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Michael M. Martin

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## Ethical Standards for Fetal Experimentation

### Cover Page Footnote

Associate Professor of Law, Fordham University School of Law. Professor Martin received his B.A. and J.D. from the University of Iowa where he was Editor-in-Chief of the Iowa Law Review, and a B. Litt. from Oxford University.

# ETHICAL STANDARDS FOR FETAL EXPERIMENTATION

MICHAEL M. MARTIN\*

## I. INTRODUCTION

**M**EDICAL experimentation involving prenatal or aborted human subjects has become a matter of increasing controversy<sup>1</sup> as legal abortion<sup>2</sup> has added to the number of subjects available for fetal experimentation<sup>3</sup> and dissatisfaction in some quarters with "liberal" abortion laws has prompted attempts to limit their effect by restricting fetal research.<sup>4</sup> A number of states have adopted legislation regulating such research<sup>5</sup> and several bills prohibiting federal funding have been

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\* Associate Professor of Law, Fordham University School of Law. Professor Martin received his B.A. and J.D. from the University of Iowa where he was Editor-in-Chief of the *Iowa Law Review*, and a B. Litt. from Oxford University.

1. See, e.g., Note, *Fetal Experimentation: Moral, Legal, and Medical Implications*, 26 *Stan. L. Rev.* 1191 (1974). See also Altman, *Curbs on Fetal Research Impede Fight on Disease*, *N.Y. Times*, Apr. 20, 1974, at 11; Randal, *Challenges To Fetal Research*, *Wash. Star-News*, July 19, 1974, at A-1.

2. See *Roe v. Wade*, 410 U.S. 113 (1973), discussed in Byrn, *An American Tragedy: The Supreme Court on Abortion*, 41 *Fordham L. Rev.* 807 (1973); Ely, *The Wages of Crying Wolf: A Comment on Roe v. Wade*, 82 *Yale L.J.* 920 (1973); 74 *Colum. L. Rev.* 237 (1974), 87 *Harv. L. Rev.* 75 (1973). See also *Doe v. Bolton*, 410 U.S. 179 (1973).

3. See Statement of Randy V. Engel, Director, U.S. Coalition for Life, in *Hearings on the Quality of Health Care—Human Experimentation Before the Subcomm. on Health of the Senate Comm. on Labor and Public Welfare*, 93d Cong., 1st Sess., pt. 2, at 568 (1973) [hereinafter cited as 1973 Hearings].

4. See Culliton, *Grave-Robbing: The Charge against Four from Boston City Hospital*, 186 *Sci.* 420, 421-22 (1974); Randal, *supra* note 1, at A-1, F-18; Rorvik, *The Embryo Sweepstakes*, *N.Y. Times*, Sept. 15, 1974, § 6 (Magazine), at 16, 60.

5. A detailed discussion of the state statutes is included in Note, *Fetal Experimentation: Moral, Legal, and Medical Implications*, 26 *Stan. L. Rev.* 1191, 1197-1203 (1974). The most common statutes prohibit experimentation on any conceptus except to preserve or protect its life or health. *La. Rev. Stat. Ann.* § 14:87.2 (Supp. 1974); *Me. Rev. Stat. Ann. tit. 22*, § 1574 (Supp. 1974); *Minn. Stat. Ann.* §§ 145, 421-22 (Supp. 1974); *Utah Code Ann.* § 76-7-312 (Supp. 1973); see ch. 421, [1974] *Mass. Ann. Laws* 257, amending *Mass. Gen. Laws ch. 112*, § 12 (prohibits, *inter alia*, use of any live fetus, before or after expulsion, for experimentation; an exception is made for studies while in utero which do not jeopardize the fetus' life or health, when the fetus is not the subject of a planned abortion); *S.D. Compiled Laws Ann.* § 34-23A-17 (Supp. 1974) (experimentation on fetuses without written consent of "the woman" prohibited); cf. *Cal. Health & Safety Code* § 25956 (West Supp. 1974) (experimentation on aborted fetus prohibited, except to preserve or protect its life); *Ind. Code* § 35-1-58.5-6 (Supp. 1974) [*Ind. Ann. Stat.* § 10-112 (Burns Cum. Supp. 1974)] (experimentation on aborted fetus prohibited); *Neb. Rev. Stat.* § 28-4,161 (Supp. 1973) (unlawful to "sell, transfer, distribute, or give away" aborted fetus for experimentation; no prohibition stated against use for that purpose).

A second type requires that abortion procedures be used which will preserve the life of a viable

introduced in Congress.<sup>6</sup> In 1974 Congress imposed a moratorium on the use of federal funds for experimentation with human fetuses, pending the adoption of standards on the matter by the National Commission for the Protection of Human Subjects in Biomedical and Behavioral Research.<sup>7</sup> The standards finally adopted by the Commission will likely be influenced by the policy being developed by the Department of Health, Education and Welfare ("HEW") for the protection of human subjects in HEW-supported biomedical research and related activities.<sup>8</sup>

The HEW's proposed regulations will be the focus of this Article. Particular attention will be given to the question of how well they fulfill their express purpose of ensuring that experiments with human subjects "conform to appropriate ethical standards and relate to important societal needs."<sup>9</sup> The analysis to be employed is founded on the

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fetus. Idaho Code § 18-608(3) (Cum Supp. 1974); Ind. Code § 35-1-58.5-7 (Supp. 1974) [Ind. Ann. Stat. § 10-113 (Burns Cum. Supp. 1974); Me. Rev. Stat. Ann. tit. 22, § 1575 (Supp. 1974); Utah Code Ann. § 76-7-310 (Supp. 1974).

A third type of statute restricts the research uses of fetal tissues after abortion. See Ill. Ann. Stat. ch. 38, § 81-18 (Smith-Hurd Supp. 1974); Ind. Code § 35-1-58.5-6 (Supp. 1974) [Ind. Stat. Ann. § 10-112 (Burns Cum. Supp. 1974)]. Other statutes expressly exclude fetal remains from the prohibition against experimentation. Cal. Health & Safety Code § 25956 (West Supp. 1974); see Minn. Stat. Ann. § 145.422(3) (Supp. 1974) (permitting sale of cell culture line from non-living human conceptus). See also Culliton, *Grave-Robbing: The Charge against Four from Boston City Hospital*, 186 *Sci.* 420 (1974); Dykes & Czapek, *Regulations and Legislation Concerning Abortus Research*, 229 *J.A.M.A.* 1303 (1974).

6. See, e.g., S. 2072, H.R. 6849, 7724, 7725, 7850, 8778, 8779, 8780, 9488, 93d Cong., 1st Sess. (1973). Federal funds are a major source of support for medical research. See Note, *Fetal Experimentation: Moral, Legal, and Medical Implications*, 26 *Stan. L. Rev.* 1191 n.2 (1974); Comment, *Non-Therapeutic Medical Research Involving Human Subjects*, 24 *Syracuse L. Rev.* 1067 n.5 (1973).

7. National Research Act § 213, 88 Stat. 353 (1974). The Commission's report to the Secretary of Health, Education, and Welfare is due not later than four months from the first day of the first month after all members of the Commission have taken office. *Id.* § 202(b), 88 Stat. 350. The version of the Act originally approved by the House of Representatives included a complete ban on federal funding of fetal experimentation. See 119 *Cong. Rec.* 4167-75 (daily ed. May 31, 1973).

8. U.S. Dept. of Health, Educ. & Welfare, *Protection of Human Subjects, Proposed 45 C.F.R. §§ 46.301-10*, 39 *Fed. Reg.* 30653 (1974) [hereinafter cited by section as HEW Proposals]. Proposed regulations for the protection of human subjects, to be generally applicable to all HEW grant-supported activity, were published October 9, 1973. HEW Proposals, 38 *Fed. Reg.* 27882 (1973). After public comment and some amendment, those regulations became effective July 1, 1974, as 45 C.F.R. §§ 46.1-.22. HEW Proposals, 39 *Fed. Reg.* 18917 (1974). Proposals for regulations governing research with subjects in special categories (children, fetuses and abortuses, prisoners, and the mentally infirm) were first published November 16, 1973. HEW Proposals, 38 *Fed. Reg.* 31738 (1973). The proposals for all categories except children were revised and resubmitted for public comment on August 23, 1974. HEW Proposals, 39 *Fed. Reg.* 30648 (1974). See also HEW Proposals, 39 *Fed. Reg.* 37993 (1974) (amending the Preamble to the August 1974 draft). This Article is principally concerned with the November 1973 and August 1974 drafts.

9. HEW Proposals, Proposed 45 C.F.R. § 46.302, 39 *Fed. Reg.* 30653 (1974).

assumption that "appropriate ethical standards" for fetal research should be consistent with the standards applied in situations having similar consequences, such as compulsory medical treatment, organ transplantation, and abortion. A comparison with the standards developed in those situations will suggest that the proposed HEW regulations for fetal research do not fully achieve their ethical objective.

### Definitions

The term "experiment," and its various forms, will be used herein to refer to medical procedures which create a risk of physical invasion<sup>10</sup> of the subject additional to, or different in nature from, that created by established and accepted procedures necessary to meet the subject's needs.<sup>11</sup> This definition encompasses both a non-standard procedure utilized for diagnosis or therapy, and standard procedures (e.g., withdrawing a blood sample for analysis) done for purposes other than relieving the subject's malady or preventing his contracting a disease.

