OFF THE PEDESTAL AND INTO THE ARENA: TOWARD INCLUDING WOMEN IN EXPERIMENTAL PROTOCOLS

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INTRODUCTION

> And the rib which the Lord God had taken from the man he made into a woman and brought her to the man.
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> Then the man said, "This at last is bone of my bones and flesh of my flesh; she shall be called Woman, because she was taken out of Man."[1]

Genesis' concept of male as norm and female as derivative—as a lesser variation on the male—reverberates throughout American views of biological differences between men and women. The assumption that women's physiology deviates from the norm has particularly damaging consequences in the field of medical research. This assumption regards dissemination of results reliable only for white men as scientifically acceptable, and therefore permits medical research which excludes women for the sake of "simplicity." Researchers regularly regard female research subjects as more vulnerable than male research subjects, and assume that experimental treatments pose unique reproductive risks to all women. Frequently, pregnant women are presumed to be incapable of adequately balancing risks to their fetus with their own well-being, and are therefore denied the opportunity to choose to participate regardless of the level of actual risk.

Such categorical exclusion from medical research is not acceptable, because it causes significant harm to innumerable women. Exclusion from medical research denies women potentially lifesaving opportunities to participate in research trials of new technologies and drugs. In some cases, these research trials represent the only therapies available. Furthermore, the exclusion of women from testing procedures often results in the approval of drugs that were never tested on women. Consequently, drugs have been, and still are, prescribed to women by doctors who can only guess at the appropriate dosage, effectiveness, and side effects the drugs will have on women patients. The near absence of women participants in medical research has also resulted in a general dearth of information regarding women's medical care. As a consequence, women are left without information vital to their health and well-being. These threats to women's health mandate the inclusion of women in medical research protocols.

In this Note, we propose a comprehensive plan to dismantle the barriers currently in place. We explore the myths and truths of difference between men and women and ask when, if ever, this difference should be factored into

1. *Genesis* 2:22-23.

decisions to include women in medical research. We examine the reasons that barriers to inclusion stand, challenge their soundness, and offer proposals for change.

After exploring the history of these exclusionary practices and setting forth the current regulatory framework governing experimental protocols, we probe and dispel researchers' fears of tort liability, including liability for fetal damage, finding solutions in the doctrine of informed medical consent and in specialized compensation plans. We then discuss constitutional grounds to challenge routine exclusion of women from medical research protocols and conclude with a possible legislative solution to the problem.

I.
THE MISGUIDED HISTORY OF EXCLUSIONARY POLICIES

History reveals numerous instances of medical researchers using their power to exploit vulnerable groups. Perhaps the most notorious example of medical exploitation in the United States was the Tuskegee syphilis study, a so-called natural history study in which researchers who hoped to determine death rates for untreated cases of syphilis recruited infected black men by promising free treatment. Instead of treating these men, the researchers documented the progress of their disease and watched them die.[2] Less well known examples include a study on rejection of transplants that involved injecting live cancer cells into Jewish patients with chronic debilitating diseases;[3] a contraceptive study involving poor Mexican-American women who were told they would receive birth control (instead, half of them received placebos);[4] and a medical study at an institution for mentally disabled people in which chil-

2. The study of 400 subjects ran from 1932 to 1972. ROBERT J. LEVINE, ETHICS AND REGULATION OF CLINICAL RESEARCH 69-70 (2d ed. 1986). For a more extensive discussion of the experiment, see JAMES H. JONES, BAD BLOOD: THE TUSKEGEE SYPHILIS EXPERIMENT (1981).

3. Subjects in the Jewish Chronic Disease Hospital Study were not told that they were going to be injected with cancer cells due to concern that they would be unnecessarily frightened. R. LEVINE, *supra* note 2, at 71. Such a study is objectionable because the researchers lacked the informed consent of their patients; that is, they did not permit capable patients to decide whether or not to participate based on all pertinent information. The informed consent doctrine has traditionally recognized that where receipt of medical information would harm patients, there is an exception to the general rule of disclosure. *See* Canterbury v. Spence, 464 F.2d 772, 789 (D.C. Cir.), *cert. denied*, 409 U.S. 1064 (1972). Even the *Canterbury* court, however, indicated that this exception

> must be carefully circumscribed . . . for otherwise it might devour the disclosure rule itself. The privilege does not accept the paternalistic notion that the physician may remain silent simply because divulgence might prompt the patient to forego therapy the physician feels the patient really needs. That attitude presumes instability or perversity for even the normal patient, and runs counter to the foundation principle that the patient should and ordinarily can make the choice for himself.

Id. at 789.

4. Roughly one third of the women who received placebos became pregnant during the study. R. LEVINE, *supra* note 2, at 71-72.

dren were purposely infected with hepatitis.[5]

A. The Protectionist Rationale

In the 1950s, thalidomide, a drug aggressively promoted as an over-the-counter sedative, caused thousands of birth defects and an unknown number of deaths at birth.[6] This catastrophe, in conjunction with furor over the previously mentioned studies, spurred protectionist research policies which, ironically, often harmed women. Even today, the possible recurrence of a similar disaster is frequently cited as a justification for total exclusion of women from drug protocols.[7] To avoid perpetuating the history of abuse in research, many vulnerable populations (such as prisoners, people of color, elderly people, drug users, children, low-income populations, and women) have been automatically excluded from research protocols.[8]

Though the protective impulse is understandable, these exclusionary policies are misguided because they do not address the causes of the abuse. For example, the thalidomide disaster might have been prevented by controlled, pre-marketing research. Despite early reports of thalidomide's side-effects, and a general awareness that the drug was capable of affecting fetuses, no animal tests were conducted by Grunenthal, the West German firm that marketed the drug in Europe as "completely non-toxic."[9] Animal tests in use at the time would have established thalidomide's teratogenic effects.[10] Thus, harm was the result not of any special vulnerability of women, but of greed and fraud on Grunenthal's part.[11]

Typical research protocols exclude pregnant and nursing women, as well

5. In defense of their actions, those who conducted the hepatitis study claimed that most of the children residing there would contract the infection anyway, and therefore might be better off if they became infected as part of a program to develop hepatitis treatments. *Id.* at 70.

6. Carol Levine, *An Act of Greed*, HASTINGS CENTER REPORT, 43, 44 (June 1979) (book review of INSIGHT TEAM OF THE SUNDAY TIMES OF LONDON, SUFFER THE CHILDREN: THE STORY OF THALIDOMIDE (1979)) [hereinafter C. Levine *An Act of Greed*].

7. Carol Levine, *Women and HIV/AIDS Research*, 14 EVALUATION REVIEW 447, 452-53 (Oct. 1990).

8. We recognize that these exclusions are significant and that each poses distinct problems. For example, low-income populations often lack access to primary health care and thus do not receive medical attention until their conditions become acute. Poor nutrition and other poverty-related factors present additional complications. These health needs, often ignored in developing and testing new drugs and therapies, merit immediate consideration. This Note, however, focuses on the exclusion of women. To the extent possible, the general policies it develops should extend to all groups excluded from medical research, but each group deserves detailed attention beyond the scope of this project. *See also* Wafaa El-Sadr and Linnea Capps, *The Challenge of Minority Recruitment in Clinical Trials for AIDS*, 267 JAMA 954 (1992) (discussing issues specific to the underrepresentation of African Americans and other ethnic minorities).

9. C. Levine, *An Act of Greed, supra* note 6.

10. *Id.*

11. Despite the fact that some policies which keep women out of research protocols are motivated by genuine (yet misguided) concern for women, Grunenthal's actions may point to a more common reason companies market products with inadequate testing. Because the profit motive is the driving force behind the development of new drugs and medical technologies,

as "women of childbearing age." The few studies that do include pre-menopausal women stringently regulate their reproductive behavior. Protocols often exclude women automatically, acting on a presumption of risk to women and/or their fetuses absent any evidence of such risk. Men, on the other hand, are neither restricted nor excluded from protocols absent affirmative evidence of "potential mediation of toxicity through the male parent."[12] This double standard bars women from inclusion in research when inclusion would be in their best interests, and exposes men to unexplored or ignored dangers.

Contrary to common assumptions, men, as well as women, may incur reproductive risks when exposed to a variety of drugs, therapies or other substances.[13] Animal studies have indicated significant negative effects when fathers are exposed to a range of substances. For instance, paternal exposure of rats to methadone greatly increases the mortality and decreases the birthweights of offspring, leading to the theory that the drug affects maturing sperm at a critical time.[14] Caffeine administered to males in some cases doubles neonatal mortality.[15] Men who smoke cigarettes have a greater than average chance of fathering low-birthweight infants, and their infants undergo increased rates of neonatal mortality and congenital anomalies.[16]

Specialists writing as early as 1860 postulated severe reproductive effects, including increased rates of spontaneous abortions, stillbirths, and neonatal mortality, in the families of men whose trades exposed them to lead.[17] Yet these effects have not been studied further. As two researchers remarked about the results of the cigarette-smoking study: "We were surprised that we were unable to find additional studies that would confirm or deny this important observation."[18] They concluded that additional research was "urgently needed"[19] and that such studies might introduce new dimensions to traditional understanding of reproductive biology. Research has also linked marijuana use to infertility in men, and many experts think frequent cocaine use could have a similar effect, though studies regarding cocaine use have not yet been conducted.[20] While the thalidomide disaster ignited awareness of the teratogenic effects of drugs administered to pregnant women, evidence of det-

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developers have an incentive to put products on the market as quickly as possible, in order to capture the largest clientele possible.

12. Vanessa Merton, *Community-Based AIDS Research*, 14 EVALUATION REV. 502. Of 26 drug protocols submitted to the New York City Community Research Initiative's institutional review board (IRB) through April 1990, 16 required negative pregnancy tests, nine required women to use barrier contraception, and only 6, including 4 that were variant protocols from the same investigators, required contraceptive use by men as well as women. *Id.* at 518.

13. LESTER F. SOYKA & JUSTIN M. JOFFE, DRUG AND CHEMICAL RISKS TO THE FETUS AND NEWBORN 59 (1980); *see also Sins of the Father*, THE ECONOMIST, Feb. 23, 1991, at 87.

14. SOYKA & JOFFE *supra* note 13, at 50-54.

15. *Id.*

16. *Id.* at 59.

17. *Id.* at 58-59.

18. *Id.* at 59.

19. *Id.* at 65.

20. Anne Meriwood, *Sperm Under Siege*, 23 HEALTH, Apr. 1991, at 53.

rimental effects passed to offspring when the male parent was exposed to drugs or chemicals remains unacknowledged.[21]

Research likely to yield information about negative reproductive effects on men is overwhelmingly absent. Such information might cause men to decline to participate in development of some drugs and therapies. Yet reproductive research is the first and often only experimentation routinely performed on women. It is possible that researchers, manufacturers of drugs, employers who expose their workers to toxic substances, and other individuals and institutions who rationalize exclusion of women as a means of avoiding liability are actually risking liability by failing to consider male reproductive effects.

An additional problem with the protectionist rationale is that it constructs an adversarial relationship between woman and fetus, which is based on an assumption that fetuses need protection from the women who carry them. This assumption artificially pits women against their own fetuses and generates a so-called maternal-fetal conflict. The concept of maternal-fetal conflict may spring in part from the alchemy of new reproductive technologies and corresponding idealized formulations of motherhood.[22] Our ever-expanding ability to affect fetal health, using methods as divergent as fetal surgery and social services for pregnant women, carries with it a threat to women's privacy and autonomy.[23] Fetal rights advocates urge the subordination of women's self-determinative rights to the rights of their fetuses, alleging legal bases for their assertions in sources such as *Roe v. Wade*'s[24] acknowledgement of a possible state interest in the viable fetus.[25]

A fetal rights emphasis in maternal-fetal issues has already resulted in forced surgery upon women on behalf of their fetuses,[26] and could result in regulation of what women eat, whether they exercise, whether they take a puff on a cigarette, and whether they can sip a glass of wine with dinner. Pitting womb against woman replaces the "mother's child-of-her-womb . . . [with] the fetal citizen. With the creation of this pre-born, pre-sentient, and invisible citizenry, a woman's quite legitimate expectation of privacy and control in pregnancy is being obliterated."[27]

Critics of the maternal-fetal conflict often rely on cases which establish that one person's body may not be invaded, appropriated, or subordinated for another's benefit. A leading example is *McFall v. Shimp*,[28] which held that a man could not be compelled to donate bone marrow to his cousin, despite the

21. *Id.*

22. Alida Brill, *Womb Versus Woman*, DISSENT, Summer 1991, at 395.

23. *Id.* at 395-97.

24. 410 U.S. 113 (1973).

25. *See generally* Janet Gallagher, *Prenatal Invasions & Interventions: What's Wrong With Fetal Rights*, 10 HARV. WOMEN'S L.J. 9 (1987).

26. *See infra* notes 35-48 and accompanying text.

