20, 1974, the Acting Assistant Secretary for Administration approved the recharter and extension of the Committee for two additional years, pursuant to Section 5(c)(1) of the Export Administration Act of 1969, as amended, 50 U.S.C. App. Sec. 2404(c)(1) (Supp. III, 1973) and the Federal Advisory Committee Act. The Technology Transfer Subcommittee of the Computer Systems Technical Advisory Committee was initially established on April 10, 1974. On July 8, 1975, the Director, Office of Export Administration, approved the reestablishment of this Subcommittee pursuant to the charter of the Committee.

The Committee advises the Office of Export Administration, Bureau of East-West Trade, with respect to questions involving technical matters, world-wide availability and actual utilization of production and technology, and licensing procedures which may affect the level of export controls applicable to computer systems, including technical data related thereto, and including those whose export is subject to multilateral (COCOM) controls. The Technology Transfer Subcommittee was formed to examine the impact of transferring Automatic Data Processing technology to communist destinations.

The Subcommittee meeting agenda has six parts:

GENERAL SESSION

(1) Opening remarks by the Subcommittee Chairman.

(2) Presentation of papers or comments by the public.

(3) Review of past Subcommittee activities.

(4) Discussion of export control of computer software.

(5) Discussion of work program and assignment of tasks for the coming year.

EXECUTIVE SESSION

(6) Discussion of matters properly classified under Executive Order 11652, dealing with the U.S. and COCOM control program and strategic criteria related thereto.

The public will be permitted to attend the General Session, at which a limited number of seats will be available to the public. To the extent time permits members of the public may present oral statements to the Subcommittee. Written statements may be submitted at any time before or after the meeting.

With respect to agenda item (6), the Assistant Secretary of Commerce for Administration, with the concurrence of the delegate of the General Counsel, formally determined on December 16, 1974, pursuant to Section 10(d) of the Federal Advisory Committee Act that the matters to be discussed in the Executive Session should be exempt from the provisions of the Act relating to open meetings and public participation therein, because the Executive Session will be concerned with matters listed in 5 U.S.C. 552(b)(1), i.e., it is specifically required by Executive Order 11652 that they be kept confidential in the interest of the national security. All materials to be reviewed and discussed by the Subcommittee during the Executive Session of the meeting have been properly classified under the Executive Order. All Subcommittee members have appropriate security clearances.

Copies of the minutes of the open portion of the meeting will be available upon written request addressed to the Freedom of Information Officer, Room 3100, Domestic and International Business Administration, U.S. Department of Commerce, Washington, D.C.

For further information, contact Mr. Charles C. Swanson, Director, Operations Division, Office of Export Administration, Domestic and International Business Administration, Room 1620, U.S. Department of Commerce, Washington, D.C. 20230, telephone: A/C 202/967–4196.

In accordance with paragraph (4) of the Order of the United States District Court for the District of Columbia in Aviation Consumer Action Project, et al., v. C. Langhorne Washburn, et al., September 10, 1974, as amended, September 23, 1974 (Civil Action No. 1838–73), the Complete Notice of Determination to close portions of the series of meetings of the Computer Systems Technical Advisory Committee and of any subcommittees thereof, was published in the FEDERAL REGISTER (40 FR 2243, appearing in the issue of January 10, 1975).

Dated: August 7, 1975.

LAWRENCE J. BRADY,
Acting Director, Office of Export Administration, Bureau of East-West Trade, U.S. Department of Commerce.

[FR Doc.75–20999 Filed 8–7–75;11:50 am]

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FRIDAY, AUGUST 8, 1975

PART II:

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Public Health Service

■

QUALIFICATION OF HEALTH MAINTENANCE ORGANIZATIONS

Title 42—Public Health

CHAPTER I—PUBLIC HEALTH SERVICE, DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

PART 110—HEALTH MAINTENANCE ORGANIZATIONS

Subpart F—Qualification of Health Maintenance Organizations

On December 9, 1974, there was published in the FEDERAL REGISTER (39 FR 43044–47) a notice of proposed rulemaking setting out the procedures for obtaining a determination of whether an organization is a "qualified health maintenance organization" within the meaning of Title XIII of the Public Health Service Act (42 U.S.C. 300e et seq.), as added by the Health Maintenance Organization Act of 1973, Pub. L. 93–222. Interested persons were given until January 8, 1975, to submit written comments or suggestions thereon. Twenty comments were received on or before January 8, 1975, and two comments were received thereafter. All comments received were considered in revising the regulations.

Comments suggesting changes in requirements which are mandated by the statute were rejected. Comments requesting greater specificity were incorporated in the regulations wherever appropriate. In addition to changes made in response to public comment, changes intended to clarify the requirements for qualification with respect to eligible applicants and with respect to the documentation and narrative descriptions required of applicants were made.

The relevant comments received, responses thereto, and the changes in the proposed regulations are summarized below.

1. A new section, "Definitions", was added (§ 110.602). The terms "operational qualified HMO", "transitionally qualified HMO", and "pre-operational qualified HMO" have been included in the definitions section to clarify the different findings that the Secretary may make with respect to applications for qualification under this subpart.

In light of comments received in connection with the proposed regulations implementing section 1310, "Employees' Health Benefits Plans" (40 FR 6602, Feb. 12, 1975), the Department has given further consideration to the status of a transitionally qualified HMO with respect to pre-existing service contracts. Upon such reconsideration, the Department has concluded that the HMO is appropriately considered a qualified HMO with respect to both new and pre-existing contracts and has amended § 110.602(b) accordingly. This does not, of course, preclude an employer from offering a different qualified HMO to its employees nor does it relieve the employer of its obligation to include the various types of HMO's in its offer, as required by section 1310(b) of the Act.

2. Section 110.603(b)(2)(ii) has been revised to permit the phase-in of the requirement that supplemental health services payments which are fixed on a prepayment basis be fixed under a community rating system.

3. One commenter indicated that it would be unreasonable to require a transitionally qualified HMO to provide the assurances specified in § 110.603(b) as part of its application, since it would be assuring the provision of services and the revision of its organization and operation as of an unknown date—the date of the Secretary's determination that it is a transitionally qualified HMO. The commenter suggested that some lead time would be required before such services could be provided and such revision could be accomplished. This suggestion has been accepted and § 110.604(c)(2) has been revised to indicate that the assurances specified in § 110.603(b) need not be executed by the applicant until it has been notified by the Secretary that the application is otherwise approvable. Upon such notification, the applicant will indicate the date on which such assurances will be made effective and will execute the assurances. The Secretary's approval of the application will be effective on the date of such assurances.

4. A number of comments suggested that the 3-year maximum "phase-in" period (§ 110.603(b)(2)(iii)) be changed—i.e., be extended to 5 years, apply to all contracts, or be deleted altogether. The 3-year "phase-in" period was deemed reasonable and will be applied on a case-by-case basis only to existing contracts.

5. Sections 110.604(b)(1)(vii) and (xvii) have been revised to provide that applicants desiring waivers of the limitations on Medicare and Medicaid members (42 CFR 110.109(c)) or of the open enrollment requirement (42 CFR 110.108 (e)) should include requests for such waivers as part of their applications for qualification.

6. A comment was received suggesting that the regulations should describe the responsibilities of designated planning agencies under section 1122 of the Social Security Act. The suggestion was rejected, since qualification procedures do not in themselves give rise to capital expenditures subject to review under section 1122. Moreover, the responsibilities of designated planning agencies under section 1122 are set forth in detail in regulations issued under such section (42 CFR Part 100, Subpart A).

7. Several comments suggested that § 110.604(d)(1) should be revised to require that information on prospective group health plan purchasers be included in the application only if such information is available to the applicant. Since this information is required only "to the extent known", this concern has been met and no revision is required.

8. In response to comments requesting clarification of procedures which are applicable following a determination by the Secretary that an applicant is not a qualified HMO, § 110.605 has been revised. Section 110.605(e) now sets forth procedures for requesting a reconsideration of such determination. Section 110.605(f) provides that applicants dissatisfied with initial or reconsidered determinations may request a fair hearing. It is anticipated that regulations governing fair hearings will be promulgated as proposed rules in the future. Pending such promulgation, applicants requesting a fair hearing will be provided a copy of applicable procedures.

9. The items included as "Application Requirements" (§ 110.604) have been reordered and, in some instances, clarified. This section now provides that an application for qualification shall be divided into two major parts: a narrative description section, and a documentation section. In addition, for ease of reference, the application elements listed are followed by references to related requirements, if any, of other subparts of this Part.

10. Several minor editorial changes were made and several typographical errors were corrected.

There is hereby established in 42 CFR Part 110, Subpart F, "Qualification of Health Maintenance Organizations", as follows:

Effective date. In order to permit immediate applications for qualification, which is a necessary prerequisite to the implementation of various provisions for Federal assistance under the HMO Act, this subpart shall be effective August 8, 1974, in accordance with the statement of such intention contained in the notice of proposed rulemaking (39 FR 43044).

Dated: June 19, 1975.

THEODORE COOPER,
Assistant Secretary for Health.

Approved: July 29, 1975.

CASPAR W. WEINBERGER,
Secretary.

Subpart F—Qualification of Health Maintenance Organizations

Sec.
110.601 Applicability.
110.602 Definitions.
110.603 Requirements for qualification.
110.604 Application requirements.
110.605 Evaluation and determination of qualification.

AUTHORITY: Sec. 215, 58 Stat. 690 (42 U.S.C. 216); Secs. 1301–1315, 87 Stat. 914–933 (42 U.S.C. 300e–300e–14).

Subpart F—Qualification of Health Maintenance Organizations

§ 110.601 Applicability.

The regulations of this subpart apply to any entity seeking a determination by the Secretary under section 1310(d) of the Act that it is a qualified health maintenance organization. (See § 110.109 of this Part concerning the requirements for a health maintenance organization with members who are entitled to insurance benefits under Title XVIII (Medicare) of the Social Security Act or to medical assistance under a State plan approved under Title XIX (Medicaid) of such Act.)

§ 110.602 Definitions.

In addition to the terms defined in § 110.101 of this Part, as used in this subpart:

(a) "Operational qualified health maintenance organization" means a health maintenance organization which the Secretary has determined provides basic and supplemental health services to all of its members in accordance with Subpart A of this Part and is organized and operated in accordance with Subpart A of this Part.

(b) "Transitionally qualified health maintenance organization" means an entity which operates a prepaid health care delivery system and which the Secretary has determined meets the requirements of § 110.603(b). (A transitionally qualified health maintenance organization is deemed a "qualified health maintenance organization" for the purpose of compliance by an employer which has a contract with such health maintenance organization with the requirements of section 1310(a) of the Act so long as the health maintenance organization complies with its time-phased plan approved by the Secretary under § 110.603(b)(2)(iii).)

(c) "Pre-operational qualified health maintenance organization" means an entity which the Secretary has determined will, when it becomes operational as a prepaid health care delivery system, be an operational qualified health maintenance organization.

§ 110.603 Requirements for qualification.

Upon the basis of an application submitted in accordance with this subpart and such additional information and investigation (including site visits) as the Secretary may require:

(a) The Secretary will determine that an entity is an operational qualified maintenance organization, if he finds that the entity meets the requirements of Subpart A of this Part.

(b) The Secretary may determine that an entity is a transitionally qualified health maintenance organization if the entity currently is organized and currently is providing prepaid health services as described in this subparagraph, and provides assurances satisfactory to the Secretary that it will:

(1) With respect to all new group and individual (non-group) contracts which it enters into after the date of the Secretary's determination that the entity is a transitionally qualified health maintenance organization, provide basic and supplemental health services to members enrolled under such contracts and will provide such services in the manner prescribed by subpart A of this Part and will, with respect to such members, be organized and operated in accordance with § 110.108 of this Part.

(2) With respect to its group and non-group contracts which are in effect on the date of such determination, and which are renewed or renegotiated during the period approved by the Secretary under paragraph (b)(2)(iii) of this section in accordance with the plan so approved:

(i) Provide at least those services specified in the following sections of this Part: § 110.102(a)(1) (physician services); § 110.102(a)(2) (outpatient services and inpatient hospital services, except that the inpatient hospital services need not be unlimited as to time and cost); § 110.102(a)(3) (medically necessary emergency health services); and § 110.102(a)(6) (diagnostic laboratory and diagnostic and therapeutic radiologic services);

(ii) Be organized and operated in accordance with § 110.108 of this Part (except that it need not assume full financial risk for the provision of basic health services as required by § 110.108(b), and need not abide by the limitations on insurance of § 110.108(b) (1) and (3)) and provide that payment for basic health services shall be in accordance with § 110.105 of this Part (except that it need not comply with the community rating system as required by § 110.105 (a)(3), and need not comply with the limitations on copayments of § 110.105 (a)(4), and the requirement of § 110.-106(b) that supplemental health services payments which are fixed on a prepayment basis be fixed under a community rating system);

(iii) Implement a time-phased plan acceptable to the Secretary which specifies definite steps for meeting, on a contract-by-contract (or category of contracts) basis, within a period not to exceed 3 years from the date of the Secretary's determination of qualification, all the requirements of Subpart A of this Part; and

(iv) Upon completion of the time-phased plan:

(A) Provide basic and supplemental health services to all of its members;

(B) Provide such services to all of its members in the manner prescribed by Subpart A of this part; and

(C) Be organized and operated in the manner prescribed by subpart A of this Part.

(c) The Secretary may determine that an entity is a preoperational qualified health maintenance organization if it provides assurances satisfactory to the Secretary that it will become operational within 30 days following the Secretary's determination of qualification, and will, when it becomes operational, meet the requirements of subpart A of this Part. Upon notification by the entity to the Secretary that the entity has become operational, the Secretary will, within 30 days of such notification, make a determination whether the entity is an operational qualified health maintenance organization; in the absence of such a determination, the organization is not an operational qualified health maintenance organization even though it becomes operational.

§ 110.604 Application requirements.

(a) An entity seeking a determination that it is a qualified health maintenance organization pursuant to this subpart shall apply to the Secretary at such time and in such form and manner as the Secretary may prescribe.[1] The application must be executed by an individual authorized to act for the applicant and to assume on behalf of the applicant the obligations imposed by the statute and the regulations of this Part.

(b) An application by an entity for a determination under § 110.603(a) that it is an operational qualified health maintenance organization shall contain:[2]

(1) A concise narrative description of the entity's future goals, objectives, history, and operation. This narrative shall describe at least:

(i) Objectives for health services delivery such as staffing, facilities, and enrollment.

(ii) Legal history and current legal status of the entity, including identification of predecessor organizations, corporations, or other entities. (See § 110.-101(a).)

(iii) The organizational arrangements the entity will employ to provide basic and supplemental health services, i.e., a health maintenance organization staff, or a contract with an individual practice association or associations, or a contract with a medical group or groups. In the event that an entity contracts or proposes to contract for the provision of basic health services directly with health professionals who are not employed by the entity as part of its staff or who are not members or contractors of a medical group or individual practice association with which the entity has contracted or proposes to contract, the entity must demonstrate that the employment of such professionals as part of its staff, the membership of such professionals in a medical group or individual practice association, and the utilization of such health professionals by the medical group or individual practice association, are prohibited by law. (See § 110.104(a).)

(iv) The incentives designed to avoid unnecessary or unduly costly utilization of health services which have been accepted by medical groups or individual

[1] Applicants should be aware that provisions of the Freedom of Information Act, 5 U.S.C. 552, may require disclosure of certain official Government records. Regulations of the Department of Health, Education, and Welfare, 45 CFR 5.71, provide exceptions to disclosure. Applicants submitting material which they feel is covered by these exceptions should label such material "Privileged" and include a concise explanation of the applicability of 45 CFR 5.71. In the event that the Secretary determines that such material is not appropriately labeled "Privileged" under 45 CFR 5.71, he will inform the applicant of such determination and, if the applicant does not concur, allow the applicant to withdraw his application. Otherwise, the Secretary will not voluntarily disclose such material and will notify the applicant of any court process or subpoena to compel such disclosure.

[2] For ease of reference, the application elements listed are followed by references to related requirements, if any, of this Part.

practice associations with which the entity has entered into written services arrangements. (See § 110.104(a).)

(v) Any management, administrative, or marketing arrangements (including risk-taking) which the entity has made with other organizations or companies. If the entity assumes risk directly for which insurance or other arrangements are allowed under § 110.108(b) of this Part, describe the experience to date, reserves maintained, and method of computation. (See § 110.108(b).)

(vi) Interrelationships, if any, between the entity and any of the entity's contractors which provide a professional health service or administrative function or service to the entity. Such description should include identification of interrelationships such as common financial or beneficial ownership, or common directorship or trusteeship. However, descriptions of contracts for nonmedical services are required only if the interrelationship represents, in the aggregate, dollar amounts in excess of 5 percent of either party's income or expenses, whichever is smaller. If no such interrelationships exist, the application shall so state.

(vii) The current service area and the proposed service area (if different) and the characteristics of the population or populations served and planned to be served by the entity, including the number of Medicare and Medicaid members and members from medically underserved areas and the percentage of the total membership (enrolled and projected) such members represent. An applicant may seek a waiver of the 50-percent limitation on Medicare and Medicaid members as part of its application. (See §§ 110.101(d) and (e); 110.108(c); and 110.109(c).)

(viii) The composition and operation of the entity's Board of Directors or other policy-making body. (See § 110.108(h).)

(ix) Names and resumes of the entity's officers and other key management and key professional staff.

(x) The procedures for the resolution of grievances or disputes between the entity and health professionals. (See § 110.108(l).)

(xi) A citation to and a concise summary of State laws, regulations, and other requirements relating to the operation of the entity as a health maintenance organization including laws relating to health professionals' practice, marketing, and reserve requirements, and an opinion of legal counsel whether the entity complies (or will be able to comply) with such laws, regulations, and requirements. If operation under such State requirements will require the application of section 1311 of the Act, the opinion shall so state. (See § 110.101(a) and § 110.108(a)(2).)

(xii) The entity's fiscal soundness, the provision against the risk of insolvency, the assumption of full financial risk for the provision of basic health services, and the entity's ability to meet debt service requirements (if any) and to develop such reserves as may be required under law. (See § 110.108(a).)

(xiii) The methods and procedures designed to avoid unduly costly and unnecessary use of health services. (See § 110.104(a).)

(xiv) Methods for third party liability collections. (See §§ 110.108(a); 110.105(b); and 110.106(c).)

(xv) The organizational arrangements and methods employed in an ongoing quality assurance program for health services. If a drug profile is utilized, describe the components of the system. (See §§ 110.108(j) and 110.103(b).)

(xvi) Procedures for assuring that the health maintenance organization is organized and operated in a manner intended to preserve human dignity. (See § 110.108(p).)

(xvii) The marketing and enrollment methods (including method for compensation of marketing representatives), membership servicing procedures, and eligibility determination methods employed by the entity. In addition to describing group-related activities, this description should indicate the procedures for and dates of individual open enrollment periods. An applicant may seek a waiver of the individual open enrollment requirement pursuant to section 1301(c)(4) of the Act, as part of its application. (See § 110.108(c), (d), (e), and (f).)

(xviii) Procedures for instructing members with regard to obtaining medically necessary emergency services, and the methods for determining whether services are medically necessary and for processing claims. (See § 110.104(b).)

(xix) A precise service area map with the mean travel time (by public and private transportation) from the service area boundaries indicated to the location(s) where basic and supplemental health services are available. (If the applicant received a grant or loan guarantee under this title, it should note whether the service area is the same as or different from that approved under the grant or loan guarantee.) List the health service facilities utilized or operated by the providers of health services, note their locations, describe their physical characteristics, indicate whether the facilities are owned or leased by the entity or the providers of health services, and report the hours of operation. Except with respect to institutional care, indicate staffing patterns for each facility, indicate whether such patterns are within described and generally accepted norms for meeting the projected membership needs, and furnish a list of participating physicians by specialty. (See § 110.107(b)(1) and (2).)

(xx) The health care delivery system, including a discussion of the integration of all provider entities. This shall cover the arrangements, both formal (as specified in contracts and membership brochures) and informal (as practiced without such formal documentation), for the delivery of the basic and supplemental health services, and the procedures employed to ensure the coordination and continuity of such care. (See § 110.107(c)(2) and § 110.108(r).)

(xxi) Arrangements made to provide a health professional who is primarily responsible for coordinating the member's overall health care. (See § 110.107(c)(1).)

(xxii) Arrangements with providers for in-area medically necessary emergency services on a 24-hour-a-day, 7-day-a-week basis. (See § 110.107(b)(1).)

(xxiii) For each basic and supplemental health service, how that service will be provided (by staff, through a contract with an individual practice association or medical group, or by other arrangement). Indicate those services, if any, which are considered unusual or infrequently used, and the basis for such a determination. (See § 110.104(a) and (c).)

(xxiv) Each item listed in § 110.102(b) of this Part which is not included as a basic health service. (See § 110.102(b).)

(xxv) Organizational arrangements for health education. (see § 110.108(m).)

(xxvi) Procedures for the provision of medical social services (See § 110.108(n).)

(xxvii) The methods by which the entity established and operates or will establish and operate its community rating system. Differentials in rates for individuals and groups shall be described. If an applicant plans or has established a separate community rate for separate regional components, evidence as described in § 110.101(l) of this Part shall be submitted. (See §§ 110.101(l); 110.105(a)(3); and 110.106(b).)

(xviii) The methods by which the entity establishes copayment levels in compliance with copayment limitations. (See § 110.105(a)(4)(i) and (ii).)

(2) Documenation as follows:

(i) Written assurances satisfactory to the Secretary that the entity:

(A) Provides and will provide basic and supplemental health services to its members;

(B) Provides and will provide such services in the manner prescribed by section 1301(b) of the Act and Subpart A of this Part;

(C) Is organized and operated, and will continue to be organized and operated, in the manner prescribed by section 1301(c) of the Act and Subpart A of this Part;

(D) Under arrangements which will safeguard the confidentiality of patient information and records, will provide access to the Secretary and the Comptroller General or any of their duly authorized representatives for the purpose of audit, examination or evaluation to any books, documents, papers, and records of the entity relating to its operations as a health maintenance organization, and to any facilities operated by the entity; and

(E) Will continue to comply with any other assurances which the entity has given to the Secretary under §§ 110.203(e); 110.303(b); and 110.403(b) of this Part.

(ii) A copy of each of the following:

(A) Incorporation or chartering documents bearing the date of receipt, registration number, or file designation as

provided by the State or other regulatory body;

(B) Current bylaws or their equivalent; and

(C) Such licenses, certificates, and other evidence of regulatory body approvals as are required under State law. (See § 110.101(a).)

(iii) Organization chart, including the entity's services and administrative components, showing the relationships with providers of health services, contractors for management and risk-taking, and other relevant entities.

(iv) Evidence that the entity has procured and maintains in force a fidelity bond or bonds, in such amount, but not less than $100,000, as may be fixed by its Board of Directors or other policy-making body, covering every officer and employee entrusted with the handling of its funds. The bond may have reasonable deductibles, based upon the financial strength of the entity. (See § 110.108(a)(3).)

(v) Incorporation, partnership, or other organizational documents, and bylaws, for the individual practice association(s) or medical group(s) with which the entity contracts for the delivery of services. If the medical group members have less than 50 percent of their professional activities in the aggregate for health maintenance organization activities, the applicant shall submit a time-phased plan, to which the medical group is committed, to meet this requirement within 3 years from the date the entity is found to be a qualified health maintenance organization. (See §§ 110.104(a); 110.101(i)(1), (2), and (3)(i) and (ii); and 110.101(j)(1).)

(vi) Any contracts between the entity and providers of basic or supplemental health services, i.e., medical groups, individual practice associations, other entities composed of health professionals, or individual health professionals. In addition, a copy of each type of contract between such groups associations, or entities, and the individual health professionals providing services to the entity's members shall be provided. (See § 110.104(a).)

(vii) Contracts between the entity and hospitals, home health agencies, intermediate care facilities, skilled nursing facilities, and other institutional providers of inpatient or outpatient health services and any other contracts or agreements for the provision of basic or supplemental health services. (See §§ 110.102, 110.103; 110.104(a); and 110.108 (i) through (r).)

(viii) Sample copies of current subscriber medical service agreements including each class or group service contract (and member certificate or agreement, if any), conversion contract, individual contract, other benefit packages contract, Medicaid contract, Medicare contract, and Federal Employees Health Benefits Plan contract. (See §§ 110.102; 110.103; 110.105; 110.106; 110.108 (b), (f), (g), and 110.109.)

(ix) Copies of minutes, memoranda, findings, or other records representative of the results of previous proceedings conducted under the procedures established for hearing and resolving grievances between the entity (including the staff of the health maintenance organization, the medical group, and the individual practice association) and the members of the organization. (See § 110.108(l).)