"Fetal experimentation" has been used to describe a number of situations in which products of human conception are put at risk. These situations may conveniently be categorized as *in vitro*, *in utero*, and abortus experiments.<sup>12</sup> *In vitro* experimentation involves development of the conceptus<sup>13</sup> when it is outside the human

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10. Non-invasive research procedures (e.g., urinalysis, ophthalmoscopic examination, EEG, pressure pulse measurement) are not "experimental" by this definition. However, even procedures which do not create physical risks may raise ethical problems to the extent they have a psychological or social effect on the subject. For this reason, the HEW Proposals define "subject at risk" to include physical, psychological, sociological, and other risks. HEW Proposals, 45 C.F.R. § 46.3(b), 39 Fed. Reg. 18917 (1974); see id., Proposed 45 C.F.R. § 46 24(b), 38 Fed. Reg. 31746 (1973). See generally Altman, *New Rules Spark Controversy Over Human Biologic Materials*, N.Y. Times, Apr. 30, 1974, at 35, cols. 1-3. Since only physical risks are presently of significance in fetal experimentation (and the applicable principles should be the same in any case), the definition used herein is limited accordingly.

11. See HEW Proposals, Proposed 45 C.F.R. § 46.3(b), 39 Fed. Reg. 18917 (1974). Whether procedures are "established and accepted" is necessarily a matter of professional judgment in light of both national and local standards of practice. See U.S. Dept. of Health, Educ. & Welfare, *The Institutional Guide to DHEW Policy on Protection of Human Subjects 3* (undated), in 1973 Hearings, pt. 2, at 534. Even established and accepted procedures may be experimental if employed for purposes other than the strict interests of the subject. For example, it is experimental to assign a patient arbitrarily to one accepted therapeutic regimen in order to compare its effectiveness with that of another which also is established and accepted. Any alteration of the choice, scope, or timing of an established method in the interests of research is experimental under this definition. Id. at 3-4, in 1973 Hearings, pt. 2, at 534-35. See also Visscher, *The Two Sides of the Coin in the Regulation of Experimental Medicine*, 169 *Annals N.Y. Acad. Sci.* 319, 324 (1970). "Experimental," as used herein, does not mean "harmful." See HEW Proposals, 38 Fed. Reg. 31739 (1973).

12. See HEW Proposals, 38 Fed. Reg. 31738 (1973).

13. A "conceptus" is "that produced as a result of conception; embryo." *Stedman's Medical*

womb.<sup>14</sup> Research in this area is focused on the fertilization of a human ovum in a laboratory culture and its subsequent implantation in the uterus.<sup>15</sup> The subject of *in utero* experimentation is a conceptus in the womb, at any time from fertilization until its delivery (spontaneous or induced) or death.<sup>16</sup> Recent *in utero* experimentation has included studies regarding the diagnosis of genetic problems from amniotic fluid samples,<sup>17</sup> the effects of drugs and vaccines on fetal and maternal health,<sup>18</sup> and the immunological processes involved in pregnancy.<sup>19</sup> An abortus is a whole conceptus exhibiting vital signs which is expelled (either spontaneously or as a result of medical or surgical intervention) from the uterus.<sup>20</sup> However, if the aborted fetus has the ability to survive outside the womb to the point where it can indepen-

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Dictionary 276 (22d ed. 1972). See Minn. Stat. Ann. § 145.421(2) (Supp. 1974): " 'Human conceptus' means any human organism, conceived either in the human body or produced in an artificial environment other than the human body, from fertilization through the first 265 days thereafter."

14. See HEW Proposals, Proposed 45 C.F.R. § 46.303(g), 39 Fed. Reg. 30653 (1974); Edwards, Control of Human Development, in *Artificial Control of Reproduction* 93-100, 148-49 (C. Austin & R. Short eds. 1972).

15. See HEW Proposals, 38 Fed. Reg. 31743 (1973). See generally Karp, *Meanwhile the Mad Scientist Created an Airborne Division . . .*, N.Y. Times, Oct. 28, 1974, at 31, col. 4; Rorvik, *The Embryo Sweepstakes*, N.Y. Times, Sept. 15, 1974, § 6 (Magazine), at 16.

16. The HEW Proposals define "fetus" as "the product of conception from the time of implantation to the time of delivery." HEW Proposals, Proposed 45 C.F.R. § 46.303(d), 39 Fed. Reg. 30653 (1974).

17. See, e.g., *Amniotic Fluid* (D. Fairweather & T. Eskes eds. 1973); Conference on Antenatal Diagnosis (A. Dorfman ed. 1972); Nadler, *Fetal Diagnosis Utilizing Amniotic Fluid Cells, in Fetal Growth and Development* 141 (H. Waisman & G. Kerr eds. 1970); Levin, Oxman, Moore, Daniels & Scheer, *Diagnosis of Congenital Rubella in Utero*, 290 N. Eng. J. Med. 1187 (1974); Montagne, *Hemolytic Disease of the Fetus, in Intra-Uterine Development* 443 (A. Barnes ed. 1968).

18. See, e.g., Edsall, *Letter*, 186 Sci. 195 (1974); Marx, *Drugs during Pregnancy: Do They Affect the Unborn Child?*, 180 Sci. 174 (1973); Vaheri, Vesikari, Oker-Blum, Seppala, Parkman, Veronelli & Robbins, *Isolation of Attenuated Rubella-Vaccine Virus from Human Products of Conception and Uterine Cervix*, 286 N. Eng. J. Med. 1071 (1972).

19. See, e.g., J. Anderson, *Nature's Transplant* (1972); *Immunology and Reproduction* (R. Edwards ed. 1969).

The Thalidomide tragedy of the early 1960s would be included within the category of *in utero* experimentation, since it involved administration of a non-standard drug to pregnant women, putting the fetuses at risk. See generally Senate Comm. on Gov't Operations, 88th Cong., 1st Sess., *Interagency Coordination in Drug Research and Regulation*, pts. 1-2, 4 at 1912-25 (Comm. Print 1963).

20. See HEW Proposals, Proposed 45 C.F.R. § 46.303(f), 39 Fed. Reg. 30653 (1974). The term does not apply to the placenta, macerated fetal material, or cells, tissue, or organs from a dead fetus. *Id.* Stedman's Medical Dictionary 3 (22d ed. 1972) defines "abortus" as: "The embryo or product of conception that is lost in an abortion." *Contra*, Williams, *Obstetrics* 1026-27 (14th ed. L. Hellman & J. Pritchard 1971): "[A]bortus is defined as a nonviable conceptus . . .;" see Dykes & Czapek, *Regulations and Legislation Concerning Abortus Research*, 229 J.A.M.A. 1303, 1304 (1974) (discussion of abortus research deals mainly with fetal remains).

dently maintain vital functions (especially circulation and respiration), it is said to be "viable" and is treated as a premature infant.<sup>21</sup> Non-viable abortuses have been used as subjects for investigations into congenital infections and defects,<sup>22</sup> tissue and organ transplantation,<sup>23</sup> and improved techniques for the care of premature babies.<sup>24</sup>

## II. THE HEW PROPOSED REGULATIONS

Two sets of regulations have been proposed by HEW.<sup>25</sup> Major provisions relating to fetal experimentation contained in the first draft, promulgated in November 1973, included:

- (1) a prohibition against any research activity involving a nonviable abortus which would prolong heart beat and respiration for research purposes or terminate heartbeat and respiration;<sup>26</sup>

21. See *Roe v. Wade*, 410 U.S. 113, 160 (1973); HEW Proposals, Proposed 45 C.F.R. 46.303(e), 39 Fed. Reg. 30653 (1974). See also, e.g., La. Rev. Stat. Ann. § 14:87.2 (Supp. 1974) (defining "live birth," for purpose of prohibiting experimentation, as complete extraction and any evidence of life); Minn. Stat. Ann. § 145.421 (Supp. 1974) (defining "living conceptus," for purpose of prohibiting experimentation, as including any human organism from fertilization to 265 days' gestation and evidencing any movement or circulatory, respiratory, EEG, or EKG activity); N.Y. Pub. Health Law § 4130(1) (McKinney 1971) (defining "live birth," for purpose of requiring vital statistics report, as "complete expulsion or extraction from its mother of a product of conception, irrespective of the duration of pregnancy, which, after such separation, breathes or shows any other evidence of life . . .").

22. See, e.g., Enders, Letter, 290 N. Eng. J. Med. 1199 (1974); Vaheri, et al., *supra* note 18; Letter from Charles A. Janeway, M.D., Dep't of Pediatrics, Harvard Med. School, to Dr. Robert Stone, Director, Nat'l Inst. of Health, Jan. 3, 1973. See also Philipson, Sabath & Charles, Transplacental Passage of Erythromycin and Clindamycin, 288 N. Eng. J. Med. 1219 (1973).

23. See, e.g., R. Billingham & W. Silvers, *The Immunobiology of Transplantation* 168 (1971); Walbert, Preface to *Abortion, Society and the Law* at xv n.1 (D. Walbert & J. Butler eds. 1973).

