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Medical Gender Bias and Managed Care

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I. INTRODUCTION

Medical gender bias permeates every aspect of the practice of medicine. Gender bias begins with medical education and taints research, diagnosis and treatment decisions, and the administration and effectiveness of pharmaceuticals. Obviously, the medical impact of gender bias primarily affects women, but there is also some indication that gender bias may negatively impact the health of men as well.
Medical science evolved from studying the male of the human species, resulting in a gender bias toward the treatment and study of men. Therefore, the problem of gender bias has persisted since the beginning of the practice of medicine.

Medical scholars believed that the problem of gender bias could be eroded through enlightening physicians, the inclusion of women in medical research studies, and the entry of more women into the practice of medicine. However, this hope was predicated before the managed care revolution. Time could perhaps have alleviated the problems created by gender bias under the traditional fee-for-service approach to the practice of medicine. However, managed care may hinder the


4. "Science has a long history of viewing men as the standard by which all things are measured. `Like the pronoun `he,' it was taken for granted that the white male subject stood for all of us.'" Karen H. Rothenberg, Gender Matters: Implications for Clinical Research and Women's Health Care, 32 HOUS. L. REV. 1201, 1206 (1996) [hereinafter Gender Matters] (quoting Rebecca Dresser, Wanted: Single, White Male for Medical Research, 22 HASTINGS CENTER REP. 24, 27 (1992)).


6. Fee-for-service health care was the norm for this country prior to managed care. As such, most of the scientific proof of gender bias arose during the era when fee-for-service plans predominated. For example, hysterectomy was at one time the most frequently performed surgery nationwide. Approximately nine out of ten were elective; few, in comparison, were to remove malignancies. More than half of American women were without their uterus by age sixty-five. Arguably many of the hysterectomies had little value to women. SUE FISHER, IN THE PATIENT’S BEST INTEREST: WOMEN AND THE POLITICS OF MEDICAL DECISIONS 33 (1990) [hereinafter IN THE PATIENT’S BEST INTEREST]. Part of the answer to the question why so many were performed is because the predominate medical system was fee-for-service. Hysterectomies generated over one billion dollars annually in medical fees under the fee-for-service approach. Id. at 39-40. In prepaid health plans, hysterectomies are performed four times less often than in fee-for-service plans. Id. at 40. There are at least two other reasons why hysterectomies were performed at such a high rate. First, obstetrics/gynecology is a surgical specialty. There are twice as many surgeons in the United States compared to England and Wales, which has led to twice the amount of surgeries and twice as many hysterectomies by comparison. Id. at 39. Second, physicians are trained to believe that “once reproduction is over the uterus is not only a useless organ, but a potentially disease-producing one.” Id. at 3.

Some sources contend that 90% of all hysterectomies are not necessary. STANLEY WEST, THE HYSTERECTOMY HOAX 1 (1994) [hereinafter THE HYSTERECTOMY HOAX] (Unnecessary is defined as conditions that are not life threatening. “Most of the ‘female problems’ that lead to hysterectomy are medically trivial. They can be
elimination of gender bias, and instead may actually affirmatively aid in its perpetuation.

The revolution toward managed care sprang from the desire to curb the skyrocketing cost of medicine. Managed care was designed to reduce medical costs while at the same time providing quality health care benefits. Managed care organizations use various cost-containment techniques including the use of primary health care providers (gatekeepers), prospective utilization review, capitated payments, and referral or shared-risk pools. All cost-containment techniques are designed with one goal in mind: reducing the cost of the delivery of health care to the consumer. Thus, any prejudices built into the practice of medicine are less likely to be eradicated and more likely to be uncomfortable. Untreated, some can make your life miserable. But they will not kill you.” Many laywomen might not agree that a hysterectomy is unnecessary if it cures a condition making life miserable.) Proponents of managed care would also point out that “[g]ender-specific preventive services—breast examinations, Pap smears and mammograms—are more likely to be provided to women enrolled in managed care plans.” Ridgely Benjamin, Women Enrolled in Managed Care Receive More Gender-Specific Preventive Services, Jacobs Institute of Women’s Health (June 25, 2001) at http://www.jiwh.org.

7. Randolph E. Sarnacki, Comment, Contractual Theories of Recovery in the HMO Provider-Subscriber Relationship: Prospective Litigation for Breach of Contract, 36 BUFF. L. REV. 119, 120 n.3 (1987). The other motivation for the creation of HMOs was to provide health care coverage to a broader segment of the population. Rand E. Rosenblatt, Equality, Entitlement, and National Health Care Reform: The Challenge of Managed Competition and Managed Care, 60 BROOK. L. REV. 105 (1994); Louis G. Trubek, Making Managed Competition a Social Arena: Strategies for Action, 60 BROOK. L. REV. 275 (1994).