(x) Contracts which the entity or its affiliated groups or associations have with other organizations for management, risk-taking for risks associated with utilization of health services by members, insurance or other arrangements for payment of medically necessary services, malpractice insurance, and enrollment of members. (See § 110.108(b).)

(xi) Evidence of certification of participating providers under Title XVIII or XIX of the Social Security Act, where appropriate. (See § 110.108(k).)

(xii) Financial documents including:

(A) A complete financial statement, including a balance sheet, a statement of income and expenses including available subsidiary detail, and source and use-of-funds statement, for each of the prior 3 fiscal year (or for each year the entity has existed, if the entity has existed for less than 3 years);

(B) A current complete financial statement audited by a certified public accountant;

(C) A copy of projected financial statements for the next 3 years, including an income and expense statement, balance sheet, projected capital expenditures, expected or applied loans with repayment schedules, cash flow schedules, except that applicants for loans or loan guarantees under section 1305 shall provide 5-year projections. (For cash flow schedules, specify assumptions in narrative form.) Projected financial statements must demonstrate consistency among statements;

(D) A financial statement for each medical group or individual practice association with which the entity has contracted for the provision of health services, and for each guarantor of health maintenance organization obligations. Such statements shall include an audited balance sheet and/or commercial rating and, where applicable, a copy of the guarantor letter of support, letter of credit, bond, or loan document; and

(E) Copies of annual reports made by the entity to applicable State regulatory and/or supervisory agencies for the prior 3 years (or for each year the entity has existed, if the entity has existed for less than 3 years). (See § 110.108(a).)

(xiii) Documentation of the organizational arrangements and methods employed in an ongoing quality assurance program for health services provided by the entity, including summary reports of the quality assurance program's operation over the prior 3 years (or such shorter period as the quality assurance program has been in place) which indicate the number and percentage of total cases reviewed and the findings and actions emanating from the reviews. (See § 110.108(j).)

(xiv) Copies of the materials used in the orientation of marketing representatives and in marketing of the plan, for both group and individual open enrollment periods. (See § 110.108(c).)

(xv) Documentation of the procedures and materials used in the member health education and medical social services programs. (See § 110.108(m) and 110.108(n).)

(xvi) Documentation of the entity's health record system, including the methods employed to assure confidentiality of patient records. If the entity arranges for services by providers who do not use the entity's health records, the entity must indicate how it requires providers to assure confidentiality of patient records. (See §§ 110.107(c)(2); 110.101(i)(3)(iii) and (j)(1)(ii)(B); and 110.108(q).)

(xvii) Documentation of the arrangements for continuing education for the entity's health professional staff. (See §§ 110.108(l); 110.101(i)(3)(v) and (j)(1)(ii)(C).)

(xviii) A complete list of all existing group service contracts for health care, including their renewal dates, the premium or dues rates established by the entity for each contract, the basis used to establish the premium or dues rates, the copayment schedule, if any, and the number of individuals and families enrolled. In addition, the entity shall also provide a summary of non-group contracts that indicates by groups or classes of health coverages provided, the number of individuals and families enrolled, the premium or dues rates established for each group or class of non-group contracts, and the basis used to establish the premium or dues rates.

(xix) A report containing the information described in § 110.108(o) of this Part for the current year. (See § 110.108(o).)

(xx) Such other pertinent information as the Secretary may require in the process of evaluating the applicant's compliance with the requirements of Subpart A and applicable sections of the Act.

(c) An application submitted by an entity under §110.603(b) for a determination that it is a transitionally qualified health maintenance organization must provide:

(1) Each of the application elements specified in paragraph (b) of this section, except for the assurances required by paragraph (b)(2)(i) of this section.

(2) The text of the assurances specified in § 110.603(b). (Such assurances need not be executed on behalf of the entity until it has been notified that the application is otherwise approvable. At such time, the applicant must specify the date on which such assurances will be made effective and must execute the assurances accordingly. The Secretary's approval of the application will be effective on the date so specified.)

(3) A time-phased plan which (i) specifies each requirement of section 1301(b) and section 1301(c) of the Act and of the applicable regulations which is not met by the entity at the time of application, (ii) describes the methods by which the entity proposes to meet such requirements within a period not to exceed 3 years from the date of the Secretary's de-

termination of qualification with respect to all members covered by group and non-group contracts in effect on the effective date of the assurances described in paragraph (c)(2) of this section, and (iii) identifies for each existing contract or type of contract described in § 110.604 (b)(2)(xvii), the target date and methods to be employed to achieve full compliance with section 1301 of the Act and Subpart A of this Part.

(d) An application submitted by an entity under § 110.603(c) for a determination that it is a pre-operational qualified health maintenance organization must provide each of the application elements specified in paragraph (b) of this section, except that when the data for specified application elements are unavailable because the entity has not yet put such elements of its program into operation, the entity shall submit information on such application elements in the form of plans. When application elements are submitted in the form of plans, such plans shall include the dates on which the planned elements are expected to be in operation, and the entity shall notify the Secretary of any changes in such plans and dates which are made prior to the Secretary's determination of qualification. In addition, to the extent known, these plans shall incorporate at least:

(1) Names of principal potential group health benefits plan purchasers and their present health plan coverages, including total costs of, and employer contribution to, the existing health benefits plan;

(2) Estimated health maintenance organization enrollment by such group purchasers; and

(3) Rates and health plan coverages proposed by the entity.

§ 110.605 Evaluation and determination of qualification.

(a) The Secretary will evaluate applications submitted under this subpart, and will obtain such additional information as he may require, employing site visits, public hearings or any other procedures determined appropriate by him and will determine whether the applicant meets the appropriate requirements of §§ 110.603 and 110.604 of this subpart, section 1301 of the Act, and Subpart A of this Part.

(b) The Secretary will notify each entity applying for qualification under this subpart of his determination and the basis for such determination, and will publish in the FEDERAL REGISTER the names, addresses and descriptions of the service areas of the newly qualified health maintenance organizations on a monthly basis, and a cumulative list of all qualified health maintenance organizations on an annual basis.

(c) Copies of lists published pursuant to paragraph (b) of this section may be obtained from, and additional information regarding qualified health maintenance organizations will be available for public inspection between the hours of 8:30 a.m. and 5 p.m., Monday through Friday at the Office of the Administrator, Health Services Administration, Department of Health, Education, and Welfare, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20852.

(d) Upon the denial of an application for qualification under this subpart, the Secretary will, in writing, so notify the entity making such application and shall provide such entity a reasonable opportunity for a reconsideration of such determination under paragraph (e) of this section or for a fair hearing under paragraph (f) of this section.

(e) A request for reconsideration shall be submitted in writing, within 60 days following the date of the notification of denial, addressed to the officer or employee of the Department of Health, Education, and Welfare who has denied the application, and shall set forth the grounds upon which such reconsideration is requested, specifying the material issues of fact and of law upon which the applicant relies. Reconsideration will be based upon the record compiled during the qualification review proceedings, materials submitted in support of the request for reconsideration, and other relevant materials available to the Secretary. Written notice of the reconsidered determination will be provided to the entity seeking reconsideration. Such notice shall set forth the basis for the determination and shall inform the entity of its rights to seek a fair hearing under paragraph (f) of this section.

(f) Any entity dissatisfied with an initial determination or a reconsidered determination of its application for qualification under this subpart may, within 60 days following the date of notification of any such determination, request a fair hearing. Such request shall be made in writing and shall specify the material issues of fact upon which it is based. (Note: Pending promulgation of regulations governing fair hearings, applicants requesting a hearing will be provided a copy of applicable procedures.)

Subpart I—Continued Regulations of Health Maintenance Organizations [Reserved]

Subpart J—Fair Hearings [Reserved]

[FR Doc.75-20727 Filed 8-7-75;8:45 am]

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FRIDAY, AUGUST 8, 1975

PART III:

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Office of the Secretary

■

PROTECTION OF HUMAN SUBJECTS

Fetuses, Pregnant Women, and In Vitro Fertilization

Title 45—Public Welfare

SUBTITLE A—DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

PART 46—PROTECTION OF HUMAN SUBJECTS

Fetuses, Pregnant Women, In Vitro Fertilization

Basic regulations governing the protection of human subjects involved in research development, and related activities supported or conducted by the Department through grants and contracts were published in the FEDERAL REGISTER on May 30, 1974 (39 FR 18914).[1] At that time it was indicated that notices of proposed rulemaking would be developed to provide additional protection for subjects of research who may have diminished capacity to provide informed consent. On August 23, 1974, a notice of proposed rulemaking was published for public comment (39 FR 30648) in which it was proposed to amend 45 CFR Part 46 to provide further protective measures for the fetus, the abortus, prisoners, and the institutionalized mentally disabled as subjects of research activities.

On July 12, 1974, the National Research Act (Pub. L. 93-348) was signed into law, thereby creating the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. One of the charges to the Commission was to investigate and study the nature and extent of research involving the living human fetus and to recommend to the Secretary the circumstances (if any) under which such research should be conducted or supported by the Department. Pursuant to section 202(b) of that Act, the Commission has transmitted Recommendations to the Secretary. Pursuant to section 205 of the Act, the Secretary is publishing that Report elsewhere in this issue of the FEDERAL REGISTER.

After considering both the pubic comments to the proposed rulemaking published August 23, 1974, and the Recommendations of the Commission, the Secretary has determined to amend 45 CFR 46 by adding a subpart governing research involving the fetus, the pregnant woman, and products of human *in vitro* fertilization consistent with the public comments and the Recommendations of the Commission. This amendment to the regulations is to be effective immediately. The Secretary, as required by Pub. L. 93-348, section 205, will take into consideration any comments submitted regarding the Recommendations and, if it appears necessary, will propose further rulemaking with respect to any amendments to these regulations which appear warranted.

The Secretary also concludes that the moratorium on fetal research which was imposed by the Department on August 27, 1974 (39 FR 30962) may now be lifted, allowing research to go forward under the regulations issued herewith. The Secretary notes in this regard that the restrictions imposed by section 213 of the National Research Act (Pub. L. 93-348) extended only until the Commission had submitted its Recommendations to the Secretary on May 21, 1975.

Over 125 individuals commented on subpart C (here stated as subpart B) of the proposed rulemaking which pertains to the fetus, the abortus, the pregnant woman, and the products of human *in vitro* fertilization. Those comments, and the Recommendations of the Commission, are summarized as follows:

Applicability. Commenters objected to the applicability of this subpart to "activities involving women who could become pregnant, except where the applicant or offeror shows to the satisfaction of the Secretary that adequate steps will be taken to avoid involvement of women who are pregnant." Concern was expressed that implementation of such a provisions might involve numerous pregnancy tests during the course of an investigation, and still not achieve this goal. The Department notes that although the Commission expressed concern that the fetus not be involved unintentionally in research activities, it did not make a specific recommendation with respect to this. The Department concludes that the Institutional Review Boards should determine whether adequate measures will be taken to avoid unintentional involvement of pregnant women in research activities which are not designed to include pregnant women or the fetus and which might present a risk to a fetus if such existed. Section 46.102(b)(5) of subpart A is therefore amended to add such determinations as one of the duties of the Institutional Review Board.

The notice published August 23, 1974, was limited to biomedical research. That limitation has been removed because, while the Department believes that this subpart applies primarily to biomedical research, other research may be proposed which might fall under the scope of this subpart.

Definitions. The Department has reviewed with care the definitions adopted by the Commission, and determined that those definitions should be incorporated substantially as drafted into the regulations. It should be noted that in so doing, the Department has extended the meaning of the term "fetus" to include the fetus *ex utero* until such time as such a fetus is determined to be viable. The effect of this change is to delete the term "abortus" which appeared in the proposed rulemaking, and refer instead to a fetus *ex utero*. The Department agrees with the Commission that such usage serves the interests of both consistency and clarity, although it may vary at times from legal, medical, or common usage. Also, consistent with the determination discussed above, the definition of "biomedical research" has been dropped.

Ethical advisory boards. A number of respondents expressed concern that an Ethical Advisory Board, as proposed, would be overburdened and would add an unnecessary layer to a review process which is already time consuming. It was also suggested that the Institutional Review Boards can, and in many instances already do, perform at the local level many of the tasks suggested for the Board. On the other hand, some respondents endorsed the proposal as a welcome measure to insure that projects would be stringently reviewed at a national level for ethical considerations prior to receiving support with public monies.

The Commission recommended that a national review body (similar to that proposed by the Department) consider the ethical problems raised by research proposals to which the application of standards enumerated in their recommendations proves difficult.

The Department has considered these suggestions and agrees that whereas the Institutional Review Boards may be able to assume a large share of the ethical review of proposals, it is also true that there will be instances in which the application of standards to specific cases will be difficult or in which review at the national level is desirable. The Department therefore has determined that such an Ethical Advisory Board is necessary to assure that projects supported or conducted by the Department meet ethical standards acceptable to the general community. However, because the nature of the activities may be different and the number of activities requiring review may be large, one Board will be established to provide advice to the Public Health Service and one Board will be established to provide advice to other components of the Department, with respect to policy governing certain kinds of research, and also with respect to the funding of individual proposals which raise ethical problems. While the Boards will propose to the Secretary categories of research which the Board believes either require or do not require their review, research protocols and procedures which involve minimal or no risk, and which clearly conform to the requirements of this subpart, generally need not be reviewed by the Ethical Advisory Board. Research proposals which are judged by agency advisors or staff to require further evaluation of risk or the interpretation of the requirements the Secretary unless the Ethical Advisory Board, or which raise ethical problems, may not be conducted or supported by the Secretary unless the Ethical Advisory Board has reviewed and rendered its advice concerning the research activity. It is intended, ultimately, that a similar requirement for Board review be extended to other classes of research subjects.

A number of comments were received regarding the composition of the Ethical Advisory Board, its duties, or the manner in which it should conduct its meetings. Specifically, the Commission recommended that women and minorities be adequately represented on the Board, and that its deliberations be conducted with full public participation. Many of the suggestions are currently incorporated in regulations governing Federal committee membership and activities. Others will be addressed in the Charter of the Board which the Secre-

[1] These were readopted with minor technical amendments in the FEDERAL REGISTER for March 13, 1975 (40 FR 11854).

tary will publish in the FEDERAL REGISTER at a later date.

Establishment of a consent committee. Although there was general agreement among commenters that provisions should be made to monitor conditions surrounding the consent process, there was criticism of the proposal to create separate committees to perform this function. For the most part, it was felt that the Institutional Review Boards could and should perform this function as part of continuing responsibility for the protection of human subjects. It was further suggested that additional panels should not be created unless the Department has evidence that the necessary functions could not be performed by the Institutional Review Boards or other existing committees.

The Commission noted that it will be undertaking a study, as part of its mandate under Pub. L. 93-348, of the effectiveness of Institutional Review Boards in implementing DHEW regulations for the protection of human subjects. It recommended that until the study is completed, the responsibility for monitoring the consent process should be assumed by the Institutional Review Boards. The Department agrees. The provisions for creating Consent Committees have therefore been deleted, and the duties delegated to them in the proposed rulemaking have been given to the Institutional Review Boards. This is reflected in § 46.205, titled "Additional duties of the Institutional Review Boards in connection with activities involving fetuses, pregnant women, or human *in vitro* fertilization."

The Department received a number of criticisms regarding the provision that the Consent Committee be authorized to terminate the participation of subjects without their consent (§ 46.305(a)(2) of the proposed rulemaking). It was argued that this would be an unwarranted infringement of an individual's right to consent. The Department agrees, and such authority has been deleted.

Research involving in vitro fertilization. Commenters generally endorsed the Department's proposal not to regulate research involving human *in vitro* fertilization other than to require that all proposals involving such research be reviewed for approval by the Ethical Advisory Board. The Commission did not make any recommendation concerning this category of research in the report submitted on May 21. The Department therefore makes no change from the proposed rulemaking with respect to research involving *in vitro* fertilization. The requirement that all such proposals be reviewed by the Ethical Advisory Board, as well as by the Institutional Review Board, appears in §§ 46.204(c) and 46.205 respectively.

Because biomedical research is not yet near the point of being able to maintain for a substantial period the non-implanted product of *in vitro* fertilization, these regulations do not address this point. Given the state of the research, we believe that regulations would be premature. However, the Department anticipates that such a regulation will be prepared when the state of biomedical science so warrants.

Activities involving fetuses in utero or pregnant women. A number of commenters suggested that the rulemaking, as proposed, would hamper research necessary to meet the health needs of pregnant women, fetuses, and neonates. The most frequent references were to studies on placental transfer, the normal course of pregnancy, and the delivery process. Some individuals objected to the prohibition of research prior to the commencement of a procedure to terminate pregnancy, while others objected to any conduct of research even during the process of abortion.

The Commission, in its Recommendations, separated that category of research directed toward the pregnant woman from that directed toward the fetus *in utero*. It further distinguished between therapeutic research and nontherapeutic research, finding therapeutic research to be generally acceptable and desirable, whether directed toward the fetus or the pregnant woman, provided certain specified preconditions are met. The Department agrees that it is useful to distinguish between the fetus *in utero* and the pregnant woman as the primary subject of a research activity and also that research directed at meeting the health needs of the subject is generally acceptable provided certain conditions are met. The regulations therefore address these topics in separate sections.

A. *General limitations.* There were no substantive objections to the intent of restrictions which appeared in various parts of the proposed rulemaking pertaining to: (1) the necessary completion of appropriate animal studies; or (2) the separation of research personnel from decisions regarding the timing or method of terminating pregnancy or regarding the viability of a delivered fetus. Some commenters, and the Commission, recommended the addition of appropriate studies on nonpregnant humans as a prerequisite for research activities covered by this subpart. The Commission further recommended that there should be no significant changes introduced into a delivery procedure solely in the interests of research. The Department has incorporated these provisions in a section titled "General limitations" (§ 46.206) which governs all research activities covered by this subpart.

B. *Activities directed toward pregnant women as subjects.* As noted above, there was little objection from commenters on from the Commission regarding research directed toward the health needs of the pregnant woman. In fact, some respondents urged that care be taken not to infringe the woman's right to privacy and her access to health care. With respect to women's rights, a number of individuals objected to the provision requiring consent other than that of the pregnant woman for research directed toward the health needs of the pregnant woman, and some objected to such consent provisions even when the woman would be participating in nontherapeutic research activities.

The Commission considered that the woman's right to health care is preeminent, and recommended essentially no restrictions on research directed toward the health care of the pregnant woman, so long as the risks to her fetus are minimized as much as possible consistent with meeting her health needs, and provided that she is fully advised of the risks to herself and her fetus. In addition, the general provisions for prerequisite research and for adequate review and supervision of the consent process should be met. The Department agrees.

With respect to research directed toward the pregnant woman but which is not directed toward her health care, there seems to be general agreement that such research should be permitted only if it imposes minimal or no risk to the fetus. There is disagreement among the commenters with respect to paternal consent for this category of research. The Department has considered with care the various arguments with respect to consent other than the pregnant woman's for nontherapeutic research involving the pregnant woman, and concludes that such consent should be obtained except where such research involves the health needs of the woman.

In general, women who are victims of rape are not appropriate subjects for nontherapeutic research. There are some instances, however, in which their participation may be sought (as in studies concerning the effects of rape.) Consent other than hers is not necessary in such cases.

It should be noted in this regard that the Commission, in a number of instances, recommended that research be permitted if the mother has consented and the father has not objected. The Department has concluded that implementation of a provision for absence of objection might present serious problems. Since the absence of objection can best be verified by requesting consent, the Department has retained the requirement for paternal consent when the father's identity and whereabouts can reasonably be ascertained, and if he is reasonably available.

C. *Activities directed towards fetuses in utero as subjects.* No comments were received which expressed objections to the conduct of research activities directed toward the health care of the fetus *in utero*. Rather, the Department was urged not to restrict, and even to encourage, such research.

On the other hand, there was considerable division of opinion regarding research directed toward the fetus which is not related to its health care. Concern was expressed that the fetus might be used as an experimental "object," in a manner inconsistent with its human genetic heritage. This is particularly true when termination of pregnancy is a factor in the research, as in protocols designed to determine the effect on the fetus of drugs administered to a pregnant woman. Questions were raised regarding the ethical validity of consent by a pregnant woman on behalf of a fetus, for its inclusion in a research activity of no benefit to that fetus, especially if the

woman has already decided to terminate her pregnancy.

The Department is sensitive to these concerns. It has reviewed the Recommendations of the Commission regarding this category of research, and is persuaded that those recommendations are sound; namely, that no research be conducted or supported which fails to treat the fetus with proper care and dignity. In addition, the Department agrees that a pregnant woman need not be presumed to lack interest in her fetus even when she has decided to terminate her pregnancy; thus, she may validly be asked for consent for research involving the fetus.

The Department notes that the Commission was created to represent the best judgment of the community, and to make recommendations following an intensive study of the issues. All of the arguments which were submitted to the Department were considered by the Commission in its deliberations, and it is therefore reasonable to accept the findings of the Commission as the best possible judgment on the matter. The Department concludes that the Recommendations of the Commission with respect to research involving the fetus *in utero* should be adopted. These are incorporated in the regulations in § 46.208, with modifications, as noted above, in the provisions for paternal consent.

Activities directed toward fetuses ex utero as subjects. Although some commenters suggested that no research be permitted on the fetus *ex utero*, others were concerned that the proposed rulemaking was too restrictive, and would preclude the development of technology for sustaining premature infants. The Commission recommended that no procedures be applied to a nonviable fetus *ex utero* which would alter its duration of life. It further recommended that if the fetus might possibly be viable, but has not yet been determined to be so, no additional risk to the well-being of that fetus should be imposed by research. It is expected that no procedures will be undertaken which fail to treat the fetus with due care and dignity, or which affront community sensibilities. Further, it is required that if a delivered fetus is determined to be viable, it will be treated as a premature infant, and may be included in research activities according to the regulations to be proposed governing the participation of children in research.

For the reasons stated above, the Department has concluded that the Recommendations of the Commission regarding research on the fetus *ex utero* should be adopted, for the most part. These are incorporated in § 46.209 of the regulations with modifications, as noted above, in the provisions for paternal consent. However, the Secretary is persuaded by the weight of scientific evidence that research performed on the nonviable fetus *ex utero* has contributed substantially to the ability of physicians to bring to viability increasingly small fetuses. The Secretary perceives that it is in the public interest to continue this successful research and accordingly an exception is made to the Recommendations of the Commission to permit research to develop new methods for enabling fetuses to survive to the point of viability.

Activities involving the dead fetus, fetal material, or the placenta. The Department notes, as did the Commission, that research involving the dead fetus and fetal material is governed in part by the Uniform Anatomical Gift Act which has been adopted by 49 States, the District of Columbia and Puerto Rico. There were no substantive recommendations concerning this section, and the regulation therefore differs from the proposed rulemaking only with respect to minor additions for clarification. Any applicable State or local laws regarding such activities are, of course, controlling.

Activities to be performed outside the United States. Consistent with the Commission's Recommendations, § 46.210 of the proposed rulemaking has been deleted, thereby making these regulations applicable to all research conducted or supported by the Department within the United States or abroad.

Modification or waiver of specific requirements. Recognizing the difficulty of applying a specific set of regulations to all situations that may arise in the future, the Department has elected to provide a mechanism for waiver or modification of specific provisions under certain circumstances. Requests from an applicant or offeror for such a waiver or modification must be reviewed by the appropriate Ethical Advisory Board, which after opportunity for public input, shall advise the Secretary as to whether or not the request should be approved. These Boards will conform to the operating procedures required by the Federal Advisory Committee Act.

Activities conducted by departmental employees. In order to make it clear that the requirements of these regulations (Part 46) apply to activities conducted by its own employees, the Department is adding subpart C titled "Activities Conducted by Departmental Employees" as § 46.301.

The moratorium on fetal research imposed on August 27, 1974, is hereby lifted, but such research will be conducted or supported by the Department only in accordance with the following regulations.

Written comments concerning the Recommendations of the Commission may be sent to the Office of Protection from Research Risks, National Institutes of Health, 9000 Rockville Pike, Bethesda, Maryland 20014. All comments received will be available for inspection at the National Institutes of Health, Room 303, Westwood Building, 5333 Westbard Avenue, Bethesda, Maryland, weekdays (Federal holidays excepted) between the hours of 9 a.m. and 4:30.

These regulations shall become effective on August 8, 1975.

Date: July 17, 1975.

THEODORE COOPER,
Assistant Secretary for Health.

Approved: July 29, 1975.

CASPAR W. WEINBERGER,
Secretary.

Accordingly Part 46 of 45 CFR Subtitle A is amended by:

§§ 46.101–46.122 [Redesignated]

1. Designating §§ 46.1 through 46.22 as Subpart A, renumbering these as §§ 46.101 through 46.122, and modifying all references thereto accordingly.