27. Brill, *supra* note 22, at 395.

28. 127 Pitts. Leg. J. 14 (Allegheny Cty., July 26, 1978).

fact that the cousin's doctors regarded the marrow transplant to be his only chance of survival.[29] Opponents of fetal rights point out that when bodily invasions and restrictions are required, they are permissible because they promote the general well-being of the public, including the individual upon whom they are imposed.[30] Vaccinations, blood and "breathalyzer" tests, quarantines, seat belt requirements, and other such mandatory health measures "are not carried out or imposed on behalf of a specific individual no matter how innocent or deserving."[31]

Analogous lines of cases suggest a solution to the supposed maternal-fetal conflict in the context of research. Courts have often allowed parents to make choices that cause risk to their children and offer no physical benefit to the children themselves. For example, courts have recognized that parents may consent to their children's donation of organs.[32] Such cases support allowing the pregnant woman to choose a mode of treatment that she desires, though it might also create a risk to her fetus. In employing this analogy, we do not intend to afford the fetus the status of a human child. Our point is that if one who is unquestionably a person (a born child) may for valid reasons be put at risk by her parents, then a fetus logically deserves no greater protection.

It may be argued that these cases provide imperfect analogies, because they do not pit the self-interest of the individual rendering consent against the interests of the individual at risk; the parents, physically unconnected to their children, have less self-interest than a pregnant woman seeking treatment for herself at the supposed expense of the fetus within her. However, the web of family relationships often creates interconnected interests.[33] It follows that parental consent may be sufficient to permit a child to undergo the risk of a medical procedure even when the potential beneficiary of the procedure is not the child, but a third person.[34] This illustrates that the law presumes parents to be acting in the best interests of their children, absent contrary evidence. This reasoning applies with equal force to pregnant women.

Women who choose to maintain a pregnancy should be assumed to care about their fetuses. An adversarial depiction of a pregnant woman and her fetus is simplistic and unnecessary:

> [B]y granting rights to the fetus assertable against the pregnant woman, and thus depriving the woman of decision-making autonomy, the state affirmatively acts to create an adversarial relationship between the woman and the fetus. By separating the interests of the fetus from those of the pregnant woman, and then examining, often

29. *Id.*

30. *See, e.g.*, Gallagher, *supra* note 25, at 14-15.

31. *Id.*

32. *See* Bonner v. Moran, 126 F.2d 121 (D.C. Cir. 1941) (parental consent valid to allow teenaged child's skin graft for cousin); Hart v. Brown, 289 A.2d 386 (Conn. 1972) (parental consent adequate to allow seven-year-old to donate a kidney to her twin sister).

33. *Bonner*, 126 F.2d at 122.

34. Id. at 123; *Hart*, 289 A.2d at 390.

> post hoc, the effect on the fetus of isolated decisions made by the woman on a daily basis during pregnancy, the state is likely to exaggerate the potential risks to the fetus and undervalue the costs of the loss of autonomy suffered by the woman.[35]

There may not always be a perfect answer. However, in situations where the state has prized fetal welfare over maternal self-determination, the results have been catastrophic. An illustration of this mistake is the case of court-ordered caesarean sections.[36] The shocking facts of In re *A.C.*[37] compelled many people to recognize the damage done to women forced to undergo caesarean sections against their will. In that case, a Superior Court judge in the District of Columbia ordered that a caesarean section be performed upon a woman with terminal bone cancer, against the expressed wishes of the woman's family, her doctors, and the woman herself. Though Angela Carder could not speak, when asked whether she would consent to the operation she mouthed: "I don't want it done."[38] The forced-caesarean decision, upheld by the Court of Appeals, was termed "human sacrifice" by the woman's doctor.[39] To justify his decision, Judge Nebeker stated that "[t]he Cesarean section would not significantly affect A.C.'s condition because she had, at best, two days left of sedated life."[40] Angela Carder's baby died two hours after the caesarean, and Angela Carder died two days later.[41]

Faced with the horrifying outcomes of such cases, some courts have begun to recognize a pregnant woman's right to select options that best suit her own health needs or personal preferences, despite recommendations that alternative treatments would better serve fetuses. In vacating and remanding the case of A.C.,[42] the appellate court, rehearing en banc, noted that "courts do not compel one person to permit a significant intrusion upon his or her bodily integrity for the benefit of another person's health"[43] and rejected the concept that "fetal cases are different because a woman who 'has chosen to lend her

35. Dawn E. Johnsen, *The Creation of Fetal Rights: Conflicts with Women's Constitutional Rights to Liberty, Privacy, and Equal Protection*, 95 YALE L.J. 599, 613 (1986).

36. Ordered for the supposed benefit of the fetus, caesareans pose a risk of death for women who undergo them roughly four times that of vaginal delivery. The chance of post-operative infections is up to ten times as high as for women who deliver vaginally. Nancy K. Rhoden, *The Judge in the Delivery Room: The Emergence of Court-Ordered Caesareans*, 74 CAL. L. REV. 1951, 1958 (1986) (citing NAT'L INST. OF HEALTH, U.S. DEP'T OF HEALTH AND HUMAN SERV., PUB. NO. 82-2067, CESAREAN CHILDBIRTH: REP. OF A CONSENSUS DEV. CONF. 51, 268).

37. 533 A.2d 611 (D.C. 1987), *vacated*, 539 A.2d 203 (D.C. 1988), *vacated and remanded*, 573 A.2d 1235 (D.C. 1990) (en banc).

38. In re A.C., 573 A.2d at 1241.

39. Margaret Diamond, *Echoes from Darkness: The Case of Angela C.*, 51 U. PITT. L. REV. 1061, 1062 (1990) (citing O'Brien, *Patient's Lawyer Calls A.C. Case Human Sacrifice*, AM. MED. NEWS, March 11, 1988, at 18).

40. In re A.C., 533 A.2d at 617.

41. Id. at 1238.

42. *Id.* at 1253.

43. *Id.* at 1243-44.

body to bring [a] child into the world' has an enhanced duty to assure the welfare of the fetus, sufficient even to require her to undergo cesarean surgery."[44] The anguish and death of Angela Carder illustrate the danger of disregarding a woman's wishes, subordinating her health and autonomy to the supposed interests of a fetus.

The range of outcomes in reported cases where caesareans were compelled by court order furnishes compelling reasons to allow women to make their own decisions regarding medical procedures and treatment. In *Jefferson v. Griffin Spalding County Hospital Authority*,[45] the Georgia Supreme Court ordered a pregnant woman to have a caesarean section against her wishes after doctors testified that she had only a fifty percent chance of surviving vaginal delivery and that her fetus had a likelihood of death during vaginal delivery of virtually one hundred percent.[46] The court awarded temporary custody of the fetus to the state and ordered Jessie Mae Jefferson to submit first to a sonogram[47] and then to a caesarean section if her doctor determined it to be warranted.[48] Jefferson, who rejected the caesarean procedure for religious reasons, defied the court order and went into hiding, delivering a healthy child on her own, with no adverse effects.[49]

The imperfection of medical science is another strong reason to support informed decisionmaking by pregnant women, as recognized by the American College of Obstetricians and Gynecologists (ACOG). ACOG's ethics committee recommends that when a patient refuses to follow medical advice, particularly in cases of so-called maternal-fetal conflict, a doctor should respond by conveying reasons for the advice and "encouraging responsible behavior through education and counseling."[50] ACOG correctly leaves the ultimate decision with the pregnant woman, noting that:

> [m]edical knowledge and judgment have limitations and fallibility. . . . Methods for detecting fetal distress or deterioration are not always reliable indicators of poor outcome; therefore, assigning a degree of risk to the fetus is difficult. In addition, expected benefits for the fetus cannot always be achieved.[51]

Many medical professionals thus acknowledge the pregnant woman as the ultimate decisionmaker, because once informed, she is best equipped to balance risks.

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44. *Id.* at 1244 (rejecting Robertson, *Procreative Liberty*, 69 VA. L. REV. at 456).

45. 274 S.E.2d 457 (Ga. 1981).

46. *Id.* at 458.

47. *Id.* at 459.

48. *Id.* at 460.

49. Diamond, *supra* note 39, at 1068 (citing Berg, *Georgia Supreme Court Orders Caesarean Section—Mother Nature Reverses on Appeal*, 70 J. MED. ASS'N GA. 451 (1981)).

50. *Committee Opinion from the Committee on Ethics: The American College of Obstetricians and Gynecologists*, 1 WOMEN'S HEALTH ISSUES 13 (1990).

51. *Id.* at 13-14.

B. *The Efficiency Rationale*

A protectionist rationale is not the only reason given for excluding women as subjects in medical research. Purported interests in conducting studies with homogeneous populations and running cost-effective studies have been asserted to justify exclusion of just about everyone except white men from medical research.[52] But researchers often fail to pursue more effective methods of ensuring homogeneity than blanket exclusion of women. Many classifications used to obtain supposed homogeneity in clinical trials, such as gender and race, are overly simplistic, "weak surrogates for medically relevant parameters."[53] For example, in the case of Acquired Immune Deficiency Syndrome (AIDS) research, more reliable indices of homogeneity would include "[d]efining a range of T-cell values or other immunologic, virologic, and hematologic abnormalities characteristically associated with AIDS."[54] By ignoring these and other vital variables that complicate or disrupt homogeneity, such as amount and quality of primary medical care, investigators may infuse their studies with the potential for significant error.[55]

There are times when researchers feel ethically bound to accept less than perfect homogeneity. For example, AIDS and other life-threatening diseases call into question the ethics of the common requirement that subjects refrain from using any other concomitant therapy.[56] Recognizing an ethical duty (and perhaps a practical necessity) to allow people with AIDS to use concomitant therapies, some institutional review boards (IRBs)[57] encourage investigators to record, not bar, concomitant therapies. Rather than insisting on homogeneous medical treatment, researchers record each participant's individualized medical care program and stratify the study's results.[58] Because researchers have the ability to compensate for lack of homogeneity through methods such as careful record-keeping, the ethical duty to accept

52. The community of clinical researchers is split between two groups: those who advocate clinical trials that reflect practical uses of a drug or therapy under diverse conditions by diverse patients, thus producing results that may be generalized immediately to patients, and those who promote trials designed to eliminate every possible confounding factor, thereby postponing resolution of the problems of application to persons outside of the study group until a future stage of the research process. Merton, *supra* note 12, at 508. Unfortunately, researchers often forego this future stage rather than simply postponing it.

53. *Id.* at 515.

54. *Id.* at 515-16.

55. *Id.* at 516.

56. *Id.* at 523.

57. Institutional review boards are institution-based committees responsible for approval or rejection of institution-sponsored research proposals. These committees are composed primarily of members with some affiliation with the institution. *See* 45 C.F.R. § 46.107 (1983) (providing detailed requirements for board composition). For an intriguing proposal that works within the current IRB framework to increase participation of traditionally excluded populations, see Merton, *supra* note 12.

58. Another solution is to ask subjects to disclose their medications and request that they continue taking the medications for three months before they partake in the research. This allows researchers to measure the effects of experimental treatment against an individual subject's own baseline. Merton, *supra* note 12.

nonhomogeneity in order to advance the health of an affected population should be the norm rather than the exception.

Unfortunately, many researchers feel no similar ethical duty to include women in research protocols despite the harm done to women by gross underrepresentation. Researchers claim that male physiology is "simpler," and that it is therefore easier to conduct studies on males and generalize to female populations than to conduct research directly on women. In fact, one study on the links between obesity and breast and uterine cancer used only men as research subjects.[59] Researchers justified the use of male subjects by theorizing that studies could be conducted more quickly using men because men do not have menstrual cycles.[60] Researchers and those who fund research also claim that men are cheaper to study and easier to recruit as subjects because certain conditions chosen for study occur more frequently in men,[61] or because studying women may require funding for child care.[62] Such theories and applications reflect an underlying belief in a white, male "standard" population from which treatments for other groups should be extrapolated.

Researchers further claim that women are less reliable than men and fail to follow through with research protocols.[63] Women are considered unreliable because they may have child care responsibilities that require them to discontinue their participation in studies. Additionally, it is feared that they may become pregnant while enrolled in research and either drop out of the program or be forced out by researchers who assume that allowing a pregnant woman to remain will create a high risk of liability. Dismissal of pregnant women from studies for noncompliance has a punitive effect where medical research trials are the only treatment available, either because there is no approved treatment or because available medical treatments cannot be used on a patient with other incompatible conditions.[64] Women subjects who become pregnant are considered noncompliant even when their pregnancy is not the result of disregard of the requirements of a medical study, but of imperfect methods of birth control. In contrast, few precautions are taken to prevent

59. Jaschik, *Report Says N.I.H. Ignores Own Rules on Including Women in Its Research*, CHRON. OF HIGHER EDUC., June 27, 1990, at A27.

60. *Id.* at n.1. Recent research demonstrating hormonal cycles in men as well as women calls into question the validity of this justification. In the recent studies, in fact, men showed a larger seasonal hormonal variation in cognitive ability than did women. Sandra Blakeslee, *Men's Test Scores Linked to Hormone*, N.Y. TIMES, Nov. 14, 1991, at B14. This research conforms with earlier, less-publicized research. *Id.* The lack of publicity suggests a blind eye to information that might challenge the stereotyped views researchers hold.

61. *But see supra* text accompanying note 12 (describing sexist standards for male and female subjects).

