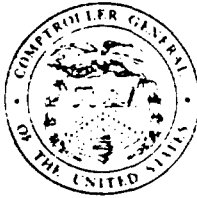


# DECISION



THE COMPTROLLER GENERAL  
OF THE UNITED STATES  
WASHINGTON, D. C. 20548

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FILE: B-143181

DATE: OCT 9 1975

MATTER OF: National Commission for the Protection of Human  
Subjects of Biomedical and Behavioral Research

- DIGEST:
1. Since National Commission for Protection of Human Subjects of Biomedical and Behavioral Research must depend on Department of Health, Education, and Welfare (HEW) for funding, it cannot be viewed as wholly independent of HEW. Nevertheless, National Research Act clearly contemplates that Commission will have considerable independence of judgment in performing its advisory functions. Thus it was not intended that Commission and its staff be subject to day-to-day supervision of HEW.
  2. Although National Commission for Protection of Human Subjects of Biomedical and Behavioral Research has dual function under National Research Act of advising both Secretary of Health, Education, and Welfare (HEW) and Congress, role of assisting HEW is clearly Commission's primary function. Accordingly, Commission is viewed as established to advise Federal agency within scope of, and therefore subject to, Federal Advisory Committee Act.

This decision is in response to a letter dated April 3, 1975, from the Chairman, National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (hereinafter the "Commission"), presenting several questions concerning the relationship between the Commission and the Department of Health, Education, and Welfare (HEW), and the applicability of the Federal Advisory Committee Act to the Commission. The Chairman's questions are as follows:

1. "Is the Commission independent and not an agent of the Executive Branch in organizing and operating so as to carry out its Congressional mandate, despite the Secretary of HEW's ministerial functions of appointing Commissioners and providing a mechanism for Congressional funding of the Commission?"

2. "Are Commission staff and consultants, Commission employees responsible to the Commission and not any other agency or Department, despite the fact that the funds for their salaries may come through appropriations made to the Secretary of HEW?
3. "Is the Commission subject to the provisions of the Federal Advisory Committee Act even though it was created by, and reports to, the Congress merely because copies of its reports and recommendations on matters concerning HEW programs are provided to the Secretary for his mandatory adoption or adverse comment?
4. "Does the specific grant of authority to the Commission in P.L. 93-348, Section 204(a) to establish its own procedures required to fulfill its Congressional mandate govern Commission operations or is the Commission limited by the general advisory committee procedures in P.L. 92-463 [the Federal Advisory Committee Act], Section 10?"

With reference to question 1, the Commission was established by title II of the National Research Act, Pub. L. No. 93-348, §§ 201-205 (July 12, 1974), to conduct various studies and to make reports and recommendations thereon to the Secretary of HEW and to Congress, and appears to have been placed under the general auspices of HEW. The Senate version of the Act, derived from an earlier Senate bill, S. 2072, 93d Cong., had explicitly provided for the establishment of the Commission within HEW. The Senate version further provided that Commission members were to be appointed by the President, and authorized appropriations of \$3,000,000 in each of fiscal years 1974 and 1975. See S. Rep. No. 93-381, 93d Cong., 1st Sess. 88-96 (1973). The final version of the bill, as adopted by conference, although lacking the language which expressly places the Commission within HEW, nevertheless does not appear to have given the Commission total independence inasmuch as the power to appoint Commission members was placed in the Secretary of HEW, and separate funding for the Commission was deleted from the bill.

Testimony by Dr. Henry E. Simmons, Deputy Assistant Secretary for Health and Scientific Affairs, HEW, before the Senate Subcommittee on Health, Committee on Labor and Public Welfare, brought to the attention of the subcommittee an alleged inconsistency within S. 2072, in having a body ultimately responsible to the Secretary subject to the appointive powers of the President. Hearings on S. 2072 Before the Subcommittee on Health of the Senate Committee on

Labor and Public Welfare, 93rd Cong., 1st Sess. pt. 4, at 1493 (1973). None of the subcommittee members indicated at that time, or thereafter, that their intent in drafting the legislation was not to establish a body responsible to the Secretary.