§ 46.102 [Amended]

2. Adding the word "and" at the end of § 46.102(b)(2), changing the semicolon at the end of § 46.102(b)(3) to a period, and deleting § 46.102(b)(4).

3. Redesignating § 46.102(c) as § 46.102(e) and inserting the following new §§ 46.102(c) and 46.102(d):

§ 46.102 Policy.

* * * * *

(c) Unless the activity is covered by Subpart B of this Part, if it involves as subjects women who could become pregnant, the Board shall also determine as part of its review that adequate steps will be taken in the conduct of the activity to avoid involvement of women who are in fact pregnant, when such activity would involve risk to a fetus.

(d) Where the Board finds risk is involved under paragraph (b) of this section, it shall review the conduct of the activity at timely intervals.

* * * * *

4. Adding the following new Subparts B and C.

Subpart B—Additional Protections Pertaining to Research, Development, and Related Activities Involving Fetuses, Pregnant Women, and Human In Vitro Fertilization

Sec.
46.201 Applicability.
46.202 Purpose.
46.203 Definitions.
46.204 Ethical Advisory Boards.
46.205 Additional duties of the Institutional Review Boards in connection with activities involving fetuses, pregnant women, or human in vitro fertilization.
46.206 General limitations.
46.207 Activities directed toward pregnant women as subjects.
46.208 Activities directed toward fetuses in utero as subjects.
46.209 Activities directed toward fetuses ex utero, including nonviable fetuses, as subjects.
46.210 Activities involving the dead fetus, fetal material, or the placenta.
46.211 Modification or waiver of specific requirements.

Subpart C—General Provisions

Sec.
46.301 Activities conducted by Department employees.

AUTHORITY: 5 U.S.C. 301.

Subpart B—Additional Protections Pertaining to Research, Development, and Related Activities Involving Fetuses, Pregnant Women, and Human In Vitro Fertilization

§ 46.201 Applicability.

(a) The regulations in this subpart are applicable to all Department of Health, Education, and Welfare grants and contracts supporting research, development, and related activities involving: (1) The fetus, (2) pregnant women, and (3) human *in vitro* fertilization.

(b) Nothing in this subpart shall be construed as indicating that compliance

with the procedures set forth herein will in any way render inapplicable pertinent State or local laws bearing upon activities covered by this subpart.

(c) The requirements of this subpart are in addition to those imposed under the other subparts of this part.

§ 46.202 Purpose.

It is the purpose of this subpart to provide additional safeguards in reviewing activities to which this subpart is applicable to assure that they conform to appropriate ethical standards and relate to important societal needs.

§ 46.203 Definitions.

As used in this subpart:

(a) "Secretary" means the Secretary of Health, Education, and Welfare and any other officer or employee of the Department of Health, Education, and Welfare to whom authority has been delegated.

(b) "Pregnancy" encompasses the period of time from confirmation of implantation until expulsion or extraction of the fetus.

(c) "Fetus" means the product of conception from the time of implantation until a determination is made, following expulsion or extraction of the fetus, that it is viable.

(d) "Viable" as it pertains to the fetus means being able, after either spontaneous or induced delivery, to survive (given the benefit of available medical therapy) to the point of independently maintaining heart beat and respiration. The Secretary may from time to time, taking into account medical advances, publish in the FEDERAL REGISTER guidelines to assist in determining whether a fetus is viable for purposes of this subpart. If a fetus is viable after delivery, it is a premature infant.

(e) "Nonviable fetus" means a fetus *ex utero* which, although living, is not viable.

(f) "Dead fetus" means a fetus *ex utero* which exhibits neither heartbeat, spontaneous respiratory activity, spontaneous movement of voluntary muscles, nor pulsation of the umbilical cord (if still attached).

(g) "*In vitro* fertilization" means any fertilization of human ova which occurs outside the body of a female, either through admixture of donor human sperm and ova or by any other means.

§ 46.204 Ethical Advisory Boards.

(a) Two Ethical Advisory Boards shall be established by the Secretary. Members of these Boards shall be so selected that the Boards will be competent to deal with medical, legal, social, ethical, and related issues and may include, for example, research scientists, physicians, psychologists, sociologists, educators, lawyers, and ethicists, as well as representatives of the general public. No board member may be a regular, full-time employee of the Federal Government.

(b) One Board shall be advisory to the Public Health Service and its components. One Board shall be advisory to all other agencies and components within the Department of Health, Education, and Welfare.

(c) At the request of the Secretary, the appropriate Ethical Advisory Board shall render advice consistent with the policies and requirements of this Part as to ethical issues, involving activities covered by this subpart, raised by individual applications or proposals. In addition, upon request by the Secretary, the appropriate Board shall render advice as to classes of applications or proposals and general policies, guidelines, and procedures.

(d) A Board may establish, with the approval of the Secretary, classes of applications or proposals which: (1) Must be submitted to the Board, or (2) need not be submitted to the Board. Where the Board so establishes a class of applications or proposals which must be submitted, no application or proposal within the class may be funded by the Department or any component thereof until the application or proposal has been reviewed by the Board and the Board has rendered advice as to its acceptability from an ethical standpoint.

(e) No application or proposal involving human *in vitro* fertilization may be funded by the Department or any component thereof until the application or proposal has been reviewed by the Ethical Advisory Board and the Board has rendered advice as to its acceptability from an ethical standpoint.

§ 46.205 Additional duties of the Institutional Review Boards in connection with activities involving fetuses, pregnant women, or human in vitro fertilization.

(a) In addition to the responsibilities prescribed for Institutional Review Boards under Subpart A of this part, the applicant's or offeror's Board shall, with respect to activities covered by this subpart, carry out the following additional duties:

(1) Determine that all aspects of the activity meet the requirements of this subpart;

(2) Determine that adequate consideration has been given to the manner in which potential subjects will be selected, and adequate provision has been made by the applicant or offeror for monitoring the actual informed consent process (e.g., through such mechanisms, when appropriate, as participation by the Institutional Review Board or subject advocates in: (i) Overseeing the actual process by which individual consents required by this subpart are secured either by approving induction of each individual into the activity or verifying, perhaps through sampling, that approved procedures for induction of individuals into the activity are being followed, and (ii) monitoring the progress of the activity and intervening as necessary through such steps as visits to the activity site and continuing evaluation to determine if any unanticipated risks have arisen);

(3) Carry out such other responsibilities as may be assigned by the Secretary.

(b) No award may be issued until the applicant or offeror has certified to the Secretary that the Institutional Review Board has made the determinations required under paragraph (a) of this section and the Secretary has approved these determinations, as provided in § 46.115 of Subpart A of this part.

(c) Applicants or offerors seeking support for activities covered by this subpart must provide for the designation of an Institutional Review Board, subject to approval by the Secretary, where no such Board has been established under Subpart A of this part.

§ 46.206 General limitations.

(a) No activity to which this subpart is applicable may be undertaken unless:

(1) Appropriate studies on animals and nonpregnant individuals have been completed;

(2) Except where the purpose of the activity is to meet the health needs of the particular fetus, the risk to the fetus is minimal and, in all cases, is the least possible risk for achieving the objectives of the activity;

(3) Individuals engaged in the activity will have no part in: (i) Any decisions as to the timing, method, and procedures used to terminate the pregnancy, and (ii) determining the viability of the fetus at the termination of the pregnancy; and

(4) No procedural changes which may cause greater than minimal risk to the fetus or the pregnant woman will be introduced into the procedure for terminating the pregnancy solely in the interest of the activity.

(b) No inducements, monetary or otherwise, may be offered to terminate pregnancy for purposes of the activity.

§ 46.207 Activities directed toward pregnant women as subjects.

(a) No pregnant woman may be involved as a subject in an activity covered by this subpart unless: (1) The purpose of the activity is to meet the health needs of the mother and the fetus will be placed at risk only to the minimum extent necessary to meet such needs, or (2) the risk to the fetus is minimal.

(b) An activity permitted under paragraph (a) of this section may be conducted only if the mother and father are legally competent and have given their informed consent after having been fully informed regarding possible impact on the fetus, except that the father's informed consent need not be secured if: (1) The purpose of the activity is to meet the health needs of the mother; (2) his identity or whereabouts cannot reasonably be ascertained; (3) he is not reasonably available; or (4) the pregnancy resulted from rape.

§ 46.208 Activities directed toward fetuses in utero as subjects.

(a) No fetus *in utero* may be involved as a subject in any activity covered by this subpart unless: (1) The purpose of the activity is to meet the health needs of the particular fetus and the fetus will be placed at risk only to the minimum extent necessary to meet such needs, or (2) the risk to the fetus imposed by the re-

search is minimal and the purpose of the activity is the development of important biomedical knowledge which cannot be obtained by other means.

(b) An activity permitted under paragraph (a) of this section may be conducted only if the mother and father are legally competent and have given their informed consent, except that the father's consent need not be secured if: (1) His identity or whereabouts cannot reasonably be ascertained, (2) he is not reasonably available, or (3) the pregnancy resulted from rape.

§ 46.209 Activities directed toward fetuses ex utero, including nonviable fetuses, as subjects.

(a) No fetus *ex utero* may be involved as a subject in an activity covered by this subpart until it has been ascertained whether the particular fetus is viable, unless: (1) There will be no added risk to the fetus resulting from the activity, and (2) the purpose of the activity is the development of important biomedical knowledge which cannot be obtained by other means.

(b) No nonviable fetus may be involved as a subject in an activity covered by this subpart unless: (1) Vital functions of the fetus will not be artificially maintained except where the purpose of the activity is to develop new methods for enabling fetuses to survive to the point of viability, (2) experimental activities which of themselves would terminate the heartbeat or respiration of the fetus will not be employed, and (3) the purpose of the activity is the development of important biomedical knowledge which cannot be obtained by other means.

(c) In the event the fetus *ex utero* is found to be viable, it may be included as a subject in the activity only to the extent permitted by and in accordance with the requirements of other subparts of this part.

(d) An activity permitted under paragraph (a) or (b) of this section may be conducted only if the mother and father are legally competent and have given their informed consent, except that the father's informed consent need not be secured if: (1) his identity or whereabouts cannot reasonably be ascertained, (2) he is not reasonably available, or (3) the pregnancy resulted from rape.

§ 46.210 Activities involving the dead fetus, fetal material, or the placenta.

Activities involving the dead fetus, mascerated fetal material, or cells, tissue, or organs excised from a dead fetus shall be conducted only in accordance with any applicable State or local laws regarding such activities.

§ 46.211 Modification or waiver of specific requirements.

Upon the request of an applicant or offeror (with the approval of its Institutional Review Board), the Secretary may modify or waive specific requirements of this subpart, with the approval of the Ethical Advisory Board after such opportunity for public comment as the Ethical Advisory Board considers appropriate in the particular instance. In making such decisions, the Secretary will consider whether the risks to the subject are so outweighed by the sum of the benefit to the subject and the importance of the knowledge to be gained as to warrant such modification or waiver and that such benefits cannot be gained except through a modification or waiver. Any such modifications or waivers will be published as notices in the FEDERAL REGISTER.

Subpart C—General Provisions

§ 46.301 Activities conducted by Department employees.

The regulations of this part are applicable as well to all research, development, and related activities conducted by employees of the Department of Health, Education, and Welfare, except that each Principal Operating Component head may adopt such non-substantive procedural modifications as may be appropriate from an administrative standpoint.

THE NATIONAL COMMISSION FOR THE PROTECTION OF HUMAN SUBJECTS OF BIOMEDICAL AND BEHAVIORAL RESEARCH

RESEARCH ON THE FETUS

Report and Recommendations

MAY 21, 1975.

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I. THE MANDATE

The National Research Act (Pub. L. 93-348) established the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research and gave the Commission a mandate to investigate and study research involving the living fetus, and to recommend whether and under what circumstances such research should be conducted or supported by the Department of Health, Education, and Welfare. A deadline of four months after the members of the Commission took office was imposed for the Commission to conduct its study and make recommendations to the Secretary, DHEW. The priority assigned by Congress to research involving the fetus indicates the concern that unconscionable acts involving the fetus may have been performed in the name of scientific inquiry, with only proxy consent on behalf of the fetus.

The members of the Commission determined at the outset to undertake a careful study of the nature and extent of research on the fetus, the range of views on the ethical acceptability of such research, and the legal issues involved, prior to formulating their recommendations. To this end, the Commission has accumulated an extensive body of information, held public hearings, questioned a panel of distinguished ethicists, and conducted lengthy deliberations. In the course of these activities, the Commission has given close scrutiny to many important questions that surround research on the fetus, for example: What are the purposes of research on the fetus? What procedures have been employed in such research? Are there alternatives to such research? Can appropriate consent to such research be obtained by proxy? Under what conditions may research be done on a fetus that is to be aborted, or a nonviable delivered fetus? What review of proposed research should be required?

In the remainder of Section I, the background and activities of the Commission are summarized, and the definitions used in this report are set forth. Reports, papers and testimony that were prepared for or presented to the Commission are summarized in Sections II

to VII of this report. The Commission's own statement of its deliberations and conclusions appears in Section VIII, and the recommendations themselves are set forth in Section IX, together with a statement by a member of the Commission dissenting in part from the recommendations. Separate views of members of the Commission are set forth in Section X.

The Appendix to the report contains the entire text of the papers and reports that were prepared under contract to the Commission, and certain other materials that were reviewed by the Commission during its deliberations.

Legislative background. The National Research Act contains two provisions regarding research on the fetus: (1) the mandate to the Commission to conduct studies and make recommendations to the Secretary, DHEW (section 202(b)), and (2) a prohibition, in effect until the Commission has made recommendation, on "research [conducted or supported by DHEW] in the United States or abroad on a living human fetus, before or after the induced abortion of such fetus, unless such research is done for the purpose of assuring the survival of such fetus" (section 213). These two provisions were drafted by a conference committee that resolved the differences between the acts originally passed in 1973 by the House of Representatives and Senate, respectively.

The original House act contained a prohibition against the conduct or support by DHEW of research that would violate any ethical standard adopted by the National Institutes of Health or the National Institute of Mental Health. This provision was preceived as a prohibition of research on the living fetus, as a result of policy then in force at NIH. In addition, both the House and Senate acts contained floor amendments explicitly prohibiting the conduct or support of research on the fetus by DHEW. The House amendment, adopted by a vote of 354 to 9, proscribed research on a fetus that is outside the uterus and has a beating heart, while the Senate prohibition applied to research in connection with an abortion. Among other differences between the acts, the House prohibitions were permanent, while the Senate prohibition was temporary. The conference committee applies to research conducted imposing a moratorium until this Commission made recommendations. The moratorium adopted by the conference committee applies to research conducted on a fetus before or after an induced abortion of the fetus (except to assure the survival of the fetus); the mandate for the Commission's study and recommendations applies more generally to research involving the living fetus.

The Commission has reviewed the committee reports (Nos. 93-244, 93-381, and 93-1148), and the record of the floor debate that led to the passage of the National Research Act (*Congressional Record*, daily eds. May 31, 1973; September 11, 1973; June 27 and 28, 1974). Other legislative materials that have been reviewed include the Hearings on Biomedical Research Ethics and the Protection of Human Subjects, before the House Subcommittee on Public Health and Environment (September 27 and 28, 1973), and the Hearing on Fetal Research before the Senate Subcommittee on Health (July 19, 1974).

It is clear from the legislative history that the National Research Act, as passed by both Houses and signed into law by President Nixon on July 12, 1974, reflects an acknowledgement by the majority of legislators that the issues surrounding research on the fetus require much study and deliberation before policies are established regarding support by the Secretary, DHEW. That assignment was given to the Commission, and this report describes how the assignment was carried out and the conclusions that were reached.

Existing codes and other relevant material. To assist its deliberations, the Commission referred to the following pre-existing codes and other materials relating to human experimentation:

1. *The Nuremberg Code* (1946-1949).
2. *The Declaration of Helsinki* (revised, 1964).
3. *The Use of Fetuses and Fetal Material for Research*, Report of the Advisory Group, chaired by Sir John Peel (London, 1972).
4. *Protection of Human Subjects: Policies and Procedures*, draft document of the Department of Health, Education, and Welfare (38 FEDERAL REGISTER No. 221, Part II, November 16, 1973).
5. *Protection of Human Subjects: Proposed Policy*, Department of Health, Education, and Welfare (39 FEDERAL REGISTER No. 165, Part III, August 23, 1974).

(The above documents are included in the Appendix to this report.)

Meetings of the Commission. Secretary Weinberger administered the oath of office to the members of the Commission on December 3, 1974, thereby fixing the deadline for this report. Section 202(b) of the National Research Act requires that recommendations of the Commission with respect to research on the living fetus be transmitted to the Secretary "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 members of the Commission have taken office." This 4-month period expired April 30, 1975.

The Commission conducted seven meetings devoted primarily to the topic of research on the fetus. These meetings were well attended by the public. One day of the February meeting was devoted to a public hearing of the views of persons interested in research on the fetus; oral testimony was given by 23 witnesses, some representing research, religious or other organizations and some appearing as concerned citizens to express their viewpoints (see Section VI for summaries of the views presented). At the March meeting, three public officials testified about the involvement of their respective agencies or offices in research on the fetus (see Section VI), and the members of the Commission held a roundtable discussion with several ethicists who had prepared papers covering a wide spectrum of secular opinion and religious persuasion (see Section V for summaries of these papers).

Studies and investigations. The Commission contracted for a number of studies and investigations. These included a study, undertaken primarily through review of the literature, of the nature, extent and purposes of research on the fetus, conducted under contract with Yale University (see Section II); an historical study of the role of research involving living fetuses in certain advances in medical science and practice, conducted under contract with Battelle Columbus Laboratories (see Section III); and a study utilizing available data to establish guidelines for determining fetal viability and death, conducted under contract with Columbia University (see Section VII).

In addition to these studies, papers outlining their views on research on the fetus were prepared by the following ethicists and philosophers: Sissela Bok of Harvard University; Joseph Fletcher of the Institute of Religion and Human Development; Marc Lappé of the Hastings Institute of Society, Ethics, and the Life Sciences; Richard McCormick and LeRoy Walters of the Kennedy Institute for the Study of Human Reproduction and Bioethics; Paul Ramsey of Princeton University; Seymour Siegel of the Jewish Theological Seminary; and Richard Wasserstrom of the University of California at Los Angeles (see Section V). Stephen Toulmin, of the University of Chicago, prepared an analysis of the ethical views that were presented to the Commission, identifying areas of consensus as well as divergence. Leon Kass, of Georgetown University, prepared a philosophical paper on the determination of fetal viability and death (see Section VII). Papers on the legal issues of research on the fetus were prepared by Alexander M. Capron, of the University of Pennsylvania Law School, and John P. Wilson, of Boston University Law School (see Section IV).

(All of the above studies, investigations and papers appear in the Appendix.)

Definitions. For the purposes of this report, the Commission has used the following definitions which, in some instances, differ from medical, legal or common usage. These definitions have been adopted in the interest of clarity and to conform to the language used in the legislative mandate.

"Fetus" refers to the human from the time of implantation until a determination is made following delivery that it is viable or possibly viable. If it is viable or possibly viable, it is thereupon designated an infant. (Hereafter, the term "fetus" will refer to a living fetus unless otherwise specified.)

"Viable infant" refers to an infant likely to survive to the point of sustaining life independently, given the support of available medical technology. This judgment is made by a physician.

"Possibly viable infant" means the fetus *ex utero* which has not yet been determined to be viable or nonviable. This is

a decision to be made by a physician. Operationally, the physician may consider that an infant with a gestational age of 20 to 24 weeks (five to six lunar months; four and one-half to five and one-half calendar months) and a weight between 500 to 600 grams may fall into this indeterminate category. These indices depend upon present technology and should be reviewed periodically.

"Nonviable fetus" refers to the fetus *ex utero* which, although it is living, cannot possibly survive to the point of sustaining life independently, given the support of available medical technology. Although it may be presumed that a fetus is nonviable at a gestational age less than 20 weeks (five lunar months; four and one-half calendar months) and weight less than 500 grams, a specific determination as to viability must be made by a physician in each instance. The Commission is not aware of any well-documented instances of survival of infants of less than 24 weeks (six lunar months; five and one-half calendar months) gestational age and weighing less than 600 grams; it has chosen lower indices to provide a margin of safety. These indices depend upon present technology and should be reviewed periodically.

"Dead fetus" ex utero refers to a fetus *ex utero* which exhibits neither heartbeat, spontaneous respiratory activity, spontaneous movement of voluntary muscles, or pulsation of umbilical cord (if still attached). Generally, some organs, tissues and cells (referred to collectively as fetal tissue) remain alive for varying periods of time after the total organism is dead.

"Fetal material" refers to the placenta, amniotic fluid, fetal membranes and the umbilical cord.

"Research" refers to the systematic collection of data or observations in accordance with a designed protocol.

"Therapeutic research" refers to research designed to improve the health condition of the research subject by prophylactic, diagnostic or treatment methods that depart from standard medical practice but hold out a reasonable expectation of success.

"Nontherapeutic research" refers to research not designed to improve the health condition of the research subject by prophylactic, diagnostic or treatment methods.

II. The Nature and Extent of Research Involving the Fetus and the Purposes for Which Such Research Has Been Undertaken

An extensive review of the scientific literature, focusing on a period covering the last 10 years, formed the basis for the Commission's investigation of the nature, extent and purposes of research on the fetus. The review was conducted under contract with Yale University, Maurice J. Mahoney, M.D., Principal Investigator. The investigation included an all-language review of published research, utilizing the MEDLARS computer indexing and search system of the National Library of Medicine, a review of selected bibliographies and abstracts, a survey of departments of pediatrics and obstetrics at medical schools in the United States and Canada to identify current research on the fetus, and a review of NIH grant applications and contracts since 1972 involving research on the fetus. In addition, the Food and Drug Administration provided information on fetal research conducted in fulfillment of its regulations.

For the purpose of summarizing the review, research involving the fetus has been considered in four general categories.

1. *Assessment of fetal growth and development in utero.* Over 600 publications dealing with investigations of fetal development and physiology were identified. In general, the purpose of these investigations was to obtain information on normal developmental processes, as a basis for detecting and understanding abnormal processes and ultimately treating the fetal patient. To this end, numerous experimental approaches were employed.

Studies of normal fetal growth relied primarily on anatomic studies of the dead fetus. Studies of fetal physiology involved both the fetus *in utero* and organs and tissues removed from the dead fetus. In some instances, this research required administration of a substance to the mother prior to an abortion or delivery by caesarean section, followed by analysis to detect the presence of the substance or its metabolic effects in blood from the umbilical cord or in tissues from the dead fetus. Information on the normal volume of amniotic fluid at various stages of pregnancy was obtained by injecting a substance into the fluid and assessing the degree of dilution of that substance; these studies were performed before abortion, during management of disease states (Rh disease), and in normal term pregnancies. Similarly, numerous chemicals were measured in amniotic fluid to establish normal data.

Research also focused on the development of fetal behavior *in utero.* Fetal breathing movements were detected by ultrasound as early as 13 weeks after conception. Fetal hearing was documented by demonstrating changes in fetal heart rate or EEG in response to sound transmitted through the mother's abdomen. Vision was inferred from changes in fetal heart rate in response to light shined transabdominally. Increased rates of fetal swallowing after injection of saccharin into amniotic fluid suggested the presence of fetal taste capability. Observation of the fetus outside the uterus indicated response to touch at 7 weeks and the presence of swallowing movements at 12 weeks of gestation.

2. *Diagnosis of fetal disease or abnormality.* Well over 1000 papers have been published in the last 10 years dealing with intrauterine diagnosis of fetal disease or abnormality. Much of this research involved amniocentesis, a procedure in which a needle is inserted through the mother's abdomen into the uterus and amniotic fluid is removed for analysis. Amniocentesis originally came into extensive use for monitoring the status of the fetus affected by Rh disease in the third trimester of pregnancy. Research related to treating Rh disease indicated that the yellow color of the amniotic fluid correlated with the severity of anemia in the fetus. This color index later was used as an indication of the need for intrauterine transfusion, a procedure subsequently developed to treat severely affected infants.

The knowledge that amniocentesis was safe in the third trimester of pregnancy, coupled with the demonstration that cells shed from the skin of the fetus into the amniotic fluid could be grown in tissue culture, led to application of amniocentesis to detection of genetic disease in the second trimester. The research conducted in developing this procedure focused first on demonstrating in fetal cells from amniotic fluid the normal values for enzymes known to be defective in genetic disease. The research was conducted largely on amniotic fluid samples withdrawn as a routine part of the procedure of inducing abortion. Once it had been demonstrated that the enzyme was expressed in fetal cells and normal values were known, application to diagnosis of the abnormal condition in the fetus at risk was undertaken. The reported research documents a steady progression in development and application of amniocentesis, so that potentially over 60 inborn errors of metabolism (such as Tay-Sachs disease) and virtually all chromosome abnormalities (such as Down's syndrome), as well as the lack of these defects in the fetus at risk, can be diagnosed *in utero*, at a time when the mother can elect therapeutic abortion of an affected fetus.