62. THE ACT UP/NEW YORK WOMEN AND AIDS BOOK GROUP, WOMEN, AIDS, AND ACTIVISM 73 (1990) [hereinafter ACT UP].

63. The same claim is made regarding intravenous drug users, a significant percentage of whom are women. In addition, since the majority of intravenous drug users in America are African American and Latino, a disturbing deprivation correlated to race is evidenced in excluding that group. Merton, *supra* note 12, at 515.

64. Timothy F. Murphy, *Women and Drug Users: The Changing Faces of HIV Clinical Drug Trials*, QUALITY REV. BULL., Jan. 1991, at 26.

men who participate in experimental protocols from fathering children during their tenure within the studies.[65]

C. *The Unstated Rationale: Funding Driven by Fear*

Despite the purported protectionist and efficiency rationales for excluding women from medical research protocols, the fact that United States research and medical staffs are largely composed of men[66] is consistent with the hypothesis, articulated most succinctly by *Boston Globe* columnist Ellen Goodman, that the scientific establishment "funds what it fears."[67] This theory suggests that particular diseases, conditions, and subjects are more readily selected for study because they match the concerns of those conducting research. The lack of funding for research on osteoporosis, breast cancer, endometriosis, contraceptives, and AIDS in women is also consistent with this claim.[68]

II.
CURRENT REGULATORY ACTIVITY: FDA AND DHHS

Medical research in the United States is regulated by the Food and Drug Administration (FDA) and the Department of Health and Human Services (DHHS). The DHHS regulations apply to research funded by the Department,[69] while the FDA regulations apply primarily to research involving products which will ultimately require FDA approval.[70] If research is both federally funded and concerns specified products, it may be governed by both sets of regulations. Both the DHHS and FDA regulations require that selection of all subjects be "equitable."[71] However, this vague and malleable re-

65. *Id.* at 519.

66. Only fourteen percent of the top staff positions at the National Institutes of Health (NIH) are filled by women. Joanne Silberner and Dorian R. Friedman, *Health: Another Gender Gap*, U.S. NEWS & WORLD REP., Sept. 24, 1990, at 54, 55. Women have recently filled some notable health-related positions. Bernadine Healy heads NIH; Gail Wilensky now runs the Health Care Financing Administration, which oversees Medicare and Medicaid; and the President George Bush recently appointed the first woman Surgeon General in the United States, Antonia Novello. *Top Ten 1991*, U.S. NEWS & WORLD REP., May 20, 1991, at 94. But women remain vastly underrepresented throughout the field of science. Of sixty American scientists elected to the prestigious National Academy of Sciences in 1991, only six were women. Yet women have been swelling the lower and middle ranks of the profession for years, and they currently make up almost one-third of the total number of American scientists.

67. "The fund-what-you-fear bias in health research goes straight through the medical system. After all, who decides what we should study, what is important and who is important? The dearth of female researchers, female reviewers, female doctors and female administrators at NIH has directly resulted in a dearth of research on women's health issues.

"But conversely, the rise of women in medical and policy-making positions in the rest of the world has put these issues in the public eye." *Ellen Goodman*, N.Y. NEWSDAY, June 23, 1990, at 74 (personal column).

68. *See generally* CONG. CAUCUS FOR WOMEN'S ISSUES, THE WOMEN'S HEALTH EQUITY ACT, at 2-9 (July 1990) [hereinafter CONG. CAUCUS FOR WOMEN'S ISSUES].

69. 45 C.F.R. § 46.101(a) (1990).

70. 21 C.F.R. § 56.101(a) (1991).

71. 21 C.F.R. § 56.111(a)(3) (1991) (in determining what is equitable, "the IRB should

quirement has not prevented the categorical exclusion of women from most research protocols. Pregnant women are regularly excluded from trials even when those trials pose no risk to them. Moreover, nonpregnant women are often excluded because they could become pregnant. These exclusions are permitted because the requirement of equity has gone unenforced—largely for lack of a consistent definition.[72]

Finally, a substantial proportion of medical research in the United States is free from any regulation regarding subject selection. Purely private research is not reached by federal regulations. Thus private researchers are under no obligation to select subjects "equitably."[73]

A. DHHS Regulations

Under DHHS regulations, subjects may be exposed only to risks that are reasonable in relation to anticipated benefits.[74] This requires researchers and institutional review boards to screen out unreasonable risks from the beginning. Furthermore, whatever risk is present must be minimized, and experimental procedures may not be randomly substituted for procedures already being used successfully for the patient's primary care.[75]

These regulations are protective, but they place more control in the patient's hands—at least when the patient is not a pregnant woman—than prior regulations. Previous regulations required that risks be outweighed by enough potential benefit "so as to warrant a decision to *allow* the patient to undertake the risk."[76] The current regulations entrust IRBs with the primary responsibility of ensuring that, except when the risk is "extremely unreasonable,"[77] sufficient information is given to the subject to enable her, rather than the researcher, to weigh the risks.

1. DHHS Regulations Regarding Pregnant Women and Children

In contrast to a general philosophy that would allow patients to weigh risks for themselves, DHHS regulations require researchers and IRBs to engage in stringent risk-benefit analyses when research involves pregnant women

take into account the purposes of the research and the setting in which the research will be conducted"); 45 C.F.R. § 46.111(a)(3) (1990) (imposing requirements identical to those in section 56.111(a)(2) and adding that IRBs should "be particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons")

72. UNITED STATES GENERAL ACCOUNTING OFFICE, NAT'L INST. OF HEALTH: PROBLEMS IN IMPLEMENTING POLICY ON WOMEN IN STUDY POPULATIONS, at 5 (June 18, 1990).

73. In practice, institutional review boards may apply the same rules to privately sponsored research. In addition, states may impose laws regulating private studies. Nonetheless, there is no uniform regulation of such research.

74. 45 C.F.R. § 46.111(a)(2) (1990).

75. 45 C.F.R. § 46.111(a)(1) (1990).

76. R. LEVINE, *supra* note 2, at 63 (citing 45 C.F.R. § 46.102 (rescinded)) (emphasis added).

77. *Id.*

or their fetuses. The regulations mandate that research on pregnant women or fetuses create no more than minimal risk to the fetus unless the health of the mother or fetus is at stake.[78] Thus, under these regulations, research that does not directly benefit the health of a pregnant woman or fetus, but benefits third parties or society at large, is not considered reasonable under most circumstances where risk is involved.

This restriction is logically at odds with the regulations regarding research on children. The DHHS regulations do permit research to be conducted on children when there is greater than minimal risk and no prospect of direct benefit to a child in cases where such research is likely to yield "generalizable knowledge of vital importance" regarding the child's condition.[79] No such provision permitting potentially harmful research if it could yeild such significant benefits exists for pregnant women. The regulations regarding pregnant women, therefore, are stricter than the provisions designed to protect children.

This inconsistency is perhaps explained by the history of how the rules were formulated. The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, whose recommendations form the basis of many of the current regulations, was allotted only four months to investigate and make recommendations to Congress regarding fetal research and research on pregnant women. In contrast, it had two years to make recommendations regarding all other human-subject research, including research performed on children.[80] The fact that the fetal regulations were in place before the Commission had time to consider its overall approach indicates that inconsistencies between approaches in the earlier regulations should be resolved in a manner consistent with the recommendations made without the strict time constraint.

Argument over the status of fetal personhood rages. But regardless of the debate's outcome, a fetus has no greater claim of personhood than does a child. Current regulations overprotect fetuses and make important research difficult.[81] Overprotection of a fetus while inside a mother's body is a form of disrespect to the woman and to her right of self-determination.[82]

2. *The Effect of DHHS Regulations on Nonpregnant Women*

Complications also arise when the DHHS regulations are applied to women who, although not pregnant, could become pregnant. IRBs are currently authorized to suspend or terminate research if an unexpected serious harm arises.[83] Relying on this provision, researchers may terminate research when-

78. 45 C.F.R. §§ 46.206-46.207 (1990).
79. 45 C.F.R. § 46.406 (1991).
80. R. LEVINE, *supra* note 2, at 299.
81. *Id.* at 63.
82. *See generally infra* note 199 and accompanying text (defining a right to reproductive self-determination).
83. 45 C.F.R. § 46.113 (1990).

ever a subject unexpectedly becomes pregnant. This practice may be costly, since the research arguably must be repeated with a new subject. Consequently, potential pregnancy, however remote, has served as a rationale for excluding all women from experimental protocols for the sake of cost-efficiency. But automatic termination in the absence of evidence of harm to the pregnant woman is unnecessary, and drop-out rates can be factored into any experiment. Like any research subject, a pregnant woman must be given the option to leave, but she should never be forced out.

B. NIH Response to the Problem

The National Institutes of Health (NIH) administers the DHHS regulations. Recognition of the harm women suffer from their exclusion from research sparked NIH to issue a new policy in 1987 that encouraged the inclusion of women in clinical studies.[84] This policy required grant applicants to provide clear rationales for excluding women from their study populations.[85] Yet a General Accounting Office (GAO) study found that NIH's policy had not been followed consistently until 1990.[86] The study also revealed that NIH had no system for monitoring the policy's effectiveness, and that when researchers did adhere to the policy, they did not take advantage of the inclusion of women in order to determine whether diseases or treatments affect women differently than men. GAO concluded that its policy was undermined by two things: the failure of researchers to consider inclusion of women as a key factor in determining a proposal's scientific merit, and the application of the policy to extramural research funded by NIH but not to intramural research conducted by NIH itself.[87]

NIH has more recently indicated a desire to address these internal problems by amending its requirements for grant applicants. As of April 1991, grant applicants were required either to include women in research proposals or to provide compelling justification for not doing so.[88]

Attempting to remedy bias and to increase funding for research on women's health issues, Representatives Patricia Schroeder (D-Colo.) and Olympia Snowe (R-Me.) introduced the Women's Health Equity Act (WHEA).[89] The Act, proposed in 1990 and reintroduced in 1991,[90] would codify the NIH policy. The Act would also officially authorize the Office of Research on Wo-

84. CONG. CAUCUS FOR WOMEN'S ISSUES, *supra* note 68, at 3.

85. *Id.*

86. U.S. GENERAL ACCOUNTING OFFICE, NAT'L INST. OF HEALTH: PROBLEMS IN IMPLEMENTING POLICY ON WOMEN IN STUDY POPULATIONS (June 18, 1990).

87. *Id.* at 3-4.

88. How broadly "compelling justification" will be interpreted and how vigorously the policy will be enforced remains to be seen.

89. H.R. 5397, 101st Cong., 2d Sess. (1990).

90. H.R. 1263, 102d Cong., 1st Sess. (1991) (The Act states the following as its purpose: "[T]o promote greater equity in the delivery of health care services to American women through expanded research on women's health issues, improved access to health care services, and the development of disease prevention activities responsive to the needs of women.")

men's Health, established in 1990, to oversee women's health research at NIH, to evaluate representation of women among physicians and scientists, and to develop an obstetrics and gynecology program at NIH.[91] Though this office has already been established, to be effective it must be given sufficient oversight power to ensure that the study of women's health issues is no longer neglected.

The proposed Act also authorizes funding for research on a number of traditionally underfunded women's health issues, such as breast cancer, osteoporosis, and AIDS.[92] Its most recent incarnation would narrow permissible exclusions of women and minority groups from research funded by NIH or the Alcohol, Drug Abuse, and Mental Health Administration. WHEA's policy of inclusion may be suspended only when inclusion is "inappropriate with respect to the health of the subjects . . . the purpose of the research . . . [or] under such other circumstances as the Secretary may designate."[93] Unfortunately, that final, yet-to-be-defined loophole may be large enough to encompass all of the current exclusionary practices now considered reasonable by researchers. Current DHHS and FDA regulations contain no affirmative requirement that women be included in research and have allowed automatic exclusion of both nonpregnant and pregnant women regardless of whether any danger to a fetus exists.

The proposed Act is encouraging, but it will not necessarily prevent researchers from excluding women when researchers sincerely believe that reproductive capacity is a rational basis for exclusion. Furthermore, WHEA does not alter FDA regulations. Amendment of both the FDA and DHHS regulations is necessary and should be given due attention. However, regulatory amendments and stopgap funding measures alone will not break down the resistance to inclusion of women in research.

III.
HARM CAUSED BY EXCLUSION

A. Research Protocols, Women, and AIDS

The emergence of AIDS highlights the importance of access to experimental therapies. First, in contrast to concern over protecting disadvantaged or vulnerable populations from experimental exploitation, AIDS is a powerful reminder of how inclusion in research protocols can benefit individuals. In the case of AIDS, a disease with no known cure, access to experimental therapies may be the only hope for survival. As of January 1991, nearly 11,000 people with HIV-related conditions had participated in federally sponsored clinical trials, with an unknown number participating in private trials.[94] Women were

91. THE WOMEN'S HEALTH EQUITY ACT, CONG. CAUCUS FOR WOMEN'S ISSUES, at 1 (Feb. 1991).

92. *Id.* at 5-8.

