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TESTIMONY OF THE ASSOCIATION OF AMERICAN MEDICAL COLLEGES

TO THE ETHICS ADVISORY BOARD

SEPTEMBER 15, 1979

I am Thomas E. Morgan, M.D., Director of the Division of Biomedical Research at the Association of American Medical Colleges. Our Association represents the 126 medical schools of this country, more than 400 teaching hospitals and 70 societies comprised of the faculty who carry out research and teach in the hospitals and medical schools. An organization with a constituency such as ours is obviously very concerned with the issues before the Ethics Advisory Board this morning. We are pleased to be allowed to present our views.

Indeed, the Association's long-standing interests in the effects of the Freedom of Information Act on biomedical research led us to publish five propositions in the January, 1976, issue of "Clinical Research":

(1) We believe that the research grant application must be carefully reviewed to assure protection of human subjects of biomedical research if such subjects are involved. This requires a measure of disclosure.

At the same time, a measure of confidentiality is required in the research process to assure that four important social goals are met:

(2) The process of research is such that new knowledge can not be regarded as definite until publication has been made in a refereed journal.

Premature disclosure of research protocols may lead to premature release of erroneous scientific hypotheses and specious "discoveries" and may thus harm the public.

(3) Preserving the confidentiality of research applications best serves the public interest by assisting in the protection of the quality of the peer review process as used by NIH and NIMH.

(4) Premature disclosure of research protocols may infringe patent rights.

(5) The ideas of scientists are intellectual property and therefore deserve protection at least equivalent to material property.

Obtaining a balance between the competing public interest in both disclosure and nondisclosure is always a delicate and difficult process. Heretofore the major preoccupation has dealt with the protection of human subjects from risks encountered in research. But, as time has passed, institutional review boards have come into widespread use. They are doing an highly effective job in the protection of subjects, thus decreasing the need for scrutiny and surveillance by other public means such as wholesale disclosure. At the same time, "government in the sunshine" has become well established and the time has come to examine whether the price paid for openess is too severe. Disclosure under the Freedom of Information Act has brought with it some disincentives for research and, more importantly, the incentives to persons to undertake careers in science have been decreased.

Present DHEW policy is 1) to disclose, upon request, funded initial grant applications and contract proposals after review for patentable material, 2) to disclose, on request, renewal and supplemental grant applications and modification and renewal contract proposals prior to funding, and 3) to conduct peer review in closed session. The DHEW policies to conduct closed peer review and to withhold applications prior to funding are based upon solid principles but they have been challenged at various times in the literature, in a suit by the Washington Research Project, and by the Congressional Research Service. The DHEW policies have been defended successfully but at times the defense was conducted with difficulty because the Freedom of Information Act was drafted to provide for "government in the sunshine" and the exceptions do not clearly fit the particular needs of the research enterprise supported by the Federal government.

The Association believes that statutory amendments to the Public Health Service Act should be enacted to clarify the applicability of the Freedom of Information Act with respect to the research process. The object of such amendments is to protect the long-term public interest by; (1) assuring the continuation of present practices with respect to initial grant and contract applications and peer review meetings, and (2) extending the present DHEW policy protecting new grant and contract applications to renewal, supplemental and modification proposals so that they may also be protected until funds have been awarded.

The Association is not alone in this view. In June, 1976, the President's Biomedical Research Panel concluded with respect to information in applications for federal grant or contract support:

"• There does not appear to be any direct, necessary, or inherent connection between disclosure of such information and protection of human subjects in research under the present system of federal regulations and review bodies, nor did testimony before the Panel argue for such full disclosure.

• There has been extremely limited interest in using large-scale disclosure of such information as means of monitoring compliance with standards and regulations of protection, and no documented results of use of such information were presented to the Panel.