That Congress intended the Commission to operate under the aegis of HEW is further reflected in the alteration during the legislative process of the effect of Commission recommendations. The earlier Senate version provided that policies established by the Commission would take precedence over existing HEW policies wherever the two were in conflict. S. Rep. No. 93-381, supra, at 29. The enacted version, however, no longer enables the Commission to determine and implement policy, but rather allows it to make recommendations which do not require adherence. Thus, section 205 of Pub. L. No. 93-348 provides as follows:

42 USC 289L-1 MP

"Within 60 days of the receipt of any recommendation made by the Commission under section 202, the Secretary shall publish it in the Federal Register and provide opportunity for interested persons to submit written data, views, and arguments with respect to such recommendation. The Secretary shall consider the Commission's recommendation and relevant matter submitted with respect to it and, within 180 days of the date of its publication in the Federal Register, the Secretary shall (1) determine whether the administrative action proposed by such recommendation is appropriate to assure the protection of human subjects of biomedical and behavioral research conducted or supported under programs administered by him, and (2) if he determines that such action is not so appropriate, publish in the Federal Register such determination together with an adequate statement of the reasons for his determination. If the Secretary determines that administrative action recommended by the Commission should be undertaken by him, he shall undertake such action as expeditiously as is feasible."

The conference report points out that, under section 205, the Commission is advisory in nature, lacking the regulatory authority proposed by the Senate version. H.R. Rep. No. 93-1148, 93rd Cong., 2d Sess. 23 (1974). During Senate consideration of the conference report, Senator Kennedy, Chairman of the Subcommittee on Health, pointed out that the section 205 procedures were established to insure accountability, Cong. Rec., June 27, 1974 (daily ed.), S11779. In our view, this reflects, rather than total independence by the Commission, a concern by the Congress that the Secretary might otherwise ignore suggestions from a body legislatively established primarily to advise him.

Additional substantiation of this interpretation is provided by the remarks of Congressman Rogers, Chairman of the House Subcommittee on Public Health and Environment of the Committee on Interstate and Foreign Commerce, and one of the managers of the bill in the House of Representatives, to the effect that the Commission was created to assist HEW in determining basic ethical principles which should underlie the conduct of biomedical and behavioral research involving human subjects. Cong. Rec., June 28, 1974 (daily ed.), at H5898.

Thus, considering the history and evolution of Pub. L. No. 93-348 in the areas outlined above, we are unable to conclude that the Commission was intended to be wholly independent of the Department of HEW. This is especially true since the Commission must obtain its funds from HEW appropriations. Nevertheless, the functions of the Commission clearly contemplate considerable independence of judgment with respect to policy and program recommendations made to the Secretary and to Congress. This is necessarily true if the congressional objectives of Pub. L. No. 93-348 are to be fulfilled. Therefore, while the funding arrangement potentially forms the basis for some conflict, we do not believe that the Commission was intended to come under the day-to-day supervision of HEW. Cf., B-179188, ✓ April 15, 1975. *42 USC 2891-1*

With reference to question 2, section 201(d) of the National Research Act provides that:

- "(1) The Commission may appoint and fix the pay of such staff personnel as it deems desirable. Such personnel shall be appointed subject to the provisions of title 5, United States Code, governing appointments in the competitive service, and shall be paid in accordance with the provisions of chapter 51 and subchapter III of chapter 53 of such title relating to classification and General Schedule pay rates.
- "(2) The Commission may procure temporary and intermittent services to the same extent as is authorized by section 3109(b) of title 5 of the United States Code, but at rates for individuals not to exceed the daily equivalent of the annual rate of basic pay in effect for grade GS-18 of the General Schedule."

The language of the statute indicates a clear intention by Congress that the Commission have control over its own staff limited only by the cited provisions of title 5 of the United States Code. Therefore, question 2 is answered affirmatively.