93. H.R. 1161, § 507(A), pp. 21-22. 102d Cong., 1st Sess. (1991).

94. Murphy, *supra* note 64, at 26.

underrepresented in or excluded from these trials.[95]

Second, the AIDS crisis illustrates how women as a class are harmed by their exclusion from research. People who fit the Centers for Disease Control's (CDC) "AIDS profile" receive relatively quick acknowledgement of their condition. Social Security benefits payments accompany that recognition. Because the Centers for Disease Control has defined AIDS according to its symptomatology in men, women are diagnosed more slowly and many women with severe HIV-related disabilities do not qualify for benefits under the Social Security Act. Women infected with HIV suffer a variety of recurring gynecological disorders, including reproductive tract infections, cervical cancer, pelvic inflammatory disease, and chronic yeast infections.[96] Yet the CDC's definition of AIDS does not reflect these symptoms.[97] Approximately sixty-five percent of the women who die of HIV-related illnesses fail to meet the CDC's criteria for an AIDS diagnosis.[98]

Once diagnosed, women with AIDS can find no treatments designed specifically to combat the disease as it affects female bodies.[99] Due to these diagnostic problems, women are not only the fastest growing group of people with AIDS,[100] but they are also, in many parts of the country, the fastest growing group of people dying with AIDS. "In 1987, AIDS became the leading cause of death in New York City for women between the ages of 25 and 34 .... [I]n 1991 it is expected to become one of the five leading causes of death in women

95. *Id.*

96. These facts have inspired the AIDS Coalition to Unleash Power's protest chant: "Women don't get AIDS. They just die from it." As a result of this profound disparity, a law suit has been initiated on behalf of people with AIDS and related conditions who have been denied presumptive benefits because their symptoms do not fit a classic HIV profile. Second Amended Class Action Complaint at 15, S.P. v. Sullivan (S.D.N.Y. 1991) (No. 90-6294). These individuals must engage in a lengthy appellate process to pursue their benefits. As a consequence they lose vital treatment time and sometimes die before the appellate process is completed. The class action notes that the CDC developed its list of AIDS indicators through research conducted primarily on the group that first acquired HIV in large numbers: middle class, white, gay men. *Id.* at 9. The class action also points out that the ways in which HIV manifested itself varied widely once it spread beyond that initial population. *Id.* at 11. The 1990 profile used to determine who receives presumptive benefits excludes all disabling gynecological impairments which are among the most common manifestations of HIV-related disease in women. *Id.* at 19.

97. ACT UP, *supra* note 62, at 33-35 (detailing female-specific AIDS symptoms).

98. Susan Y. Chu. et al., *Impact of the Human Immune Deficiency Virus Epidemic on Mortality in Women of Reproductive Age, United States*, 264 JAMA, at 225-29 (July 11, 1990). The argument that gynecological problems are so common among women that they should not be included in the definition of AIDS does not hold up in light of the dramatic need for access to benefits by people who have AIDS but are currently denied benefits. In August 1991, CDC announced its plans to broaden the definition of AIDS to include CD4 or "T-cell" counts of fewer than 200 cells per cubic milliliter of blood. This expanded definition, effective April 1, 1992, will include more women; but it still fails to consider symptoms that affect only women. Sophia W. Chang, Mitchell H. Katz, & Sandra R. Hernandez, *The New AIDS Case Definition: Implications for San Francisco*, 267 JAMA 973 (1992). Unless doctors already suspect HIV, they will not think to test for a lowered T-cell count. Thus women will still be diagnosed late in the disease's progression. L.A. TIMES, Sept. 22, 1991, at A3.

99. CONG. CAUCUS FOR WOMEN'S ISSUES, *supra* note 68, at 5-9.

100. CONG. CAUCUS FOR WOMEN'S ISSUES, *supra* note 68, at 2.

of reproductive age in the United States . . . ."[101]

> Much of the problem lies in the fact that virtually no research has been conducted on women and AIDS. What little research has been done has focused almost exclusively on women's role in transmitting the disease to others, particularly children, rather than on women as individuals at risk of contracting the disease.[102]

It is critical that women gain access to experimental AIDS therapies and be included in HIV research protocols, both for the benefit of the individual subjects and for the health of all women.

B. Research Protocols and Women as Marketplace Guinea Pigs

The overwhelmingly male composition of research protocols also means that drugs tend to reach the market with no information on what constitutes appropriate dosages for women, on possible gender-specific side-effects, or on ultimate efficacy for treating women.[103] Though post-marketing studies of drugs are sometimes performed, they are not required as a condition of drug licensing.[104] Thus women become, in effect, marketplace guinea pigs, experimented upon by their individual doctors, who have little option but to give them untested drugs.[105]

A choice between either ignoring the possibility of danger or withholding drugs from women who need them is unacceptable. While the majority of the drugs marketed without adequate testing on women do not cause unexpected reactions, those that have adverse effects injure a greater number of women than would be harmed if the drugs were systematically studied on women before marketing.[106]

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101. Merton, *supra* note 12, at 513.

102. CONG. CAUCUS FOR WOMEN'S ISSUES, *supra* note 68, at 7. For example, a recent study indicated that 80,000 women of child-bearing age in the United States alone have AIDS. The study extrapolated numbers of infected women by examining infants. According to the study's principal author, Dr. Marta Gwinn of the Centers for Disease Control, 1,500 to 2,100 babies could be born with the human immunodeficiency virus annually. *Study Finds 80,000 Women May Carry HIV*, N.Y. TIMES, April 3, 1991, at B6.

103. Merton, *supra* note 12, at 522.

104. Murphy, *supra* note 63, at 26.

105. Merton, *supra* note 12, at 522-23.

The marketplace guinea pig phenomenon is not limited to distribution of drugs. The silicone breast implant controversy is a recent illustration. As the issue unfolded, it was revealed that the manufacturer had marketed the technology to two million women despite a lack of crucial data on safety. Silicone from some of the implants was found to have entered the blood stream and migrated to organs such as the spleen, liver, and bone marrow. Silicone implants have also been associated with autoimmune diseases and caused painful internal scarring around the implants. Due to these problems, a federal advisory panel recommended that silicone gel breast implants should continue to be permitted for reconstructive surgery, but that their availability for other purposes should be severely restricted. Marlene Cimons, *FDA Panel Votes Implant Limits*, L.A. TIMES, Feb. 21, 1992, at A1.

106. R. LEVINE, *supra* note 2, at 240-41.

C. Potential Practitioner Liability

Drugs not tested on women are marked with "orphan" clauses which recommend that the drugs not be used on women.[107] In practice, these clauses are ignored by physicians in the United States.[108] Therefore, these drugs pose not only health risks to women, but legal risks to physicians. The "orphan" disclaimers may actually expose doctors to malpractice litigation for administering the drugs with deficient knowledge of their potential effects.[109] Additionally, medical professionals may incur liability for administering treatments without securing informed consent, since the potential for harm caused by these drugs is unknown, and most people visiting their doctors' offices do not expect to receive untested medication or to participate in a de facto experiment.[110] Liability is not eliminated by refusing to test drugs on women. Rather, the liability is passed from researchers to physicians, who are exposed to malpractice claims precisely because of the exclusion of women from research. Experiments performed on a controlled number of women will reduce possible liability below that resulting from the mass-marketing of drugs that have not been tested on women first.[111]

IV.
EXPLORING SOLUTIONS

A. Informed Consent: The Most Valuable Tool for Encouraging Research and Avoiding Liability

This section moves beyond the history of exclusionary policies, the morass of current agency regulations, and the harm caused by exclusion, to the search for solutions. We begin by dealing with the resistance to the inclusion of women in experimental protocols that stems from researchers' fears of legal liability.

1. Judicial Respect for Informed Consent

Any experimental treatment or research protocol may produce undesired effects. However, estimates of potential injury and accompanying liability have been largely overstated.[112] Studies of more than 29,000 subjects in 805 drug protocols revealed only fifty-eight adverse drug reactions, not one of them resulting in death or permanent disability from experimental treatment.[113] The only subject who died had received a placebo.[114] For these

107. *Id.* at 240.
108. *Id.*
109. *Id.* at 241.
110. *Id.*
111. The risk in this scenario parallels that in the thalidomide case, where the drug was distributed widely without first exploring indications of risk to women. Ironically, the exclusion of women from research, which is often explained by references to the thalidomide disaster, holds the potential to replicate the disaster. *See supra* notes 6-11 and accompanying text.
112. R. LEVINE, *supra* note 2, at 39.
113. *Id.*

29,000 subjects, participating in research was only slightly more hazardous than working as an office secretary and one seventh as dangerous as taking a job as a window washer.[115] A team of researchers reported that protocols involving 306,000 subjects over an eight-year period resulted in just thirteen insurance claims: seven awards were for $54 or less; four were for more than $410; and the largest was for $1,550.[116] Clearly, the risks of becoming a medical research subject are often exaggerated.

Conversely, benefits of experimentation and experimental treatments are often overlooked. These benefits may include improved health of the subjects themselves or progress toward treatments for conditions affecting particular subject populations. When pregnancy is a factor, knowledge of the efficacy of drugs upon pregnant women due to pregnancy's unique physiological and metabolic effects is not only desirable, but necessary. Additionally, the benefits of research accrue to the woman as well as to her offspring, who has an interest in having a healthy mother. Finally, in the case of a fatal disease, experimental treatments that save or extend a pregnant woman's life may also provide the only chance to save the life of her fetus.

Whatever danger of liability does exist in research may be controlled through the legal doctrine of informed consent. Informed consent allows subjects to accept risks inherent in experimental protocols, provided that subjects are fully informed of risks and are not coerced into participation. Judge Cardozo formulated the doctrine of informed consent in deciding a case of trespass in the form of unauthorized surgery: "Every human being of adult years and sound mind has a right to determine what shall be done with his own body; and a surgeon who performs an operation without his patient's consent commits an assault, for which he is liable in damages."[117] The doctrine of informed consent thus requires disclosure of all information material to the patient's decisionmaking process.[118]

Courts have since recognized informed consent as a bar to liability arising from experimentation. In *Whitlock v. Duke University*,[119] Leonard Whitlock alleged he had suffered organic brain damage as a result of his participating as a diver in a series of simulated deep dive experiments that studied high pressure nervous syndrome.[120] Whitlock had signed a consent form advising him

114. *Id.*

115. *Id.*

116. *Id.* at 40.

117. Schloendorff v. Society of New York Hosp., 105 N.E. 92, 93 (N.Y. 1914), *overruled on other grounds by* Bing v. Thunig, 143 N.E.2d 3 (1957).

118. Canterbury v. Spence, 464 F.2d 772, 768 (D.C. Cir.), *cert. denied*, 409 U.S. 1064 (1972); *see also* Salgo v. Leland Stanford Jr. Univ. Bd. of Trustees, 317 P.2d 170, 181 (Cal. 1957); Natanson v. Kline, 354 P.2d 670, 672-73 (Kan. 1960). Disclosure of remote or extremely minor risks, however, is not required in order to comply with the doctrine of informed consent, though *Canterbury* can be interpreted to inlcude a doctor's duty to informing a patient that there may be unknown risks involved in certain experimental medical procedures. *See* 464 F.2d at 786-87.

119. 637 F. Supp. 1463 (M.D.N.C. 1986), *aff'd*, 829 F.2d 1340 (4th Cir. 1987).

120. *Id.* at 1465-67.

of risks associated with compression and decompression during the experiment, ranging from inflammation of the ear, to lung collapse, to death.[121] The court noted that:

> the form advised that the research was experimental, that there may be unknown risks, and that injury may not necessarily be avoided even if all precautions are taken. The form advised that compensation would not be provided for injury unless it resulted from negligence.[122]

Relying upon the form, the court granted summary judgment for the defendant university.[123]

The potential benefits of experimental medical research motivate courts to hold that medical professionals may not be held liable for non-negligent injuries caused by experimental procedures in the presence of a covenant not to sue.[124] This is what the court held in *Colton v. New York Hospital.*[125] Colton decided to donate one of his kidneys in 1972, when surgical donation procedures were considered experimental.[126] He subsequently suffered renal failure, a high fever that resulted in deafness when treated, and a melanoma.[127] Despite the severity of Colton's injuries, the court held that "where a patient voluntarily agrees to undergo an experimental . . . procedure, the parties may covenant to exempt the physician from liability for injuries which are found to be the consequences of the non-negligent, proper performance of the procedure."[128] Such covenants, the court held, protect the medical professional from liability for any non-negligently produced injury, whether foreseeable or unforeseeable.[129] Thus, established public policy and judicial precedent reveal that, in the absence of negligence, informed consent as a bar to suit in the context of medical experimentation is not disfavored. Rather, as the court in *Colton* reasoned, the doctrine encourages medical progress:

> A public policy encouraging such necessary activity as experimental medical research would be utterly ineffectual if one who performs the activity may be held liable solely on account of his non-negligent performance. A patient's opportunity to be aided by innovative technology presupposes the availability of willing physicians unafraid to use it.[130]

Even in the absence of a covenant not to sue, the likelihood of liability in

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121. *Id.* at 1466.
122. *Id.*
123. *Id.* at 1476.
124. Colton v. New York Hosp., 414 N.Y.S.2d 866, 874 (Sup. Ct., N.Y. 1979).
125. *Id.*
126. *Id.* at 869.
127. *Id.* at 871.
128. *Id.* at 876.
129. *Id.*
130. *Id.* at 875.

the absence of fault is low. The President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research contemplated the possible imposition by the courts of strict liability principles to medical research.[131] It concluded that although no explicit court ruling existed on the subject, it was improbable that a court would impose strict liability.[132] The Commission further advised against extending strict liability to medical research.[133]

Though the informed consent doctrine is well established, researchers continue to fear liability. Cases involving large damage awards on behalf of children have fueled the medical establishment's fear that, despite informed consent, liability is likely for damage done to fetuses. In fact, the prospects for liability are low. Possibly the most notorious instance of liability in the context of women as experimental subjects turned not upon the effects on offspring but upon failure to secure female subjects' informed consent. The court in *Mink v. University of Chicago*[134] heard the complaint of women given diethylstilbestrol (DES) without their knowledge, much less their consent.[135] While the court considered possible claims for negligence and strict liability,[136] it sustained a battery claim, holding that "[t]he gravamen of a battery action is the plaintiff's lack of consent."[137] The primary duty found by the court was that of notifying the women involved in the experiment of risks inherent in the use of the drug.

