977, we would hope that DHEW will continue to strive for equity for its grantees and contractors.

As you undoubtedly know, the Office of Education has developed its own copyright policy to be utilized where curriculum materials are developed for publication and sale. While we do not necessarily agree with the mandatory distribution of royalties, nor do we like le necessity of keeping records over a long period of time, it would be our contention that there is no need for one office within the Department to have special rules and regulations that do not apply elsewhere within the Department. There are numerous other examples, such as with the Food and Drug Administration and the National Institutes of Health where differing rules or interpretations apply. In fact, in the broad area of grant and contract administration, we currently have a three-tier system which layers one set of regulations upon another - e.g., DHEW Guidelines, PHS Policy Statements and The NIH Grants Administration Manual. (Even within the NIH, various institutes have set up their own special requirements.) We believe every possible effort should be made by Operation Common Sense to consolidate and unify these rules and regulations so that they uniformly apply throughout the Department to the maximum extent permitted by law.

We very much appreciate the opportunity to offer these comments, a copy of which is being directed to Operation Common Sense, P.O. Box 536, Washington, D. C. 20044.

Sincerely yours,

David A. McBride Director

DAM/hpi

hcc: Operation Common Sense Reagan Scurlock, COGR Clark McCartney, USC J. Corlette, Harvard