Under the HEW Proposals, activities involving an abortus as an organ or tissue donor shall be conducted in accordance with applicable state or local laws. HEW Proposals, Proposed 45 C.F.R. § 46.309, 39 Fed. Reg. 30654 (1974). Under the Uniform Anatomical Gift Act, as adopted in most states, organs or tissues may be donated by persons of "sound mind and 18 years of age or more." Uniform Anatomical Gift Act § 2(a). In addition, the Act provides for donation of cadaver parts, in the absence of actual notice of contrary indications by the decedent or persons with a superior interest, with the permission of specified persons. Uniform Anatomical Gift Act § 2(b). See generally Note, *The Sale of Human Body Parts*, 72 Mich. L. Rev. 1182 1186-89 (1974). Under the Act, donation of an abortus' tissues, organs, or remains could be accomplished with the permission of (a) either parent, (b) an adult brother or sister, (c) a guardian of the fetus' person at the time of death, or (d) any other person authorized or under obligation to dispose of the body, assuming no opposition from a member of the same or a prior class. See Uniform Anatomical Gift Act §§ 2(b)(3)-(6).

24. See, e.g., Johnson, *The Initiation of Respiration and the Neonatal Status*, in *Intra-Uterine Development* 498 (A. Barnes ed. 1968); Letter from Keith P. Russell, M.D., Pres., Am. Coll. Ob. & Gyn., to Rep. Paul G. Rogers, Sept. 28, 1973, on file, Director, Nat'l Inst. of Health.

25. See note 8 *supra*.

26. HEW Proposals, 38 Fed. Reg. 31738, 31743 (1973); *id.*, Proposed 45 C.F.R. §§ 46.35(b)(2)-(3), 38 Fed. Reg. 31747 (1973).

(2) a prohibition against any research activity involving pregnant women which might adversely affect the fetus;<sup>27</sup>

(3) a prohibition on *in vitro* fertilization pending demonstration of its safety in sub-humans and establishment of the responsibilities of the involved parties;<sup>28</sup> and

(4) a requirement that no child (including a viable fetus) be put at risk unless the information can be gained in no other way and the risk is insignificant or far outweighed by the potential benefit.<sup>29</sup>

In addition, the proposal would create Ethical Review Boards at the funding agency to advise on ethical standards and review specific proposals,<sup>30</sup> and Protection Committees at the sponsoring institutions to oversee the selection of subjects and the conduct of research.<sup>31</sup> These two new bodies, and a provision requiring the consent of both parents,<sup>32</sup> were designed to supplement the protections afforded by present review structures and legal consent requirements.

Following extensive public comment, HEW promulgated a revised draft of the proposed regulations in August 1974.<sup>33</sup> Principal changes in the revised regulations included:

(1) the prohibition on artificial continuation of vital signs of an abortus was removed where the purpose of the research was to develop new methods to enable the abortus to survive to viability;<sup>34</sup> and

27. HEW Proposals, 38 Fed. Reg. 31738, 31739 (1973); *id.*, Proposed 45 C.F.R. §§ 46.31(a)(1), .37, 38 Fed. Reg. 31747 (1973).

28. HEW Proposals, 38 Fed. Reg. 31738, 31743 (1973); *cf. id.*, Proposed 45 C.F.R. §§ 46.31(a)(3), .33(i), .34, 38 Fed. Reg. 31747 (1973). See also *id.*, 39 Fed. Reg. 30650 (1974).

29. HEW Proposals, 38 Fed. Reg. 31740-41 (1973); see *id.*, Proposed 45 C.F.R. §§ 46.25(b), .26(b), 38 Fed. Reg. 31746 (1973).

30. HEW Proposals, 38 Fed. Reg. 31741 (1973); *id.*, Proposed 45 C.F.R. § 46.25, 38 Fed. Reg. 31746 (1973). See also *id.*, Proposed 45 C.F.R. § 46.304, 39 Fed. Reg. 30653 (1974).

31. HEW Proposals, 38 Fed. Reg. 31741-42 (1973); *id.*, Proposed 45 C.F.R. § 46.26, 38 Fed. Reg. 31746 (1973). See also *id.*, Proposed 45 C.F.R. § 46.305, 39 Fed. Reg. 30653-54 (1974).

32. HEW Proposals, 38 Fed. Reg. 31742 (1973); *id.*, Proposed 45 C.F.R. §§ 46.27(c), .38, 38 Fed. Reg. 31746, 31747 (1973). Under the revised regulations, paternal consent is required only if the activity is not responding to the health needs of the pregnant woman and the father is reasonably available. *Id.*, 39 Fed. Reg. 30651 (1974); see *id.*, Proposed 45 C.F.R. §§ 46.306(b), .307(b), 39 Fed. Reg. 30654 (1974). See also *Roe v. Wade*, 410 U.S. 113, 165 n.67 (1973).

33. HEW Proposals, 39 Fed. Reg. 30648 (1974).

34. HEW Proposals, Proposed 45 C.F.R. § 46.307(d), 39 Fed. Reg. 30654 (1974); see *id.*, 39 Fed. Reg. 30651 (1974). The provision is worded ambiguously: "Vital functions of an abortus will not be artificially maintained except where the purpose of the activity is to develop new methods for enabling the abortus to survive to the point of viability . . ." *Id.*, Proposed 45 C.F.R. § 46.307(d), 39 Fed. Reg. 30654 (1974). The inclusion of "to develop new methods" suggests that such experimentation is permissible irrespective of anticipated benefits to the particular subject, while use of the definite article in "the abortus" suggests the contrary.

A fetus surviving an abortion may be made a ward of the state. See, e.g., Ind. Code

(2) experimental activity involving pregnant women would be permitted in order to respond to the fetus' or mother's health needs, or, as part of an abortion procedure, to improve methods of prenatal diagnosis, preventing premature birth or intervention to offset genetic or congenital abnormality.<sup>35</sup>

This second proposal will serve as a focus for the analysis to be developed in this Article.<sup>36</sup>

§ 35-1-58.5-7(c) (Supp. 1974) [Ind. Ann. Stat. § 10-113 (Burns Cum. Supp. 1974)]; Minn. Stat. 145.415(3), [1974] Minn. Laws ch. 177, § 5(3); Utah Code Ann. § 76-7-311 (Supp. 1973).

35. HEW Proposals, Proposed 45 C.F.R. § 46.306(a), 39 Fed. Reg. 30654 (1974); *id.*, 39 Fed. Reg. 30651 (1974).

36. The proposed regulation provides in pertinent part:

§ 46.306. Activities involving fetuses in  
utero or pregnant women.

(a) No activity to which this subpart is applicable, involving fetuses in utero or pregnant women, may be undertaken unless: (1) the purpose of the activity is to benefit the particular fetus or to respond to the health needs of the mother, or (2) the activity conducted as part of (but not prior to the commencement of) a procedure to terminate the pregnancy and is for the purpose of evaluating or improving methods of prenatal diagnosis, methods or prevention of premature birth, or methods of intervention to offset the effects of genetic abnormality or congenital injury.

(b) Activities covered by this subpart which are permissible under paragraph (a) of this section may be conducted only if the mother and father are legally competent and have given their consent, except that the father's consent need not be secured if: (1) the purpose of the activity is to respond to the health needs of the mother or (2) his identity or whereabouts cannot reasonably be ascertained.

(c) Activities covered by this subpart which are permissible under paragraph (a)(2) of this section may not be undertaken unless individuals engaged in the research will have no part in: (1) any decisions as to the timing, method, or procedures used to terminate the pregnancy, and (2) determining the viability of the fetus at the termination of the pregnancy.

§ 46.307 Activities involving abortuses.

No activity to which this subpart is applicable, involving an abortus, may be undertaken unless:

(a) Appropriate studies on animals have been completed;

(b) The mother and father are legally competent and have given their consent, except that the father's consent need not be secured if his identity or whereabouts cannot reasonably be ascertained;

(c) Individuals engaged in the research will have no part in: (1) any decisions as to the timing, method, or procedures used to terminate the pregnancy, and (2) determining the viability of the fetus at the termination of the pregnancy;

(d) Vital functions of an abortus will not be artificially maintained except where the purpose of the activity is to develop new methods for enabling the abortus to survive to the point of viability, and

(e) Experimental procedures which would terminate the heart beat or respiration of the abortus will not be employed.

§ 46.308 Activities involving a dead fetus  
or abortus.

Activities involving a dead fetus or abortus shall be conducted in accordance with any applicable State or local laws governing autopsy.

### III. EXPERIMENTAL CONSEQUENCES RELEVANT TO THE FORMULATION OF ETHICAL STANDARDS

An act of human medical experimentation may have a number of consequences which can be, in the particular case, consistent or inconsistent with promoting "health" and "human dignity." The term "health" will be used broadly to encompass the physical, mental, and emotional well-being of the subject or other affected persons. "Dignity" is used here in the sense of "worth," or the values associated with being human. There may be other consequences of experimentation in addition to those discussed here; however, no others seem to be considered very frequently in making decisions about experimentation or deciding its permissible limits.<sup>37</sup>

#### A. *Health*<sup>38</sup>

Experimentation has beneficial health consequences for the subject when his disorder is identified (diagnosis) or relieved (therapy). The subject also benefits if the experimental procedure protects against a disorder not presently suffered but which threatens (prophylaxis). Furthermore, the subject benefits if the experiment leads to knowledge which can be used for diagnosis or therapy of a disorder he might suffer subsequent to the experiment.<sup>39</sup> On the other hand, an experimental procedure can harm the subject when it aggravates a disorder from which he suffers (or adds a separate disorder), injures the subject's good health, or makes the subject more susceptible to a disorder in the future.