This duty is actually an extension of both the duty of physicians to warn their patients of risks inherent in treatment and the continuing duty of drug manufacturers to warn of risks inherent in their products.[138] The *Mink* court strongly endorsed the binding power of informed consent, noting that "[i]f the patient has assented to the doctor's treatment, [s]he may not later maintain an

131. 1 PRESIDENT'S COMM'N FOR THE STUDY OF ETHICAL PROBLEMS IN MEDICINE AND BIOMEDICAL AND BEHAVIORAL RESEARCH, COMPENSATING FOR RESEARCH INJURIES: THE ETHICAL AND LEGAL IMPLICATIONS OF PROGRAMS TO REDRESS INJURED SUBJECTS 91-94 (1982) [hereinafter PRESIDENT'S COMMISSION].

132. *Id.* The case of Wells v. Ortho Pharmaceutical Corp., 615 F. Supp. 262 (N.D. Ga. 1985), may appear to confirm some people's fears that courts confuse strict liability and negligence. In *Wells*, a products liability case, the court stated that the elements of the plaintiffs' strict liability theory were the same as those of negligent failure to warn and allowed the case to proceed on both theories. *Id.* at 296. The court reasoned that the negligent failure to warn could be considered a "defect" for purposes of strict liability. *Id.* This language is mere dicta, however, since the court explicitly found negligent conduct in the failure to warn of anticipated risks. *Id.* at 297. The use of strict liability language was unnecessary because the plaintiff proved the defendant's negligence. This was not, therefore, a case of liability without fault.

133. PRESIDENT'S COMMISSION, *supra* note 131, at 91.

134. 460 F. Supp. 713 (N.D. Ill. 1978).

135. *Id.* at 715.

136. The court held that plaintiffs seeking to recover on a theory of strict products liability could not rely on injury to their children to state a claim for themselves, despite allegations of emotional distress. *Id.* at 719.

137. *Id.* at 717, n.4.

138. *Id.* at 720.

action in battery."[139] An institution performing research may use relatively simple procedures to procure informed consent, which creates an effective shield against liability in the absence of other negligence.[140]

A model system allowing experimentation upon women as well as men would expose institutions and individual researchers to tort liability for harm they cause a patient who has not given her informed consent. Current common law promotes that policy.[141] The Supreme Court signalled its approval by unanimous decision in *United Auto Workers v. Johnson Controls, Inc.*,[142] in which employees of a battery manufacturer successfully challenged a fetal protection policy that banned women from certain jobs entailing exposure to lead. The opinion, written by Justice Blackmun, suggests that true informed consent should shield institutions from liability for risks that are explained to and accepted by the subject. The Court noted that more than forty states recognize the right to recover for prenatal injuries based either on negligence or on wrongful death, but stated that where federal standards were followed and people exposed to possible hazards were warned, "[w]ithout negligence, it would be difficult for a court to find liability."[143] General tort principles dictate that in the absence of negligence and in the presence of informed consent on the part of the woman taking the risk, the basis for finding liability "seems remote at best."[144] Therefore, in the absence of negligence, a woman's informed consent would serve as a waiver of liability for the institution conducting the experimental protocol.

2. *Informed Consent and Parental Liability*

The possibility of parental liability to future children harmed by the parent's choice to participate in research may not be of great concern to researchers, but it merits attention if we are to defend our proposal as overwhelmingly beneficial, rather than a trade of one societal problem for another.[145] Deeply

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139. *Id.* at 718.

140. *Cf.* 45 C.F.R. § 46.116 (1988) (liability for *negligent* acts may not be waived in the process of giving informed consent). Claims of "wrongful life" against doctors by children born to patients have been overwhelmingly rejected. *See generally*, Philip J. VanDerhaef, *Washington Recognies Wrongful Birth; and Wrongful Life—A Critical Analysis*, 58 WASH. L. REV. 649 (1983).

141. In its survey of negligence causes of action, the President's Commission found that "[v]irtually all decisions resulting in the award of damages to injured research subjects appear to be based . . . upon proof that . . . the plaintiff . . . did not grant legally effective consent." PRESIDENT'S COMMISSION, *supra* note 131, at 83, n.3.

142. 111 S. Ct. 1196 (1991). Among the individual plaintiffs in *Johnson Controls* were several women and at least one man who worked for the battery manufacturing company, which had a fetal protection policy excluding fertile women from positions in which they would be exposed to certain levels of lead. *Id.* The plaintiffs challenged Johnson Controls' policy under Title VII of the Civil Rights Act of 1964, codified as amended at 42 U.S.C. § 2000e. *Id.*

143. 111 S. Ct. at 1208.

144. *Id.* at 1199.

145. Recently, a new specter of liability has appeared. To date, approximately 180 women in the U.S. have been arrested for taking drugs while pregnant. Rorie Sherman, *Split Rulings for Fetal Abuse Cases*, NAT'L L.J., Feb. 24, 1992, at 3. Some of these women have been crimi-

embedded in traditional family law lies a doctrine that appears to shield a pregnant woman from suit by her future child for alleged fetal damage. The intrafamily tort immunity doctrine, almost a century old, prevented children from bringing lawsuits for injuries caused by parental negligence or willful conduct.[146] The doctrine is, however, "based on the assumption that lawsuits brought by one family member against another destroy family unity, pose a threat to parental authority, and foster collusive lawsuits in which family members scheme to defraud insurance companies or others."[147] The oft-fictional nature of this assumption has led at least twenty-nine states[148] to abrogate the doctrine to some extent in cases of parental negligence.[149] In abandoning parental immunity, courts have noted that negligent action is not a parent's right, that injured parties should have a right to compensation,[150] and that the actual parties in many cases of family litigation are not child and parent but child and insurance company.[151]

One of the most common exceptions to total abrogation of the doctrine, however, occurs when an alleged negligent act involves an exercise of ordinary parental discretion with respect to providing food, clothing, housing, dental services, and *medical care*.[152] Such an interpretation could be used to shield a pregnant woman from liability when making decisions regarding her medical care, as it affects the fetus. Courts have disfavored suits brought by children against their parents, except in cases where the duty breached was one owed by the parent to the world at large, and the injured party happened to be a child.[153] Where the doctrine has been abrogated, recovery has often been limited to the extent of insurance coverage.[154]

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nally prosecuted for fetal neglect, abuse, and even delivering drugs to a minor. *See, e.g.*, Florida v. Gethers, 585 So. 2d 1140 (1991); Johnson v. Florida, 578 So. 2d 419 (1991). This line of case law may have serious implications for pregnant women in a number of contexts. However, these cases are distinguishable because medical research involves physician supervision and advice, the mother may be pursuing her own health needs, and even if not, strong policy considerations favor her participation in medical research.

146. MARTIN GUGGENHEIM & ALAN SUSSMAN, THE RIGHTS OF YOUNG PEOPLE 170-71 (1985).

147. *Id.* at 171.

148. As of 1985, the immunity rules had been abolished or limited in Alaska, Arizona, California, Connecticut, Delaware, Florida, Iowa, Illinois, Kansas, Kentucky, Maine, Massachusetts, Michigan, Minnesota, Montana, New Hampshire, New Jersey, New York, North Carolina, North Dakota, Pennsylvania, Rhode Island, South Carolina, Virginia, West Virginia, Washington, and Wisconsin. Three states never adopted the immunity in the first instance: Hawaii, Nevada, and Vermont. *Id.*

149. *Id.*

150. *Id.* (discussing Gibson v. Gibson, 479 P.2d 648 (1971)).

151. The widespread, compulsory nature of automobile liability insurance was a major influence on such cases. *Id.* (discussing Gelbman v. Gelbman, 245 N.E.2d 192 (N.Y. 1969)).

152. *Id.* at 172.

153. *Id.*

154. *Id.*

3. *Compensation Schemes*

Some risk of injury necessarily accompanies all medical research. We therefore suggest compensating people who give true and voluntary informed consent and are subsequently injured in pursuit of the benefits of experimentation. We advocate adopting some version of established compensation plans, such as those employed in similar circumstances in which recognized societal benefit is paired with some degree of risk. The federal government has created such plans to promote coal mining while compensating for mining-related disability and death[155] and to facilitate nationwide vaccination of children,[156] which carries a variety of serious risks, including death. Such governmental plans include standard recoveries, caps on liability, or indemnification against liability. They offer injured people quick recovery, limited to compensation for injury and economic loss, and eliminating years of litigation and the risk of losing entirely. They also lessen fears of rampant, unwarranted litigation and bank-breaking awards for noneconomic loss.

This compensation system will defuse researchers' fears of unreasonable liability awards granted by juries sympathetic to injured plaintiffs. The system as a whole would provide automatic and timely compensation for non-negligent injury (though, as we have explained previously, in the presence of informed consent neither such compensation nor a right to sue is required by law). The compensation system would not preclude suits for negligence, failure to warn, failure to obtain informed consent, or other wrongdoing. Funding for such a compensation program could be included within federal grants for research. Alternatively, fixed payments, as to an insurance plan, could be made by all entities engaging in research.[157]

Drawbacks of no-fault schemes include the requirement of a substantial initial monetary investment and the impossibility of predicting the potential number of injuries to be covered by a plan.[158] The scope of both problems is greatly diminished in the experimental research context. Compensation plans for people injured during research would require a smaller initial investment than would many other plans. The potential number of injuries covered by the plan would be fewer, since the affected research population is quite limited as compared to, for example, the population of children in the United States who receive vaccinations.

B. Constitutional Claims to Access

The long history of reluctance to include women in research protocols

155. Black Lung Benefits Act, 30 U.S.C. §§ 901-932 (1986).

156. National Childhood Vaccine Injury Act of 1986, 42 U.S.C. § 300aa-1-33 (1991).

157. PRESIDENT'S COMMISSION, *supra* note 131, at 98-100 (addressing the scope of compensation programs and suggesting that court review be precluded initially, that dollar ceilings be set on awards, and that these features be reexamined after several years of experience).

158. Leslie A. Rubin, *Confronting a New Obstacle to Reproductive Choice: Encouraging the Development of RU-486 Through Reform of Products Liability Law*, 18 N.Y.U. REV. L. & SOC CHANGE 131, 157 (1990-91).

suggests that women's full participation in clinical research will not occur without an explicitly inclusive policy. Women denied access to participation in clinical trials need a mechanism to challenge their exclusion. Participation in clinical research is usually limited to a small number of people; any single protocol will accommodate only a set number of subjects. Thus, it is not feasible to honor every woman's demand to enter the particular protocol she desires. A claim of access to research is therefore actually a claim to counter automatic exclusion or, in other words, the vindication of a right to apply to and be considered as a potential subject for a protocol without being discriminated against on the basis of sex or pregnancy alone.

Aside from the Thirteenth Amendment, the United States Constitution does not protect against acts by private parties.[159] State action is required before an individual can claim protection of the Fourteenth Amendment.[160] Of course, actions taken by government must meet constitutional standards, so a constitutional claim against government agencies such as NIH or the FDA is sustainable. But to sue an institution other than NIH or the FDA, it is necessary to determine whether actions of the institution may be considered actions of the state.

Situations in which the actions of private parties have been found to constitute state action involve a narrow, yet unclear set of circumstances. Factors that appear most persuasive to the Supreme Court include the extent of state protection of a monopoly,[161] the strength of the government's duty to provide the service or other commodity in question,[162] the exercise of a state's coercive power or provision of significant overt or covert encouragement,[163] and possibly the direct involvement with a particular project or service such that the government provides more than mere rubber stamp approval of a private act.[164]

Public funding alone does not transform private activity into state action.[165] For example, in *Rendell-Baker v. Kohn*,[166] the actions of a private institution which received ninety percent of its funding from government

159. LAURENCE H. TRIBE, CONSTITUTIONAL CHOICES 246 (1985).

160. Rendell-Baker v. Kohn, 457 U.S. 830, 837 (1982).

161. Jackson v. Metropolitan Edison Co., 419 U.S. 345 (1974); *see also* LAURENCE H. TRIBE, AMERICAN CONSTITUTIONAL LAW, (2d ed. 1988) 1755-56, 1717 [hereinafter TRIBE, AMERICAN CONSTITUTIONAL LAW].