Research directed at prenatal diagnosis of disease currently focuses on three main objectives. The first involves attempts to extend diagnostic capability to additional diseases, such as cystic fibrosis of the pancreas, which cannot now be detected by amniocentesis. A second approach attempts to detect fetal cells in the maternal circulation and separate these from maternal cells for chemical analysis, thus avoiding any risks and difficulties encountered during amniocentesis. The third direction is the development of fetoscopy, a process by which an instrument is inserted into the uterus and a sample of fetal blood is obtained from the placenta under direct visualization. The blood sample is analyzed to diagnose disorders such as sickle cell disease or thalassemia which cannot be detected by amniocentesis. The time needed for laboratory analysis following fetoscopy is markedly shorter than the four to six weeks required to obtain tissue culture results in amniocentesis. Fetoscopy also permits visual examination of the fetus for external physical defects.

Because of the unknown but theoretically significant risks that remained following animal studies, fetoscopy was developed selectively in women undergoing elective abortion. The first clinical applications have been reported in recent months: three fetuses at risk for beta-thalassemia, whose mothers were seeking abortion to avoid the possibility of having

an affected child, were diagnosed as free of disease following fetoscopy. All three have been born and are normal.

Research has also been directed at the identification of physical defects in the developing fetus. The most handicapping defects are those of the neural tube (anencephaly or meningomyelocele). Initial research efforts were devoted to developing X-ray techniques to view the fetus for these defects by injection of radioopaque substances into amniotic fluid (amniography or fetography). These studies primarily involved women having a family history of neural tube defects and whose fetuses were consequently at increased risk. More recently, elevated levels of alpha fetoprotein in amniotic fluid (or maternal blood) were found to be associated with neural tube defects, and may serve as a screening test for these disorders. Ultrasound has come into use to determine internal and external structural detail of the developing fetus and thereby to detect anencephaly, meningomyelocele, and even congenital heart disease.

Amniocentesis also opened another area of fetal research: the assessment of fetal lung maturity. Studies of normal amniotic fluid in the last trimester of pregnancy provided an indication that increased concentrations of lecithin relative to sphingomyelin reflect maturation of the fetal lung; infants with mature lungs did not develop respiratory distress. This predictive test (the L/S ratio) was applied when women went into premature labor, or when induced delivery was indicated due to Rh disease or maternal diabetes, to assess risk that the delivered infant would develop respiratory distress. When the lungs were immature, delivery could be delayed, depending on the relative risks of intrauterine versus extrauterine life. In the last three years, attempts to induce fetal lung maturation by administration of cortico-steroids to the mother have added a new dimension to this clinical situation. Following animal studies indicating that this procedure was safe and effective, human studies were undertaken intending to benefit the fetus involved. Results reported to date suggest that the procedure is successful, but studies of possible long-term side effects of this intrauterine therapy are continuing.

Assessment of fetal well-being is another goal of fetal research. Ultrasound has been used to assess fetal size and gestational age, and to monitor fetal respiratory movements, certain types of which have been found to indicate fetal distress. Studies of hormones, metabolic products and chemicals in amniotic fluid (and in maternal blood and urine) identified numerous substances associated with either abnormalities of fetal growth or with fetal distress. In the last decade, monitoring the fetal heart rate and sampling fetal scalp blood during labor developed from research techniques to clinical application for indication of fetal distress.

3. *Fetal pharmacology and therapy.* Over 400 publications in the last 10 years involving fetal pharmacology were identified in the literature search; less than 20 percent of these included research on the living fetus. Of the latter studies, the majority were coincidental studies conducted as an adjunct to clinically accepted procedures. For example, the largest category encompassed studies of transplacental drug movement or effects on the fetus of analgesic or anesthetic agents given to the mother during labor and delivery.

The research techniques employed in investigations of this type included antepartum transfusion of the fetus with blood containing drugs, and administration of drugs or agents to the mother for therapeutic or research reasons. The ensuing studies involved assessment of effects on the fetal electrocardiogram, determination of fetal movements or structures by ultrasound, amniotic fluid sampling, scalp or umbilical cord blood sampling, and studying placental passage and fetal distribution patterns in tissues of the dead fetus. The studies were conducted either prior to abortion or in normal pregnancies, usually at the time of delivery.

In general, studies to determine the effects of a drug on the fetus were retrospective, involved the fetus incidentally or after death, or involved the infant, child or adult. Thus, all studies of the influence of oral contraceptives or other drugs on multiple births or congenital abnormalities were retrospective. Study of the effects on the fetus of drugs administered to treat maternal illness during pregnancy (including anticonvulsants, antibiotics, hormones and psychopharmacologic agents) in which the fetus was an incidental participant, were also largely retrospective. Studies of effects on the fetus and newborn infant of analgesic and anesthetic agents given at delivery also involved the fetus incidentally, but were conducted prospectively. Recently attempts were made to focus prospective pharmacologic studies of antibiotics intentionally, rather than incidentally, on the fetus. Different antibiotics were administered to pregnant women before abortion to compare quantitative movement of these agents across the placenta, as well as absolute levels achieved in fetal tissues. The results served as a guideline for drug selection to treat intrauterine infections, particularly syphilis. Studies conducted on the dead fetus after abortion showed the clear superiority of one drug over the other.

In addition to assessing effects of drugs on the fetus and measuring placental transfer of drugs, fetal pharmacologic research included attempts to modify drug structures so that they will or will not cross the placenta to affect the fetus. Such research also included study of the effects of certain drugs (such as phenobarbital or corticosteroids) in inducing enzyme activity in the fetus (to prevent hyperbilirubinemia or speed fetal lung maturation and prevent respiratory distress syndrome).

Effects on the fetus of live attenuated virus vaccines administered to the mother were also examined. Preliminary testing of rubella vaccine in monkeys indicated that the vaccine virus did not cross the placenta. In contrast, studies on women requesting therapeutic abortion showed clearly that the vaccine virus did indeed cross the placenta and infect the fetus, indicating the danger of administering the vaccine during pregnancy. Similarly, a study conducted with mumps vaccine virus showed that the virus infected the placenta, but not the fetus.

Attempts at fetal therapy *in utero*, in addition to blood transfusion for Rh disease and corticosteroid administration to speed fetal lung maturity, were conducted recently as an adjunct to amniocentesis. Examples of this type of fetal therapy include the administration of hydrocortisone to the fetus *in utero* to treat the adrenogenital syndrome, maternal dietary therapy for fetal galactosemia, and administration to the mother of large doses of vitamin B_{12} to treat fetal methylmalonic acidemia.

4. *Research involving the nonviable fetus.* The quantity of research on the nonviable fetus *ex utero* has been small; much of such research included the nonviable fetus only as the extreme end of the spectrum of studies of premature infants. Such studies included measurements of amino acid levels in plasma of infants with intrauterine malnutrition, administration of bromide to measure total body water in low birth weight infants, and the study of hemoglobin in blood from the umbilical cord as an indicator of fetal maturity. The purpose of this research was to gain information that could be of benefit to other fetuses and infants.

Research was also conducted involving the nonviable fetus during abortion by hysterotomy but before the fetus and placenta were physically removed from the uterus. A study conducted in the United States reported the feasibility of delivering a portion of the umbilical cord from the uterus and using it as a site for drug administration and blood sampling. Another study, this one undertaken in Finland, employed the technique to infuse noradrenaline via the umbilical vein; study of metabolites subsequently obtained demonstrated the functional maturity of the fetal sympathetic nervous system. Several studies in Sweden used similar techniques: radiolabeled chemicals were administered to the fetus via the umbilical vessels, and metabolites were then studied in the umbilical vein and, following completion of the abortion, in the fetus. In another Finnish study, arginine and insulin were injected into blood vessels of 8 fetuses (450–600 grams) with the placenta attached to the uterus, and blood samples were taken from the umbilical cord to assess fetal endocrine regulation of glucose metabolism. These studies were conducted solely to gain information on fetal metabolism for the benefit of other fetuses and infants.

The nonviable fetus was the subject of research to develop a life-support system

("artificial placenta") for sustaining very small premature infants, as well as to obtain data on normal fetal physiology. Some of this life support system research was conducted only with larger infants (viable by weight criteria) who had failed on respirators and were tried on experimental systems as an ultimate therapeutic effort to achieve survival. Of the published studies with clearly nonviable fetuses, one was conducted in the United States. Published in 1963, this research involved 15 fetuses, obtained following therapeutic abortion at 9–24 weeks gestational age. The fetuses were immersed in salt solution containing oxygen at extremely high pressure, in an attempt to provide oxygen for the fetus through the skin. The longest survival was 22 hours. In an earlier study in Scandinavia, 7 fetuses weighing 200–375 grams, from both spontaneous and induced abortions, were perfused with oxygenated blood through the umbilical vessels. Longest survival was 12 hours. A third study, conducted in England, utilized a similar method and included 8 fetuses obtained following hysterotomy abortion and weighing 300–980 grams. Longest survival was 5 hours. No other studies of this type involving nonviable fetuses were found in the literature review.

Studies of fetal physiology conducted on the delivered fetus utilized several experimental approaches. In a study conducted in Sweden, the intact fetal-placental unit obtained by hysterotomy abortion was removed and utilized for perfusion studies. A study performed in England involved cannulating the carotid and umbilical arteries of the aborted fetus and measuring fetal glucose levels in response to administration of growth hormone. Four fetuses from hysterotomy abortions at 16–20 weeks gestation were perfused via the umbilical vessels in a study in Scotland which demonstrated that the fetus could synthesize estriol independent of the placenta. A similar study by the same investigators involving six fetuses demonstrated that the 16–20 week fetus could synthesize testosterone from progesterone. To learn whether the human fetal brain could metabolize ketone bodies as an alternative to glucose, brain metabolism was isolated in 8 human fetuses (12–17 weeks gestation) after hysterotomy abortion by perfusing the head separated from the rest of the body. This study, conducted in Finland, demonstrated that the human fetus, like previously studied animal fetuses, could modify metabolic processes to utilize ketone bodies.

These studies of the nonviable fetus represent the total number reported in the world scientific literature, as well as could be ascertained from review of the most comprehensive bibliographic search ever undertaken of research involving the human fetus. The total number of citations involving fetal research was well in excess of 3000; the reports of research on the nonviable fetus that were found numbered less than 20. Certainly some reports of such research may have been missed even by this thorough review, but it is safe to conclude that the amount of research conducted on the nonviable fetus has been extremely limited. Of the principal investigators conducting this type of research, three were from the United States; two of these investigators conducted their research abroad. The only research conducted in the United States on the nonviable fetus *ex utero* was the study involving attempts to develop an artificial life support system. The literature survey disclosed no reports of research conducted in the United States on the nonviable fetus intended solely to obtain information on normal physiologic function.

In summary, research involving the fetus includes a broad spectrum of studies of the fetus both inside and outside the uterus. The research may be as innocuous as observation, or involve mild manipulation such as weighing or measuring, or more extensive manipulation such as altering the environment, administering a drug or agent, or noninvasive monitoring. Diagnostic studies may involve sampling amniotic fluid, urine, blood, or spinal fluid, or performing biopsies. The most extensive or invasive procedures include perfusion studies and other attempts to maintain function.

The extent of research on the fetus is reflected by the more than 3000 citations included in the literature review of such research. Most involved the fetus *in utero*; less than 20 articles involved the nonviable fetus.

The purposes for which research on the fetus has been undertaken include obtaining knowledge of normal fetal growth and development as a basis for understanding the abnormal; diagnosing fetal disease or abnormality; studying fetal pharmacology and the effects of chemical and other agents on the fetus, in order to develop fetal therapy; and developing techniques to save the lives of ever smaller premature infants.

III. Alternative Means for Achieving the Purposes for Which Research Involving Living Fetuses Has Been Undertaken

In the development of new medical procedures or drugs to be employed in the treatment of humans, research is usually initiated with animal models, which are used until probable effectiveness and low degree of risk are determined. Ultimately, it becomes necessary to conduct the research on humans, since initial human applications are experimental regardless of the amount of preceding animal research. In some instances, pertinent animal models may not exist or may have certain limitations, so that studies on humans begin at a relatively early stage. In all instances, however, the question may be asked whether studies on humans began at an appropriate time, or whether the information that was required could have been obtained using alternative research means, i.e., studies on animal models.

The broad nature of the survey of the nature and extent of research on the fetus (Section II) did not permit detailed evaluation of alternative means. Therefore, the Commission contracted with Battelle Columbus Laboratories to conduct a more intensive analysis of this issue in connection with four advances in which research on the fetus played a part. The Battelle report to the Commission traces the historical development of (1) rubella vaccine, (2) the use of amniocentesis for prenatal diagnosis of genetic defects, (3) the diagnosis and treatment, as well as prevention, of Rh isoimmunization disease, and (4) the management of respiratory distress syndrome. The study identifies pertinent animal research that was conducted and attempts to assess whether the human research was necessary and appropriate, or whether animal models could have been substituted. Finally, the study evaluates the likelihood that the advance would have been achieved if all research on the fetus, both therapeutic and nontherapeutic, had been prohibited. In preparing the report and analysis, extensive bibliographies on each topic, prepared by staff of the National Library of Medicine, were utilized. In addition, a number of scientists whose research had been of greatest importance to the advances were interviewed.

1. In the case of *congenital rubella syndrome*, descriptions of the condition (which comprises congenital heart disease, cataracts, deafness and mental retardation) and its etiology (maternal rubella infection during pregnancy) were drawn from research on the living child and material from dead fetuses. Attenuation of the rubella virus for vaccine purposes was accomplished in tissue culture using nonhuman cells. Vaccine trials were conducted on adults and children. The vaccine was found safe and effective, and it was licensed in 1969, 28 years after the congenital rubella syndrome was first described.

No research on the living human fetus was required to develop the vaccine. A question remained, however, as to the safety of administering the vaccine during pregnancy or to women in the childbearing years. Should a pregnant woman, without immunity to rubella, be vaccinated to prevent the risk to the fetus that would ensue if she contracted natural rubella? Some experimental animal models for the rubella condition had been developed, the rhesus monkey being the closest one to the human. Accordingly, pregnant monkeys were inoculated with either rubella virus or the vaccine virus. Subsequent study showed that five of six monkey fetuses whose mothers received slightly attenuated rubella virus were infected, but none of the six monkey fetuses whose mothers received vaccine virus was infected. Thus, the animal model suggested that the vaccine virus did not cross the placenta and was safe to administer during pregnancy, although other vaccine viruses were known to cross the human placenta.

Human studies were then undertaken. Because of the potential risk to the fetus, women requesting therapeutic abortion

were employed as subjects. These volunteers received the vaccine and underwent the abortion 11 to 30 days later. Examination of tissues from the dead aborted fetuses showed that, in contrast to the results in monkeys, the vaccine virus did cross the human placenta and infect the fetus. On the basis of this research involving the fetus in anticipation of abortion, as well as subsequent reports of damage to the fetus following accidental rubella vaccination during pregnancy, administration of rubella vaccine to pregnant women or women who might become pregnant within 60 days of vaccination is proscribed.

Two alternatives to the planned testing of rubella vaccine on pregnant women in anticipation of abortion can be considered. First, more extensive animal testing of the vaccine could have been conducted. The usefulness of such a procedure, however, would be questionable. Based on prior experience with the inconsistencies of placental passage of any agent, the human situation would remain unknown after any amount of animal testing. Testing in the human is still required even after negative results in animal models, with the same safeguards as if no animal testing had been conducted.

The second alternative would be to wait for the accidental vaccination of pregnant women and observe the outcome. This in fact occurred in several instances after the planned testing. The women involved, who had wanted pregnancies, elected instead to terminate their pregnancies by abortion due to the risk to the fetus, and studies of tissue from the dead fetuses confirmed that they had been infected by the virus. Thus, the effect in humans could have been learned in this instance by retrospective research. At issue here in the selection of alternatives is the question whether it is preferable to proceed by design with women planning abortions, or to work retrospectively with women who desire pregnancy but were accidentally vaccinated.

2. The use of *amniocentesis* (removal of amniotic fluid via a needle inserted into the uterus through the mother's abdomen) as a clinical procedure dates from 1882, when it was introduced as a treatment for polyhydramnios (excess accumulation of amniotic fluid). There is no evidence that animal studies were conducted prior to that time, and comparatively little research has been done on amniocentesis as a procedure apart from its applications. The Battelle study of amniocentesis thus involved evaluation of the uses to which the procedure has been put, as well as alternative means for developing the procedure. Amniocentesis has found application in three main areas of research: prenatal diagnosis of genetic disease, diagnosis of Rh disease, and assessment of fetal maturity related to respiratory distress syndrome. Its use in the latter two areas will be discussed in parts 3 and 4 of this section.

Two lines of research provided impetus for prenatal diagnosis of genetic disease: development of the technology for tissue culture and identification of the sex chromatin as an indicator of sex in single cells. In 1955 it was shown that fetal sex could be predicted from the sex chromatin pattern of amniotic fluid cells. Application of this technique to prenatal detection of sex-linked disorders was first reported in 1960. Rapid progress in tissue culture research led to success in culturing fetal amniotic fluid cells in 1966, intrauterine diagnosis of a chromosome abnormality in 1967, and the first intrauterine diagnosis of metabolic disorders using cultured amniotic fluid cells in the following year. Research in this area steadily expanded as chromosomal and metabolic disorders were added to the list of conditions diagnosable *in utero*. At present, virtually any chromosomal anomaly and potentially over 60 metabolic disorders can be detected prenatally by amniocentesis. The possibility of diagnosis and selective abortion of abnormal fetuses has enabled the birth of normal children to families that otherwise would not have risked pregnancy, and has permitted families to avoid the impact of the birth of a defective or doomed child.

All research to detect genetic defects involved the living human fetus. Much of it utilized amniotic fluid obtained in the normal course of abortion, in order to ascertain normal values. Such research was obviously nonbeneficial for the fetuses involved. Only research conducted on women at risk for having a fetus with the disorder in question could be considered beneficial, in that many of these women desired an abortion unless it could be shown that the fetus would be normal.

An alternative means to develop the procedure of amniocentesis would have been to conduct more extensive animal research. Animal models have numerous limitations with regard to amniocentesis, however, including shape of the pelvis, size and shape of the uterus, number of fetuses present (which confounds cell analysis), and the marked irritability of the uterus in many species such that even slight manipulation induces abortion, fetal resorption or congenital malformations. Recently some animals have been found in which amniocentesis can be performed, but even in these it is difficult in mid-pregnancy, when it must be done for effective intrauterine diagnosis of genetic defects.

While animal models might have been utilized more extensively in developing the technique of amniocentesis, there is no alternative to human experimentation for the purpose of developing the diagnostic tests for genetic metabolic disorders used with amniocentesis. The conditions are unique to the human species. Only by study of cells in amniotic fluid from pregnant humans, both normal and those at risk for genetic disease in the fetus, was it possible to assess whether the genetic defect was expressed in these cells, and to determine the normal and abnormal values for the responsible enzymes in the cells as the basis for prenatal diagnosis. This research utilized only amniotic fluid and the fetal cells in it, and thus was not invasive of the fetus. In the early stages of developing the technique, however, the possible risks to the fetus were greater than those for many invasive procedures.

3. The history of *Rh isoimmunization disease* encompasses the description of the disorder, determination of its cause, initiation of successful treatment, and development of effective prevention, all within four decades. Characterization of this disorder, which combines hemolytic anemia, jaundice, and intrauterine death or (if delivered) severe brain damage, was accomplished in the 1930's from study of autopsy material and newborn infants. Research on blood groups, utilizing both human and animal material, led in 1941 to the demonstration from studies of mothers and newborns that Rh sensitization in an Rh negative mother to an Rh positive fetus produced hemolytic anemia in the fetus. In 1945, treatment of affected newborn infants by exchange transfusion was initiated and mortality began to decline.

Use of amniocentesis was introduced in 1956 to obtain amniotic fluid which provided an indicator of how severely the fetus was affected and, late in pregnancy, whether labor should be induced to enable treatment of the fetus outside the uterus. In 1963, treatment of the severely affected fetus by intrauterine blood transfusion was initiated, resulting in a 60 percent reduction of the stillbirth rate for affected infants. Ongoing studies of the etiology of the disease, using pregnant women, provided indications that sensitization of the mother usually occurred at the time of delivery of her first Rh positive infant, when a large volume of fetal Rh positive cells entered the mother's circulation. As the result of research conducted largely with prisoners, a vaccine was developed to prevent this sensitization. Trials of the vaccine, administered to women after delivery, began in 1964. Results indicated virtually complete effectiveness, and the vaccine (RhoGam) became commercially available in 1968.

Research on the fetus played no part in developing the RhoGam vaccine, but such research was essential in demonstrating the basic cause of the disease and in developing methods for prenatal diagnosis and treatment. All significant research on the fetus related to Rh disease was conducted on mothers and fetuses at risk for the disease, and can be categorized as beneficial research. The size of the benefits achieved may be appreciated by reviewing statistics related to the disorder. Approximately 12 percent of couples in the United States are at risk for having an affected infant. Nearly 25,000 infants could be affected yearly. Since initiation of exchange transfusion, neonatal mortality of affected infants has dropped to about 2.5 percent. Intrauterine transfusion has reduced the annual number of stillbirths due to the disease from 10,000 to less than half that number. The entire amount of money used to support Rh disease research from 1930 through the successful development of the vaccine in 1966 is the equivalent of the present cost to society

for lifetime care of six children irreparably brain damaged by the disease.

Limited animal models were available for study of Rh disease and were utilized in some instances. Intrauterine transfusion, for example, was first conducted on animals. Extensive research has been conducted to develop an animal model of the actual disease, but the hamadrayas baboon is the only species that has been found in which the disease is sufficiently similar to the condition in man for the animal to serve as a useful model. The limitations of animal models and the urgency of developing a treatment for fetuses otherwise likely to die led physician researchers to attempt experimental therapy with favorable risk/benefit ratio in hunam subjects. In these instances, the risk of not doing the research was approximately 50 percent intrauterine death; in the face of such odds, even such a hazardous experimental therapeutic procedure as intrauterine transfusion was considered acceptable.

4. *Respiratory distress syndrome* (RDS) is a major cause of infant mortality. In the United States approximately 40,000 cases occur annually; 95 percent of these cases are premature infants, and overall mortality is in excess of 25 percent. Study of the development of advances related to this condition revealed a picture of frequent interaction of animal model and clinical studies involving the living human fetus in the third trimester. In addition, advances in therapy were achieved from research involving affected premature infants.

The key experimental work elucidating the basic cause of the condition involved study of the lungs of deceased infants who died of RDS or other causes. This research indicated that lungs of infants with RDS lacked a chemical (surfactant) which acted to keep open the smallest air passages in the lung; surfactant was present in the lungs of unaffected infants. Subsequent studies, again relying primarily on autopsy material, delineated the biochemistry of surfactant, and it was suggested that amniotic fluid might provide an indicator of the presence of surfactant. Studies were then conducted of amniotic fluid obtained at various stages in the last trimester of pregnancy, solely to learn the normal values of the phospholipid components of surfactant; this research was nonbeneficial for the fetuses involved. Results indicated that a marked increase in the content of lecithin relative to sphingomyelin in amniotic fluid correlated with the appearance of surfactant in the fetal lung, and indicated that the lungs were mature enough that the fetus, if delivered, would probably not develop RDS. The report of these studies in 1971 strongly influenced obstetric management of premature labor and diabetic pregnancy, by providing an index of the time when delivery could proceed with minimum risk of RDS.

Another line of research quickly had an impact on RDS management. Animal studies in the 1950's showed that steroids were capable of inducing enzyme activity in the fetus. Studies involving the pregnant woman and the living fetus in 1961 demonstrated that cortisone crossed the human placenta. Animal studies in the late 1960's and early 1970's indicated that corticosteroid could induce enzymes and thereby increase surfactant in fetal lungs. In the species studied (lambs, rabbits and rats) the steroids did not cross the placenta and had to be administered directly to the fetus. Based on the previous demonstration that steroids crossed the human placenta, and later clinical studies of mothers receiving steroid therapy during pregnancy that had not suggested any ill effects on the fetus, clinical trials were initiated in pregnant women at risk of having infants affected by RDS. The results obtained to date indicate that corticosteroids are highly effective in preventing RDS, without undesirable side effects. Although the treatment remains experimental, it holds promise for markedly reducing the incidence of RDS.

The interplay between animal and human studies was essential in achieveing the advances in clinical management and prevention of RDS. Relevant animal models were used when available, and although no extensive search for an animal model was evident before the human steroid trials, the research appeared to be a logical and carefully planned step undertaken to provide therapy for a condition of high risk to the fetuses treated.