Experimentation may also have consequences for individuals other than the subject. Those who suffer from the same or a similar disorder as the subject may benefit because the knowledge obtained can be applied to their diagnosis or therapy. Even when their health condition differs from the subject's, others can still benefit when the knowledge about human biological processes gained from the experiment is ap-

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37. The categorization of consequences which has been adopted herein has been influenced by Callahan's explication of the "rule systems" subsumed under the principle of "the sanctity of life." D. Callahan, *Abortion: Law, Choice & Morality* 327-33 (1970) [hereinafter cited as Callahan].

38. Compare the five categories of pediatric experiments set out in Mitchell, *The Child and Experimental Medicine*, 1 *Brit. Med. J.* 721, 723 (1964): "1. An experiment in treatment with the immediate aim of curing the child's disease. 2. An experiment on an ill child in order to find out more about his condition. 3. An experiment on an ill child in order to learn more about the disease from which he is suffering. 4. An experiment on a child who is either well or suffering from another disease in order to find out more about a particular disease. 5. An experiment, usually on a healthy child, designed to provide information about children in general."

39. See 1973 Hearings, pt. 4, at 1270 (remarks of Albert Sabin, M.D., on testing polio vaccine).

plied to their cases.<sup>40</sup> For example, dispensing new drugs to normal "control" subjects is used to establish safe dosage levels for therapeutic purposes.<sup>41</sup> Detrimental effects on the health of nonsubjects can occur when the experiment causes a disease to spread. Harm to the subject can also affect the emotional well-being of friends and relatives.

Experimentation may also have such widespread consequences on the health of others as to affect a community or mankind as a whole. For example, experimentation can result in knowledge which might stop the spread of an epidemic threatening to destroy a whole community. Plague and smallpox have historically been such threats.<sup>42</sup> Survival of the human species has not yet been an objective of medical experimentation; it might become so if, for example, further environmental pollution were to produce significant genetic mutations. It should be noted that a distinction is drawn here between consequences which involve individuals, whether singly or in large groups, and those related to the survival of the community or species as a whole. For example, while numerous persons could be restored to health by kidney transplants,<sup>43</sup> the survival of society is hardly affected by whether those persons die of acute renal failure now or arteriosclerosis later.<sup>44</sup>

### B. *Dignity*

The concept of human "dignity" reflects our society's esteem for the status of being human. This esteem is evidenced by the protections society provides, and to which each individual is entitled solely because of his status as a human. One particularly sensitive consequence of experimentation is the touching, entering, or otherwise changing of the subject's body. Irrespective of any modification brought on thereby in the subject's well-being, the contact violates his

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40. See, e.g., Blumgart, *The Medical Framework for Viewing the Problem of Human Experimentation*, in *Experimentation with Human Subjects* 39, 42-43 (P. Freund ed. 1970).

41. See 21 C.F.R. § 312.1(a)(2), Form FD-1571, item 10(a) (1974). See also Cavers, *The Legal Control of the Clinical Investigation of Drugs: Some Political, Economic, and Social Questions*, in *Experimentation with Human Subjects* 225 (P. Freund ed. 1970); Curran, *Governmental Regulation of the Use of Human Subjects in Medical Research: The Approach of Two Federal Agencies*, in *Experimentation with Human Subjects* 402 (P. Freund ed. 1970).

42. See *Jacobson v. Massachusetts*, 197 U.S. 11, 28 (1905); Jonas, *Philosophical Reflections on Experimenting with Human Subjects*, in *Experimentation with Human Subjects* 1, 11-13 (P. Freund ed. 1970).

43. See, e.g., Dempsey, *Transplants Are Common; Now It's the Organs That Have Become Rare*, *N.Y. Times*, Oct. 13, 1974, § 6 (Magazine), at 56, 57 (8000 candidates per year for kidney transplants); Note, *The Sale of Human Body Parts*, 72 *Mich. L. Rev.* 1182, 1201-03 (1974).

44. See Jonas, *supra* note 42, at 11; cf. Brauer, *Moral and Ethical Considerations Concerning Abortion*, in *Conference on Antenatal Diagnosis* 243, 245-46 (A. Dorfman ed. 1972).

bodily integrity. His individuality is reduced by sharing his corporeal being with another.

A second effect of experimentation is to exploit<sup>45</sup> the subject, in that the invasion or manipulation of his body provides benefits to others. The subject's withholding, or others' claiming, of those benefits will have the effect of increasing, in the former case, and reducing, in the latter, the subject's individuality.

Experimentation can also have consequences for the subject's "self-determination." If he chooses to be experimented upon, he is "[making] for himself [one of] those choices which significantly affect[s] his personal fate."<sup>46</sup> However, if he is made an experimental subject without such a choice, his individuality (in the sense of being independent of the effects of others' acts and decisions) is again diminished.

Finally, the manner in which experimentation is conducted may affect the trust among members of the community that society will protect the dignity of an individual irrespective of that individual's ability to assert and enforce a claim to such protection. When the bodily integrity of an experimental subject is invaded for the benefit of others and without his free choice, the effect can be (depending on other circumstances) to weaken the mutual trust which helps hold the members of a community together, because they can no longer be sure they will be protected when unable to protect themselves.

### C. *Health and Dignity Consequences of the HEW Proposed Regulations*

The most recent proposed HEW regulations in effect say that the Department will provide financial support for research involving physical invasions of conceptuses only when an anticipated consequence is a benefit to the health of the subject or to that of the mother.<sup>47</sup> A benefit to the health of others may not be, by itself, a consequence sufficiently valuable to justify invading the bodily integrity of the fetus, although health benefits to others are a permissible incidental effect of experimentation. However, when the subject is a conceptus in the process of abortion or an abortus (living and outside the mother, but non-viable),<sup>48</sup> a physical invasion is permissible if an anticipated

45. Use of the word "exploit" is intended to be without any negative connotation. It is perhaps indicative of the values involved that one has great difficulty finding a word which will convey the idea of "providing benefit to others" without either positive or negative connotation.

46. Callahan 332; see *Schloendorff v. Society of N.Y. Hosp.*, 211 N.Y. 125, 129-30, 105 N.E. 92, 93 (1914), overruled on other grounds, *Bing v. Thunig*, 2 N.Y.2d 656, 143 N.E.2d 3, 163 N.Y.S.2d 3 (1957).

47. See HEW Proposals, Proposed 45 C.F.R. § 46.306(a)(1), 39 Fed. Reg. 30654 (1974).

48. See HEW Proposals, Proposed 45 C.F.R. § 46.303(f), 39 Fed. Reg. 30653 (1974).

consequence is a benefit to the health of others.<sup>49</sup> Such permissible invasions do not include those which would be a serious health detriment to the subject by terminating vital signs or which would constitute a substantial manipulation of the subject's bodily processes by prolonging life when the expected benefit to health is not as substantial as allowing the fetus to survive to viability.<sup>50</sup>

The apparent premises of the proposed regulations include the following: first, benefit to the health of others is usually not as valuable a consequence as preserving human individuality from physical invasion and exploitation. Permitting experimentation on the conceptus for the benefit of the mother is, of course, an exception to this premise. Second, the human dignity of an abortus is not as valuable as that of a conceptus being carried to term. This may reflect a specific determination that (a) the abortus is "less human" or "non-human" and therefore less injured by physical invasion and exploitation; or (b) that the mutual trust that society will protect the vulnerable is less affected when the subject is an abortus. We can test these two major premises (and the implicit values they reflect) by a comparison with other situations involving similar consequences. Such a comparison may be facilitated by focusing on three specific questions: (1) what consequences are more valued than physical inviolability; (2) is the same relative valuation applied to all subjects of experimentation; and (3) if not, what factors affect the valuation?

#### IV. COMPARABLE SITUATIONS

This section investigates other situations which produce health and dignity consequences similar to those of fetal experimentation, with a view to determining the relative value society assigns the consequences.

##### A. *Compulsory Medical Treatment*

Compulsory medical treatment can have consequences similar to those resulting from experimentation. Instances in which compulsory medical treatment has become the subject of litigation include vaccinations to prevent disease or stop its spread,<sup>51</sup> transfusions for patients in

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49. Cf. HEW Proposals, Proposed 45 C.F.R. §§ 46.306(a)(2), .307, 39 Fed. Reg. 30654 (1974).

50. See HEW Proposals, Proposed 45 C.F.R. §§ 46.307(d), (e), 39 Fed. Reg. 30654 (1974). Query whether a similar limitation on application of life-support procedures would or should be made in the case of terminally-ill adults. See generally J. Katz, *Experimentation with Human Beings* ch. 14 (1972).

51. See, e.g., *Jacobson v. Massachusetts*, 197 U.S. 11 (1905).

extremis,<sup>52</sup> and reconstructive surgery for an infant.<sup>53</sup> In each of these instances (except possibly vaccination to stop the spread of disease), the principal effect of the treatment was to improve the health of the subject. However, if anything were to go wrong, the subject's health could be impaired. Incidental effects on the health of others could likewise be either beneficial or detrimental: in some instances, the treatment may stop the spread of disease, but in others the treatment may upset the emotional well-being of the subject's relatives (*e.g.*, giving a blood transfusion to a child of a Jehovah's Witness). Usually, compulsory medical treatment is not exploitative, but it does involve the invasion of the subject's bodily integrity, and this may be without (or contrary to) his exercise of free choice.