With reference to question 3, the provisions of the Federal Advisory Committee Act, 5 U.S.C. App. I §§ 14 et seq. (Supp. III, 1973), must be considered along with those provisions of the National Research Act, Pub. L. No. 93-348, which delineate the Commission's duties. Section 3(2) of the Federal Advisory Committee Act provides:

*5 U.S.C. 211, et. seq.*  
"The term 'advisory committee' means any committee, board, commission, council, conference, panel, task force, or other similar group, or any subcommittee or other subgroup thereof (hereinafter in this paragraph referred to as 'committee'), which is--

"(A) established by statute or reorganization plan, or

"(B) established or utilized by the President, or

"(C) established or utilized by one or more agencies, in the interest of obtaining advice or recommendations for the President or one or more agencies or officers of the Federal Government, except that such term excludes (i) the Advisory Commission on Intergovernmental Relations, (ii) the Commission on Government Procurement, and (iii) any committee which is composed wholly of full-time officers or employees of the Federal Government."

*42 USC 289L-1 11/79*  
Section 202 of the National Research Act provides in part:

"(a) the Commission shall carry out the following:

"(1) (A) The Commission shall (i) conduct a comprehensive investigation and study to identify the basic ethical principles which should underlie the conduct of biomedical and behavioral research involving human

subjects, (ii) develop guidelines which should be followed in such research to assure that it is conducted in accordance with such principles, and (iii) make recommendations to the Secretary (I) for such administrative action as may be appropriate to apply such guidelines to biomedical and behavioral research conducted or supported under programs administered by the Secretary, and (II) concerning any other matter pertaining to the protection of human subjects of biomedical and behavioral research.

\* \* \* \* \*

"(C) The Commission shall consider the appropriateness of applying the principles and guidelines identified and developed under subparagraph (A) to the delivery of health services to patients under programs conducted or supported by the Secretary.

"(2) The Commission shall identify the requirements for informed consent to participation in biomedical and behavioral research by children, prisoners, and the institutionalized mentally infirm. The Commission shall investigate and study biomedical and behavioral research conducted or supported under programs administered by the Secretary and involving children, prisoners, and the institutionalized mentally infirm \* \* \*. On the basis of such investigation and study the Commission shall make such recommendations to the Secretary as it determines appropriate to assure that biomedical and behavioral research conducted or supported under programs administered by him meets the requirements respecting informed consent identified by the Commission. \* \* \*"

"(3) The Commission shall conduct an investigation and study to determine the need for a mechanism to assure that human subjects in biomedical and behavioral research not subject to regulation by the Secretary are protected. If the Commission determines that such a mechanism is needed, it shall develop and recommend to the Congress such a mechanism. \* \* \*

"(b) The Commission shall conduct an investigation and study of the nature and extent of research involving living fetuses, the purposes for which such research has been undertaken, and alternative means for achieving such

purposes. The Commission shall, not later than the expiration of the 4-month period beginning on the first day of the first month that follows the date on which all the members of the Commission have taken office, recommended to the Secretary policies defining the circumstances (if any) under which such research may be conducted or supported.

"(c) The Commission shall conduct an investigation and study of the use of psychosurgery in the United States during the five-year period ending December 31, 1972. The Commission shall determine the appropriateness of its use, evaluate the need for it, and recommend to the Secretary policies defining the circumstances (if any) under which its use may be appropriate. \* \* \*.

"(d) The Commission shall make recommendations to the Congress respecting the functions and authority of the National Advisory Council for the Protection of Subjects of Biomedical and Behavioral Research to be established under section 217(f) of the Public Health Service Act."

In addition, section 203 directs the Commission to undertake a "comprehensive study of the ethical, social, and legal implications of advances in biomedical and behavioral research and technology." Section 204(d) directs the Commission to make periodic reports and a final report on its activities under sections 202 and 203 to the President, the Congress, and the Secretary of HEW.

In addressing question 3, there is also for consideration section 2(a) of the Federal Advisory Committee Act, which makes it clear that the main focus of the Act was on advisory committees in the executive branch of the Government:

"The Congress finds that there are numerous committees, boards, commissions, councils, and similar groups which have been established to advise officers and agencies in the executive branch of the Federal Government and that they are frequently a useful and beneficial means of furnishing expert advice, ideas, and diverse opinions to the Federal Government."

