

MEMORANDUM

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
OFFICE OF THE SECRETARY

File - SOPA

TO : Inez Smith Reid
Deputy General Counsel for Regulation Review
Room 716-E, South Portal Bldg.

DATE: August 25, 1977

FROM : Norman J. Latker
Patent Counsel
OS/GCB

SUBJECT: Federal Register Notice of August 15, 1977, Page 41140, "Closing of Advisory Committee Meetings - Intent to Amend Regulations"

Reference our conversation of August 19, regarding subject Federal Register Notice.

I. Brief History of Past Reviews on the Impact of Public Access to Research Information Furnished to the Government by Private Parties.

As I advised, there are a number of different reviews indicating that the exemptions available under the Freedom of Information Act (FOIA) and the Federal Advisory Committee Act (FACA) do not sufficiently protect research information submitted to the Government by private parties either to comply with laws, aid in satisfying the needs of the Government, or to obtain Government funding to support research and development efforts. The unpredictability of protection afforded by FOIA and FACA due to the inability to precisely define the terms "trade secret" and "proprietary information", and the resulting recommendations for statutory amendment have been pointed out most prominently in at least the following:

- (A) A report by "The President's Panel on Biomedical Research,"
- (B) A report by "The National Commission for the Protection of Human Subjects"
- (C) A December 11, 1975, agreement between Congressman John E. Moss, the identified father of FOIA, and Congressman Goldwater,
- (D) A November 18, 1975, letter from the Department of Justice.
(All of these materials are enclosed.)

Both the reports of (A) and (B) were responsive to a joint charge by the House Committee on Interstate and Foreign Commerce, and the Senate Committee on Labor and Public Welfare to determine in part the effect of "Disclosure of Research Information" on the

- (i) proprietary interest in research protocols, hypotheses or designs from which such information was disclosed and on patent rights;
- (ii) ability of peer review systems to insure high quality federally funded research; ...

(The charge from the Committees is found on page XIV of the Commission report or on Appendix A of the Panel report.)

The President's Biomedical Research Panel Report was generated through the use of available expertise, while the National Commission report was generated through the use of such expertise plus public comments elicited under Federal Register Notice, 42 FR 56239, December 27, 1976, copy attached herewith. It should be noted that the Federal Register notice generated approximately 240 responses, which I am enclosing herewith, and would appreciate your returning after review. Discussion of the comments elicited by the Commission are discussed on pages 19-30 of the Commission Report.

As I advised, reports (A) and (B) conclude with a recommendation that the peer review system remain unchanged and, if necessary, legislative amendment of FOIA and FACA be sought in order to accomplish this end. In light of the Panel and Commission recommendations, I believe the most representative responses to the Commission are those of Philip Handler, President, National Academy of Sciences, and Dr. John A. Cooper, President, American Association of Medical Colleges.

II. Proposed Legislation for Regulation of Recombinant DNA.

It appears clear that the above information plus additional public input prompted that "research information" be treated as follows in the present version of Sec. 480 of the Rogers bill, H.R. 7897 on "Recombinant DNA":

" A research hypothesis, design, or protocol shall, for the purpose of this paragraph, be considered to be information which is exempt from disclosure pursuant to subsection (a) of Section 552 of Title 5, United States Code, by reason of Subsection (b)(4) of such Section." (emphasis added)

While the original Kennedy versions of legislation to regulate Recombinant DNA contained similar protection for research protocols, etc., the final version is now silent on this subject. However, it has been indicated that Senator Gaylord Nelson will introduce DNA legislation which will probably follow the Rogers treatment of research protocols, etc.

III. October Hearings Are Scheduled by the House Subcommittee on Government Information and Individual Rights.

It has been announced that the above Subcommittee will conduct hearings in early October on problems involving the (b)(4) exemption of FOIA and FACA. One of the problems identified for consideration will be premature access to research information of benefit to competing science investigators. This problem is alternatively described by some as "reverse FOIA" or "industrial espionage" situations. The staff member implementing these hearings is aware of reports I.(A) and (B) and Sec. 480 of H.R. 7897.