162. West v. Atkins, 487 U.S. 42, 56 (1988); Rendell-Baker v. Kohn, 457 U.S. 830, 842 (1982).

163. Blum v. Yaretsky, 457 U.S. 991, 1004 (1982).

164. *Jackson*, 419 U.S. at 356-57.

165. Rendell-Baker v. Kohn, 457 U.S. 830, 840 (1982) (analogizing school's receipt of public funds to private corporation's contracts to perform services for the government); San Francisco Arts and Athl. Inc. v. U.S. Olympic Comm., 483 U.S. 522, 542 (1987) (United States Olympic Committee not a federal government actor even though the federal government granted it a corporate charter and even though Congress intended to help it obtain funds). *But cf.* West v. Atkins, 487 U.S. 42 (1988) (acts of physicians under contract with government to provide medical care to prison inmates are state acts).

166. 457 U.S. 830 (1982).

sources were not considered state action. Thus, NIH funding of a research institution will not in itself be a sufficient basis on which to rest a constitutional challenge based on the Fourteenth Amendment.[167]

Similarly, a government contract alone is not sufficient to create state action.[168] However, the Supreme Court did find state action in *West v. Atkins*,[169] which involved a physician under contract to provide medical care to state prison inmates. The Court held that the physician acted under color of state law when fulfilling the terms of the contract. Although medical research might be analogized to a government contract due to the extensive research which historically has been and continues to be performed by the NIH itself, *Atkins* is distinguishable because courts recognize a strong government obligation to provide medical care to prisoners. Thus, funding and government contracting are not likely to be useful vehicles for imputing state action in medical research.

Alternatively, extensive NIH and FDA agency regulation, including mandated, internal monitoring by institutional review boards, may amount to government action.[170] In *Seidenberg v. McSorleys Old Ale House, Inc.*,[171] a state license to operate a bar represented sufficient involvement to make some of the licensee's acts those of the state for Fourteenth Amendment purposes. *Seidenberg*, however, has not generally been followed. While no case has explicitly overruled *Seidenberg*, subsequent cases suggest that a court is most likely to find state action where the regulatory scheme is so pervasive as to create a monopoly.[172]

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167. For example, in Stanturf v. Sipes, 224 F. Supp. 883 (W.D. Mo. 1963), private hospitals were held not to be bound by the Fourteenth Amendment even if they accepted federal or state funds.

168. *Rendell-Baker*, 457 U.S. at 451.

169. 487 U.S. 42 (1988).

170. NIH and FDA regulations require selection of subjects to be equitable. 45 C.F.R. § 46.111(a)(3); 21 C.F.R. § 56.111(a)(3). These regulations notwithstanding, an institution will *not* be able to claim that the granting of the funds by DHHS or licensing by the FDA in itself is evidence that selection of subjects was equitable and that the institution is thus immune from discrimination claims. *See* Cypress v. Newport News General and Nonsectarian Hosp. Ass'n., 375 F.2d 648 (4th Cir. 1967) (Department of Health, Education and Welfare certificate of compliance with Title VI, the Public Accommodations Act, which was part of the requirements of eligibility for federal assistance, held not to preclude suit for racial discrimination in violation of Title VI).

171. 308 F. Supp. 1253 (S.D.N.Y. 1969). *But cf. Rendell-Baker*, 457 U.S. at 841 (extensive state regulation of private schools in general did not mean that personnel decisions, in which regulators showed little interest, were transformed into state action); Blum v. Yaretsky, 457 U.S. 991, 1007 (1982) (state regulation of private business, even if extensive and detailed, not sufficient to create state action).

172. TRIBE, AMERICAN CONSTITUTIONAL LAW, *supra* note 161 at 1561, 1717. Indeed, *Seidenberg* itself implies this possibility:

> "While considerable question exists as to whether defendant's activities herein may properly be deemed governmental in nature, when a significantly restricted and regulated license is granted by the State to exercise a privilege of serving the public where that privilege would be impermissible without such license, there may well exist sufficient State involvement to make the acts of the licensee those of the State itself."

In *Jackson v. Metropolitan Edison Co.*,[173] the Supreme Court found that a private electric company certified by a public utilities commission and extensively regulated by the state was not acting on the state's behalf. The Court conceded, however, that "it may well be that acts of a heavily regulated utility with at least something of activities subject to a governmentally-protected monopoly will more readily be found to be state acts."[174] Medical research falls within this category of extensive government regulation. The government's bar on commercial distribution of drugs absent compliance with FDA regulations creates a monopoly.

In addition, as Laurence Tribe points out, state action should be found when access to a desired or essential commodity is controlled by the government:

> [W]hen government creates a situation of scarcity, whether by conferring territorial monopoly power or by issuing a limited number of licenses and forbidding performance of a designated service without a license, the very decision to permit the monopolist or the licensee to deny service at his discretion—a decision unmistakably the government's—is arguably unconstitutional insofar as it causes injury that would not have occurred in the absence of government's restriction of the market, and that would be forbidden to government as a matter of explicit choice.[175]

This argument is persuasive in the context of medical research. Good health is a highly desired commodity. The government, through active participation by NIH and the FDA's stringent control of the pharmaceutical marketplace, exercises a sufficient degree of control over people's participation in medical research to transform private action into state action.

1. Claims Based on a Substantive Due Process Right to Privacy

Once a woman seeking to participate in medical research shows state action, she may bring a constitutional claim invoking a substantive due process right to privacy. The Supreme Court has long recognized privacy as a fundamental right.[176] Substantive due process jurisprudence dictates that governmental infringement upon a fundamental right is constitutional only when

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173. 419 U.S. 345 (1974).

174. *Id.* at 351.

175. TRIBE, AMERICAN CONSTITUTIONAL LAW, *supra* note 158, at 1717.

176. The right to privacy has been found to emanate from various constitutional provisions, beginning with Meyer v. Nebraska, 262 U.S. 390, 399 (1923) (which stated that Fourteenth Amendment liberties include the right to privacy); Griswold v. Connecticut, 381 U.S 479, 484-86 (1965) (which found a privacy right for marital relations in penumbras emanating from specific guarantees in the Bill of Rights; Goldberg, J., concurring, found such a right in the Ninth Amendment); Eisenstadt v. Baird, 405 U.S. 438, 453 (1972) (which extended the *Griswold* privacy right to all individuals regardless of marital status); and culminating in Roe v Wade, 410 U.S. 113, 153 (1973) (which held that regardless of where the right to privacy is based, it includes the absolute right to terminate a first-trimester pregnancy).

necessary to further a compelling state interest.[177] Thus, the most effective constitutional claim would establish a woman's right to participate in medical research as founded in the fundamental right to privacy.

While courts have recognized that those in state custody have a basic right to medical treatment,[178] they acknowledge no such right to treatment for voluntary patients.[179] However, the right to make decisions regarding one's medical treatment is recognized. In *Cruzan v. Director, Missouri Dept. of Health*,[180] the Supreme Court recognized a competent individual's right to refuse medical treatment based in the doctrine of informed consent[181] or in Fourteenth Amendment liberty interests.[182] *Cruzan* involved a young woman in a persistent vegetative state. Her family claimed she would have chosen to terminate artificial feeding and hydration. Although the Court refused to invalidate Missouri's procedures for allowing surrogate decisionmaking, it "assume[d] that the United States Constitution would grant a competent person a constitutionally protected right to refuse lifesaving hydration and nutrition."[183]

Other courts have recognized a privacy right encompassing the right to accept or reject medical treatment. In *Andrews v. Ballard*,[184] the court invalidated a Texas law that prohibited those who were not licensed physicians from practicing acupuncture.[185] In *Andrews*, the safety and effectiveness of acupuncture were not demonstrated, just as the safety and effectiveness of experimental medical treatments cannot be demonstrated. The state sought to regulate the practice of acupuncture because of its unknown potential for causing harm.[186] Under a strict scrutiny analysis, the statute was invalidated as unnecessary to the state's interest in health of patients. The court pointed out that "health is a uniquely personal possession. The decision of how to treat that possession is of a no less personal nature."[187] Because the patient is the person who must live with the choice, she ought to be the person who makes the decision.[188] The *Andrews* court emphasized that the importance of

177. *Roe*, 410 U.S. at 155 (1972).

178. Youngberg v. Romeo, 457 U.S. 307 (1982).

179. Goodman v. Parwatikar, 431 F. Supp. 1250, 1254 (E.D. Mo. 1977), *vacated on other grounds*, 570 F.2d 801 (8th Cir. 1978). Nor does the Supreme Court recognize a substantive right to a basic state of welfare. Rather, it has held that once government chooses to provide welfare benefits, it must do so without discriminating and with procedural due process. *See* U.S. Dep't of Ag. v. Moreno, 413 U.S. 528 (1973) (food stamps); Goldberg v. Kelly, 397 U.S. 254 (1970); Dandridge v. Williams, 397 U.S. 471 (1970) (Aid for Families With Dependent Children).

180. 110 S. Ct. 2841 (1990).

181. *Id.* at 2847.

182. *Id.* at 2851, n. 7.

183. *Id.* at 2852.

184. 498 F. Supp. 1038, 1045 (S.D. Tex. 1980). *But cf.* Cruzan v. Director, Missouri Dep't of Health, 110 S. Ct. at 2841, 2852 (finding liberty interest rather than right to privacy).

185. *Andrews*, 498 F. Supp. at 1053.

186. *Id.*

187. *Id.* at 1047.

188. *Id.* Future children may in some cases have to live with consequences of this deci-

decisions affecting one's health cannot be overstated.[189] The right to be considered for access to research is properly understood as a decision affecting health. It should therefore be protected on privacy grounds.

The court in *New York State Ophthalmological Society v. Bowen*[190] did not find a privacy right to make every medical choice, but indicated that there was a fundamental right to protect one's health. The case involved a class action by ophthalmologists and their patients who, on privacy and autonomy grounds, challenged regulations prohibiting Medicare billing for the services of an assistant surgeon unless approved by an insurance carrier or designated state peer review organization.[191] In rejecting this challenge, the court stated that "not every decision relating to body or bodily integrity is sufficiently intimate and personal to merit enhanced protection."[192] The court pointed to compulsory vaccination as an example of an intrusion not recognized by the Supreme Court to involve a fundamental interest.[193] Despite its adverse ruling, the court recognized a right to self-determination, stating that a privacy claim could be maintained when medical necessity was demonstrated and no equally effective therapy was available.[194] The *New York State Ophthalmological Society* test would likely support a right to inclusion in medical research that directly benefitted a subject's health, but not to research that indirectly benefitted a subject.

The *New York State Ophthalmological Society* court was concerned about a broad right that would apply to choices of personal taste or convenience, because it believed there was no manageable way to define its limits.[195] Yet such choices are too important to leave unprotected; they may be necessary to maintaining physical health, mental health, and personal well-being. Medical decisionmaking often incorporates issues such as convenience and personal lifestyle in determining what treatment will be most successful for a particular patient. Such protection should extend to decisions to participate in medical research providing indirect, as well as direct, benefits to subjects.

The *Andrews* rationale protects a broader spectrum of personal choices than does *New York State Ophthalmological Society*. Based on the principles of *Roe v. Wade* and other reproductive rights cases, *Andrews* protects any medical decision involving oneself or one's family which profoundly affects one's life or development as an autonomous being.[196] Both direct and indirect benefits are valid factors to be considered by a woman contemplating risks that could profoundly affect her family, her life, and possibly personal devel-

sion. Nonetheless, of those who will live with the decision, the woman is the only person who has decisionmaking capacity.

189. *Id.* at 1045.
190. 854 F.2d 1379 (D.C. Cir. 1988).
191. *Id.* at 1381-82.
192. *Id.* at 1391.
193. *Id.*
194. *Id.*
195. *Id.* at 1389.
196. Andrews v. Ballard, 498 F. Supp. 1038, 1046 (S.D. Tex. 1980).

opment. Reproductive issues, including pregnancy, can be similarly analyzed. Although the *New York State Ophthalmological Society* court declined to apply the reproductive rights cases to the facts of that case, the court indicated that if presented with different facts, it might follow the lead of *Andrews* and focus heightened scrutiny on interference with a choice exercised as a means of reproductive self-determination.[197]

The health-related choices of a pregnant woman which may affect the fetus she carries in her womb constitute precisely such means of reproductive self-determination. It may be argued that reproductive self-determination includes only the decision whether or not to abort. However, the ability to make decisions about all issues that affect reproduction, particularly when they affect one's body and will determine the course of one's life, is necessarily an issue of self-determination. These decisions are thus protected.[198] It follows that exclusion of women from research on the basis of possible future pregnancy is even less defensible than exclusion on the basis of actual pregnancy. Exclusion forecloses women from making certain reproductive decisions before any risk to an arguable state interest arises.

The state may infringe on constitutional rights in limited circumstances. Interest in a woman's health and welfare fits well within the state's police power. A drug's dangerousness or ineffectiveness, where proven, may be relevant to the weight of the state's interests.[199] But because a woman's privacy interest is fundamental, the state must have a compelling interest to justify abridgement of that woman's right. An interest compelling enough to exclude nonpregnant women from research would be found if a drug were proven to cause, or perhaps shown highly likely to cause, serious harm to women specifically due to their sex. The state cannot exclude women who are not pregnant from research protocols on the basis of an asserted interest in a possible future fetus, because such exclusion is neither compelling nor drawn sufficiently narrowly to serve such interests. Both the fetus and the risks are merely hypothetical, and such hypotheticals are not a legitimate ground for exclusion.