The legislative history of the Federal Advisory Committee Act discloses that the earlier versions of the bills which resulted in the Act included advisory committees established or organized to advise and make recommendations to the Congress, but these references to the Congress were deleted before final passage. Thus it would appear that Congress did not intend to make advisory committees established by law for the purpose of advising and making recommendations to the Congress subject to the Act. The Commission involved here is composed of 11 members, all appointed by the Secretary of HEW. As shown in the above-cited portions of section 202 of the National Research Act, the Commission's responsibilities are divided between advising the Secretary on certain matters and advising the Congress on others, as well as making reports to the President. As discussed above, we believe the Commission was viewed by Congress as a body intended primarily to provide assistance to the Secretary. Certainly the thrust of section 202 is directed at HEW.

We note that the legislative history of Pub. L. No. 93-348 does not specifically indicate whether or not the Commission was considered subject to the Advisory Committee Act. However, section 211 of Pub. L. No. 93-348 provides as well for the establishment of a permanent "National Advisory Council for the Protection of Subjects of Biomedical and Behavioral Research" under a new subsection 217(f) of the Public Health Service Act, to come into existence on July 1, 1976. It is clear that this Advisory Council is to be subject to the Advisory Committee Act. For example, subsection 217(f)(4) exempts the Council from section 14 of the Advisory Committee Act, relating to termination of advisory committees, thereby confirming that the Council is subject to the other sections of that Act. It is also clear that the Advisory Council was designed in effect as a successor to the instant Commission, which has only a 2-year existence. See H.R. Rep. No. 93-1148, *supra*, at 23-25; Cong. Rec., June 27, 1974 (daily ed.), S11777 (remarks of Senator Kennedy); *id.*, June 28, 1974, H5898 (remarks of Representative Staggers). Thus Pub. L. No. 93-348 as a whole tends to support the conclusion that the Commission would also be subject to the Advisory Committee Act.

For the foregoing reasons, we believe that the Commission falls within the definition of "advisory committee" in section 3(2) of the Advisory Committee Act, and accordingly is subject to the provisions of that Act.

*5096 9/11, 20, 10*

With reference to question 4, section 10 of the Federal Advisory Committee Act provides the following restrictions on advisory committee procedures:



"(a) (1) Each advisory committee meeting shall be open to the public.

"(2) Except when the President determines otherwise for reasons of national security, timely notice of each such meeting shall be published in the Federal Register, and the Director shall prescribe regulations to provide for other types of public notice to insure that all interested persons are notified of such meeting prior thereto.

"(3) Interested persons shall be permitted to attend, appear before, or file statements with any advisory committee, subject to such reasonable rules or regulations as the Director may prescribe.

"(b) Subject to section 552 of Title 5, the records, reports, transcripts, minutes, appendixes, working papers, drafts, studies, agenda, or other documents which were made available to or prepared for or by each advisory committee shall be available for public inspection and copying at a single location in the offices of the advisory committee or the agency to which the advisory committee reports until the advisory committee ceases to exist.

\* \* \* \* \*

"(d) Subsections (a) (1) and (a) (3) of this section shall not apply to any advisory committee meeting which the President, or the head of the agency to which the advisory committee reports, determines is concerned with matters listed in section 552(b) of Title 5. Any such determination shall be in writing and shall contain the reasons for such determination. \* \* \*

"(e) There shall be designated an officer or employee of the Federal Government to chair or attend each meeting of each advisory committee. The officer or employee so designated is authorized, whenever he determines it to be in the public interest, to adjourn any such meeting. No advisory committee shall conduct any meeting in the absence of that officer or employee.

"(f) Advisory committees shall not hold any meetings except at the call of, or with the advance approval of,

a designated officer or employee of the Federal Government and in the case of advisory committees (other than Presidential advisory committees), with an agenda approved by such officer or employees."