• As a consequence, uncontrolled disclosure of research information seems to offer neither compelling grounds nor a convincing record that it serves the aim of protecting human subjects of research. But such disclosure does leave unprotected the intellectual property rights of researchers and, in all probability, jeopardizes the timely transfer of research innovations to the delivery of health care."

The Panel recommended that applications should be kept confidential prior to funding and that peer review meetings should be closed. They suggested that the Public Health Service Act should be amended accordingly.

In April, 1977, after prolonged study, public hearings and debate the Commission for the Protection of Human Subjects of Biomedical and Behavioral Research also recommended "that (a) Initial, renewal and supplemental grant applications and initial, modification and renewal contract proposals under the Public Health Service Act are disclosable when funds have been awarded, subject to existing statutory exemptions and review for patentable material; (b) Such applications and proposals are not disclosable prior to the award of funds unless the investigator and the contractor or grantee have consented; and (c) Initial review group and advisory council meetings are closable when such applications and proposals are reviewed." The Association position therefore is essentially concordant with that of two distinguished groups of diverse composition that it is in the public interest to provide confidentiality for research applications and to assure closed peer review sessions.

The application of the principles which I have outlined logically leads us to wholehearted support of the two proposals under consideration by the Ethics Advisory Board, namely, that arrangements be made to insure protection from disclosure of:

- The identity of health care providers who voluntarily submit to the CDC information intended to facilitate "disease investigation, epidemiological monitoring or epidemiological study"; and
- "the data from clinical trials and observational epidemiological studies which are preliminary, incomplete or not yet validated."

The Association also vigorously supports the concept of statutory protection, where necessary and appropriate.

The proposed remedy for the problem faced by the CDC seems entirely appropriate and clearly necessary. There can be no reasonable doubt that the information at issue must be revealed if requested under the FOIA, and that its release is seldom if ever in the public interest and almost invariably contrary to that interest. No mechanism, other than the creation of a statutory shield, is available. That shield should be narrow and specific, and should be incorporated into the authorities of the Public Health Service. Thus, the identity of informants would be protected under Section 552 (b) (3) of the FOIA.

The remedies proposed for achieving the critically important objective of protecting data from clinical trials, etc. from premature disclosure present a much more complex problem. Several caveats seem in order.

The data whose temporary protection from disclosure is sought is generated from expenditure of Federal funds under three possible mechanisms---

research grants, research contracts or research activities of Federal employees. The Association holds, as explicated in the *amicus curiae* brief which it recently filed before the Supreme Court in the Forsham vs. Califano case, that data collected as a result of activities funded by Federal research grants are not agency records and are therefore not within the reach of the FOIA. This view has been sustained by the lower courts and the Goverment is convinced that the Supreme Court will concur. Therefore, the Association does not believe that any statutory shield is required to protect grant-generated data. Moreover, we see serious peril in seeking such statutory protection, in the following sense. Efforts to protect a specific subset of grant-generated data---that related to clinical trials and observational epidemiological studies---implies that the generic class---grant-generated data---falls within the reach of FOIA.

Clinical trials or epidemiological studies funded by Federal agencies under research contracts are subject to the terms and conditions specified in the contract. One of these defines the rights of the contractor and contractee to the data produced in the performance of the contract. The Association suggests that the "rights in data" clauses of the contracts could be written in explicit enough terms to assure the degree of temporary protection that is essential to subserve the public interest. However, our legal expertise is limited and, if the preponderance of legal expertise holds that a statutory shield is required, the Association would support a move to obtain one.

Clearly, the data generated by Federal scientists is vulnerable to premature disclosure. This fact, coupled with the intense involvement of PHS and VA scientists in clinical trials and epidemiological studies, lends urgency to the enactment of a statutory shield.

We have appreciated the opportunity to present our views on this problem. In the five minutes allotted I was not able to answer specifically the questions you have published in your notice of August 1, 1979 but most of these have been covered in the propositions I have outlined. The Association would be glad to reply in detail to each of these questions at your request.

I will be glad to try to answer questions.