Roe v. Wade held that the state may assert a compelling interest in fetal life after viability, defined as the period following the second trimester.[200] *Webster v. Reproductive Health Services*[201] upheld a state statute that required doctors to perform pre-abortion viability tests on fetuses as early as twenty weeks into pregnancy. The Court, holding that the statute merely created a rebuttable presumption of viability at twenty weeks, avoided officially overruling the *Roe* trimester framework,[202] but nonetheless criticized it.[203] Narrowly

197. *New York State Ophthalmological Society* 854 F.2d at 1389.

198. No one may be forbidden to reproduce, despite the chance of having imperfect children. Skinner v. Oklahoma, 316 U.S. 535 (1942) (holding that prisoners could not be sterilized on the basis of possibly hereditary criminal characteristics).

199. *Andrews*, 498 F. Supp. at 1053.

200. Roe v. Wade, 410 U.S. 113, 163 (1972).

201. 492 U.S. 490 (1989).

202. *Id.* at 515-16.

interpreted, *Roe* and *Webster* hold only that in the case of abortion, where death of the fetus is certain, the state may assert a compelling interest in the life of the fetus after viability, and it may assume viability when there is actually only a possibility of viability.

For a number of reasons, it seems unwise to formulate a standard for determining when a state's interest in preventing risks to fetal health arises based on the trimester framework of *Roe*, or even on a less definite concept of viability. First, *Roe*'s framework may be rejected by the Supreme Court in the near future.[204] Second, with scientific advances bringing the point of viability closer and closer to conception, the recognition of a pregnant woman's right of access to research protocols only until a fetus becomes viable may eventually encompass such a short span of time as to become nonexistent. Third, clinical research is simply not analogous to abortion. Research generally involves a small or nonexistent risk of death to the fetus. Fourth, the abortion cases do not delineate a state's interest in having a fetus born in perfect health, but rather the much more basic interest in having the fetus born alive. Medical research presents more complex issues, not addressed by the stark assertion of an interest in preventing abortion.

It takes more than an interest in a fetus that may or may not be harmed to outweigh a woman's interests. Clearly, a state has no compelling interest if there are few or no indications of risk to a fetus. A state may have more valid arguments where the risk to a fetus is likely and severe. Yet any asserted interest in a fetus must be extreme to outweigh a woman's interest in her autonomy, her health, and overarching benefits to society provided by the research. Indirect benefits, often ignored, are nevertheless essential, since research aids other pregnant women and fetuses by increasing knowledge and thereby improving physicians' ability to minimize the risks others will endure in the future.

For a woman who has chosen to bring her pregnancy to term, the choice to expose the fetus to risks means that her involvement in medical research has personal significance sufficient to outweigh those risks. While there may come a point where the risks to a fetus are so great, and the benefits to a woman or to society so low, that it would be morally abhorrent for pregnant women to enroll in a particular research protocol, it is impossible to determine where this point is. The significance of research to any individual woman may stem from her own physical need, from her acute awareness of a social crisis

203. Dicta from the majority opinion indicates a desire to extend the period of time when the state's interests are compelling: "We do not see why the State's interest in protecting human life should come into existence only at the point of viability, and that there should therefore be a rigid line allowing State regulation after viability but prohibiting it before. . . ." *Id.* at 436.

204. *See* City of Akron v. Akron Center for Reproductive Health, Inc., 462 U.S. 416, 458 (O'Connor, J., dissenting) ("[t]he *Roe* framework . . . is clearly on a collision course with itself."). This framework may be overturned entirely as the U.S. Supreme Court considers Planned Parenthood v. Casey, 947 F.2d 682 (3d Cir. 1991) *cert. granted in part*, 112 S. Ct. 931 (1992) (limiting abortion rights by requiring 24-hour waiting period, consent of one parent for minors, consent of husband for married women).

justifying the research, or from her personal attachment to third parties who might benefit from the research. The state cannot balance all of these factors accurately, and thus the locus of decisionmaking should remain with the woman. The state's only duty is to demand that researchers minimize subjects' risks to the extent possible.

2. *Claims Based On Equal Protection: Juggling* Geduldig *and Title VII*

a. Geduldig v. Aiello: *Are Pregnancy Classifications Sex-Based?*

Another approach for remedying the exclusion of women from medical research is through equal protection challenges. Under the strict scrutiny standard, an equal protection claim involving a fundamental right will succeed unless the court finds that the challenged practice is necessary to further a compelling governmental interest, and employs narrowly tailored means to do so.[205] It is possible, however, that courts may not agree that the fundamental right to privacy should extend to women seeking access to medical research because this doctrine has fallen out of favor with the current Supreme Court.[206]

If courts fails to recognize a fundamental right to privacy in the context of experimental protocols, we must rely on the less stringent analysis courts use in gender discrimination cases: intermediate scrutiny.[207] Sex-based classifications will be upheld only if they exist to further an important state objective and employ means that are substantially related to the expressed objective.[208] Unfortunately, in medical research, where lay people may be inclined to defer to assumptions by medical professionals that biological differences are significant, sex-based exclusions might survive intermediate scrutiny because they would be assumed to meet the substantial relation test. Moreover, a classification that does not explicitly discriminate on the basis of sex will be subjected to the even less rigorous scrutiny of a rational basis test, which requires only that the governmental action be rationally related to the classification in question.[209]

Given the Supreme Court's decision in *Geduldig v. Aiello*,[210] courts are likely to exclude pregnancy discrimination from the definition of sex discrimination, and therefore use the rational basis test to analyze research protocols barring only pregnant women. *Geduldig* concerned a challenge by four women to a state disability insurance program that exempted from coverage any work loss resulting from pregnancy. The Court held that classifications con-

205. *Skinner*, 316 U.S. at 541.

206. For example, the Court has refused to extend the privacy doctrine to include protection for private acts of homosexual sodomy. Bowers v. Hardwick, 478 U.S. 186, 195-96 (1986).

207. Craig v. Boren, 429 U.S. 190 (1976).

208. *Id.* at 197.

209. *See* Personnel Administration of Massachusetts v. Feeney, 442 U.S. 256 (1979) (recognizing covert sex discrimination, but subjecting statutes not based on sex to low-level scrutiny to determine whether the impact could be explained on neutral grounds).

210. 417 U.S. 484 (1974).

cerning pregnancy were not necessarily sex-based and so were not presumed to be invidiously discriminatory.[211] It stated that discrimination based on pregnancy was legitimate and not to be equated with sex-based discrimination.

b. The Title VII Solution

Geduldig is no longer applied in employment situations, since the Pregnancy Discrimination Act of 1978[212] (PDA) explicitly bars employment discrimination on the basis of pregnancy. However, the PDA, as a legislative action, does not remove the spectre of the Court's constitutional holding in *Geduldig* being applied in other contexts. Therefore, unless *Geduldig* is overturned, pregnancy is presumptively a legitimate classification in areas other than employment.[213]

The PDA extended Title VII's ban on sex discrimination in employment to include classifications based on "pregnancy, childbirth or related medical conditions."[214] In so doing, the PDA effectively heightened scrutiny of pregnancy classifications in the employment context. Title VII now mandates that employment discrimination based on pregnancy be treated as sex-based discrimination.[215] Most pregnancy discrimination cases following enactment of the PDA have been litigated under that act, because the majority of such claims were employment-related, and, given the holding in *Geduldig*, the PDA was a stronger tool than the Constitution.[216]

From the first case litigated under the PDA, *Newport News Shipbuilding and Dry Dock Company v. EEOC*,[217] to the recently decided *Johnson Controls*, the Supreme Court has followed Congress' statutory directions to consider all employment-related pregnancy discrimination presumptively invalid. *Johnson Controls* directly addressed the issue of danger to the fetus, and, via the PDA, left the locus of decisionmaking with the woman.[218] The women who brought the case were not pregnant, but the decision implies that pregnant women could be similarly protected. Although the case was litigated under Title VII as amended by the PDA, and the opinion in *Johnson Controls* was explicitly limited to that statute,[219] the problems posed parallel those in research. In

211. *Id.* at 497 n.20 and accompanying text.

212. 42 U.S.C. § 2000e(k) (1988).

213. *See* Sylvia Law, *Rethinking Sex and the Constitution*, 132 U. PA. L. REV. 955, 984 nn.110-12 (1984). Professor Law suggests that enactment of the Pregnancy Discrimination Act constitutes a congressional rejection of the Court's reasoning *Geduldig*. She indicates that the successful implementation of the Pregnancy Discrimination Act and the general acceptance of the policies which propel it make *Geduldig* ripe for challenge.

214. 42 U.S.C. § 2000e(k) (1988).

215. *Id.*

216. Wendy Williams, *Equality's Riddle: Pregnancy and the Equal Treatment/Special Treatment Debate*, 13 N.Y.U. REV. L. & SOC. CHANGE 325, 374-75 (1984-85).

217. 462 U.S. 669 (1983).

218. Int'l Union, UAW v. Johnson Controls, Inc., 115 S. Ct. 1196 (1991) (prohibiting employers from barring fertile women from work requiring hazardous exposure to lead, which could potentially a woman's fetus or future child).

219. *Id.* at 1204.

both situations, someone other than the woman claims that pregnancy and protection of the potential fetus are valid justifications for the exclusion of women in general. Both situations revolve around a presumed conflict between a woman and her fetus. And both situations involve a failure to treat men and women similarly.[220]

Feminists have debated the best approach for dealing with pregnancy as a classification. Professor Wendy Williams would attribute the success of Title VII to its equal treatment approach, treating all people identically and pregnancy as simply a condition similar to other "disabilities." Williams suggests that pregnancy ought to be seen as irrelevant so long as it does not interfere with job performance.[221] Thus, Williams chooses an androgynous prototype rather than requiring that women accommodate to a male standard.[222]

Professor Sylvia Law, on the other hand, recognizes that while Title VII may have been successful, "equality doctrine that denies the reality of biological difference in relation to reproduction reflects an idea about personhood that is inconsistent with people's actual experience of themselves and the world."[223] Pregnancy is sui generis; there are no similarly situated classes of men, and trying to convince the public that there are would be futile.[224] Professor Law thus proposes an alternative equality doctrine that closely parallels the logic of substantive due process claims for reproductive autonomy.[225] Her proposed approach requires that distinctions based upon reproductive characteristics be examined to determine whether they have a significant impact on the perpetuation of either women's oppression or culturally imposed sex-role constraints on freedom. If they have such an impact, they must be justified as the best means of serving a compelling state purpose.[226] The test focuses on the impact rather than the purpose of the statute, because decisions based on biological distinctions that appear to be valid grounds for restrictive legislation may actually be self-fulfilling prophesies—socially constructed assumptions that have little analytical value and merely promote women's oppression.[227]

Perhaps society is not ready to recognize these socially constructed assumptions. If it is not, Law's solution may recreate the problem. It is unrealistic to concede potential the relevance of biological distinctions and then require a court nonetheless to recognize that, by failing to determine the actual

220. The Court's action in *Johnson Controls* demonstrates strong support for Title VII and the PDA; presumably, a court disinclined to apply constitutional protection to certain aspects of reproductive freedom would look favorably upon legislation in this area. Thus, in the following section of this Note, we propose a statute addressing sex- and pregnancy-based discrimination in research.

221. Williams, *supra* note 215, at 357.

222. *Id.* at 367.

223. Law, *supra* note 212, at 955.

224. *Id.* at 1008.

225. *Id.* at 1011. Professor Law also suggests that cases which might have been brought as equal protection cases seem to be decided on the substantive due process rationale of a right to privacy when decided in favor of the woman. *Id.* at 981-82.

226. *Id.* at 1008.

227. *Id.*

relevance of those distinctions, it is perpetuating oppression or culturally imposed sex roles. Law cites a long history of the use of biology as the central justification for subjugation of women and of protection as the core mechanism of such subjugation.[228] That history is not behind us. Tracing the same pattern, the medical establishment actually serves its own interests in the guise of protecting women, and hearkens back a century to the practices of the legal establishment in *Bradwell v. Illinois*.[229] When *Bradwell* was decided, married women were incapable of entering binding contracts. An "unmarried woman's destiny" was to marry, and thus the court upheld a state's decision to prohibit women from becoming attorneys.[230] The Court explained that "[t]he natural and proper timidity and delicacy which belongs to the female sex . . . unfits it for many . . . occupations."[231]

Bradwell is now recognized as an outrageously outdated attempt to keep women out of a profession, regardless of their true abilities and needs. However, the societal belief that it is rational and beneficial to prevent women from accessing medical research remains firmly entrenched. The medical establishment seeks to justify excluding women from research as protection, when in reality it is a form of oppression. The practice assumes dangers to women, and, ironically, has led to marketing medical products of doubtful safety for women and for pregnant women in particular. It has left seriously ill women with no ability to obtain experimental treatment that may be their only chance for survival, while men have such an ability. The illogic of such exclusion, and its harmful results, belie the rationale that it is for women's own benefit, and reinforce the conclusion that it is thinly disguised oppression.