According to section 4 of the Act, the above-quoted provisions apply to each advisory committee "except to the extent that any Act of Congress establishing any such advisory committee specifically provides otherwise."

Pertinent administrative provisions in the National Research Act are set forth below:

"Sec. 204. (a) The Commission may for the purpose of carrying out its duties under sections 202 and 203 hold such hearings, sit and act at such times and places, take such testimony, and receive such evidence as the Commission deems advisable.

"(b) The Commission may secure directly from any department or agency of the United States information necessary to enable it to carry out its duties. Upon the request of the chairman of the Commission, the head of such department or agency shall furnish such information to the Commission.

"(c) The Commission shall not disclose any information reported to or otherwise obtained by it in carrying out its duties which (1) identifies any individual who has been the subject of an activity studied and investigated by the Commission, or (2) which concerns any information which contains or relates to a trade secret or other matter referred to in section 1905 of title 18 of the United States Code."

50 USC 217(f)(4), 214

In general, in order for a statutory provision to "specifically provide otherwise" for purposes of section 4 of the Advisory Committee Act, we believe it must refer to the Act or to some particular provision or provisions thereof (see, e.g., the new section 217(f)(4) of the Public Health Service Act, discussed supra), or must recite the requirement from which exemption is to be made in language which closely parallels the corresponding requirement in the Advisory Committee Act so as to make it clear that the exemption is intended. Section 204 does not meet this test.

First, section 204(a) cannot be deemed to supersede the notice provision mandated by section 10(a)(2) of the Federal Advisory

42 USC 2891-1 note

Committee Act. The Commission can still hold such meetings as it deems advisable, while complying with the requirement that it publish timely notice of said meetings in the Federal Register.

Second, there is no irreconcilable conflict between Congress' mandate that the Commission keep certain items of information confidential, and the requirement of section 10(a)(1) of the Federal Advisory Committee Act that all advisory committee meetings be open to the public. Section 10(d) of the Federal Advisory Committee Act provides for the holding of nonpublic meetings when the head of the agency to which the advisory committee reports determines that the meeting concerns matters listed in 5 U.S.C. § 552(b) Among the matters listed therein are those "specifically exempted from disclosure by statute," 5 U.S.C. § 552(b)(3) Therefore it follows that closed, or partially closed, meetings would be warranted to the extent that the Commission will be discussing any information which identifies any individual who has been the subject of an activity studied or investigated by the Commission, or which contains or relates to a trade secret or other matter referred to in 18 U.S.C. § 1905.

Finally, in order for the Commission to comply with sections 10(e) and (f) of the Federal Advisory Committee Act, an officer or employee of the Federal Government must be designated to call the meetings and approve the agenda. To designate a Commission member as the section 10 official would not, in our opinion, be consistent with the purposes of the Advisory Committee Act. In reporting on the provisions of S. 3529 which, with exceptions not herein pertinent, became sections 10(e) and (f) of the Advisory Committee Act, the Senate Committee on Government Operations stated:

"These provisions are here for a basic purpose: to assure that a Federal official will be available at all times to supervise and monitor the activities and discussions of the committee members, and particularly to guard against possible . . . conflicts of interest. This is added insurance against potential abuse of the advisory privilege, particularly where the meetings are closed under appropriate authority." S. Rep. No. 92-1098, 92d Cong., 2d Sess. 17 (1972).

Although it might be viewed as another potential source of conflict between HEW and the Commission, we do not believe that the section 10 requirement may properly be used to interfere with the legitimate operations of the Commission. In this connection, the above-cited Senate Report further stated:

"However, the provisions [of the present sections 10(e) and (f)] are not intended to be used to restrict or interfere with the legitimate functions of advisory committees, such as, for example, those committees charged by statute with the responsibility for reviewing and evaluating Federal agency programs. Nor should these procedural requirements be used to prevent the consideration of matters of proper concern to an advisory committee." Id.

In sum, it is our view that the Commission is subject to the procedural requirements of the Advisory Committee Act as discussed above.

Thomas D. Morris

Acting Comptroller General  
of the United States