The following conclusions are drawn from the Battelle study:

A. Animal models were utilized extensively, but adequate and appropriate models were not always available when they were needed. In some instances little or no animal research preceded human studies. In other instances intensive searches for animal models were undertaken (as in Rh disease), but investigators appear to have been reluctant to postpone therapeutic research until an animal model was found.

B. Investigators generally proceeded to clinical trials characterized by very high ratios of benefit to risk.

C. A total ban on all research on the fetus, or postponement of such research until more appropriate and exact animal models were sought and studied, would probably have significantly delayed or halted indefinitely the progress in three of the four areas that were analyzed. Only development of the rubella vaccine could have progressed unimpeded.

A more limited ban would have had less effect, depending on the nature and scope of the prohibitions imposed. For example, a ban only on nontherapeutic research on the fetus would not have affected research on Rh disease, but would have sharply curtailed research with amniocentesis, due to the resulting inability to determine normal values for abnormal enzymes in metabolic disorders. The research which developed L/S ratios, used in RDS diagnosis, might have been possible making use of fluid obtained during caesarean sections or in Rh disease studies. A selective ban on research before or after induced abortion would clearly have permitted the L/S ratio research for RDS diagnosis, but could still have severely curtailed development of amniocentesis for prenatal diagnosis by making ascertainment of normal values extremely difficult. A ban on invasive research on the fetus would have permitted development of amniocentesis, although the risks to the fetus from this noninvasive procedure were potentially greater than those from many invasive procedures.

IV. Legal Issues

Papers on the legal issues involved in research on the fetus were prepared for the Commission by Professor Alexander M. Capron, University of Pennsylvania Law School, and Assistant Dean John P. Wilson, Boston University School of Law. Both papers are structured, at least in part, according to categories of research, that is, whether the research is therapeutic or nontherapeutic, whether the fetal subject is viable, nonviable or dead, and whether it is inside or outside the uterus. The interests of the fetus at different stages of development are balanced against the interests of other parties, and the protection of fetal interests is addressed in discussion of appropriate consent requirements. A summary of both papers follows.

The dead fetus. The Uniform Anatomical Gift Act (UAGA), which has been adopted in all fifty states and the District of Columbia, permits research on the dead fetus and the products of conception, provided consent has been given by either parent and the other parent has not objected. Professor Capron states that the UAGA should be read in the context of common law requirements on consent; thus, the authorization should be "informed" and "voluntary". In the latter regard, consent should not unnecessarily be sought immediately before or after an abortion. Dean Wilson suggests that it is wise to require the consent of both parents.

Aside from UAGA, Professor Capron points out that the statutes of five states presently impose varying degrees of restriction on research on the dead fetus (Massachusetts, South Dakota, Illinois, Indiana, and Ohio); all of these restrictions apply only to the products of induced and not spontaneous abortions. Other laws that might affect research on the dead fetus are the grave robbing statutes, which would apply only when the consent required by the UAGA has not been obtained. As a matter of medical practice, however, maternal consent is not generally sought for postabortion examinations. (Both authors note and discuss a pending Massachusetts case.)

Professor Capron states that the various state laws on death certification provide little guidance on the question of defining death with respect to the fetus. Such laws do, however, introduce another complication by recognizing different categories requiring certification. (Other reports prepared for the Commission suggest medical criteria for de-

termining fetal death; see Section VII of this report.)

The viable infant. Research on the viable infant is discussed at length by Professor Capron. He states that therapeutic research on a viable infant, whether or not there has been an induced abortion, is generally sanctioned under criminal and civil law. The law is presently unsettled with respect to nontherapeutic research, and, as a practical matter, the exercise of caution in introducing any risk is indicated. The recently enacted fetal research statutes have probably not altered the common law with respect to research on the viable infant after induced abortion, i.e., therapeutic research may be conducted. In the absence of a special statute, the protection afforded the viable infant attaches only after it is in fact *ex utero*.

Although the interests of the viable infant do not depend on the manner in which it came to be alive *ex utero*, Professor Capron points out that this might be relevant to the issue of appropriate consent to involvement of the infant in research. The question is whether the decision to abort should disqualify the parents (or at least the mother) from exercising further control after the infant is alive *ex utero*. The argument for disqualification has an obvious rationale in conflict of interest, but it faces at least three problems: (1) Since the Supreme Court has declared in *Roe v. Wade* that women have a constitutional right to abortion, basing maternal disqualification on the exercise of that right may be an unconstitutional penalty. (2) Since the abortion itself is legal, the fetus is not thereby deprived of any rights which the parents were obliged to protect. (3) The decision to abort does not necessarily cast the woman as being irrevocably opposed to the rights of the fetus, since the mother's decision was based on the erroneous assumption that there would be no live issue from the pregnancy. Professor Capron suggests that rather than presumptive disqualification in all cases, judicial proceedings may be an appropriate forum for balancing the rights of all concerned, and that it would be preferable to presume that parents retain control over a viable infant. Certain states, however, have written into their abortion statutes some form of parental forfeiture of rights (Louisiana, Missouri, Montana, Kentucky, Indiana, South Dakota).

Dean Wilson suggests that, at least with respect to therapeutic research, the power of consent should not be removed from a mother and father because they are minors. Also, he expresses the belief that only therapeutic research should be conducted on the viable infant.

The fetus in utero. Although the fetus does not achieve the interests of a full person until live birth, it is not entirely without protection while still *in utero*. Professor Capron points out that the criminal law in various states, with expansions under civil law, recognizes interests of the fetus *in utero* in two ways of possible relevance to research. First, there are some recent statutes seeking to safeguard the fetus *in utero* against life threatening intentional injury, and some older statutes that depart from the common law by prohibiting "feticide". It is unlikely that the older statutes would apply to research on the fetus, since the element of intent to do harm would be missing. All of these statutes must, of course, be examined in the light of *Roe* v. *Wade*.

Second, interests of the fetus *in utero* are recognized in the criminal law by protecting the fetus against injuries which cause its death or impairment after it is born alive. The effect of such protection is to put pressure on those involved to assure that the abortion is "effective". Thus, Professor Capron suggests, the law may be recognizing, not fetal interests, but the interests of human beings, after birth, not to suffer because of culpable acts of other persons.

In some jurisdictions, Professor Capron finds that the civil law recognizes a broader fetal interest in protection against harm *in utero*. The courts in at least 21 states have recognized a cause of action for injuries to a viable fetus that lead to its stillbirth. Once the fetus is viable, Professor Capron states, the decision in *Roe* v. *Wade* does not appear to be an absolute bar to holding that the fetus and its parents have an interest in its potentiality for life.

If the fetus is in fact born alive, the protection under civil law is even broader, with no importance being attached to the question whether the injury that causes impairment or subsequent death occurred before or after viability. (Professor Capron expresses his disagreement with the argument that subsequent live birth is not a necessary element in court decisions regarding the vesting of property interests.)

Finally, if the fetus is both injured and dies before it is viable, recovery for its wrongful death has not been allowed under civil law.

Dean Wilson expresses the opinion that there should be no difference in the rights accorded to the fetus *in utero* before or after viability, and only therapeutic research or nontherapeutic research that imposes no risk should be permitted in both cases. He would apply the same conditions to research in anticipation of abortion. As grounds for protecting the fetus *in utero* before viability, he suggests that research on such a fetus might have a brutalizing effect on society as a whole.

With respect to the question of consent to research on the fetus *in utero*, Professor Capron holds that if the fetus is viable, it is in approximately the same position as a viable infant, i.e., consent by the parents to therapeutic research would be appropriate, but nontherapeutic research that introduces genuine risk should not be undertaken at all. If the fetus is not yet viable, Professor Capron discerns two difficult consent issues: (1) Should there be a separate consent, in addition to that of the mother, when the research is directed at the fetus? A possible answer is that the mother's right of decision to destroy the fetus, recognized by *Roe* v. *Wade*, includes a right to permit the fetus to be used in research that is less harmful than total destruction and is done for legitimate scientific reasons. (2) Can the consent of the mother to participate in (nontherapeutic) research directed at the fetus be tied to an agreement to abort? Without such an agreement, parties such as the father and state welfare officials may have grounds to insist that their interests in the potential child be protected. On the other hand, an agreement to abort would probably be unenforceable.

Professor Capron sees no clear answer to the question of appropriate consent to research on the fetus *in utero* before viability. He suggests a partial solution along the lines of the Massachusetts fetal research statute, which provides that research may take place when the fetus is not the subject of a planned abortion and that a statement, signed by the woman, that she is not planning an abortion supplies conclusive evidence on the point. Such an arrangement would not be immune from attack in light of the *Roe* v. *Wade* decision, but it would raise fewer questions, Professor Capron states, if it were a condition of government funding.

In accordance with his views concerning permissible research on the fetus *in utero*, Dean Wilson expresses the belief that the woman should be permitted to consent only to therapeutic research and nontherapeutic research that imposes no risk.

The nonviable fetus ex utero. Professor Capron notes that the law generally does not distinguish between viability and nonviability after birth. Full protection as a person is given, notwithstanding that immaturity may preclude the nonviable fetus from having an independent existence. Professor Capron suggests that legislative consideration of the concept of viability as currently understood might lead to distinctions being made on that basis.

With respect to consent, Professor Capron states that the same rules would apply for therapeutic research on the viable fetus as for such research on the viable infant. For nontherapeutic research on the nonviable fetus, he suggests that judicial review might be appropriate.

V. Ethical Issues

Eight ethicists and philosophers prepared for the Commission papers outlining their views on research on the fetus. Summaries of each of these papers follows:

Sissela Bok, Ph.D. Dr. Bok identifies two lines of argument opposed to research on the fetus: (1) the fetus is a person and, consequently, research without its consent and not for its benefit is an assault upon its humanity; and (2) research on the fetus will lead society to condone research on other categories of the defenseless. Dr. Bok answers these arguments and concludes that, in order to seek knowledge not otherwise obtainable, research should be permitted at early gestational stages, provided careful safeguards are utilized.

The first argument is countered by a presentation and discussion of four reasons for protecting humans from harm: (1) the victim's anguish, suffering and deprivation of continued experience of life; (2) the brutalization of the agent; (3) the grief of those who care about the victim; and (4) the establishment of a pattern that ultimately will harm all of society. Dr. Bok contends that none of these reasons apply in the early stages of gestational life.

The second argument against research on the fetus advances the last reason for protecting humans from harm as crucial even with respect to research in the first weeks of gestational life. Dr. Bok asserts that no data have been developed to support the applicability of the fourth reason to research on the fetus, and that, in any case, safeguards can be developed to prevent the alleged sequential abuses.

Since the fetus is not a person, consent on its behalf is unnecessary. However, maternal consent should be obtained, even for research following abortion, in deference to the woman's sensitivities.

Dr. Bok concludes that since the means are defensible and the end is desirable, research on the fetus should be permitted during the first 18 weeks of gestational age and when the fetus is under 300 grams in weight. These limits provide a margin of safety to prevent accidental experimentation on a viable fetus. Only therapeutic research on a fetus older than 18 weeks or more than 300 grams in weight should be permitted.

Dr. Bok would permit research on a fetus scheduled for abortion, provided the mother consents and the research is properly reviewed. She would not prohibit experimentation which keeps a nonviable fetus alive for a period of time or which hastens its death.

Joseph Fletcher, D.D. "Rightness and wrongness are judged according to results, not according to absolute prohibitions or requirements." This statement provides a key to understanding the position taken by Dr. Fletcher regarding the ethics of research on the fetus. The result which justifies such research is the safety of people, especially children, from genetic and congenital disorders, uterine infections and a host of other maladies.

Dr. Fletcher states that the core question is whether the fetus is a person. He contends that although the fetus is a potential person, it does not become an actual person, ethically and legally, until it is born alive and lives entirely outside the mother's body with an independent cardiovascular system. Until the fetus becomes an "actual person" it is an "object," a nonpersonal organism which has value only insofar as it is wanted by its progenitors. It is not entitled to protection as a human subject whether viable or not until it becomes a live-born baby.

Dr. Fletcher states that the following categories of research on the fetus may be justified, depending upon the clinical situation and the design: (1) use of a dead fetus *ex utero* with or without maternal consent; (2) use of a live fetus *ex utero*, nonviable or viable, if survival is not wanted and there is maternal consent; (3) use of a live fetus *in utero* if survival is not wanted and there is maternal consent; and (4) use of a live fetus *in utero*, even if survival is intended, if there is no substantial risk to the fetus and if there is maternal and paternal-spouse consent.

Finally, Dr. Fletcher concludes that regulations by the Executive Branch and legislation by Congress (even though temporary) restricting research on the fetus are unethical if the ethics they are based upon are not fully and frankly disclosed.

Marc Lappé, Ph. D. Dr. Lappé's essay is developed from a "natural law" perspective. It defends five principles pertaining to research on the fetus and makes five policy recommendations to the Commission.

(1) The wanted fetus has a right to protection *in utero*. This principle is based on its unique vulnerability to environmental insult which might interfere with the fulfillment of its genetic potential.

(2) Principle (1) is not altered by societal acceptance of abortion. The Supreme Court has allowed a woman to decide that a fetus will no longer receive her protection; it does not follow that others in society are similarly authorized. Further, living fetuses *ex utero* have claims on our duties to afford them protection from experimentation by virtue of our basic medical tenets to preserve life. The Supreme Court offered no guidance on how to treat the fetus once out of the womb.

(3) The conditions under which society respects the fetus' right to protection are compromised by the decision and actions taken in the course of an abortion. Moral concern for the fetus dictates a choice of procedures which subject the woman to minimal morbidity risks while expeditiously expelling the fetus and rendering it incapable of survival.

(4) The costs of research on the fetus should be balanced by resultant goods. Society should make efforts to endow the abortion process with values it would not otherwise have had. Abortion-related research is therefore justified if and only if it is intended to aid other fetuses.

(5) The definition of fetal death and the application of the definition must be made independently from any possible future use of the fetus in experimentation.

Dr. Lappé notes that the problem of consent gives us most difficulty in that even if the fetus were accorded full rights of personhood, it would not do to delegate the parent as proxy since (in the case of abortion) the parent cannot be said to have the interests of the fetus at heart. He offers no solution to the problem, however, except to observe that were the fetus regarded as worthy of all the rights of personhood, we would not sanction nontherapeutic research at all.

Dr. Lappé recommends that the Commission (1) affirm its commitment to protect fetuses *in utero;* (2) provide a statement of concern for abortion-related abuse or neglect, including maternal exposure to harmful agents and insensitive or unethical choice of abortifacients; (3) limit research on the fetus *in utero* which is to be a subject of abortion to cases where no risk to the fetus is involved and the purpose of the research is to aid fetuses as a class; (4) restrict basic nonviable fetal research intended to benefit society generally to dead fetuses; and (5) require that fetal death be ascertained by criteria which separate the purposes of experimentation from the choice of abortion method and from the methodology used to ascertain that death has occurred.

Richard A. McCormick, S.T.D. Dr. McCormick defends a moral position concerning research on the fetus and distinguishes it from an acceptable public policy concerning such research. Public policy is to be determined, not only by morality, but by feasibility as well. The feasibility test is particularly difficult in a society characterized by moral pluralism and cultural pragmatism.

Dr. McCormick holds that parents may give proxy or vicarious consent for a child to participate in nontherapeutic experimentation where there is "no discernible risk or undue discomfort." Proxy consent is morally legitimate insofar as it is a reasonable construction of what the child *ought* to choose if it were able. This position is rooted in the premise that all humans, including children, have an obligation in social justice to contribute to the benefit of the human community. The same obligation can be extended to the fetus. Research on the fetus is morally permissible if maternal proxy consent is obtained, abortion is not contemplated, the risk or discomfort to the fetus is not discernible, and the results of the experiment cannot be obtained in any other way. Because Dr. McCormick judges most abortions to be immoral, experimental procedures prior to, during, and after abortion (except in the rare instances of legitimate abortion) are morally objectionable because they cooperate with and profit from an immoral system. While Dr. McCormick regards such cooperation as morally objectionable, he believes that his moral position cannot be fully adopted as public policy, since it cannot pass the feasibility test in a society which allows large-scale abortions.

Dr. McCormick recommends that the measure of proxy consent regarded as valid for subjects of research who are children is suitable to determine acceptable research on the fetus. He makes the following policy proposals which acknowledge both the moral pluralism and the cultural pragmatism characteristic of American society: (1) the research must be necessary; (2) the researcher bears the onus of showing the necessity; (3) there must be no discernible risk for the fetus or the mother or, if the fetus is dying, there must be no added pain or discomfort;

(4) the researcher bears the onus of showing that there is no discernible risk; (5) these policy demands must be secured by adequate review and prior approval of all research on the fetus.

Paul Ramsey, Ph.D. Dr. Ramsey seeks to distinguish between fetal life and fetal viability. Life, he suggests, should be defined for the fetus according to the presence or absence of vital signs which define life and death in other individuals. Viability should not be confused with life, for a fetus may be living yet nonviable. This new human research subject, one which is neither dead nor viable, is the subject of Dr. Ramsey's essay. He is not willing to say it may be entered into research protocols, but he does say that care should be taken not to enter a viable infant by mistake. To this end he recommends that viability be defined for research purposes on the safe side of possibly viable birth weight, crown-rump length or gestational age. He makes the following proposals to the Commission:

(1) The Peel Report prohibits procedures carried out with the deliberate intent of ascertaining the harm they might do to the fetus. Such a prohibition should be included in the American policy as well. "Do not harm" encompasses "intend no harm." This principle embraces the intention of the physician and not merely "codes of action."

(2) The subjective rule (Peel) must be supplemented by an objective limitation of risks by categorically prohibiting research in anticipation of abortion if that research entails known or uncertain risks.

(3) Respect for the dignity of human life must not be compromised whatever the age, circumstances, or expectation of life of the individual. The recent Supreme Court decision on abortion did not nullify the obligation to protect the developing fetus from harm, even if that harm is less than abortion.

(4) Vital functions of an individual abortus should not be artificially maintained except where the purpose of the activity is to develop new methods for enabling that abortus to survive to the point of viability.

(5) Ethical standards applicable to research on the fetus are the same as would be subscribed to in proposed research on the unconscious, on the dying (in the case of spontaneous abortion), on the (perhaps justly) condemned (in cases of induced abortion), or in experimentation with children.

For the most part, this means that the use of these subjects in nontherapeutic research is an *abuse*, for one ought not to "presume" or "construe" consent for acts of charity. Dr. Ramsey agrees with Dr. McCormick that "one stops and should stop precisely at the point where 'construed' consent does indeed involve self-sacrifice or works of mercy. The dividing line is reached when experiments involve discernible risk, undue discomfort, or inconvenience."

Seymour Siegel, D.H.L. Dr. Seigel makes the following points:

(1) A bias for life is the foundation of the Judeo-Christian world-view and it undergirds medical research. It may be affirmed outside the Judeo-Christian tradition. The bias for life requires individuals to strive to sustain life where it exists, not to terminate or harm life, and in cases of doubt to be on the side of life. A present individual takes precedence over a possible future individual. The bias for life is to be exercised whatever the status of the life before us and whatever the life expectation may be.

(2) The indeterminancy of the future requires that utmost caution should be employed in all decisions relating to research on the fetus, since neither the medical nor the social effects of such research can be predicted with certainty.

(3) The fetus is not the same as an infant since it has no independent life system and is tied to the mother.

(4) A fetus has real but limited rights, derived from its potential human life. The fetus' right to life is mitigated when the fetus threatens someone else's life; however, unless such a threat is present, the fetus' potential humanity requires that we protect and revere its life.

(5) The fetus *in utero* may be the subject of research that (a) helps the mother, (b) is harmless to the fetus, or (c) is designed to help the fetus. Dr. Siegel endorses the Peel Commission dictum that no procedures may be carried out to see what harm they might do the fetus.

(6) The fetus *ex utero* has more rights than the fetus *in utero*. Prolongation or early termination of the nonviable fetus should be prohibited.

(7) Criteria for death of the fetus should be the same as for other individuals.

(8) Consent of the mother or guardian is ordinarily sufficient, but parental consent, when an abortion is contemplated, is dubious. For such cases, consent should be supplemented by a special board. There must be strict separation of attending physician and researcher.

(9) Proposed guidelines: (a) fetal research should be limited to cases which present no harm or offer assistance to the life system of the subjects; (b) no procedures should be permitted which are likely to harm the fetus—before, during, or after abortion; (c) a fetus *ex utero* and alive should not be subject to research unless it is intended to enhance the life of that fetus or unless the research involves no risk to the subject; and (d) criteria for determining death of the fetus should be the same as for other human individuals.

Leroy Walters, Ph. D. Dr. Walters surveys various ways of categorizing research on the fetus: (1) according to the condition of the fetus, (2) according to the chronological age of the fetus, and (3) according to the formal object of the research.

He concludes that research on the fetus is not one but many things, and he focuses on nontherapeutic research on the fetus because it seems to raise serious public policy questions, and on research before, during and after induced abortion since that is a primary concern of the Commission's authorizing legislation. Four possible positions can be developed with respect to such research. Dr. Walters defends the position that nontherapeutic research on the fetus should be permitted only to the extent that such research is permitted on children or on fetuses which will be carried to term.

The essay endorses McCormick's thesis that parents may properly consent to a child's participation in nontherapeutic research which the child should be willing to take part in if the child were able to consent. This position is extended to cover the prenatal period as well. Because of difficulties associated with consent in cases where an abortion decision has been made, nontherapeutic research procedures should be permissible in the case of fetuses before or after abortion to the extent that they are permissible in the case of fetuses which will be brought to term. This position supposes that there is substantial continuity between previable and viable fetal life and postnatal life.

Although public policy making includes an ethical component, it also includes other factors, such as continuity with generally accepted societal principles, accommodation of a variety of belief systems and interests, and clearly understandable formulation. Three public policy propositions are recommended, all of which are based upon a policy of equality of treatment for all categories of human subjects: (1) nontherapeutic research on children should be permitted, if such research involves no risk or only minimal risk to subjects; (2) nontherapeutic research on fetuses which will be carried to term should be permitted, if such research involves no risk or minimal risk to the subjects; (3) nontherapeutic research procedures which are permitted in the case of fetuses which will be carried to term should also be permitted in the case of (a) live fetuses which will be aborted and (b) live fetuses which have been aborted.

Richard Wasserstrom, Ph. D. Dr. Wasserstrom identifies four views concerning the status of the human fetus. He endorses the view that the fetus is in a unique moral category, closest to that of a newborn infant. The fetus has great value because of its potential to become a fully developed human being. It follows that abortion is morally worrisome because it involves destruction of an entity that possesses the potential to be and to produce things of the highest value. It also follows that if abortion has already taken place and the fetus is nonviable, then research in no way affects the fetus' ability to realize any of its potential.

Dr. Wasserstrom states that the resolution of the problem of consent for research on the fetus depends entirely on how one views the status of the fetus. That is, if one views the fetus as tissue, then consent on behalf of the fetus is meaningless. If one views the fetus as a child, then proxy consent is necessary. Dr. Wasserstrom believes, however, that even if the fetus is considered to be only tissue, consent should be obtained from

the parents out of respect for their sensitivities.

Because abortion is a morally worrisome act, the decision to have an abortion should be kept easily revocable until the time of its performance. For this reason, Dr. Wasserstrom recommends that no research on the fetus *in utero* should be permitted if it involves a substantial risk of injury to the fetus.

Dr. Wasserstrom concludes that research on the nonviable fetus *ex utero* is permissible provided that: (1) the mother (if unmarried) or both parents consent before the abortion; (2) a review body has determined that the research may yield important information not otherwise obtainable; (3) the medical counselors of the pregnant woman have in no way been affiliated with the experimentation; and (4) the fetus is not possibly viable.

(An analysis of the papers summarized above was prepared for the Commission by Stephen Toulmin, Ph.D. This analysis is set forth in its entirety in the Appendix.)

VI. VIEWS PRESENTED AT PUBLIC HEARINGS

Public hearings were held by the Commission to provide interested persons with an opportunity to present their views on research on the fetus. Testimony was given by scientists, physicians, representatives of various organizations, concerned private citizens, lawyers and public officals. They presented a broad range of views that received careful consideration at the hearings and in the subsequent deliberations of the Commission. Brief summaries of the presentations follow.

1. *C. D. Christian, M.D.* (American College of Obstetricians and Gynecologists.) Dr. Christian presented to the Commission a set of guidelines for the conduct of research on the pregnant woman and fetus, as prepared by the Committee on Bioethics of the College. The guidelines include recommendations that animal models be fully explored before human research is initiated, that clinical management of the patient should not be altered by research objectives, that research which would knowingly harm the fetus is not appropriate even in anticipation of abortion, that a fetus of doubtful viability should be treated as a viable infant, and that prolonging or shortening the life of the nonviable fetus only for research purposes is not appropriate.