IV. Federal Register Notice of August 15, 1977.

It appears from the Notice (whether intended or not) that the most relevant message ascertained from the information cited above - that "trade secrets" and "proprietary information" are not definable terms absent court pronouncement on a case-by-case basis - has been rejected by the Department. This conclusion is drawn since the Notice appears to be attempting to formulate a system which makes these terms definitive of whether an advisory committee meeting should be open or closed.

It seems appropriate to me for the Department to support the handling of research protocols, hypotheses, and designs in the manner suggested by Sec. 480 of H.R. 7897 for all peer review meetings, for the following reasons:

- (A) Sec. 480 is a reflection of strong public opinion made known to the Department through its association with the Panel and Commission.
- (B) When functioning under FOIA and FACA it is very difficult (if not impossible) to determine at the design phase of an experiment exactly what is or is not proprietary. As to those portions that might be deemed proprietary, it is even more difficult to segregate data of value from those of no value. In fact, the experiment itself, if funded, is conducted to answer these questions. Dr. Handler's letter is eloquent testimony on this point. The Sec. 480 approach eliminates the need to make such considerations.
- (C) Section 480 approach recognizes the fact that the owner of information is in the best position to decide what is or is not proprietary. Furthermore, the owner's interest in protecting his property is immediate and primary, while the Government's interest is derivative and secondary.
- (D) When functioning under FOIA and FACA, the definition of "trade secret" or "proprietary information," as noted, becomes definitive of disclosure, but the definition is embodied in the common law and, therefore, must await case-by-case enunciation. The Sec. 480 approach eliminates the uncertainty and cost of such case-by-case review.
- (E) The Sec. 480 approach eliminates the possible injustice of compelling an individual seeking Department support which may not be forthcoming to jeopardize his proprietary rights on one hand and to pay the costs of his vindication on the other, as would be required by FOIA and FACA.

V. Recommendations

- (A) Clearly distinguish advisory committee meetings involving the submission of research protocols, hypotheses and designs for Department funding from other advisory committee meetings.
- (B) Support the Sec. 480 of H.R. 7897 approach to treatment of research protocols, hypotheses and designs submitted to the Department for funding.
- (C) Obtain necessary clearances to support (B) at the hearings scheduled by the Subcommittee on Government Information and Individual Rights on (b)(4) problems.

cc: Dr. Richmond
Dr. Harmison
Dr. Fredrickson
Dr. Akers
Mr. Libassi
Mr. Feiner

41140

EDWARD F. TUERK,
Acting Assistant Administrator,
For Air and Waste Management.

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**DEPARTMENT OF HEALTH,
EDUCATION, AND WELFARE**

Office of the Secretary

[45 CFR Part 11]

**CLOSING OF ADVISORY COMMITTEE
MEETINGS**

Intent To Amend Regulations

AGENCY: Health, Education, and Welfare Department.

ACTION: Notice of intent to amend rule.

SUMMARY: The Secretary of Health, Education, and Welfare has under consideration a proposed amendment to the Department's Committee Management Interim Regulations published Monday, August 23, 1976, 41 FR 35654-8. In particular, the Secretary will propose amendments to 45 CFR 11.5(a)(6) "Closing Advisory Committee Meetings." Changes are required because of the amendment to the Federal Advisory Committee Act by the enactment of the Government in the Sunshine Act (Pub. L. 94-409, § 5). That amendment changed the criteria for the closing of meetings of Federal Advisory Committees. Instead of relying on the exemption under the Freedom of Information Act, agencies now must utilize the criteria of the Government in the Sunshine Act in order to close committee meetings.

While making the technical changes required by the amendment to the Federal Advisory Committee Act, the Secretary wishes to review the Department's overall policy on the closing of advisory committee meetings. He therefore invites comments on policies and procedures regarding the closing of such meetings. In considering changes, the Secretary particularly wants to comply with the Congressional intent that, in general, meetings be open to the public. He recognizes, however, that there will be situations which will dictate that certain meetings or portions of meetings be closed. The proposed amendment to the regulation should establish criteria which must be met before a determination can be made to close a meeting or any portion of a meeting. The Secretary specifically invites comments on how such criteria may be refined in order to assure that meetings which should be closed may be closed, but to assure, to the extent feasible, that meetings which do not need to be closed are open to the public.

DATES: Comments must be received on or before September 29, 1977.