### B. *Organ Transplantation*

Organ transplantation can also have consequences akin to those of experimentation.<sup>54</sup> The donor may benefit physically through better medical care incident to the donation and emotionally through a sense of having helped another.<sup>55</sup> However, the donor's health may also be injured, either by a mishap in the medical procedure or by an increased susceptibility to future disorders.<sup>56</sup> For the donee, the benefit to his health provides the incentive to transplant, but if there is a mishap in the operation, the transplant fails to take, or immunosuppressive drugs sufficiently lower his resistance to disease, his health may be impaired rather than benefitted. The health effects of transplantation on others are most likely to be related to emotional well-being: for example, there may be both relief at having the donee

52. See, *e.g.*, *Application of President & Dirs. of Georgetown Coll., Inc.*, 331 F.2d 1000, petition for rehearing en banc denied per curiam, 331 F.2d 1010 (D.C. Cir.), cert. denied, 377 U.S. 978 (1964); *Holmes v. Silver Cross Hosp.*, 340 F. Supp. 125 (N.D. Ill. 1972); *United States v. George*, 239 F. Supp. 752 (D. Conn. 1965); *In re Osborne*, 294 A.2d 372 (D.C. Ct. App. 1972); *In re Estate of Brooks*, 32 Ill. 2d 361, 205 N.E.2d 435 (1965); *John F. Kennedy Mem. Hosp. v. Heston*, 58 N.J. 576, 279 A.2d 670 (1971); *Erickson v. Dilgard*, 44 Misc. 2d 27, 252, N.Y.S.2d 705 (Sup. Ct. 1962); *In re Clark*, 185 N.E.2d 128 (Ohio Ct. C.P. 1962); Note, *Compulsory Medical Treatment: The State's Interest Re-evaluated*, 51 Minn. L. Rev. 293 (1966).

53. See *In re Seiferth*, 285 App. Div. 221, 137 N.Y.S.2d 35 (4th Dep't), rev'd, 309 N.Y. 80, 127 N.E.2d 820 (1955); *Green Appeal*, 448 Pa. 338, 292 A.2d 387 (1972).

54. See generally *Hart v. Brown*, 29 Conn. Supp. 368, 289 A.2d 386 (Super. Ct. 1972); *Strunk v. Strunk*, 445 S.W.2d 145 (Ky. 1969); *In re Richardson*, 284 So. 2d 185 (La. App.), cert. denied, 284 So. 2d 338 (La. 1973); Curran, *A Problem of Consent: Kidney Transplantation in Minors*, 34 N.Y.U.L. Rev. 891 (1959) (three unreported Massachusetts cases discussed).

55. See *Hart v. Brown*, 29 Conn. Supp. 368, 374-75, 289 A.2d 386, 389 (Super. Ct. 1972) (strong identification between donor and donee, as twin sisters); *Strunk v. Strunk*, 445 S.W.2d 145, 146 (Ky. 1969) (incompetent donor devoted to donee-brother, emotional benefit found).

56. See *Ciba Found. Symposium, Ethics in Medical Progress* 19 (G. Wolstenholme & M. O'Connor eds. 1966).

healthier and guilt at having subjected the donor to sacrifice of an organ.<sup>57</sup> At the present time, organ transplantation is not so widespread as to have a significant effect on the well-being of the community or species.

Looking to the "dignity" effects of organ transplantation, it is clear that the donor's physical integrity has been breached. This is exploitative of the donor since the principal purpose of the invasion is to benefit another, with only incidental benefit accruing to the donor. On some occasions the donation can result from the donor's exercise of free choice. If that choice is not freely exercised, however, the individuality of the donor is reduced, thereby weakening trust in society's protections for the vulnerable.

### C. *Abortion*

In abortion, it is the detriment to the health of the subject (*abortus*) which is most obvious, although if birth would result in a defective child, it has been argued that death is a health benefit to the subject.<sup>58</sup> Abortion can be a direct health benefit to the mother by terminating a pregnancy causing or threatening physical harm; it can be an indirect health benefit by preventing the birth of a child who would compete for scarce resources. On the other hand, the mother's physical health can be harmed in the abortion procedure and her emotional well-being can suffer from shame, guilt, or remorse. The health benefits to people other than mother and *abortus* come from lessened competition for resources. As far as the community and species are concerned, benefits come from avoiding overpopulation and having to care for numerous people with congenital defects; but if abortion becomes too frequent, the society or species cannot reproduce itself.<sup>59</sup>

In the current context, the principal "dignity" effects of abortion are the benefits to the mother's self-determination by permitting her to choose how to use her body and the detriment to the conceptus' bodily

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57. See Note, *Transplantation—Incompetent Donors: Was the First Step or the Last Taken in Strunk v. Strunk?*, 58 Calif. L. Rev. 754, 766 (1970); cf. 16 Wayne L. Rev. 1460, 1469-70 (1970).

58. See H. Rudel, F. Kincl & M. Henzl, *Birth Control* 232-39 (1973); Niswander, *Abortion Practices in the United States: A Medical Viewpoint*, in *Abortion, Society, and the Law* 199, 206-08 (D. Walbert & J. Butler eds. 1973). But see *Gleitman v. Cosgrove*, 49 N.J. 22, 30, 227 A.2d 689, 693 (1967); *Stewart v. Long Island Coll. Hosp.*, 58 Misc. 2d 432, 436, 296 N.Y.S.2d 41, 46 (Sup. Ct. 1968), modified, 35 App. Div. 2d 531, 313 N.Y.S.2d 502 (2d Dep't 1970), *aff'd mem.*, 30 N.Y.2d 695, 283 N.E.2d 616, 332 N.Y.S.2d 640 (1972); Callahan, *Abortion: Some Ethical Issues*, in *Abortion, Society, and the Law* 89, 96 (D. Walbert & J. Butler eds. 1973); Drinan, *The Inviolability of the Right To Be Born*, in *Abortion, Society, and the Law* 123, 129-31 (D. Walbert & J. Butler eds. 1973).

59. See Callahan 329-30.

inviolability. Some would say that the third principal effect is a reduced trust in society's commitment to protect the weak and the helpless.<sup>60</sup> Compulsory abortion would be detrimental to the mother's self-determination and prohibiting abortion could be detrimental by preventing her from avoiding the consequences of a previous breach of her bodily integrity (e.g., after she has been raped).<sup>61</sup>

## V. FACTORS AFFECTING THE VALUATION OF EXPERIMENTAL CONSEQUENCES

### A. *Inapplicable Factors*

The situations set out in the preceding section involve two factors not strictly applicable in the HEW regulations: species or community survival and individual self-determination. Survival of the community (or even of the species) is the objective of compulsory medical treatment such as mass immunization or quarantine. In each of those cases, any possible benefit to the health of the subject arising from the invasion of his bodily integrity and self-determination is incidental to the anticipated health benefit to the community or human race as a whole.<sup>62</sup> The HEW regulations make no reference to experimentation directed toward protection of the community or species; the assumption here is that they would not prohibit it, but that in such circumstances the value of collective survival would allow the regulations to be disregarded or amended.

The second conclusion drawn from the other situations—that the value of self-determination outweighs benefits to others or even to the subject—does not apply to fetal experimentation. Even if a particular course of action would provide a health benefit for the subject, such action is impermissible if the subject does not exercise his power to choose what will be done to his person.<sup>63</sup> Because self-determination is

60. See, e.g., Callahan 420-22; Byrn, *An American Tragedy: The Supreme Court on Abortion*, 41 *Fordham L. Rev.* 807, 857-62 (1973); Jakobovits, *Jewish Views on Abortion, in Abortion, Society, and the Law* 103, 111-16 (D. Walbert & J. Butler eds. 1973).

61. See Callahan 332-33.

62. See *Jacobson v. Massachusetts*, 197 U.S. 11, 27-30 (1905); P. Ramsey, *The Patient as Person* 15-16 (1970). See Jonas, *Philosophical Reflections on Experimenting with Human Subjects*, in *Experimentation with Human Subjects* 6-7 (P. Freund ed. 1970).

63. See, e.g., *Zoterell v. Repp*, 187 Mich. 319, 153 N.W. 692 (1915); *Bang v. Charles T. Miller Hosp.*, 251 Minn. 427, 88 N.W.2d 186 (1958); *Corn v. French*, 71 Nev. 280, 289 P.2d 173 (1955). See also *Garziona v. Vassar Bros. Hosp.*, 36 App. Div. 2d 390, 320 N.Y.S.2d 830 (1st Dep't 1971), *aff'd mem.*, 30 N.Y.2d 857, 286 N.E.2d 731, 335 N.Y.S.2d 293 (1972). See generally W. Prosser, *Torts* 34-37, 101-05 (4th ed. 1971). When an emergency threatens death or serious bodily harm to an unconscious patient, consent to remedial measures is "implied," protecting the actor from liability. *Id.* at 103, 104.

so highly valued, every major ethical code<sup>64</sup> makes informed consent a prerequisite to experimentation on a competent adult.<sup>65</sup> Similarly, informed consent is required of adult organ donors.<sup>66</sup> In fact, the principle has been extended to permit patients to refuse medical treatment which would save their lives.<sup>67</sup> The high value given self-determination is manifest when the subject is incompetent: for example, when a court honors the previously expressed wishes of an unconscious patient not to have a life-saving treatment<sup>68</sup> or when a decision about corrective surgery for a teenager is postponed until he is old enough to choose for himself.<sup>69</sup> However, the power to make the decisions significantly affecting one's life implemented by the requirement of consent,<sup>70</sup> is usually reserved to those capable of rationally exercising the power (even though they are free to act irrationally in its exercise).<sup>71</sup> Because the fetus is unable to exercise self-determination in

64. See *United States v. Karl Brandt: 2 Trials of War Criminals Before the Nuremberg Military Tribunals* 181-82 (1947); cf. *American Medical Ass'n, Opinions and Reports of the Judicial Council* iii-vii, 9 (1969); *World Medical Ass'n, Declaration of Helsinki*, in J. Katz, *Experimentation with Human Beings* 312; *Medical Research Council, Report for the Year 1962-1963*, Cmnd. No. 2382, at 23 (1964).