2. *Robert G. Marshall* (Special Assistant for Congressional Affairs, U.S. Coalition for Life). Mr. Marshall opposed any research that is not directed at preserving the life or restoring the health of the immediate patient. In addition, he suggested adoption of the Golden Rule as a criterion for experimentation; a prohibition on the participation of the medically needy as subjects of research, except in circumstances of immediate danger to life; and a requirement that prospective participants be required to write out their understanding of the purpose of an experiment prior to being accepted as subjects. (During questioning, Mr. Marshall said that he would not object to observational procedures including, for example, fetoscopy.)

3. *Thomas K. Oliver, Jr., M.D.* (Association of American Medical Colleges). Dr. Oliver cited improvement in statistics of infant mortality and morbidity, which may be attributed directly to research on the fetus and newborn infant. He described the research leading to improved care of Rh disease and respiratory distress syndrome, which could have been conducted only on the human fetus and newborn, as specific examples of advances resulting from research on the fetus. He urged the creation of an Ethical Advisory Board to review those research proposals which raise ethical questions, rather than the imposition of guidelines that would not be responsive to changing circumstances.

4. *Judith Mears* (Reproductive Freedom Project, American Civil Liberties Union.) Ms. Mears urged that the Commission not draft protections for the fetus that would undermine the Supreme Court's rulings in *Doe* v. *Bolton* and *Roe* v. *Wade* regarding a woman's rights with respect to abortion. In addition, she urged the support of research to improve the safety of abortion procedures. (Ms. Mears agreed, during questioning, that the *Roe* and *Doe* decisions do not speak to the issue of experimentation and would not, therefore, render regulation of such research unconstitutional so long as a woman's access to abortion and other health services is not abridged.)

5. *David G. Nathan, M.D.* (Professor of Pediatrics, Harvard Medical School). Dr. Nathan focused his discussion on fetoscopy. He described this experimental technique for obtaining a sample of fetal blood to enable prenatal detection of disorders such as sickle cell disease and thalassemia, the reasons for conducting initial trials in women about to undergo abortion, and the evolution of the technique to the point where it has had successful clinical application. Dr. Nathan stressed the importance of studies that can be conducted simultaneously with the abortion procedure and consequently avoid any possibility of a change of mind about abortion after the research has begun.

6. *Audrey McMahon* (mother of two developmentally disabled children). Ms. McMahon stressed the need for research into the causes and treatment of developmental disabilities, and urged that such research not be curtailed.

7. *Robert Greenberg, M.D.* (Society for Pediatric Research and the American Pediatric Society). Dr. Greenberg presented statistics on the high rates of infant mortality and abnormal fetal development as indicators that the current health status of the fetus is poor. Dr. Greenberg stated that genuine concern for the fetus requires marked improvement of the health care available to the developing human during intrauterine life. Such improvements in health care require acquisition of further understanding through increased research.

8. *Sumner Yaffe, M.D.* (American Academy of Pediatrics). Dr. Yaffe cited numerous advances in fetal therapeutics resulting from research on the fetus and emphasized the acute need for more extensive research in fetal clinical pharmacology. He presented the Academy's code of ethics for research involving the fetus and fetal material. The code states that research intended to benefit the mother or fetus *in utero* may be conducted with informed consent; that research on the viable delivered fetus (premature infant) may be carried out as long as nothing is done that is inconsistent with treatment necessary to promote the life of the infant; and that research on the nonviable fetus before or after abortion should be permitted, providing appropriate animal studies have been completed, parental consent is obtained, the researchers have no part in deciding timing or procedures for terminating the pregnancy or in determining viability, the research has been approved by an Institutional Review Board which is satisfied that the information cannot be obtained in any other way, experiments are not done in the delivery room, there is no monetary exchange for fetal material, and full records are kept.

9. *Lois Schiffer* (Women's Equity Action League, Women's Legal Defense Fund, Human Rights for Women). Ms. Schiffer cautioned against developing a policy that would abrogate constitutionally protected interests, such as the preeminence of a pregnant woman's right to health care. She underscored the need for continuing research in order to provide pregnant women with optimum medical advice and treatment (including improved abortion techniques). She suggested, additionally, that a requirement of paternal or spousal consent in conjunction with research on the fetus would contravene the holdings in the *Roe* and *Doe* decisions and that such consent serves no legitimate purpose if no child will be born. Finally, she urged the adequate representation of women on ethical review committees that will be applying policy to specific cases.

10. *Kay Jacobs Katz* (National Capital Tay-Sachs Foundation). Ms. Katz described the illness and death of her daughter, a victim of Tay-Sachs disease, and emphasized that only because of the availability of prenatal diagnosis did she have the courage to risk a further pregnancy that has resulted in the birth of a normal child. She urged the Commission not to restrict research that might develop procedures for prenatal diagnosis of other genetic diseases, nor to curtail research that might lead to the development of effective therapy for inborn errors of metabolism.

11. *Arthur M. Silverstein, Ph.D.* (American Society for Experimental Pathology). Dr. Silverstein pointed out the limitations of animals as models for the human fetus in experimentation. He cited the numerous uses of cells and tissues from the dead fetus in biomedical science, and urged that scientists not be deprived of the opportunity to study such tissues. He urged continued availability of fresh fetal materials for study and for use in transplantation. He concluded by

asking the Commission to recognize that society owes to the developing fetus an acknowledgment of its special problems and a determination to attempt to solve these problems and do medical justice to the fetus through research.

12. *Msgr. James T. McHugh* (U.S. Catholic Conference). Msgr. McHugh stated that the fetus is a human being from the earliest stages of development, and that the ethical norms governing research on the fetus derive from those governing research on all human subjects, especially infants and children. Pre-abortion research is inconsistent with human dignity and is therefore unacceptable. Consent by the mother to such research is a mockery, he said, inasmuch as she has already decided to extinguish the life of the fetus; further, such research would eliminate any possibility of a mother's change of mind concerning abortion.

He urged Federal regulation of research on the fetus to permit only projects involving, for example, amniocentesis, fetoscopy, tissue culture, or procedures that would entail no risk to the fetus, and to limit those to circumstances in which their application would serve the purpose of protecting maternal health and assuring safe delivery of the fetus. He urged that animal models be used to the extent possible, even if this would be more expensive and demanding. He stated that the Government should permit research on the fetus only for the purpose of enhancing the survival or well-being of the fetus involved, and only if it can be conducted in a manner that will respect the rights and dignity of the fetus.

13. *Jo Anne Brasel, M.D.* (Endocrine Society). Dr. Brasel cited examples of contributions of fetal endocrinologic research to fetal welfare and survival. Continuation of research on the fetus was urged to permit study of such problems as hormonal deficiency states and care of the fetus of the diabetic mother. She expressed the full support of the Society for efforts to see that ethical considerations are met in the conduct of human research, but asserted that the welfare of future mothers and infants would not be served by wholesale interdiction of research.

14. *Nancy Raymond, R.N.* (Public Relations Director, Maryland Action for Human Life). Ms. Raymond urged that the fetus be treated with fairness and dignity, whether or not an abortion is anticipated or has been conducted. She advocated a prohibition of research on the fetus, but would make the following exceptions from such a prohibition: remedial procedures; procedures to study the fetus within the womb, if they do not substantially jeopardize the fetus and it is not a candidate for planned abortion; diagnostic procedures that do not substantially jeopardize the fetus, even if it is a candidate for planned abortion; and diagnostic procedures that are judged to be in the best interest of the particular fetus and will provide the mother with information about her fetus, even if an abortion is contemplated. She suggested that a panel of medical and nonmedical persons be created to advise scientists on the acceptability of research on the fetus.

15. *Sean O'Reilly, M.D.* (Professor of Neurology at George Washington University). Dr. O'Reilly's testimony (read in his absence) urged protection of the fetus from experimentation without its informed consent. He stated that the fetus obviously cannot give consent, and that parents can consent only to therapeutic research on the fetus. He argued that parents forfeit any right to consent to any other research on the fetus once they have elected to abort it.

16. *Chris Mooney* (President, Pregnancy Aid Centers, Inc.) Ms. Mooney viewed abortion as the worst solution to the problem of unwanted pregnancy, preferring to improve methods and availability of counseling and contraception. She expressed the fear that research on the fetus before and after abortion will further entrench our dependence on this pseudo-solution, by persuading women to abort in order to contribute to the cause of science. If science becomes dependent on abortion for research subjects, scientists and society will be even less inclined to develop viable alternatives to abortion. She urged that no money be offered for the use of an aborted fetus in research. (During questioning, Ms. Mooney said she has no knowledge of cases in which research did, in fact, operate as an inducement to abortion, and agreed that regulations could be devised to avoid that possibility.)

17. *Walter L. Herrmann, M.D.* (Society for Gynecologic Investigation). Dr. Herrmann pointed out that the interrelation of mother and fetus *in utero* requires that they both be considered in research involving either of them. He observed that the attitude of confidence rather than fear of the modern woman contemplating pregnancy is due to improved pregnancy care resulting from maternal and fetal research. Many unanswered questions remain, however, which demand continuation of such research. He urged that, in developing regulations for research on the fetus, the abortion issue be kept separate and emphasis be placed on the pregnant woman as the subject to be protected, so as not to infringe upon her rights or deprive her of the benefits of scientific discovery.

18. *Mary O'Donnell* (Nursing student; member, National Youth Pro-Life Coalition). Ms. O'Donnell argued that fetal life is human life deserving of our respect and protection. She would permit diagnostic procedures when undertaken to promote well-being or survival, and all life-preserving procedures. She would find drug research in anticipation of abortion unacceptable because it deprives a woman of the opportunity to change her mind and violates basic moral values.

19. *Leroy A. Jackson, M.D.* (obstetrician in private practice, Washington, D.C.). Dr. Jackson cited procedures derived from research on the fetus that have improved his ability as a physician to provide medical care to his patients. He focused his testimony on the need to assure that consent from the mother for research on the fetus is truly informed consent, and that minorities and other groups do not bear a disproportionate share of the research burden. To these ends, he urged that research review committees contain members racially representative of and capable of communicating adequately with individuals on whom the research is conducted, that consent form wording be reviewed in detail, and that non-Government research agencies follow Government guidelines.

20. *Karen Mulhauser* (National Abortion Rights Action League). Ms. Mulhauser urged that the Commission recommend no limitations on research on the nonviable fetus *in utero*, provided informed consent is received from the pregnant woman. She also opposed any limitation of research to develop improved and safer abortion techniques.

21. *Ernest L. Hopkins, M.D.* (Professor of Obstetrics and Gynecology, Howard University). Dr. Hopkins cited statistics indicating that black infants and mothers have markedly higher morbidity and mortality in childbirth and the first year of life than do whites, and thus have a significant stake in research directed toward pregnancy and infancy. It is essential that research be conducted, he stated, as well as mandatory that the rights of the subject be protected. He advised the Commission that a mother often arrives at a decision to terminate pregnancy because she cannot support her present family. These are honorable women with wisdom, he said. They are very emotionally involved with the pregnancy, but they know that the birth of a baby would be catastrophic. They decide, reluctantly, to have an abortion because they see no alternative.

22. *J. V. Klavins, Ph.D.* (Professor of Pathology, State University of New York at Stony Brook). Dr. Klavins suggested that research on the fetus could be conducted with consent of the mother (and father when available). Since abortion is legal, he argued, research that causes no harm or suffering to the fetus-to-be-aborted is certainly acceptable. He stated that research on the human fetus is no more likely to be dehumanizing than artificial insemination has been, that "do no harm" be used as the guiding principle in research on the fetus, and that society not be allowed to interfere with the parents' right to make decisions concerning the best interests of their offspring.

23. *Myron Winick, M.D.* (American Institute of Nutrition and the American Society for Clinical Nutrition). Dr. Winick reviewed nutrition problems relevant to the fetus and cited research needed to approach solutions to such problems. For example, knowledge is needed of the way the human fetus gets and uses essential nutrients *in utero*. Acquisition of this knowledge may require nonbeneficial research, he stated. The aim of the research, he pointed out, is to improve fetal growth and the quality of life, and, when a malnourished fetus is identified, to assist the fetus, not to terminate the pregnancy.

24. *Aubrey Milunsky, M.D.* (Assistant Professor of Pediatrics, Harvard Medical School). Dr. Milunsky presented written testimony focusing on prenatal diagnosis of genetic disease by amniocentesis. He pointed out that research on the fetus was essential to developing amniocentesis, which is now an accepted clinical procedure. The research aspects of prenatal diagnosis now involve extending diagnostic possibilities to other diseases and developing methods of prenatal treatment of an affected fetus as an alternative to abortion. He argued that to halt such research now would prohibit extending to other populations (such as those affected by sickle cell disease) the option of prenatal diagnosis, and also would prohibit the possible development of treatments for the diagnosed diseases.

25. *Louis Hellman, M.D.* (Deputy Assistant Secretary for Population Affairs, DHEW). Dr. Hellman reviewed the activities of his office in supporting research and providing services in family planning, noting that the objectives directly affected the health of mothers and infants. Enabling women to have fewer children implies that those born should have optimum chances for survival and good health. Thus, the Office of Population Affairs has an interest in all aspects of maternal and fetal research directed at reducing mortality and morbidity. In the conduct of such research, Dr. Hellman stated, obtaining properly informed consent and review of the research by a committee of peers do not constitute significant barriers. He advocated conducting such reviews locally rather than in Washington. He expressed a personal distaste for nonbeneficial research on the aborted fetus, for which an outright prohibition might be considered, but cautioned that such a course would be unlikely to stop the search for new knowledge, perhaps in another country or in another generation. He concluded that knowledge cannot be sequestered nor the course of its attainment blocked, and he suggested that the wiser direction would be adequate regulation of research on the fetus rather than outright prohibition.

26. *Norman Kretchmer, M.D.* (Director, National Institute of Child Health and Human Development, National Institutes of Health). Dr. Kretchmer summarized the policies and procedures presently in effect at NIH for the protection of human subjects studied in research activities. Proposals involving extramural research (which is conducted at institutions other than NIH) undergo a three-stage process of review, including: (1) review by the institution proposing the research, (2) review by scientific peers acting as consultants to NIH, and (3) review by the National Advisory Councils of the Institutes supporting the projects.

The first stage is performed by an Institutional Review Board (IRB), a panel consisting of members with diverse backgrounds and drawn from various disciplines. It is the responsibility of the IRB to review the proposal for scientific merit, community acceptability, the balance of risks and benefits, and any other factors that might bear upon the protection of the rights and welfare of the subjects.

The second stage of review is conducted by scientific peers, to evaluate the soundness of the research design, the relevant professional experience of the investigator, adequacy of facilities, scientific importance of the research, and the like. In addition, the reviewing body may consider the investigator's evaluation of risks and benefits, as well as any procedures suggested to protect the subjects against possible risks.

The final stage of review is conducted by a National Advisory Council, a panel composed of two-thirds scientists and one-third nonscientists. Their responsibility is to recommend policy for the Institute and to advise the Director, NIH (or, in some cases, the Secretary, DHEW) concerning funding of research proposals, giving consideration to the protection of the rights of human subjects, among other things.

Research conducted within NIH (intramural research) undergoes review by the branch chief and clinical director of the Institute conducting the research. It may also be subject to review and approval by the Clinical Research Committee and the Medical Board of the Clinical Center. The Medical Board includes in its membership clinicians, scientists and laymen. All studies involving normal volunteers must be submitted to the Medical Board. Studies which involve potential benefits to patients who have been admitted to the Clinical Center generally are reviewed by clinical associates, attending physicians and the chief of the branch involved. When such studies represent a significant deviation from accepted practice or are associated with unusual hazards, however, they must be reviewed by the Clinical Research Committee.

For fiscal year 1974, NIH has identified about one hundred projects (with a total support of $3.5 million) which involved research on the fetus. These included monitoring of labor, fetal response to growth promoting substances, development of a "fetal risk index," and others. Under the ban imposed by Pub. L. 93-348, research on the living human fetus, before or after induced abortion, is not supported by NIH unless such research is done with the intention of assisting the survival of the fetus.

27. *John Jennings, M.D.* (Associate Commissioner, Food and Drug Administration).* Dr. Jennings testified that FDA has legislative authority to ensure that research submitted to the agency by industry to show the safety and effectiveness of a drug is conducted under conditions that will protect subjects. In this regard, FDA believes it should act in accord, insofar as feasible, with DHEW guidelines for protection of human subjects in research conducted or supported by the Department.

Most drugs currently marketed bear a warning on the label that they have not been tested for safety in pregnant women. Nevertheless, Dr. Jennings stated, such drugs, with potentially harmful effects on the fetus, are being used by pregnant women and by women of childbearing age, in spite of the label disclaimers. Therefore, the American Academy of Pediatrics has recommended to FDA that all marketed drugs be evaluated regarding their potential for producing adverse effects in the fetus.

Dr. Jennings expressed confidence that although difficult ethical problems are raised by research on the fetus, the Commission would be able to develop flexible guidelines that would safeguard both consumers and subjects.

In response to questions, representatives from FDA explained that no marketing of a drug is permitted until tests on animal teratology and reproduction have been completed. These tests include: (1) studies of normal and reproductive performance from the beginning of pregnancy through delivery, following administration of the drug to both males and females, (2) studies of teratology, following administration of the drug during pregnancy at the time of organ development, and (3) tests following administration of the drug from the end of pregnancy through lactation. FDA requests additional studies in primates if first studies indicate a need for further investigation.

VII. Fetal Viability and Death

The definitions of fetal viability and death present important issues in the conduct of research on the fetus. Accordingly, the Commission contracted for two studies in this area: the first, a medical study to define fetal viability and death based on present capabilities of medical technology; the second, an analysis of ethical and philosophical as well as scientific considerations in defining fetal viability and death.

The first study was conducted under contract with Columbia University, Richard Behrman, M.D., Principal Investigator. It included (1) a survey of the changes over the last 10 years in survival rates of premature infants and the advances in technology that have contributed to improved survival; (2) an assessment of the present state of medical technology designed to sustain premature infants; and (3) based on the foregoing, a recommendation for guidelines for use by physicians in determining whether a fetus, delivered spontaneously or by induced abortion, is viable, nonviable or dead. Consultation with representatives of professional societies in pediatrics and obstetrics, surveys of selected newborn intensive care units in the United States and Canada, statistical surveys and literature reviews were employed in carrying out this charge.

Assessment of changes in survival of premature infants relied primarily on data from New York City and from geographically dispersed infant intensive care units, as no national or international data broken down by weight group under 2500 grams were available. New York data showed a 4.5 percent

*Dr. Jennings was accompanied by Dr. Frances Kelsey, Dr. Carl Leventhal and Mr. William Vodra.

increase in survival rate (26 percent reduction in mortality) of all infants under 2500 grams for the period covering the years 1962 to 1971. The improvement was primarily in the lower weight groups 68 percent increase in survival rate under 1000 grams, 20 percent increase from 1001 to 1500 grams, and 6 percent from 1501 to 2000 grams. Infants cared for in intensive care units showed an even greater improvement in survival.

Many innovations in caring for the fetus *in utero* and the delivered premature infant were introduced in the last decade. The large number of these innovations, and their introduction at different times in different centers, generally made it impossible to establish a direct correlation between a given technologic innovation and a change in infant survival. One exception, where such a correlation may be made, is the effect on survival of monitoring fetal heart rate and acid-base balance during labor. At Los Angeles County USC Medical Center, monitoring was introduced as a routine procedure for high risk obstetrical patients in 1970; low risk patients were unmonitored. Between 1970 and 1973, the intrapartum death rate of infants weighing more than 1500 grams decreased 64 percent, and the fetal death rate became lower for the monitored high risk women than in the unmonitored low risk women. Comparable results were obtained in New York City at Columbia Presbyterian Medical Center, where over 90 percent of the monitoring was done on high risk ward patients, primarily black, poor or Spanish-speaking; the low risk private patients were unmonitored. Following introduction of monitoring, the high risk monitored patients had 10 percent fewer fetal deaths, 14 percent fewer perinatal deaths, and 37 percent fewer intrapartum fetal deaths than the unmonitored low risk private patients.

Overall improvement in premature survival may be traced more generally to the gradual adoption of other innovations. For example, the improved rates during the years 1967 through 1969 may be related to advances first introduced during the years 1964 through 1966, which included amniocentesis for intrauterine diagnosis of infants severely affected with erythroblastosis; fetal transfusion *in utero;* reorganization of premature nurseries into intensive care centers; extensive monitoring of gases and other substances in blood, and of vital signs, with more aggressive attention to correction of abnormal values; hand ventilation with ambu bags; regulation of the thermal environment; and greater density of nursing personnel. Increases in survival in the period 1970 to 1973 may be correlated with a constellation of advances in the years 1968 through 1970. These included extensive study of amniotic fluid in managing high risk pregnancies; fetal heart rate and uterine pressure monitoring during labor; improved infant transport systems and referral to intensive care units; major advances in design and techniques for use of infant respirators; total intravenous alimentation; and use of phototherapy for jaundice. Numerous other innovations have been introduced, but these are the major advances that have come into widespread use.

Impact of these changes on survival is reflected in data from University College Hospital in London, where survival rate of infants 1001 to 1500 grams was a steady 45 to 50 percent during the 1950's and early 1960's. During the period 1966 to 1970, the survival rate increased to 70 percent. Equally significant is an indication of decreased morbidity. During the 1950's and 1960's, the handicap rate for infants weighing less than 1500 grams at birth ranged from 33 percent to 60 percent. A recent study evaluating the outcome of such infants born from 1966 to 1970 indicated that 90.5 percent had no detectable handicap.

Despite these advances in the technology of caring for premature infants, there remain limits beyond which the best care cannot result in survival. To ascertain the present limits, surveys were conducted of vital statistics of the United States (including individual States) and Quebec, the medical literature, and 27 major centers with obstetric services and special intensive care units for premature infants. These centers represent the optimal care that present medical technology can provide. Despite differences in data base from various sources, two facts emerged clearly: probability of survival of infants weighing less than 750 grams was extremely small, and no cases were found from any documentable source of any infant surviving with a birth weight below 600 grams at a gestational age of 24 weeks or less. Some rare cases were documented of infants surviving with birth weights below 600 grams, but in each instance the gestational age exceeded 24 weeks, and the cases thus represented more mature infants who for various reasons were small-for-dates. Other rare cases were documented of infants born before 25 weeks gestational age who survived, but in each instance birth weight exceeded 600 grams. Thus, on an empirical basis the current limits of viability are clear: there is no unambiguous documentation that an infant born weighing less than 601 grams at a gestational age of 24 weeks or less has ever survived.

The concept of viability implies a prediction as to whether a delivered fetus is capable of survival. A prematurely delivered fetus is viable when a minimal number of independently sustained, basic, integrative physiologic functions are present. The sum of these functions must support the inference that the fetus is able to increase in tissue mass (growth) and increase the number, complexity and coordination of basic physiologic functions (development) as a self-sustaining organism. This development must be independent of any connection with the mother and supported only by generally accepted medical treatments. If these coordinated functions are not present, the fetus is nonviable. This may be the case even though some signs of life are apparent.

The following functions, taken together, constitute the minimal number of basic integrative physiologic functions to support an inference of viability: (1) Perfusion of tissues with adequate oxygen and prevention of increasing accumulation of carbon dioxide and/or lactic and other organic acids. This function consists of the following components:

(a) inflation of the lungs with oxygen,

(b) transfer of oxygen across the alveolar membrances into the circulation and elimination of carbon dioxide from the circulation into the expired gas, and

(c) cardiac contractions of sufficient strength and regularity to distribute oxygenated blood to tissues and organs throughout the body, and to eliminate organic acids from those tissues and organs. (2) Neurologic regulation of the components of the cardio-respiratory perfusion function, of the capacity to ingest nutrients, and of spontaneous and reflex muscle movements.

These functions in the prematurely delivered fetus cannot at present be assessed separately in a consistent, reliable and exact manner. The absence of the sum of these functions, however, can be assessed indirectly in a reasonable and reliable manner by measurement of weight and an estimation of gestational age. Thus, organisms of less than 601 grams at delivery and gestational age of 24 weeks or less are at present nonviable; signs of life such as a beating heart, spontaneous respiratory movement, pulsation of the umbilical cord and spontaneous movement of voluntary muscles are not adequate in themselves to be used to determine the existence of basic integrative functions.

A weight of 601 grams or more and gestational age over 24 weeks may indicate that the minimal basic functions necessary for independent growth and development are present. Such a prematurely delivered fetus may be considered at least possibly viable. At these weights and gestational ages, a sign of life such as a beating heart, spontaneous respiratory movement, pulsation of the umbilical cord or spontaneous movement of voluntary muscles indicates possible viability.