ADDRESSES: Mail comments to: Department Committee Management Offi-

cer, 330 Independence Avenue
Washington, D.C. 20201. Comments
be hand delivered to Room 4357, 330 Independence Avenue SW. All comments received may be reviewed in Room 4357, 330 Independence Avenue SW.

FOR FURTHER INFORMATION CONTACT:

Russell M. Roberts. (202-245-7578).

SUPPLEMENTARY INFORMATION: The following issues are presented for comment. In considering these issues, the Secretary will also consider any additional questions raised by the comments.

1. *Protection of personal privacy.* The protection of personal privacy is of great concern to the Secretary. Advisory committee meetings may be closed under present law where an open meeting would "disclose information of a personal nature where disclosure would constitute a clearly unwarranted invasion of personal privacy" (5 U.S.C. 552b(c)(6)).

Can guidelines be formulated which would assist a government official in determining whether the right of the public to have access to information concerning a particular individual's background, qualifications, competence, financial situation, or the like, outweigh the right of an individual to personal privacy regarding such factors of his personal life?

Should the criteria for closing meetings of committees such as the Boards of Scientific Counselors, which review in-house research activities of government employees, differ from those for peer review committees which assess the work of non-Federal principal investigators on funded or potential grants and contracts?

Would discussion in an open forum in the nature of performance evaluation or appraisal of Federal employees, whether or not engaged in research, constitute a clearly unwarranted invasion of privacy?

Should the level of position or responsibility of the Federal employee affect what constitutes a clearly unwarranted invasion of privacy?

If a Federal employee is not entitled to privacy protection, is the Department entitled to discuss performance appraisal of employees in evaluating the Department's efficiency in closed sessions because such matters relate to personnel rules and practices?

2. *Trade secrets, commercial, or financial information.* To what extent should a person supplying trade secrets, commercial, or financial information to the Department, knowing that such information will be reviewed by an advisory committee, have a role in determining whether such information is privileged or confidential, thereby participating in the deliberation to close the advisory committee meeting on that basis?

Should the Department notify persons who have submitted trade secrets, commercial, or financial information prior to submitting such information for discussion in open session by an advisory committee?

Will people doing business with the Department submit proprietary information in sufficient detail to be useful to the Department if there is a possibility that such information may be disclosed in an open committee meeting?

What other safeguards should be established to assure that proprietary interests of the providers of information are fully protected, while at the same time assuring the right of the public to attend and participate in the deliberations of advisory committees to the fullest extent possible?

3. *Law enforcement investigations.* What guidelines can be established to determine when disclosure of investigatory information might interfere with enforcement proceedings?

4. *Procedures.* The interim regulations provide that the Executive Secretary of an advisory committee is responsible for justifying why a meeting, or a portion thereof, should be closed when submitting a request to the appropriate official for a determination to close a meeting. The request is to be submitted 60 days prior to the scheduled date of the meeting. Any determination to close the meeting, or any portion thereof, must be in writing and likewise contain specific reasons to support the determination. Any such determination must be reviewed and approved by the Office of General Counsel and the Office of Public Affairs.

Are further procedural requirements appropriate to prevent the improper closing of advisory committee meetings?

5. *Separating open portions of meetings from portions which may be closed under the criteria to be formulated in the regulation.* The Secretary is concerned that any determination to close a meeting, or portion thereof, restrict such closing to the shortest reasonable time. The Secretary recognizes however that under certain circumstances discussions which may fall within the criteria for closing will intertwine with discussions of matters which do not meet such criteria.

What guidelines can be established for the least amount of time consumed in mixed discussion?

Should the determination to close a meeting include a provision that the chairman, or the Federal official required to be in attendance, may open a meeting, or portion thereof, if it appears that the discussions are not intertwined or do not otherwise meet the criteria for closing meetings?

The issues set forth above are those which reflect the special concerns of the Secretary. Interested parties need not confine their comments in response to this notice of intent to the issues set forth in this notice. Any additional issues concerning the closing of advisory committee meetings may be submitted and will be considered by the Secretary in formulating his notice of proposed rule-making.

Dated: August 6, 1977.

JOSEPH A. CALIFANO, Jr.,
Secretary.

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