65. Cf. note 63 *supra*.

66. See *Note, The Sale of Human Body Parts*, 72 *Mich. L. Rev.* 1182, 1193-94 (1974).

67. In *re Osborne*, 294 A.2d 372 (D.C. Ct. App. 1972); *Erickson v. Dilgard*, 44 *Misc. 2d* 27, 252 N.Y.S.2d 705 (Sup. Ct. 1962). Note, *Compulsory Medical Treatment: The State's Interest Re-evaluated*, 51 *Minn. L. Rev.* 293 (1966). But see *United States v. George*, 239 *F. Supp.* 752 (D. Conn. 1965).

68. In *re Estate of Brooks*, 32 *Ill. 2d* 361, 205 N.E.2d 435 (1965); see *Holmes v. Silver Cross Hosp.*, 340 *F. Supp.* 125 (N.D. Ill. 1972). But see *Application of President & Dirs. of Georgetown Coll., Inc.*, 331 *F.2d* 1000, petition for rehearing en banc denied per curiam, 331 *F.2d* 1010 (D.C. Cir.), cert. denied, 377 *U.S.* 978 (1964); *John F. Kennedy Mem. Hosp. v. Heston*, 58 *N.J.* 576, 279 *A.2d* 670 (1971). The decision in *Brooks* ultimately rested on Mr. Justice Brandeis' view that "[the framers of our Constitution] conferred, as against the Government, the right to be let alone—the most comprehensive of rights and the right most valued by civilized men." *Olmstead v. United States*, 277 *U.S.* 438, 478 (1928) (dissenting opinion). As Chief Justice (then Judge) Burger noted, this protection extends to "a great many foolish, unreasonable and even absurd ideas which do not conform, such as refusing medical treatment even at great risk." *Application of President & Dirs. of Georgetown Coll., Inc.*, *supra* at 1017 (Burger, J., concurring on other grounds); accord, In *re Estate of Brooks* *supra* at 372-74, 205 N.E.2d at 442-43.

69. See In *re Seiferth*, 309 *N.Y.* 80, 85-86, 127 *N.E.2d* 820, 823 (1955); cf. *Green Appeal*, 448 *Pa.* 338, 349-50, 292 *A.2d* 387, 392-93 (1972). But see In *re Sampson*, 65 *Misc. 2d* 658, 672, 317 *N.Y.S.2d* 641, 655 (Family Ct. 1970), *aff'd mem.*, 37 *App. Div. 2d* 668, 323 *N.Y.S.2d* 253 (3d Dep't 1971), *aff'd mem.*, 29 *N.Y.2d* 900, 278 *N.E.2d* 918, 328 *N.Y.S.2d* 686 (1972).

70. See generally *Plante, An Analysis of "Informed Consent,"* 36 *Fordham L. Rev.* 639 (1968).

71. "Every human being of adult years and sound mind has a right to determine what shall be done with his own body . . ." *Schloendorff v. Society of N.Y. Hosp.*, 211 *N.Y.* 125, 129, 105 *N.E.* 92, 93 (1914) (Cardozo, J.), overruled on other grounds, *Bing v. Thunig*, 2 *N.Y.2d* 656, 143 *N.E.2d* 3, 163 *N.Y.S.2d* 3 (1957).

any sense, this consequence per se is properly disregarded in the regulations.

### B. *Benefit to the Subject*

It is clear that a breach of physical integrity for medical treatment, which would be barred in the case of a nonconsenting adult, will be permitted on the ground of a health benefit to an infant or incompetent subject.<sup>72</sup> A benefit to the well-being of the donor-subject has also been mentioned as a requirement where an organ transplant is sought from an infant or incompetent.<sup>73</sup> Furthermore, abortion is occasionally justified on the ground that a health benefit is conferred on a fetus by killing it rather than allowing it to be born severely handicapped.<sup>74</sup> To the extent, then, that the proposed regulations permit violation of the conceptus' physical integrity for the benefit of its health, they are not inconsistent with the respective valuation given those factors in similar situations.

### C. *Special Relationships*

The HEW regulation that a fetus may be put at risk by an experimental procedure only if the fetus itself is expected to benefit does not apply in two situations: when the procedure is undertaken for the benefit of the mother, and when the fetus is being, or has been, aborted.<sup>75</sup> The maternal benefit exception can be explained on the basis of a special relationship between the subject and the other party deriving principal benefit from the procedure. Such a relationship is present in the organ-transplant cases (for immunological reasons, siblings are the best donors)<sup>76</sup> and might be used to rationalize even

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72. See, e.g., *People ex rel. Wallace v. Labrenz*, 411 Ill. 618, 104 N.E.2d 769, cert. denied, 344 U.S. 824 (1952); *Raleigh Fitkin-Paul Morgan Mem. Hosp. v. Anderson*, 42 N.J. 421, 201 A.2d 537 (per curiam), cert. denied, 377 U.S. 985 (1964); *State v. Perricone*, 37 N.J. 463, 181 A.2d 751, cert. denied, 371 U.S. 890 (1962); *In re Sampson*, 65 Misc. 2d 658, 317 N.Y.S.2d 641 (Family Ct. 1970), aff'd mem., 37 App. Div. 2d 668, 323 N.Y.S.2d 253 (3d Dep't 1971), aff'd mem., 29 N.Y.2d 900, 278 N.E.2d 918, 328 N.Y.S.2d 686 (1972); *In re Clark*, 185 N.E.2d 128 (Ohio Ct. C.P. 1962). The court frequently weighs the anticipated benefits of the procedure against the risks involved. See, e.g., *In re Nemser*, 51 Misc. 2d 616, 273 N.Y.S.2d 624 (Sup. Ct. 1966) (amputation improper as not a life-saving measure); *In re Sampson*, supra at 660-61, 669-75, 317 N.Y.S.2d at 644-45, 652-58.

73. *Strunk v. Strunk*, 445 S.W.2d 145, 146, 149 (Ky. 1969); see *id.* at 151 (dissenting opinion); *In re Richardson*, 284 So. 2d 185, 187 (La. Ct. App.), cert. denied, 284 So. 2d 338 (La. 1973); Curran, *A Problem of Consent: Kidney Transplantation in Minors*, 34 N.Y.U.L. Rev. 891, 892-95 (1959) (discussing three unreported Massachusetts cases).

74. See note 58 supra and accompanying text.

75. See HEW Proposals, Proposed 45 C.F.R. §§ 46.306(a)(1)-(2), .307, 39 Fed. Reg. 30654 (1974).

76. See *Hart v. Brown*, 29 Conn. Supp. 368, 372-73, 289 A.2d 386, 388-89 (Super. Ct. 1972).

those cases where the court really paid only lip service to the idea that the donor would derive benefit from the procedure.<sup>77</sup> Valuing physical inviolability less than health benefit to another only when the other is closely related might reflect a judgment that a benefit to a sibling, for example, is somehow more desirable than a benefit to a stranger. A further judgment might be that because the possible subjects are limited in number and strictly defined (*i.e.*, siblings of a person needing a transplant), the likely effect on the mutual trust that society will protect the vulnerable is minimal.<sup>78</sup> The importance of the close relationship between subject and beneficiary is even more evident in the case of abortion. There, the fetus is a physical parasite in the mother.<sup>79</sup> As such, its presence can have an effect on the mother's health; more precisely, an abortion can be not only an indirect health benefit to the mother and others by destroying a being that would compete for the resources available, but a direct health benefit to the mother alone. Furthermore, since the fetus *in utero* is a part of the woman's body, any interference with her decision to abort is a detriment to her self-determination.<sup>80</sup> A constraint on a woman's

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77. The donor in the Strunk case was a twenty-seven year old retardate (mental age of six) residing in a state institution. A psychiatrist testified that the donor would benefit because he was emotionally and psychologically dependent on his donee-brother, and the brother's death would be traumatic for him. *Strunk v. Strunk*, 445 S.W.2d 145, 146 (Ky. 1969). Similar testimony of psychological benefit was relied upon in the unreported cases discussed in Curran, *supra* note 73, at 893. However, the proof of benefit to the donor (either in avoidance of psychological trauma or in satisfaction from giving) is tenuous in these cases, especially when the donor is young or retarded. See *Hart v. Brown*, 29 Conn. Supp. 368, 375, 289 A.2d 386, 390 (Super. Ct. 1972) (disregarding psychiatric testimony concerning benefit to seven year old donor); *Strunk v. Strunk*, *supra* at 150 (dissenting opinion); Curran, *supra* note 73, at 895-96; Note, *Transplantation—Incompetent Donors: Was the First Step or the Last Taken in Strunk v. Strunk?*, 58 Calif. L. Rev. 754, 758-63 (1970); 16 Wayne L. Rev. 1460, 1464-67 (1970).