Prediction of extrauterine viability of the fetus while it is still *in utero* takes on an additional dimension of complexity. The fetus *in* utero, in the absence of clear signs that death has occurred, is always at least potentially viable as long as it remains in the uterus. However, it cannot be weighed, size assessments based on uterine size are inaccurate, and estimates of gestational age based on menstrual history are often inexact. The best medical technology can provide at present is an index of gestational age based on measurement of head size, using ultrasound. In the best hands, this technique is accurate within ±1 week at 20–26 weeks. Relating gestational age to fetal weight, and taking into account the range of error and normal variation, an estimated gestational age of 22 weeks or less by ultrasound would virtually eliminate the possibility of fetal weight above 600 grams and actual gestational age

greater than 24 weeks. Such an estimate would permit the prediction that if such a fetus were outside the uterus, it would be nonviable.

Employing present technology, therefore, research on the fetus *in utero*, undertaken before an abortion to occur not later than 22 weeks gestational age as estimated by ultrasound, would not impact on a fetus with a chance for survival after the abortion. Any reduction of the 22 week limit would provide an additional safeguard.

Whatever the boundaries are for viability, there is always a chance that a viable infant may be born after a prediction of nonviability by gestational age. When this occurs, the premature infant clearly must be cared for in accord with accepted medical practice. Further, these criteria for viability are based on current technology, which is subject to change. Accordingly, the criteria should be reviewed periodically.

Death of the delivered fetus is judged to have occurred when there is a cessation of the minimal basic integrative physiologic functions which, considered together, may result in self-sustained extrauterine growth and development. The absence of all of the following signs indicates the cessation of these minimal basic integrative physiologic functions:

(1) heart beat,

(2) spontaneous respiratory movements,

(3) spontaneous movement of voluntary muscles, and

(4) pulsation of the umbilical cord.

Approaching the same issues of fetal viability and death from the viewpoint of a physician-scientist and philosopher, Dr. Leon Kass, in an essay prepared for the Commission, came to conclusions similar to those reached by Dr. Behrmam on criteria for determining death and defining fetal viability (through Dr. Kass was more conservative on the latter). In clarifying the terminology, Dr. Kass distinguished between the terms "viable" and "nonviable" (which refer to states of a living fetus) and "alive" and "dead" (which refer to mutually exclusive conditions of the organism independent of its stage of development). The terms "viable" and "nonviable" are predictive of future outcome, which is dependent on the fetal stage of development and relation to the environment. Thus, the determination of viability is influenced by whether the fetus is inside or outside the uterus, and by the technology available for sustaining life. A fetus that is alive inside the uterus is always at least potentially viable; the same fetus outside the uterus may be viable or nonviable.

As criteria for determining death, Dr. Kass suggested that a fetus be considered dead if, based on ordinary procedures of medical practice, it has experienced an irreversible cessation of spontaneous circulatory and respiratory functions and an irreversible cessation of spontaneous central nervous functions. These criteria are evidenced on examination of the fetus by absence of the following:

(1) spontaneous muscular movement,

(2) response to external stimuli,

(3) elicitable reflexes,

(4) spontaneous respiration, and

(5) spontaneous heart function manifested by heartbeat and pulse.

These criteria differ from those suggested by Dr. Behrman only by the addition of (2) and (3). Dr. Kass advised that the presence of any one of these functions is a sign that the fetus is alive (again in agreement with Dr. Behrman), and he further suggested that use of the EEG is unnecessary in making the diagnosis of death. Finally, he recommended that the fetus *in utero* be considered alive until proved dead, and that the fetus being aborted be presumed alive until examination reveals it to be dead.

A viable fetus was defined by Dr. Kass as one that has reached the stage of development at which it is able to sustain itself outside the mother's body. In suggeting criteria for fetal viability based on present technology, Dr. Kass supported use of essentially the same physiologic criteria as suggested by Dr. Behrman, but would not rely upon weight or gestational age to indicate the presence of these integrated functions in the delivered fetus. He suggested that the delivered fetus should be considered viable in the presence of *all five* of the functions listed above (the absence of which is definitive of death). Of these, respiratory activity is the *sine qua non* of viability. Following delivery of the fetus, adequate time should be allowed to assess the presence of life and determine viability before research involving the fetus can be considered. This evaluation should be made by the delivering obstetrician, and then only if he is not himself likely to be engaged in subsequent research involving the fetus.

It is more difficult to determine whether the fetus *in utero* would be viable, if delivered, and, due to the possibility of error, Dr. Kass advised caution. He suggested that viability of the fetus *in utero* be evaluated according to gestational age. The fetus *in utero* is potentially viable before 20 weeks gestational age, but nonviable if removed from the uterus. It should be considered viable after the age of 28 weeks. Accurate evaluation of the viability of a fetus *in utero* between 20 and 28 weeks gestational age is not possible; such a fetus should be presumed viable if a heartbeat is audible using a stethoscope. The fetus which is to be aborted before the heartbeat is audible should be regarded as potentially viable until the abortion procedure is actually in progress, after which it may be considered nonviable.

VIII. Deliberations and Conclusions

The charge to the Commission is to investigate and study research involving the living fetus and to make recommendations to the Secretary, DHEW, on "policies defining the circumstances (if any) under which such research may be conducted or supported." The Commission has attempted to fulfill that duty by conducting investigations into research on the fetus and by providing a public forum for the presentation and analysis of views on this subject. It must be recognized that the Commission was placed under severe limitations of time by its Congressional mandate. As a result, these considerations on research involving fetuses have necessarily been developed prior to the Commission's larger task of studying the nature of research, the basic ethical principles which should guide it, the problem of informed consent and the review process.

After the Commission identified the information that was required for adequate consideration of the charge, a compendium of pertinent scientific literature and medical experience was prepared by consultants and contractors. In addition, a broad range of views was presented in letters, reports and testimony by theologians, philosophers, physicians, scientists, lawyers, public officials and private citizens. The Commission then undertook critical analysis of the studies and presentations, and conducted public deliberations on the issues involved. Finally, the Commission formulated its Recommendations.

This section of the Commission's report summarizes the reasoning and conclusions that emerged during the deliberations. Section IX of the report sets forth the Commission's Recommendations to the Secretary, DHEW. These Recommendations arise from and are consistent with the Deliberations and Conclusions of the Commission. The Recommendations should be considered only within the context of the Deliberations that precede them.

A. *Preface to Deliberations and Conclusions.* Throughout the deliberations of the Commission, the belief has been affirmed that the fetus as a human subject is deserving of care and respect. Although the Commission has not addressed directly the issues of the personhood and the civil status of the fetus, the members of the Commission are convinced that moral concern should extend to all who share human genetic heritage, and that the fetus, regardless of life prospects, should be treated respectfully and with dignity.

The members of the Commission are also convinced that medical research has resulted in significant improvements in the care of the unborn threatened by death or disease, and they recognize that further progress is anticipated. Within the broad category of medical research, however, public concern has been expressed with regard to the nature and necessity of research on the human fetus. The evidence presented to the Commission was based upon a comprehensive search of the world's literature and a review of more than 3000 communications in scientific periodicals. The preponderance of all research involved experimental procedures designed to benefit directly a fetus threatened by premature delivery, disease or death, or to elucidate normal processes or development. Some research constituted an element in the health care of pregnant women. Other

research involved only observation or the use of noninvasive procedures bearing little or no risk. A final class of investigation (falling outside the present mandate of the Commission) has made use of tissues of the dead fetus, in accordance with accepted standards for treatment of the human cadaver. The Commission finds that, to the best of its knowledge, these types of research have not contravened accepted ethical standards.

Nonetheless, the Commission notes that there have been instances of abuse in the area of fetal research. Moreover, differences of opinion exist as to whether desired results could have been attained without the use of the human fetus in nontherapeutic research.

Concern has also been expressed that the poor and minority groups may bear an inequitable burden as research subjects. The Commission believes that those groups which are most vulnerable to inequitable treatment should receive special protection.

The Commission concludes that some information which is in the public interest and which provides significant advances in health care can be attained only through the use of the human fetus as a research subject. The Recommendations which follow express the Commission's belief that, while the exigencies of research and the moral imperatives of fair and respectful treatment may appear to be mutually limiting, they are not incompatible.

B. *Ethical Principles and Requirements Governing Research on Human Subjects with Special Reference to the Fetus and the Pregnant Woman.* The Commission has a mandate to develop the ethical principles underlying the conduct of all research involving human subjects. Until it can adequately fulfill this charge, its statement of principles is necessarily limited. In the interim, it proposes the following as basic ethical principles for use of human subjects in general, and research involving the fetus and the pregnant woman in particular.

Scientific inquiry is a distinctly human endeavor. So, too, is the protection of individual integrity. Freedom of inquiry and the social benefits derived therefrom, as well as protection of the individual are valued highly and are to be encouraged. For the most part, they are compatible pursuits. When occasionally they appear to be in conflict, efforts must be made through public deliberation to effect a resolution.

In effecting this resolution, the integrity of the individual is preeminent. It is therefore the duty of the Commission to specify the boundaries that respect for the fetus must impose upon freedom of scientific inquiry. The Commission has considered the principles proposed by ethicists in relation to the exigencies of scientific inquiry, the requirements and present limitations of medical practice, and legal commentary. Among the general principles for research on human subjects judged to be valid and binding are: (1) To avoid harm whenever possible, or at least to minimize harm; (2) to provide for fair treatment by avoiding discrimination between classes or among members of the same class; and (3) to respect the integrity of human subjects by requiring informed consent. An additional principle pertinent to the issue at hand is to respect the human character of the fetus.

To this end, the Commission concludes that in order to be considered ethically acceptable, research involving the fetus should be determined by adequate review to meet certain general requirements:

(1) Appropriate prior investigations using animal models and nonpregnant humans must have been completed.

(2) The knowledge to be gained must be important and obtainable by no reasonable alternative means.

(3) Risks and benefits to both the mother and the fetus must have been fully evaluated and described.

(4) Informed consent must be sought and granted under proper conditions.

(5) Subjects must be selected so that risks and benefits will not fall inequitably among economic, racial, ethnic and social classes.

These requirements apply to all research on the human fetus. In the application of these principles, however, the Commission found it helpful to consider the following distinctions: (1) therapeutic and nontherapeutic research; (2) research directed toward the pregnant woman and that directed toward the fetus; (3) research involving the fetus-going-to-term and the fetus-to-be-aborted; (4) research occurring before, during or after an abortion procedure; and (5) research which involves the nonviable fetus *ex utero* and that which involves the possibly viable infant. The first two distinctions encompass the entire period of the pregnancy through delivery; the latter three refer to different portions of the developmental continuum.

The Commission observes that the fetus is sometimes an unintended subject of research when a woman participating in an investigation is incorrectly presumed not to be pregnant. Care should be taken to minimize this possibility.

C. *Application to Research Involving the Fetus.* The application of the general principles enumerated above to the use of the human fetus as a research subject presents problems because the fetus cannot be a willing participant in experimentation. As with children, the comatose and other subjects unable to consent, difficult questions arise regarding the balance of risk and benefit and the validity of proxy consent.

In particular, some would question whether subjects unable to consent should ever be subjected to risk in scientific research. However, there is general agreement that where the benefits as well as the risks of research accrue to the subject, proxy consent may be presumed adequate to protect the subject's interests. The more difficult case is that where the subject must bear risks without direct benefit.

The Commission has not yet studied the issues surrounding informed consent and the validity of proxy consent for nontherapeutic research (including the difficult issue of consent by a pregnant minor). These problems will be explored under the broader mandate of the Commission. In the interim, the Commission has taken various perspectives into consideration in its deliberations about the use of the fetus as a subject in different research settings. The Deliberations and Conclusions of the Commission regarding the application of general principles to the use of the fetus as a human subject in scientific research are as follows:

1. *In therapeutic research directed toward the fetus,* the fetal subject is selected on the basis of its health condition, benefits and risks accrue to that fetus, and proxy consent is directed toward that subject's own welfare. Hence, with adequate review to assess scientific merit, prior research, the balance of risks and benefits, and the sufficiency of the consent process, such research conforms with all relevant principles and is both ethically acceptable and laudable. In view of the necessary involvement of the woman in such research, her consent is considered mandatory; in view of the father's possible ongoing responsibility, his objection is considered sufficient to veto.

2. *Therapeutic research directed toward the pregnant woman* may expose the fetus to risk for the benefit of another subject and thus is at first glance more problematic. Recognizing the woman's priority regarding her own health care, however, the Commission concludes that such research is ethically acceptable provided that the woman has been fully informed of the possible impact on the fetus and that other general requirements have been met. Protection for the fetus is further provided by requiring that research put the fetus at minimum risk consistent with the provision of health care for the woman. Moreover, therapeutic research directed toward the pregnant woman frequently benefits the fetus, though it need not necessarily do so. In view of the woman's right to privacy regarding her own health care, the Commission concludes that the informed consent of the woman is both necessary and sufficient.

In general, the Commission concludes that therapeutic research directed toward the health condition of either the fetus or the pregnant woman is, in principle, ethical. Such research benefits not only the individual woman or fetus but also women and fetuses as a class, and should therefore be encouraged actively.

The Commission, in making recommendations on therapeutic and nontherapeutic research directed toward the pregnant woman (Recommendations (2) and (3)), in no way intends to preclude research on improving abortion techniques otherwise permitted by law and government regulation.

3. *Nontherapeutic research directed toward the fetus in utero or toward the pregnant woman* poses difficult problems

because the fetus may be exposed to risk for the benefit of others.

Here, the Commission concludes that where no additional risks are imposed on the fetus (e.g., where fluid withdrawn during the course of treatment is used additionally for nontherapeutic research), or where risks are so minimal as to be negligible, proxy consent by the parent(s) is sufficient to provide protection. (Hence, the consent of the woman is sufficient provided the father does not object.) The Commission recognizes that the term "minimal" involves a value judgment and acknowledges that medical opinion will differ regarding what constitutes "minimal risk." Determination of acceptable minimal risk is a function of the review process.

When the risks cannot be fully assessed, or are more than minimal, the situation is more problematic. The Commission affirms as a general principle that manifest risks imposed upon nonconsenting subjects cannot be tolerated. Therefore, the Commission concludes that only minimal risk can be accepted as permissible for nonconsenting subjects in nontherapeutic research.

The Commission affirms that the woman's decision for abortion does not, in itself, change the status of the fetus for purposes of protection. Thus, the same principles apply whether or not abortion is contemplated; in both cases, only minimal risk is acceptable.

Differences of opinion have arisen in the Commission, however, regarding the interpretation of risk to the fetus-to-be-aborted and thus whether some experiments that would not be permissible on a fetus-going-to-term might be permissible on a fetus-to-be-aborted. Some members hold that no procedures should be applied to a fetus-to-be-aborted that would not be applied to a fetus-going-to-term. Indeed, it was also suggested that any research involving fetuses-to-be-aborted must also involve fetuses-going-to-term. Others argue that, while a woman's decision for abortion does not change the status of the fetus *per se*, it does make a significant difference in one respect—namely, in the risk of harm to the fetus. For example, the injection of a drug which crosses the placenta may not injure the fetus which is aborted within two weeks of injection, where it might injure the fetus two months after injection. There is always, of course, the possibility that a woman might change her mind about the abortion. Even taking this into account, however, some members argue that risks to the fetus-to-be-aborted may be considered "minimal" in research which would entail more than minimal risk for a fetus-going-to-term.

There is basic agreement among Commission members as to the validity of the equality principle. There is disagreement as to its application to individual fetuses and classes of fetuses. Anticipating that differences of interpretation will arise over the application of the basic principles of equality and the determination of "minimal risk," the Commission recommends review at the national level. The Commission believes that such review would provide the appropriate forum for determination of the scientific and public merit of such research. In addition, such review would facilitate public discussion of the sensitive issues surrounding the use of vulnerable nonconsenting subjects in research.

The question of consent is a complicated one in this area of research. The Commission holds that procedures that are part of the research design should be fully disclosed and clearly distinguished from those which are dictated by the health care needs of the pregnant woman or her fetus. Questions have been raised regarding the validity of parental proxy consent where the parent(s) have made a decision for abortion. The Commission recognizes that unresolved problems both of law and of fact surround this question. It is the considered opinion, however, that women who have decided to abort should not be presumed to abandon thereby all interest in and concern for the fetus. In view of the close relationship between the woman and the fetus, therefore, and the necessary involvement of the women in the research process, the woman's consent is considered necessary. The Commission is divided on the question of whether her consent alone is sufficient. Assignment of an advocate for the fetus was proposed as an additional safeguard; this issue will be thoroughly explored in connection with the Commission's review of the consent process. Most of the Commissioners agree that in view of the father's possible responsibility for the child, should it be brought to term, the objection of the father should be sufficient to veto. Several Commissioners, however, hold that for nontherapeutic research directed toward the pregnant woman, the woman's consent alone should be sufficient and the father should have no veto.

4. *Research on the fetus during the abortion procedure or on the nonviable fetus ex utero* raises sensitive problems because such a fetus must be considered a dying subject. By definition, therefore, the research is nontherapeutic in that the benefits will not accrue to the subject. Moreover, the question of consent is complicated because of the special vulnerability of the dying subject.

The Commission considers that the status of the fetus as dying alters the situation in two ways. First, the question of risk becomes less relevant, since the dying fetus cannot be "harmed" in the sense of "injured for life." Once the abortion procedure has begun, or after it is completed, there is no chance of a change of mind on the woman's part which will result in a living, injured subject. Second, however, while questions of risk become less relevant, considerations of respect for the dignity of the fetus continue to be of paramount importance, and require that the fetus be treated with the respect due to dying subjects. While dying subjects may not be "harmed" in the sense of "injured for life," issues of violation of integrity are nonetheless central. The Commission concludes, therefore, that out of respect for the dying subjects, no nontherapeutic interventions are permissible which would alter the duration of life of the nonviable fetus *ex utero*.

Additional protection is provided by requiring that no significant changes are made in the abortion procedure strictly for purposes of research. The Commission was divided on the question of whether a woman has a right to accept modifications in the timing or method of the abortion procedure in the interest of research, and whether the investigator could ethically request her to do so. Some Commission members desired that neither the research nor the investigator in any way influence the abortion procedure; others felt that modifications in timing or method of abortion were acceptable provided no new elements of risk were introduced. Still others held that even if modifications increased the risk, they would be acceptable provided the woman had been fully informed of all risks, and provided such modifications did not postpone the abortion beyond the 20th week of gestational age (5 lunar months, four and one-half calendar months). Despite this division of opinion, the Recommendation of the Commission on this matter is that the design and conduct of a nontherapeutic research protocol should not determine the recommendations by a physician regarding the advisability, timing or method or abortion. No members of the Commission desired less stringent measures.

Furthermore, it is possible that, due to mistaken estimation of gestational age, an abortion may issue in a possibly viable infant. If there is any danger that this might happen, research which would entail more than minimal risk would be absolutely prohibited. In order to avoid that possibility the Commission recommends that, should research during abortion be approved by national review, it be always on condition that estimated gestational age be below 20 weeks. There is, of course, a moral and legal obligation to attempt to save the life of a possibly viable infant.

Finally, the Commission has been made aware that certain research, particularly that involving the living nonviable fetus, has disturbed the moral sensitivity of many persons. While it believes that its Recommendations would preclude objectionable research by adherence to strict review processes, problems of interpretation or application of the Commission's Recommendations may still arise. In that event, the Commission proposes ethical review at a national level in which informed public disclosure and assessment of the problems, the type of proposed research and the scientific and public importance of the expected results can take place.

D. *Review Procedures.* The Commission will conduct comprehensive studies of existing review mechanisms in connection with its broad mandate to develop guidelines and make recommendations concerning ethical issues involved in research on human subjects. Until the Commission has completed these studies, it can offer only tentative conclusions

and recommendations regarding review mechanisms.

In the interim, the Commission finds that existing review procedures required by statute (Pub. L. 93-348) and DHEW regulations (45 CFR 46) suffice for all therapeutic research involving the pregnant woman and the fetus, and for all nontherapeutic research which imposes minimal or no risk and which would be acceptable for conduct on a fetus *in utero* to be carried to term or on an infant. Guidelines to be employed under the existing review procedures include: (1) importance of the knowledge to be gained; (2) completion of appropriate studies on animal models and nonpregnant humans and existence of no reasonable alternative; (3) full evaluation and disclosure of the risks and benefits that are involved; and (4) supervision of the conditions under which consent is sought and granted, and of the information that is disclosed during that process.

The case is different, however, for nontherapeutic research directed toward a pregnant woman or a fetus if it involves more than minimal risk or would not be acceptable for application to an infant. Questions may arise concerning the definition of risk or the assessment of scientific and public importance of the research. In such cases, the Commission considers current review procedures insufficient. It recommends these categories be reviewed by a national review body to determine whether the proposed research could be conducted within the spirit of the Commission's recommendations. It would interpret these recommendations and apply them to the proposed research, and in addition, assess the scientific and public value of the anticipated results of the investigation.

The national review panel should be composed of individuals having diverse backgrounds, experience and interests, and be so constituted as to be able to deal with the legal, ethical, and medical issues involved in research on the human fetus. In addition to the professions of law, medicine, and the research sciences, there should be adequate representation of women, members of minority groups, and individuals conversant with the various ethical persuasions of the general community.

Inasmuch as even such a panel cannot always judge public attitudes, panel meetings should be open to the public, and, in addition, public participation through written and oral submissions should be sought.

E. *Compensation.* The Commission expressed a strong conviction that considerable attention be given to the issue of provision of compensation to those who may be injured as a consequence of their participation as research subjects.

Concerns regarding the use of inducements for participation in research are only partially met by the Commission's Recommendation (14) on the prohibition of the procurement of an abortion for research purposes. Compensation not only for injury from research but for participation in research as a normal volunteer or in a therapeutic situation will be part of later Commission deliberations.

F. *Research Conducted Outside the United States.* The Commission has considered the advisability of modifying its standards for research which is supported by the Secretary, DHEW, and is conducted outside the United States. It has concluded that its recommendations should apply as a single minimal standard, but that research should also comply with any more stringent limitations imposed by statutes or standards of the country in which the research will be conducted.

G. *The Moratorium on Fetal Research.* The Commission notes that the restrictions on fetal research (imposed by section 213 of Pub. L. 93-348) have been construed broadly throughout the research community, with the result that ethically acceptable research, which might yield important biomedical information, has been halted. For this reason, it is considered in the public interest that the moratorium be lifted immediately, that the Secretary take special care thereafter that the Commission's concerns for the protection of the fetus as a research subject are met, and appropriate regulations based upon the Commission's recommendations be implemented within a year from the date of submission of this report to the Secretary, DHEW. Until final regulations are published, the existing review panels at the agency and institutional levels should utilize the Deliberations and Recommendations of the Commission in evaluating the acceptability of all grant and contract proposals submitted for funding.

H. *Synthesis.* The Commission concludes that certain prior conditions apply broadly to all research involving the fetus, if ethical considerations are to be met. These requirements include evidence of pertinent investigations in animal models and nonpregnant humans, lack of alternative means to obtain the information, careful assessment of the risks and benefits of the research, and procedures to ensure that informed consent has been sought and granted under proper conditions. Determinations as to whether these essential requirements have been met may be made under existing review procedures, pending study by the Commission of the entire review process.

In the judgment of the Commission, therapeutic research directed toward the health care of the pregnant woman or the fetus raises little concern, provided it meets the essential requirements for research involving the fetus, and is conducted under appropriate medical and legal safeguards.

For the most part, nontherapeutic research involving the fetus to be carried to term or the fetus before, during or after abortion is acceptable so long as it imposes minimal or no risk to the fetus and, when abortion is involved, imposes no change in the timing or procedure for terminating pregnancy which would add any significant risk. When a research protocol or procedure presents special problems of interpretation or application of these guidelines, it should be subject to national ethnical review; and it should be approved only if the knowledge to be gained is of medical importance, can be obtained in no other way, and the research proposal does not offend community sensibilities.

IX. Recommendations

1. *Therapeutic research directed toward the fetus* may be conducted or supported, and should be encouraged, by the Secretary, DHEW, provided such research (a) conforms to appropriate medical standards, (b) has received the informed consent of the mother, the father not dissenting, and (c) has been approved by existing review procedures with adequate provision for the monitoring of the consent process. (Adopted unanimously.)

2. *Therapeutic research directed toward the pregnant woman* may be conducted or supported, and should be encouraged, by the Secretary, DHEW, provided such research (a) has been evaluated for possible impact on the fetus, (b) will place the fetus at risk to the minimum extent consistent with meeting the health needs of the pregnant woman, (c) has been approved by existing review procedures with adequate provision for the monitoring of the consent process, and (d) the pregnant woman has given her informed consent. (Adopted unanimously.)