Health is vital to any person's participation in society. The exclusion of women from research protocols poses serious health risks to both the women excluded, and women who would benefit from the information provided by the research. If the true harm is recognized—although, as we have noted, widespread stereotypes often block that recognition—biological distinctions based on sex or pregnancy fail Professor Law's test of constitutionality. Use of biological distinctions to preclude women's participation in medically beneficial research often oppresses women individually. Therefore, exclusion of women from protocols is invalid if the state's interest can be furthered in another manner. The best means of serving a state's interest in protecting women is to include them in experimental protocols and to minimize risks in other ways, as already required in regulations of the DHHS and FDA.[232]

The more difficult question of research posing only indirect benefits to a pregnant woman and a high likelihood of harm to a fetus should also be con-

228. *Id.* at 957.
229. 83 U.S. 130 (1873).
230. *Id.* at 141.
231. *Id.*
232. 45 C.F.R. § 46.111(a) (1991); 21 C.F.R. § 56.111(a)(1) (1991); *see also* R. LEVINE, *supra* note 2, at 61 (most important component of risk minimization is exhaustive disclosure of risks to potential subjects).

sidered in light of the historic legal constructs that have oppressed women. Limits on a woman's control of her own reproductive capacity are classic oppressive constructs.[233] Exclusion of women from indirectly beneficial research harms and oppresses women as a class. It denies all women the benefits of such research. It perpetuates the culturally imposed stereotype, becoming more prevalent in these days of "crack babies," that pregnant women will act selfishly and impulsively and will fail to heed the best interests of their fetuses. Furthermore, exclusion fuels the misconception that women are not capable of granting carefully considered and binding informed consent. It presumes a basic female irrationality in order to justify denying women control over their own lives. Such exclusion is oppressive and therefore should be considered presumptively invalid.

C. Addressing Deficiencies of Constitutional Claims Through a New Legislative Approach

Constitutionally based challenges to discrimination are currently suffering from diminishing support in the Supreme Court and many lower federal courts. But Title VII, the Pregnancy Discrimination Act, and *Johnson Controls* illustrate the potential success of an explicitly inclusive antidiscrimination legislative scheme. Legislation also can avoid the problem of finding state action in private or partially private acts.[234] We therefore propose the following legislation:

The Fair Access to Medical Research Act

In light of the evidence presented to this legislature that exclusion of women, including pregnant women and women of childbearing potential, from research protocols has historically been oppressive and harmful to women individually, women as a group, and society as a whole, the following legislation is enacted:

Section I. Definitions:

A. The term "researcher" means a person or institution engaged in clinical research or drug studies involving more than ten human subjects per protocol.

B. The terms "human subject" and "person" refer to a human

233. Law, *supra* note 214, at 958.

234. Congress has authority to adopt this statute and regulate medical research under several possible theories. The least controversial of these is Article 1, Section 8, of the United States Constitution — the Commerce Clause — which clearly extends to even private conduct. The effects of medical research on the distribution of drugs and the use of new medical therapies throughout the states should be sufficient interstate commerce for purposes of the Commerce Clause. In addition, the authority for our proposed statute could be derived from Section 5 of the Fourteenth Amendment, authorizing Congress to enforce the Amendment. Section 5 arguably covers private conduct. *See* TRIBE, AMERICAN CONSTITUTIONAL LAW, *supra* note 161 at 352. A third theory might be to support the legislation as an enforcement of the privileges and immunities of national citizenship.

being having been born, and shall not be construed to include either a nonviable or viable fetus.

Section II. Unlawful selection of subjects:

A. It shall be an unlawful research practice for a researcher

1. to fail to include or refuse to include any person in, or to discharge any person from a research protocol or otherwise to discriminate against any person in considering admission of that person to a research protocol solely because of that person's sex, pregnancy or childbearing potential; or

2. to deprive a person of the opportunity to compete for admission to a protocol with a limited number of subjects or to otherwise adversely affect that person's opportunity to participate on the basis of sex, pregnancy or childbearing potential;

B. Unless,

1. the condition, drug or technology involved in the protocol affects only members of the sex to be included in the study or affects that sex overwhelmingly, or

2. the indications of risk of serious harm to which a subject will be exposed during the course of the protocol are enhanced particularly for that subject because of sex, pregnancy or childbearing potential.

C. Only physical harm to a human subject and not harm to an existing or potential fetus shall be a valid reason for exclusion.

Section III. Informed Consent:

A. Where there is or may be risk of harm to an existing or potential fetus, the human subject, male or female, shall be fully informed of such risk in a language and form understandable to the subject and then given the opportunity to consent.

B. Where risk may be minimized or eliminated through use of birth control, abortion or other methods, such information shall be communicated to the subject, male or female.

C. The individual human subject shall have full, unimpeded power to consent to participation in such research. Informed consent shall be binding in the absence of fraud, misrepresentation of risks, coercion, negligence or other wrongdoing on the part of the researcher or institution.

Section IV. Birth Control and Unexpected Pregnancy:

A. The researcher may require that nonpregnant subjects of reproductive capacity utilize birth control where there is a scientifically indicated causal risk of failing to develop a healthy fetus if

conception occurs during the study. Such requirements shall apply to both sexes where the risk is posed by conception by either sex.

B. Where subjects become pregnant during the course of research, regardless of any birth control requirements, they shall not be discharged from the study, nor shall they be required to terminate the fetus as a condition of remaining in the study.

C. Where such subjects choose to withdraw from the study, such primary care as was provided throughout the study shall be continued.

D. For pregnant subjects to continue participating in a study, they must give additional informed consent specific to the risk(s) incurred by virtue of the condition of pregnancy.

Section V. Child Care:

Research funding shall include provisions for child care and other reasonable accommodations to enable both sexes to participate, regardless of child care responsibilities, whenever a protocol demands that a subject be available for more than four hours at a time or more than three days consecutively. This provision shall not be construed to prohibit additional child care or other accommodations.

Section VI. Conflicting DHHS or FDA Regulations:

This legislation shall override any DHHS or FDA regulations regarding protection of fetuses and pregnant women where conflicting. Existing protections for human subjects from risk under the DHHS or FDA regulations shall remain in effect.

Section VII. Remedies:

Violation of this statute shall create a cause of action for compensatory and/or punitive damages.

F. Commentary on the Proposed Legislation

The equal treatment approach espoused by Professor Williams is appropriate in the employment context, where pregnancy by and large is accepted as having no effect on ability to perform most work. But there are more obstacles to acceptance of equal treatment in the medical context. Common experience contradicts the proposition that the medical condition of pregnancy resembles any other medical condition, disability, or illness.[235] Pregnancy simply is not an illness. It has unique effects on one's body that may appear relevant to a researcher "borrowing" that body to perform her work. Pregnancy may be treated as a disability or illness in the employment context because its relevance pertains to the amount of time a woman will be unable tc perform or be present at work. An employer generally need not be concerned

235. Law, *supra* note 214, at 955.

with the inner functioning of an employee's body, whereas the researcher by definition must. In our proposed statute, we consider pregnancy the defining characteristic of a protected group separate from women generally, rather than taking the approach of the PDA that discrimination because of sex includes discrimination because of pregnancy. The proposed statute is designed to take discretion out of the hands of researchers by creating a presumption that neither sex nor pregnancy is a valid basis for categorical exclusion from research.

The statute is further designed to deal with one of the primary characteristics of pregnancy — the existence of a fetus — by explicitly placing the interest in the health of a fetus in the pregnant woman's control rather than the researcher's control. One technique a researcher uses to minimize risk is full disclosure to the woman. The statute thus expresses a political recognition that, in light of the harm historically arising from third-party control of women's reproductive autonomy, such autonomy should be returned to women.

In excluding fetuses from the definitions of "human subject" and "person," the statute recognizes that even research aimed at a fetus has the woman as its subject. The only risk that may be a legitimate basis for exclusion from an approved experimental protocol is the risk it presents to a woman or man. Only risks to the subject, not risks to the fetus, may be weighed by an IRB to be so great as to prohibit the experiment entirely.

The harm described in Sections II(A.)-II(B.) must be the same sort of extremely unreasonable harm that would justify depriving a subject of choice under current DHHS and FDA regulations. This legislation does not change the risk-benefit analysis described in the regulations, except with regard to fetuses and pregnant women. It does not give a researcher more discretion to decide for an adult subject what level of risk is acceptable. Absolute institutional prohibitions against research on pregnant women and fetuses shall be considered an effort to avoid the statute, and thus violative of the statute.

We anticipate that IRBs will be responsible to their respective institutions for determining whether exclusion in any particular protocol falls under one of the narrow exceptions listed in section II(B) of the proposed legislation. If not, the IRB could counsel the institution to include women or reject the research. The proposed legislation creates no cause of action against the IRB or its members.

Risk to a fetus is minimized through the informed consent provision, which requires that researchers provide full information on all such risks. Given such information, a woman is presumed to act in the best interests of herself and her fetus. While we recognize that there may be an occasional tragic circumstance in which a woman makes a poor choice, the harm is greater, is more certain to occur, and will affect more people, if she is denied any power to choose.

Risk may also be minimized through birth control, if required nondiscriminatorily, and so long as discharge from the study does not occur if preg

nancy occurs. The birth control provisions may seem toothless to researchers who will not be allowed to discharge subjects for failure to comply. But compliance may be difficult to determine, and punitive use of the power to discharge subjects leads to coercion. If a subject becomes pregnant, the best course is for the researcher to explain to her any risks and any changes in the benefit of the research to the subject, and then to allow her to remain or to leave the study. To reduce factors that might coerce a pregnant woman into remaining in a trial when she would otherwise choose to leave, any primary care provided in conjunction with the study shall continue.

The statute only addresses studies with more than ten subjects, because this type of regulation would impose an unfair burden upon small studies. Because small studies are not cost efficient, it is unlikely that they will be used to avoid the mandates of this legislation. However, the legislation does apply to private research. Large-scale private research poses the same problems as does large-scale publicly funded research. In addition, there seems to be a great likelihood that, were private research left unregulated, researchers might resort to private funding alternatives in order to evade this legislation.

Researchers are not prohibited from using subjects of only one sex for a protocol studying diseases or conditions that affect that particular sex overwhelmingly or exclusively. NIH should, however, have broad oversight power to ensure that women's health issues are not neglected entirely. NIH funding should be distributed to research on diseases or conditions that affect women and men, according to the severity and frequency of occurrence in each respective population.

Our statute combats the practical problems that have historically constrained women from participation in many areas of life, including research. Because women are usually the primary caretakers of children, the statute mandates child care be provided to subjects of either sex when the research requires that they spend substantial time away from their families.

Enforcement impetus for the statute shall come primarily from aggrieved individuals or classes of individuals seeking damages. We have proposed monetary relief because it is unlikely that entrance to the particular experimental protocol from which a person has been excluded will remain available until the conclusion of litigation. The threat of such action should be sufficient to promote voluntary compliance. Traditionally, researchers have been apprehensive about unfounded liability for research subjects and their fetuses injured during the course of a medical experiment. This legislation should be enacted in combination with the compensation plan proposed earlier, providing fixed compensation for non-negligently injured research subjects. With both pieces of legislation in place, the researcher will weigh the chances of liability for exclusion against a lower threshold of liability for non-negligent injury to research subjects. This balancing, we hope, will give inclusive policies more weight than ever before.

CONCLUSION

In a culture where sexism is often ill-understood, research protocols that profess to protect vulnerable subjects or purport legitimate exclusion of certain groups should trigger careful examination. False protection in the guise of modern chivalry actually increases the dangers to those it supposedly serves. Current research parameters too often protect women right out of opportunities to develop the drugs and technologies they need. Women's exclusion from research results in fewer therapies for women and widespread use of treatments with unknown risks and efficacy. Ultimately, illnesses and deaths result where women could have been helped, if only they had been given the opportunity and respect necessary to enable them to make their own decisions.

Solutions must be powerful and specific, not optional. While recognizing that the most effective approach to the problem is an integrated one, we have proposed reforms and challenges that could work independently if necessary, moving step by step to achieve fair chances of inclusion as well as protection for women. The protections we desire are based on rights located in the United States Constitution. Unfortunately, the Supreme Court has historically shied away from absolute positions in the area of women's rights, deferring instead to legislative initiatives. The current Supreme Court may be even more reticent to define broad rights for women. Given the precarious position of a variety of women's rights in the courts, we believe a clear legislative solution is the best guarantor of these rights.

Absent some catalyst to spur inclusion, the problem will continue. Legitimate, instinctual concern for the welfare of human subjects, prompted by a series of outrageous abuses in research protocols, has too often been warped to the detriment of women. We have a choice. We may experiment inclusively, in a controlled, productive manner, or we may continue a regime of exclusionary research, with uncontrolled, post-marketing experimentation on masses of nonconsenting people. The latter scheme may yield widespread, tragic consequences and prevent real progress. There can be no such thing as life without risk, but risk can be minimized. Choosing to experiment on a representative few confronts fear, minimizes risk, and maximizes progress. That choice should unite those currently wielding the power with those subject to its whim.