78. The decision permitting transplantation in *Hart v. Brown*, 29 Conn. Supp. 368, 289 A.2d 386 (Super. Ct. 1972), seems to be founded ultimately on a decision that the benefits to the donee would be great and the risks to the donor insignificant: "A further question before this court is whether it should abandon the donee to a brief medically complicated life and eventual death or permit the natural parents to take some action based on reason and medical probability in order to keep both children alive. The court will choose the latter course . . ." *Id.* at 376, 289 A.2d at 390; see *id.* at 377-78, 289 A.2d at 390. In *Bonner v. Moran*, 126 F.2d 121 (D.C. Cir. 1941), the court implied that a skin graft from a fifteen year old would have been permissible, if only the donor's mother had consented. See *id.* at 123. Permission for transplantation in the cases discussed in Curran, *supra* note 73, may also be explained on the ground of findings that the minor donors had consented. See Curran, *supra* note 73, at 892-96; Note, *Transplantation—Incompetent Donors: Was the First Step or the Last Taken in Strunk v. Strunk?*, 58 Calif. L. Rev. 754, 762 (1970).

79. Cf. *Raleigh Fitkin-Paul Morgan Mem. Hosp. v. Anderson*, 42 N.J. 421, 423, 201 A.2d 537, 538 (*per curiam*), cert. denied, 377 U.S. 985 (1964) (transfusion of pregnant mother authorized to save life of fetus; welfare of child and mother "intertwined and inseparable").

80. See Callahan 332. The Supreme Court's decision permitting a state to proscribe abortion

freedom to make significant decisions about her life does not, of course, justify infanticide; it is only the extremely close physical relationship which permits abortion. The same considerations apply with respect to fetal experimentation: since a mother is not barred from destroying the organism *in utero*, she should not be precluded from medical treatment which would be experimental and otherwise impermissible as to the fetus.<sup>81</sup> The physical inviolability of the fetus-parasite must be given less value than the health of the mother-host.<sup>82</sup>

#### D. *Development of the Subject*

The abortion context suggests another factor which might affect the values placed on various consequences: development of the subject as a full human.<sup>83</sup> This factor might explain why it is permissible to abort

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subsequent to viability, except to preserve the life or health of the mother, values the mother's health more than her self-determination. See *Roe v. Wade*, 410 U.S. 113, 164-65 (1973). This valuation is contrary to that applied in compulsory medical treatment. See text accompanying notes 67-68 *supra*. However, it is appropriate because the death of another (the viable fetus) is a consequence of abortion but not of refused medical treatment.

81. Authority to treat the pregnant mother in a way which constitutes experimentation on the fetus does not, of course, relieve the physician of the ethical obligation to treat the mother with the good of both "patients" in mind.

"Liberalized" abortion laws have undoubtedly removed much of the incentive which previously existed to use "health needs of the mother" as a justification for invading the fetus. See Guttmacher, *The Genesis of Liberalized Abortion in New York: A Personal Insight*, in *Abortion, Society, and the Law* 63, 69 (D. Walbert & J. Butler eds. 1973).

82. See *Roe v. Wade*, 410 U.S. 113, 162 (1973).

83. The analysis in this section has been influenced by the discussion of the "beginning of human life" in Callahan chs. 10-11. He summarizes the philosophical basis of his argument as follows:

"I have argued, in the first stage, that a teleological analysis of the biological data is legitimate, necessary and illuminating as a philosophical basis for approaching an answer to the question of when life begins. I have argued, in the second stage, that an important movement in some scientific disciplines concerned with the 'human' is that the 'human' must be defined not in single-character, or essentialistic, terms but rather in terms of variety and diversity. Moreover, there is considerable agreement that an analysis of the 'human' must take account, holistically, of the biological, the psychological and the cultural; no one of them can be scanted, at the cost of misunderstanding the others. I have also tried to point out the importance of 'potentiality' and 'capacity' in analyzing 'human life,' adding an affirmation of the language of 'levels of organization' as helpful in understanding the process whereby the potential is made actual." *Id.* at 368. As a consequence he rejects both the "genetic school," which treats the question of the "beginning of human life" (for purposes of deciding the protections to be accorded prenatal beings by virtue of their being "human") as one to be decided solely on biological data, and the "social-consequences" school, which gives no effect to the biological data (defining the fetus as "non-human") and defines "human" only in terms of achieved potentialities. *Id.* at 399-400. The approach chosen is the "developmental school" which, in deciding the protection to be accorded prenatal beings, considers both the achieved biological commonality with other "human life" and the potentiality for psychological and cultural similarity. See *id.* at 384-90, 399.

a six-week embryo but not a seven-month fetus. In *Roe v. Wade*,<sup>84</sup> the Supreme Court decided that a state could not interfere on behalf of the fetus in the decision of a woman and her doctor to abort until the fetus was sufficiently developed to be able to survive outside the womb to the point where it could independently maintain vital functions.<sup>85</sup> In effect that decision says that the relative valuation of consequences to the mother's health and self-determination and the fetus' health and physical inviolability is dependent upon the stage of the fetus' development. When the subject is pre-viable, as in both abortion and fetal experimentation, its development might be a reasonable factor to consider in valuing the consequences. For example, detriments to the dignity or health of a conceptus may be seen as less significant (quantitatively) than detriments to the dignity or health of an adult or other post-viable person. Alternatively, the violation of a conceptus' bodily integrity and its exploitation might be justified on the ground that neither will have a significant effect on trust in societal protection of the vulnerable. In other words, experimentation for the benefit only of others on a two year old or a mental incompetent might make me fear experimentation if I should become comatose; but experimentation on a one-inch embryo at six weeks is so clearly distinguishable that it would have no such effect. Thus if the stage of development were taken as an acceptable factor in valuing consequences (and the abortion rules suggest it would be appropriate), the regulations could acceptably give less protection—*i.e.*, not require subject health benefit—to early prenatal life.

*Roe v. Wade* set two prenatal dividing lines relating to state involvement with abortions which might also be appropriate in the experimentation context. The first, at the end of the first trimester, marks the beginning of the period in which the state may regulate the abortion procedure in ways reasonably related to maternal health.<sup>86</sup> That point was selected because it is there that the method of abortion is usually changed and the risk to the mother is thereby substantially increased.<sup>87</sup> Because this first trimester dividing line was selected with reference only to effects on maternal health and with no consideration for the fetus' human dignity, it is not necessarily helpful in the experimentation context. The second line drawn in *Roe* was at viability of the fetus. At viability the state may regulate or proscribe abortions which are not for the purpose of preserving the life or health

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84. 410 U.S. 113 (1973).

85. *Id.* at 162-66.

86. *Id.* at 163, 164.

87. *Id.* at 149-50, 163. See generally H. Rudel, F. Kincl & M. Henzl, *Birth Control* 247-56 (1973).

of the mother.<sup>88</sup> Because this line was calculated with reference to the effects on both mother and fetus, viability might possibly serve as a useful criterion for experimentation restrictions. Since viability marks the completion of the process of biological individualization, in the sense of being physically unique, it is probably the latest point at which it is appropriate to treat the conceptus differently from an infant in regard to physical invasions.<sup>89</sup>

There are at least three problems with using viability as the lower boundary to protect the fetus against experimentation solely for the benefit of others. First, the criterion is indefinite in that, in any particular case, it requires the assessment of the varied development of numerous systems in order to determine how the organism as a whole will be able to cope with its environment.<sup>90</sup> Because of this indefiniteness and the individual judgment involved in making the determination, there may be a substantial opportunity for abuse. That opportunity could, of course, be minimized by setting the line conservatively (*e.g.*, twenty-two weeks)<sup>91</sup> or, as is done in the HEW proposals, by requiring the determination of viability to be made by persons independent of the research project.<sup>92</sup> A second objection to a viability standard is that it will vary with the available technology. At the present time, twenty-four to twenty-eight weeks' gestation is sufficient for viability;<sup>93</sup> before incubators and other such devices for neonatal care were developed, any birth before full term meant a limited chance to survive; and before too long, research into *in vitro* fertilization and an "artificial womb" may make the concept of viability meaningless.<sup>94</sup> In these circumstances, there may be some advantage in using a

88. 410 U.S. at 163-65.

89. Significant steps in the process of physical individualization are: (1) The single-cell zygote (with the usual 46 chromosomes) is formed from the union (at fertilization) of the sperm and egg cells (each bringing 23 chromosomes from the respective parent). Biological individuality is largely determined at fertilization, since the virtually infinite possibilities for chromosomal pairing make each zygote genetically unique. See Callahan 373. (2) However, at some time during the second or third week, genetically identical twins may be formed by a splitting of the embryo. See *id.* 372. See also *id.* 379-80. (3) Physical individuality, in the sense both of uniqueness and independence from the biological functioning of any other particular organism, can potentially be achieved at viability, although it is not actually accomplished until parturition. See Fletcher, *Abortion, Euthanasia, and Care of Defective Newborns*, 292 N. Eng. J. Med. 75, 76 (1975).

90. See HEW Proposals, 39 Fed. Reg. 37993 (1974).

91. See letter from Charles B. Reiner, M.D., Children's Hosp., Columbus, Ohio, to Donald T. Chalkley, M.D., Chief, Institutional Relations Branch, Nat'l Inst. of Health, Jan. 14, 1974.