3. *Nontherapeutic research directed toward the pregnant woman* may be conducted or supported by the Secretary, DHEW, provided such research (a) has been evaluated for possible impact on the fetus, (b) will impose minimal or no risk to the well-being of the fetus, (c) has been approved by existing review procedures with adequate provision for the monitoring of the consent process, (d) special care has been taken to assure that the woman has been fully informed regarding possible impact on the fetus, and (e) the woman has given informed consent. (Adopted unanimously.)

It is further provided that nontherapeutic research directed at the pregnant woman may be conducted or supported (f) only if the father has not objected, both where abortion is not at issue (adopted by a vote of 8 to 1) and where an abortion is anticipated (adopted by a vote of 5 to 4).

4. *Nontherapeutic research directed toward the fetus in utero* (other than research in anticipation of, or during, abortion) may be conducted or supported by the Secretary, DHEW, provided (a) the purpose of such research is the development of important biomedical knowledge that cannot be obtained by alternative means, (b) investigation on pertinent animal models and nonpregnant humans has preceded such research, (c) minimal or no risk to the well-being of the fetus will be imposed by the research, (d) the research has been approved by existing review procedures with adequate provision for the moni-

toring of the consent process, (e) the informed consent of the mother has been obtained, and (f) the father has not objected to the research. (Adopted unanimously.)

5. *Nontherapeutic research directed toward the fetus in anticipation of abortion* may be conducted or supported by the Secretary, DHEW, provided such research is carried out within the guidelines for all other nontherapeutic research directed toward the fetus *in utero*. Such research presenting special problems related to the interpretation or application of these guidelines may be conducted or supported by the Secretary, DHEW, provided such research has been approved by a national ethical review body. (Adopted by a vote of 8 to 1.)

6. *Nontherapeutic research directed toward the fetus during the abortion procedure and nonthereapeutic research directed toward the nonviable fetus ex utero* may be conducted or supported by the Secretary, DHEW, provided (a) the purpose of such research is the development of important biomedical knowledge that cannot be obtained by alternative means, (b) investigation on pertinent animal models and nonpregnant humans (when appropriate) has preceded such research, (c) the research has been approved by existing review procedures with adequate provision for the monitoring of the consent process, (d) the informed consent of the mother has been obtained, and (e) the father has not objected to the research; and provided further that (f) the fetus is less than 20 weeks gestational age, (g) no significant procedural changes are introduced into the abortion procedure in the interest of research alone, and (h) no intrusion into the fetus is made which alters the duration of life. Such research presenting special problems related to the interpretation or application of these guidelines may be conducted or supported by the Secretary, DHEW, provided such research has been approved by a national ethical review body. (Adopted by a vote of 8 to 1.)

7. *Nontherapeutic research directed toward the possibly viable infant* may be conducted or supported by the Secretary, DHEW, provided (a) the purpose of such research is the development of important biomedical knowledge that cannot be obtained by alternative means, (b) investigation on pertinent animal models and nonpregnant humans (when appropriate) has preceded such research, (c) no additional risk to the well-being of the infant will be imposed by the research, (d) the research has been approved by existing review procedures with adequate provision for the monitoring of the consent process, and (e) informed consent of either parent has been given and neither parent has objected. (Adopted unanimously.)

8. *Review Procedures*. Until the Commission makes its recommendations regarding review and consent procedures, the review procedures mentioned above are to be those presently required by the Department of Health, Education, and Welfare. In addition, provision for monitoring the consent process shall be required in order to ensure adequacy of the consent process and to prevent unfair discrimination in the selection of research subjects, for all categories of research mentioned above. A national ethical review, as required in Recommendations (5) and (6), shall be carried out by an appropriate body designated by the Secretary, DHEW, until the establishment of the National Advisory Council for the Protection of Subjects of Biomedical and Behavioral Research. In order to facilitate public understanding and the presentation of public attitudes toward special problems reviewed by the national review body, appropriate provision should be made for public attendance and public participation in the national review process. (Adopted unanimously, one abstention.)

9. *Research on the Dead Fetus and Fetal Tissue*. The Commission recommends that use of the dead fetus, fetal tissue and fetal material for research purposes be permitted, consistent with local law, the Uniform Anatomical Gift Act and commonly held convictions about respect for the dead. (Adopted unanimously, one abstention.)

10. The design and conduct of a nontherapeutic research protocol should not determine recommendations by a physician regarding the advisability, timing or method of abortion. (Adopted by a vote of 6 to 2.)

11. Decisions made by a personal physician concerning the health care of a pregnant woman or fetus should not be compromised for research purposes, and when a physician of record is involved in a prospective research protocol, independent medical judgment on these issues is required. In such cases, review panels should assure that procedures for such independent medical judgment are adequate, and all conflict of interest or appearance thereof between appropriate health care and research objectives should be avoided. (Adopted unanimously.)

12. The Commission recommends that research on abortion techniques continue as permitted by law and government regulation. (Adopted by a vote of 6 to 2.)

13. The Commission recommends that attention be drawn to Section 214(d) of the National Research Act (Pub. L. 93-348) which provides that:

"No individual shall be required to perform or assist in the performance of any part of a health service program or research activity funded in whole or in part by the Secretary of Health, Education, and Welfare, if his performance or assistance in the performance of such part of such program or activity would be contrary to his religious beliefs or moral convictions."

(Adopted unanimously.)

14. No inducements, monetary or otherwise, should be offered to procure an abortion for research purposes. (Adopted unanimously.)

15. Research which is supported by the Secretary, DHEW, to be conducted outside the United States should at the minimum comply in full with the standards and procedures recommended herein. (Adopted unanimously.)

16. The moratorium which is currently in effect should be lifted immediately, allowing research to proceed under current regulations but with the application of the Commission's Recommendations to the review process. All the foregoing Recommendations of the Commission should be implemented as soon as the Secretary, DHEW, is able to promulgate regulations based upon these Recommendations and the public response to them. (Adopted by a vote of 9 to 1.)

Dissenting Statement of Commissioner David W. Louisell

I am compelled to disagree with the Commission's Recommendations (and the reasoning and definitions on which they are based) insofar as they succumb to the error of sacrificing the interests of innocent human life to a postulated social need. I fear this is the inevitable result of Recommendations (5) and (6). These would permit nontherapeutic research on the fetus in anticipation of abortion and during the abortion procedure, and on a living infant after abortion when the infant is considered nonviable, even though such research is precluded by recognized norms governing human research in general. Although the Commission uses adroit language to minimize the appearance of violating standard norms, no facile verbal formula can avoid the reality that under these Recommendations the fetus and nonviable infant will be subjected to nontherapeutic research from which other humans are protected.

I disagree with regret, not only because of the Commission's zealous efforts but also because there is significant good in its Report especially its showing that much of the research in this area is therapeutic for the individuals involved, both born and unborn, and hence of unquestioned morality when based on prudent medical judgment. The Report also makes clear that some research, even though nontherapeutic, is merely observational or otherwise without significant risk to the subject, and therefore is within standard human research norms and as unexceptional morally as it is useful scientifically.

But the good in much of the Report cannot blind me to its departure from our society's most basic moral commitment: the essential equality of all human beings. For me the lessons of history are too poignant, and those of this century too fresh, to ignore another violation of human integrity and autonomy by subjecting unconsenting human beings, whether or not viable, to harmful research even for laudable scientific purposes.

Admittedly, the Supreme Court's rationale in its abortion decisions of 1973—*Roe v. Wade* and *Doe v. Bolton*, 310 U.S. 113, 179—has given this Commission an all but impossible task. For many see in that rationale a total negation of fetal rights, absolutely so for the first two trimesters and substantially so for the

third. The confusion is understandable, rooted as it is in the Court's invocation of the specially constructed legal fiction of "potential" human life, its acceptance of the notion that human life must be "meaningful" in order to be deserving of legal protection, and its resuscitation of the concept of partial human personhood, which had been thought dead in American society since the demise of the *Dred Scott* decision. Little wonder that intelligent people are asking: how can one who has no right to life itself have the lesser right of precluding experimentation on his or her person?

It seems to me that there are at least two compelling answers to the notion that *Roe* and *Doe* have placed fetal experimentation, and experimentation on nonviable infants, altogether outside the established protections for human experimentation. First, while we must abide the Court's mandate in a particular case on the issues actually decided even though the decision is wrong and in fact only an exercise of "raw judicial power" (White, J., dissenting in *Roe* and *Doe*), this does not mean we should extend an erroneous rationale to other situations. To the contrary, while seeking to have the wrong corrected by the Court itself, or by the public, the citizen should resist its extension to other contexts. As Abraham Lincoln, discussing the *Dredd Scott* decision, put it:

> (T)he candid citizen must confess that if the policy of the government upon vital questions affecting the whole people, is to be irrevocably fixed by decisions of the Supreme Court, the instant that they are made, in ordinary litigation between parties in personal actions, the people will have ceased to be their own rulers, having, to that extent, practically resigned their government, into the hands of that eminent tribunal. (4 Basler, The Collected Works of Abraham Lincoln 262, 268 (1963).)

Thus even if the Court had intended by its *Roe* and *Doe* rationale to exclude the unborn, and newly born nonviable infants, from all legal protection including that against harmful experimentation, I can see no legal principle which would justify, let alone require, passive submission to such a breach of our moral tradition and commitment.

Secondly, the Court in *Roe* and *Doe* did not have before it, and presumably did not intend to pass upon and did not in fact pass upon, the question of experimentation on the fetus or born infant. Certainly that question was not directly involved in those cases. Granting the fullest intendment to those decisions possibly arguable, it seems to me that the woman's new-found constitutional right of privacy is fulfilled upon having the fetus aborted. If an infant survives the abortion, there is hardly an additional right of privacy to then have him or her killed or harmed in any way, including harm by experimentation impermissible under standard norms. At least *Roe* and *Doe* should not be assumed to recognize such a right. And while the Court's unfortunate language respecting "potential" and "meaningful" life is thought by some to imply a total abandonment of *in utero* life for all legal purposes, at least for the first two trimesters, such a conclusion would so starkly confront our social, legal, and moral traditions that I think we should not assume it. To the contrary we should assume that the language was limited by the abortion context in which used and was not intended to effect a departure from the limits on human experimentation universally recognized at least in principle.

A shorthand way, developed during the Commission's deliberations, of stating the principle that would adhere to recognized human experimentation norms and that should be recommended in place of Recommendation (5) is: No research should be permitted on a fetus-to-be-aborted that would not be permitted on one to go to term. This principle is essential if all of the unborn are to have the protection of recognized limits on human experimentation. Any lesser protection violates the autonomy and integrity of the fetus, and even a decision to have an abortion cannot justify ignoring this fact. There is not only the practical problem of a possible change of mind by the pregnant woman. For me, the chief vice of Recommendation (5) is that it permits an escape hatch from human experimentation principles merely by decision of a national ethical review body. No principled basis for an exception has been, nor in my judgment can be, formulated. The argument that the fetus-to-be-aborted "will die anyway" proves too much. All of us "will die anyway." A woman's decision to have an abortion, however protected by *Roe* and *Doe* in the interests of her privacy or freedom of her own body, does not change the nature or quality of fetal life.

Recommendation (6) concerns what is now called the "nonviable fetus *ex utero*" but which up to now has been known by the law, and I think by society generally, as an infant, however premature. This Recommendation is unacceptable to me because, on approval of a national review body, it makes certain infants up to five months gestational age potential research material, provided the mother who has of course consented to the abortion, also consents to the experimentation and the father has not objected. In my judgment all infants, however premature or inevitable their death, are within the norms governing human experimentation generally. We do not subject the aged dying to unconsented experimentation, nor should we the youthful dying.

Both Recommendations (5) and (6) have the additional vice of giving the researcher a vested interest in the actual effectuation of a particular abortion, and society a vested interest in permissive abortion in general.

I would, therefore, turn aside any approval, even in science's name, that would by euphemism or other verbal device, subject any unconsenting human being, born or unborn, to harmful research, even that intended to be good for society. Scientific purposes might be served by nontherapeutic research on retarded children, or brain dissection of the old who have ceased to lead "meaningful" lives, but such research is not proposed—at least not yet. As George Bernard Shaw put it in "The Doctor's Dilemma": "No man is allowed to put his mother in the stove because he desires to know how long an adult woman will survive the temperature of 500 degrees Fahrenheit, no matter how important or interesting that particular addition to the store of human knowledge may be." Is it the mere youth of the fetus that is thought to foreclose the full protection of established human experimentation norms? Such reasoning would imply that a child is less deserving of portection than an adult. But reason, our tradition, and the U.N. Declaration of Human Rights all speak to the contrary, emphasizing the need of special protection for the young.

Even if I were to approach my task as a Commissioner from a utilitarian viewpoint only, I would have to say that on the record here I am not convinced that an adequate showing has been made of the necessity for nontherapeutic fetal experimentation in the scientific or social interest. The Commission's reliance is on the Battelle Report and its reliance is misplaced. The relevant Congressional mandate was to conduct an investigation and study of the alternative means for achieving the purposes of fetal research (Pub. L. 93-348, July 12, 1974, sec. 202 (b); National Research Act)

As Commissioner Robert E. Cooke, M.D., who is sophisticated in research procedures, pointed out in his Critique of the Battelle Report: "The only true objective approach beyond question, since scientists make [the analysis of the necessity for nontherapeutic fetal research], is to collect information and analyze past research accomplishments with the intention of *disproving, not proving* the hypothesis that research utilizing the living human fetus nonbeneficially is necessary" (italics in original). The Battelle Report seems to me not in accord with the Congressional intention in that it proceeds from a viewpoint opposite to that quoted, and is really an effort to prove the indispensability of nontherapeutic research. In any event, if that is its purpose, it fails to achieve it, for most of what it claims to have been necessary could be justified as therapeutic research or at least as non-invasive of the fetus (e.g., probably amniocentesis). In view of haste with which this statement must be prepared if it is to accompany the Commission's report, rather than enlarge upon these views now I refer both to the Cooke Critique and the Battelle Report itself both of which I am informed will be a part of or appended to the Commission's Report.

An emotional plea was made at the Commission's hearings not to acknowledge limitations on experimentation that would inhibit the court-granted permissive abortion. However, until its last meeting, I think the Commission for the most part admirably resisted the temptation to distort its purpose by pro-abortion advocacy. But at the last meeting, without prior preparation or discussion, it adopted Recommendation (12) promotive of research on abortion techniques.

This I feel is not germane to our task, is imprudent and certainly was not adequately considered.

Finally, I do not think that the Commission should urge lifting the moratorium on fetal research as stated in Recommendation (16). To the extent that duration of the moratorium is controlled by section 213 of the National Research Act, the subject is beyond our control and we ought not assume authority that is not ours. This is matter not for us and not, ultimately, for any administrative official, but for Congress. If the American people as a democratic society really intend to withdraw from the fetus and nonviable infant the protection of the established principles governing human experimentation, that action I feel should come from the Congress of the United States, in the absence of a practical way to have a national vote. Assuming that any representative voice is adequate to bespeak so basic and drastic a change in the public philosophy of the United States, it could only be the voice of Congress. Of course there is no reason why the Secretary of DHEW cannot immediately make clear that no researcher need stand in fear of therapeutic research.

As noted at the outset, the Commission's work has achieved some good results in reducing the possibilities of manifest abuses and thereby according a measure of protection to humans at risk by reason of research. That it has not been more successful is in my judgment not due so much to the Commission's failings as to the harsh and pervasive reality that American society is itself at risk—the risk of losing its dedication "to the proposition that all men are created equal." We may have to learn once again that when the bell tolls for the lost rights of any human being, even the politically weakest, it tolls for all.

DAVID W. LOUISELL,
ELIZABETH JOSSELYN BOALT,
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Statement of Commissioner Karen Lebacoz, With the Concurrence of Commissioner Albert R. Jonsen on the First Item

The following comments include some points of dissent from the Recommendations of the Commission. For the most part, however, these comments are intended as elaborations on the Report rather than dissent from it.

1. At several points, the Commission established as a criterion for permissible research an acceptable level of risk—e.g. "no risk" or "minimal risk." I support the Commission's Recommendations regarding such criteria, but I wish to make several interpretative comments.

First, I think it should be stressed that in the first trials on human subjects or on a new class of human subjects, the risks are almost always unknown. The Commission heard compelling evidence that differences in physiology and pharmacology between human and other mammalian fetuses are such that even with substantial trials in animal models it is often not possible to assess the risks for the first trials with human fetuses. For example, evidence from animal trials in the testing of thalidomide provided grounds for an estimation of low risk to human subjects; the initial trials in the human fetus resulted in massive teratogenic effects.

I would therefore urge review boards to exercise caution in the interpretation of "risk" and to avoid the temptation to consider the risks "minimal" when in fact they cannot be fully assessed.

Second, I think it important to emphasize the evaluative nature of judgments of risk. The term "risk" means *chance of harm*. Interpretation of risk involves both an assessment of statistical *chance* of injury and an assessment of the *nature* of the injury. Value judgments about what constitutes a "harm" and what percentage chance of harm is acceptable are both involved in the determination of acceptable risk. A small chance of great harm may be considered unacceptable where a greater chance of a smaller harm would be acceptable. For example, it is commonly accepted that a 1–2% chance of having a child with Down's Syndrome is a "high" risk, where the same chance of minor infection from amniocentesis would be considered a "low" risk. Opinions will differ both about what constitutes "harm" or injury and also about what chance of a particular harm is acceptable.

For all these reasons, the interpretation of risk and the designation of acceptable "minimal risk" merit considerable attention by the scientific community and the lay public. The provision of national review in problematic instances should engender serious deliberation on these critical issues.

Third, the establishment of criteria for "no risk" or "minimal risk" is obviously related to the interpretation of "harm." In general, the Commission has discussed "harm" in terms of two indices (1) injury or diminished faculty, and (2) pain. A third commonly accepted definition of "harm" is "offense against right or morality"; this meaning of harm has been subsumed under the rubric of violation of dignity or integrity of the fetus, and thus is separated out of the Commission's deliberations on acceptable levels of risk. In establishing acceptable levels of risk, therefore, the Commission has been concerned with injury and pain to the fetus.

Several ethicists argued cogently before the Commission that the ability to experience pain is morally relevant to decisions regarding research. Indeed, the argument was advanced that the ability to experience pain is a more appropriate consideration than is viability for purposes of establishing the limits of intervention into fetal life.

However, scientific opinion is divided on the question of whether the fetus can experience pain—and on the appropriate indices on which to measure the experience of pain. Several experts argue that the fetus does not feel pain.

I believe that the Commission has implicitly accepted this view in making Recommendation (6) regarding research on the fetus during the abortion procedure and on the nonviable fetus *ex utero*. Should this view not be correct, and should the fetus indeed be able to experience pain before the 20th week of gestation, I would modify Recommendation (6) in two ways:

First, the Recommendation as it now stands does not specify an acceptable level of risk. The reason for this omission is essentially as follows: in a dying subject prior to viability, "diminution of faculties" does not appear to be a meaningful index of harm since this index refers largely to future life expectations. Therefore, the critical meaning of "harm" for such a subject lies in the possibility of experiencing pain. If the fetus does not feel pain it cannot be "harmed" in this sense, and thus there is no risk of harm for such a fetus. It is for this reason that the Commission has not specified an acceptable level of "risk" for fetuses in this category, although it has been careful to protect the dignity of the fetus.

Clearly, however, if the fetus does indeed feel pain, then it can be "harmed" by the above definition of harm. If so, then I would argue that an acceptable level of risk should be established at the same level as that considered acceptable for fetuses *in utero*—namely, "no risk" or "minimal risk."

Second, the Commission has concluded that out of respect for the dying subject, no interventions are permissible which would alter the duration of life of the subject—i.e., by shortening or lengthening the dying process (item 6h). I find the prohibition against shortening the life of the dying fetus to be acceptable provided the fetus does not feel pain. If the fetus does feel pain, however, then its dying may be painful and respect for the dying subject may require that its pain be minimized even if its life-span is shortened in so doing.

2. The Commission has stated that its provisions regarding therapeutic and nontherapeutic research directed toward the pregnant woman are not intended to limit research on improving abortion techniques. I support this stand and wish to clarify the reasons for my support.

In supporting this statement, I neither condone nor encourage widespread abortion. However, I do believe that some abortions are both legally and morally justifiable. It is therefore consonant with the principle of minimizing harm to develop techniques of abortion that are least harmful. Indeed, under the present climate of legal freedom to abort and widespread practice of abortion, adherence to the principle of not-harming may impose an obligation on us to research abortion technology in order to minimize harm. This obligation arises not only out of consideration of the health and well-being of the woman but also from a concern for possible pain or discomfort of the fetus during the abortion procedure.

3. Evidence presented to the Commission indicates that there is a strong emphasis in the law on avoiding possible injury to a child to be born. This evidence, coupled with the uncertainty of risks in a new class of human subjects, suggests that considerable importance ought to be attached to the question of compensation for injury incurred during research.

The Commission will study this question in depth at a later time, and therefore has not made any recommendations on compensation at this time. As a matter of personal opinion, I would like to note that I am reluctant to allow any research on the living human fetus unless provision has been made for adequate compensation of subjects injured during research.

4. The Commission's Recommendation on research during the abortion procedure and on the nonviable fetus *ex utero* prevents prolongation of the dying process for purposes of research. This prohibition may appear to have the effect of preventing research on the development of an artificial placenta.

It is my understanding that such an effect does not necessarily follow. Steps toward the development of an artificial placenta are prohibited only through nontherapeutic research; innovative therapy or therapeutic research on the possibly-viable infant is not only condoned but encouraged. Thus the development of an artificial placenta may proceed, but under more restricted circumstances in which it is limited to therapeutic research or to nontherapeutic research which does not alter the duration of life. I do not believe that it was the intention of the Commission to curtail all research toward the development of an artificial placenta, nor do I believe that such will be the effect of the Commission's Recommendations.

Were the Recommendations to have such an effect, however, I would dissent. Indeed, I would argue that a prematurely-delivered fetus that is unable to survive, given the support of available medical technology, would have an interest in the development of an artificial placenta that would allow others like it to survive. Thus it would not be contrary to the interests of that fetus for it to be subjected to nontherapeutic research in the development of an artificial placenta.

In making such an argument, I invoke a principle that I call the "principle of proximity": namely, that research is ethically more acceptable the more closely it approximates what the considered interests of the subject would reasonably be. For example, Hans Jonas has argued that dying subjects should not be used in nontherapeutic research, even when they have consented, unless the research deals directly with the cause from which they are dying; that is, it is presumed that a dying subject has an interest in his/her own disease which legitimates research on that disease where research in general would not be legitimate.

Such a principle is, of course, open to wide interpretation. But I think it not unreasonable to suggest that the dying fetus would have an interest in the cause of its dying or in the development of technology which would allow others like it to survive. On such a principle, one might argue that it is more ethically acceptable to use dying fetuses with Tay-Sachs disease as subjects in nontherapeutic research on Tay-Sachs disease than in nontherapeutic research on general fetal pharmacology. Similarly, one might argue that it is ethically acceptable to use nonviable fetuses *ex utero* as subjects in nontherapeutic research on the development of an artificial placenta. The development of a full rationale for such a position would require an analysis along the lines suggested by McCormick and Toulmin, and I cannot attempt that here. At this point I simply wish to suggest that I believe it is possible to argue for both therapeutic and nontherapeutic research directed toward the development of an artificial placenta.

5. Finally, members of the Commission disagreed about changes in the timing or method of abortion in relation to research. Recommendation (10) states clearly that the recommendations of a physician regarding timing and method of abortion should not be determined by the design or conduct of nontherapeutic research. I am in full agreement with this Recommendation.

The provision in Recommendation (6) (item g), however, is more ambiguous. I would argue that changes in timing or method of abortion are ethically acceptable provided that they are freely chosen by the woman and that she has been fully informed of all possible risks from such changes. I base this argument on the right of any patient to be informed about alternative courses of treatment and to choose between them. It seems to me that the pregnant woman, as a patient, may choose the timing and method of abortion, provided that she has been fully informed of the following: (1) the relation of alternative methods of abortion to possible research on the fetus; (2) risks to herself and to possible future children of alternative possible methods of abortion; and (3) procedures which would be introduced into the abortion as part of the research design which would not be medically indicated.

Some members of the Commission have argued that a woman might choose such changes provided that they entail no additional risk. While I appreciate the concern to protect the woman's health and well-being, such a restriction seems to me a violation of her right to freedom of choice as a patient. Thus I would allow a woman to chose to delay her abortion until the second trimester for purposes of research, *provided that* she has been fully informed of all risks in so doing. One restriction seems imperative to me, however: in no case, should she be allowed to delay the abortion beyond the 20th week of gestation *for research purposes*. This position is reflected in the Deliberations and Conclusions of the Commission's Report.

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