Report of the
President's
Biomedical
Research Panel

DISCLOSURE OF RESEARCH INFORMATION

submitted to the

Committee on Interstate and Foreign Commerce
of the House of Representatives

and the

Committee on Labor and Public Welfare
of the Senate

pursuant to

Title III of Public Law 94-278

June 30, 1976

U.S. DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
Public Health Service
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RECOMMENDATIONS AND CONCLUSIONS

The Panel's mandate under Public Law 93-352 called for review and assessment of biomedical and behavioral research supported by the National Institutes of Health and the Alcohol, Drug Abuse, and Mental Health Administration. The Panel's recommendations in its Report[1] to the President and the Congress outlined steps that should be taken to strengthen and improve the biomedical and behavioral research efforts of those agencies.

Several of the recommendations addressed specific issues regarding the effect of the Freedom of Information Act of 1967 (and as amended in 1974), the Federal Advisory Committee Act, and the Privacy Act of 1974, popularly known, as a group, as the "sunshine laws," and the recommendations are cited here because of their relevance to the present report.

> The Panel recommends that the Public Health Service Act be amended to provide statutory assurance that the initial review for scientific and technical merit ("peer review") remain totally confidential.
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> The Public Health Service Act also should be amended to provide a statutory exemption from disclosure in accordance with exemption (3) of the Freedom of Information Act for research designs and protocols contained in grant applications and contract proposals until the grant or contract funds have been received by the grantee institution or contractor. Unfunded grant applications and contract proposals should remain confidential.
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> In the case of grant applications and contract proposals that contain clinical protocols, there must be a period of thirty days for public review of clinical protocols before research is commenced.
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> The Public Health Service Act should be amended to provide protection from premature disclosure of data that are (1) part of a larger data set and can only be reviewed within the greater context; (2) data that are incomplete, such as interim reports of clinical trials; and (3) data obtained by federally employed investigators and scientists, either as part of their own research or obtained in conjunction with nonfederal scientists, until such time as the study has been published in a professional periodical.

In this present study and report, pursuant to Title III of Public Law 94-278, the Panel has addressed the issue of the effect of the disclosure to the public of information contained in research protocols, hypotheses, and designs. Specifically, the Panel has inquired as to whether there are aspects of the disclosure of such information that serve to strengthen or to interfere with the biomedical and behavioral research effort in this nation.

The present study provides additional evidence that leads the Panel to recommend further that the Public Health Service Act be amended (1) to provide adequate protection for intellectual property rights of investigators who submit applications or proposals for support of research and of those investigators whose research is supported under the authority of that Act, and (2) to protect the patent rights of discoveries and innovations resulting from research supported by the Department of Health, Education, and Welfare.

The Panel is convinced that an area of vital national interest--the federal biomedical and behavioral research effort and its impact on the health of the nation--is likely to be impaired unless such legislative action is taken. Several findings of the present study support that conviction.

First, on the basis of the number and nature of requests for disclosure of information and the review of responses to the questionnaire, the Panel did not find indication that the opportunity for disclosure of previously protected information has had more than isolated impact on the interest in the protection of human subjects. The exact extent to which proprietary interests and future patent rights may already have been jeopardized by disclosure can only be assessed at a future date, although there is no question that disclosure does infringe upon such rights.

Second, the Panel found that intellectual property rights of researchers whose investigations are federally supported cannot be protected adequately by the federal government under present court rulings. Further, the Panel found clear evidence that the existence of a licensable patent right, which is contingent on protection of intellectual property rights, is a primary factor in the successful transfer of research innovation to industry and the marketplace. In light of the effect of disclosure of research information on intellectual property rights and in light of the importance of such rights to the transfer of research innovations to the delivery of health care, it is clear that the present mechanism of complete "openness" ensures public accountability at the cost of sacrificing protection of intellectual property rights of demonstrable potential benefit to the nation.

Third, the Panel found no evidence that disclosure of information had contributed, or appeared relevant, to improvements in the ability of the peer review system to ensure high-quality federally funded research. The Panel did

find reason to believe that the possibility of uncontrolled disclosure could impair the ability of the peer review system to ensure high quality. The Panel also found from its questionnaire a high proportion of requests to review successful research applications and proposals indicating the potential for derivative and imitative research projects.

Fourth, the Panel's consideration of the relationship of protection of human subjects in research and informed consent procedures to disclosure of information contained in research protocols, hypotheses, and designs led to three conclusions.

- 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 a 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.

Recommendations

The Commission recommends to Congress that appropriate legislation be enacted to insure 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.

Comment: Present DHEW practice is to disclose, upon request, funded initial grant applications and contract proposals, after review for statutory exemptions from FOIA, and to conduct peer review in closed session. Renewal and supplemental grant applications and modification and renewal contract proposals are treated as disclosable prior to funding. None of these practices has been clearly affirmed, either judicially or by legislation. The Commission is accordingly recommending that appropriate legislation be enacted to insure continuance of the present practices with respect to initial grant applications and contract proposals, and the closing of peer review meetings. With respect to renewal and supplemental grant applications and modification and renewal contract proposals, the Commission has concluded that they should be treated in the same manner as initial applications and proposals, and is accordingly recommending that appropriate legislation be enacted to provide a clear legal justification for such treatment.

The Commission recommends to the Secretary of Health, E
Welfare that appropriate administrative action be taken to i
(A) THE CONSENT FORMS TO BE USED IN RESEARCH INVOLVING HUMAN
DISCLOSABLE WHEN FUNDS FOR SUCH RESEARCH HAVE BEEN AWARDED;
ONGOING STUDY OF THE EFFECTS OF DISCLOSURE OF FUNDED RESEARC
REVIEW PROCESS AND THE PROTECTION OF HUMAN SUBJECTS BE CONDU
REPORT OF THE FINDINGS OF SUCH STUDY BE SUBMITTED TO CONGRES
YEARS.