92. HEW Proposals, Proposed 45 C.F.R. §46.307(c)(2), 39 Fed. Reg. 30654 (1974).

93. See *Roe v. Wade*, 410 U.S. 113, 160 (1973).

94. See HEW Proposals, 39 Fed. Reg. 30651 (1974); Culliton, *Manslaughter: The Charge against Edelin of Boston City Hospital*, 186 Sci. 327, 330 (1974); *Experiments on the Fetus*, 2 Brit. Med. J. 433, 434 (1970). But see HEW Proposals, 39 Fed. Reg. 37993 (1974).

dividing line which is less a function of technology and more related to the conceptus' development toward full humanness. The third, and most persuasive, objection to a viability standard is that, for the foreseeable future at least, it would afford protection against being used only at a point later than is probably acceptable to many people. At six months' gestation, a normal fetus is about thirteen inches in height and two pounds in weight.<sup>95</sup> As the fetus is quite recognizably human at that stage,<sup>96</sup> many people might be reluctant not to treat it in the same manner as a newborn infant for experimentation purposes (*i.e.*, the detriment to mutual trust in social protection for the vulnerable would be too significant).

A better dividing line could be drawn at about forty-five days' gestation. This point is significant in two respects. First, the end of the seventh week marks the end of the embryonic and the beginning of the fetal periods.<sup>97</sup> Although by that time the beginning of all essential external and internal structures are present, the conceptus is under one and one-quarter inches in height and its face will not have a human appearance for another two weeks.<sup>98</sup> In addition, central nervous system ("CNS") electrical activity ("brain waves") has been detected beginning early in the seventh week.<sup>99</sup> The commencement of brain functioning marks a significant stage in the development of the organism toward full "humanness."<sup>100</sup> Relating protection of human dignity to CNS activity at the beginning of life is in a sense symmetrical with the modern definition of death as a flat electroencephalogram.<sup>101</sup> Just as we say that the "person-hood" has passed with cessation of CNS activity even though human genetic material may continue alive with artificial support, so may we say that

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95. See K. Moore, *Before We Are Born—Basic Embryology and Birth Defects*, 57, 60 (1974).

96. See *id.* at 63.

97. See *id.*; letter from James W. Lash, M.D., Univ. of Pennsylvania School of Med., to Director, Nat'l Inst. of Health, Nov. 28, 1973.

98. See K. Moore, *supra* note 95, at 4.

99. Borkowski & Bernstine, *Electroencephalography of the Fetus*, 5 *Neurology* 362 (1955). Theoretically, some electrical activity should be detectable in the fetal heart as early as 25-30 days. Bernstine & Borkowski, *Prenatal Fetal Electrocardiology*, 70 *Am. J. Ob. & Gyn.* 631 (1955).

100. See Hamlin, *Life or Death by EEG*, 190 *J.A.M.A.* 112, 113 (1964).

101. See, e.g., *Kan. Stat. Ann.* § 77-202 (Supp. 1973) ("absence of spontaneous brain function" and if resuscitation will not succeed); *Va. Code Ann.* § 32-364.3:1 (Supp. 1974) ("absence of spontaneous brain functions and spontaneous respiratory functions" and if resuscitation will not succeed); Beecher, *Definitions of "Life" and "Death" for Medical Science and Practice*, 169 *Annals N.Y. Aca. Sci.* 471 (1970); Fletcher, *Ethical Aspects of Genetic Controls*, 285 *N. Eng. J. Med.* 776, 781 (1971); Report of Ad Hoc Comm. of Harv. Med. School to Examine Definition of Brain Death, *A Definition of Irreversible Coma*, 205 *J.A.M.A.* 337 (1968).

"person-hood" is not significantly attained before such activity begins in human genetic material.<sup>102</sup>

Although under this proposal the human dignity of conceptuses of forty-five days is valued less than that of older subjects, the regulations should reflect some minimal value for the human dignity of the embryonic subject since the subject is "human" as a biological matter, regardless of its state of development.<sup>103</sup> For this reason, experimentation affecting subjects prior to forty-five days' gestation should at least distinguish the undeveloped human subject from non-human experimental objects. Thus, even the most primitive product of human conception should not be put at risk to obtain knowledge for the benefit of non-human organisms, nor to obtain information which is obtainable from non-human organisms or objects. To fail to give the conceptus this protection is to deprive it totally of human dignity by treating it as non-human, rather than the undeveloped human it is. A further restriction may also be appropriate at this level: if the information sought is available from more developed humans, it should be obtained there, subject to the restrictions imposed at the higher levels. The idea behind this restriction is to ensure that, while one human organism at the embryonic level of development may be used to give benefit to another, the subject will not be chosen to confer this benefit solely because it is most convenient (in the sense of being a member of the least protected class). Rather, the subject will be used as a source of knowledge because it is in the class best able to provide the knowledge.<sup>104</sup>

## VI. ABORTUSES AS SUBJECTS: AN EVALUATION

The HEW regulations which would permit experimentation on an abortus while prohibiting experimentation on a conceptus of the same age<sup>105</sup> appear to reflect a judgment that the respective valuations of "human dignity" against other consequences may be changed if the subject's life expectancy is certain rather than indefinite. In other words, an individual becomes less human (*i.e.*, physical integrity and not being exploited are less valued than other consequences) when the time of his death is known. So stated as a general rule, the proposition would have few adherents. An injury to one in extremis does not any

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102. See Jacobs & Louisell, Book Review, 58 Calif. L. Rev. 1257, 1263 (1970).

103. See note 83 *supra*.

104. See Jonas, Philosophical Reflections on Experimenting with Human Subjects, in *Experimentation with Human Subjects* 1, 19-20 (P. Freund ed. 1970).

105. Compare HEW Proposals, Proposed 45 C.F.R. § 46.307, 39 Fed. Reg. 30654 (1974), with HEW Proposals, Proposed 45 C.F.R. § 46.306, 39 Fed. Reg. 30654 (1974). See also HEW Proposals, 39 Fed. Reg. 30651 (1974).

less give rise to tort liability for that fact.<sup>106</sup> A terminal condition does not make a patient any more available for experimentation.<sup>107</sup> The result should be no different when the subject is an abortus. First, the minimal development of the subject is already given effect in the experimental rules which apply to all at that stage of development.<sup>108</sup> Second, none of the other factors which go to reducing the value of human dignity are present in experimentation with abortuses. This is not a situation where all of the consequences taken together arguably reach a balance which is protective of the subject's individuality. In the case of compulsory medical treatment, protection of dignity could well be at the expense of life. This is not a situation where there is always a great health benefit to another closely related to the subject, with little health detriment to the subject. That combination of factors seems to be required in the organ transplant cases which do not strictly apply a "benefit to the subject" analysis.<sup>109</sup> This is not a situation, like abortion, where the effect of the detriment to the subject's dignity is to benefit the dignity of one extremely closely related and substantially more "human."<sup>110</sup> Finally, because there are no other substantial factors, acts pursuant to the proposed rule could have a substantial detrimental effect on the mutual trust that society will protect the vulnerable. Without the limitations imposed by the close relationship or subject benefit in the cases just described, no one can be secure against exploitation in extremis.

Put another way, what is offensive about the provisions which permit experimentation during abortion, even for such laudatory purposes as "evaluating or improving methods of prenatal diagnosis, methods of prevention of premature birth, or methods of intervention to offset the effects of genetic abnormality or congenital injury,"<sup>111</sup> is that the particular subjects are being selected only because they are convenient. Experimentation for those purposes would not be permitted if the fetuses were to be carried to term; so it is only the decision to abort which makes the subjects available. But the decision to abort is based primarily on an evaluation of the consequences to the mother as against those to the fetus. This evaluation of the act of abortion,

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106. See *Pieczonka v. Pullman Co.*, 89 F.2d 353, 356 (2d Cir. 1937); cf. *Dillon v. Twin State Gas & Elec. Co.*, 85 N.H. 449, 456-57, 163 A. 111, 114-15 (1932). See generally *Carpenter, Concurrent Causation*, 83 U. Pa. L. Rev. 941, 949-51 (1935); *Peaslee, Multiple Causation and Damage*, 47 Harv. L. Rev. 1127, 1134-41 (1934).

107. But see *Blumgart, The Medical Framework for Viewing the Problem of Human Experimentation, in Experimentation with Human Subjects* 39, 60-61 (P. Freund ed. 1970).

108. See text accompanying notes 83-85 *supra*.

109. See text accompanying note 77 *supra*.

110. See text accompanying notes 79-81 *supra*.

111. HEW Proposals, Proposed 45 C.F.R. § 46.306(a)(2), 39 Fed. Reg. 30654 (1974).

involving a special relationship, does not consider the consequences of the entirely separate experimental act.<sup>112</sup> Therefore, the restrictions on experimentation should be applied without regard to whether the subjects are being aborted.

#### VII. CONCLUSION

To the extent that the proposed HEW regulations limit violations of prenatal beings to those done for the benefit of the subject or the mother, they are consistent with presently applied standards. In fact, those standards would probably permit some relaxation of the limitation when the subject is a fetus of very limited development. On the other hand, to the extent that the regulations distinguish between abortuses and conceptuses in permitting experimentation on the former which would be impermissible on the latter, they fail to conform to appropriate ethical standards and should be modified to treat all fetuses of the same development similarly.

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112. Making the propriety of experimentation turn on whether the decision to abort is irrevocable, see HEW Proposals, 39 Fed. Reg. 37993 (1974) completely neglects the dignity consequences to the abortus-subject.