11. In 1977, the executive vice president of the American Medical Association stated that a hysterectomy was “beneficial to women with excessive anxiety.” In the same year, the treating physician for Vice President Hubert Humphrey declared that “women were not fit to be president because of ‘raging hormonal imbalances’ that rendered them unfit
institutionalized in systems of health care delivery where there is an increased pressure to save money. Therefore, medical gender bias could become more entrenched given the prevalence of managed care.

This article will discuss the origins of medical gender bias and the areas of the practice of medicine and research where gender bias has been most apparent. Next, the impact of managed care on all consumers will be examined. Finally, this article will explore some areas where there is evidence that managed care has a tendency to negatively impact the health of women as compared to men. While there is no empirical data that currently supports the proposition that managed care hurts women more than men, the main goal of this article is to raise the haunting question whether managed care has the built-in propensity to perpetuate—if not sanction and encourage—medical gender bias to the detriment of the health of women enrolled in managed care plans.

II. A WRONG WITHOUT A REMEDY

We live in a litigious society. An initial reaction, upon hearing of the differences between the way men and women are treated by the medical profession, might be to jump on the litigation bandwagon and assume that litigation can cure any discrepancies. Certainly, the pharmaceutical and research industries face exposure to civil liability. Liability could be predicated on the company’s failure to include women in clinical trials. The exclusion of women might result in a drug being manufactured that has toxic effects on women, effects that could have been discovered had women initially been included in the research and development of the drug. Conversely, there could also be liability against a pharmaceutical company for inclusion of a woman in clinical trials if the woman is or becomes pregnant and the drug has teratogenic effects on the unborn child. However, causes of action against medical practitioners would

for decision-making,” THE HYSTERECTOMY HOAX, supra note 6, at 19.

12. However, women are the largest consumers of health care in this country. Terri D. Keville, The Invisible Woman: Gender Bias in Medical Research, 15 WOMEN’S RTS. L. REP. 127 (1994) [hereinafter Invisible Woman]. If women use health care more, it stands to reason that a system to cut cost will impact more women than men. Furthermore, women currently spend sixty-eight percent more in out-of-pocket expenses for healthcare than men. Lisa A. Hayden, Gender Discrimination Within the Reproductive Health Care System: Viagra v. Birth Control, 13 J. L. & HEALTH 171, 173 (1998).

13. For liability concerns for inclusion or exclusion of women in research studies, see INSTITUTE OF MEDICINE, 1 WOMEN AND HEALTH RESEARCH: ETHICAL AND LEGAL ISSUES OF INCLUDING WOMEN IN CLINICAL STUDIES 150-167 (Anna C. Mastroianni, et al, ed.
probably not be fruitful. Before undertaking a detailed examination of
gender bias, it is important to understand the very real limitations of the
judicial and legislative system in attacking this problem, as it exists in
the day-to-day practice of medicine. Arguably, gender discrepancies in
medical practices are more of a societal concern when the safety net of
the judicial system is lacking. There is no quick fix for this problem.
One cannot undo years of medical learning and instantaneously gain
enough scientific knowledge to close the gender gap immediately.
Certainly, society would not want to throw away years of medical
advances because gender bias taints some areas of medical practices.
It
would appear from an outsider’s viewpoint that the medical profession is
just beginning to understand the depth of gender discrepancies in
treatment. Arguably, remedying gender bias will be achieved more
slowly due to the lack of available legal alternatives to assist in the
solution.

A. Constitutional Attacks

Medical gender bias is an elusive concept\textsuperscript{14} and is generally not the
result of a conscious decision to discriminate against women.
Oftentimes, gender bias results in women being inappropriately treated
by the physician’s decisions to treat them the same as a man.\textsuperscript{15} Other
times, women are treated improperly by the medical profession by

\textsuperscript{14} A “bias” is defined as “fostering prejudice.” “Prejudice” means a “partiality or
presumption grounded upon feeling, fancy, or associations.” \textit{WEBSTER’S DICTIONARY}
(1984). Medical gender bias consists of allowing gender to consciously or unconsciously
influence behavior or decisions in treatment or diagnosis based on feelings regarding men
or women. Obviously, gender may be a very appropriate consideration when treating
some human conditions, such as pregnancy, menopause, or impotency. In other areas of
medicine, such as treatment of cardiovascular problems, gender considerations may lead
to inappropriate treatment.

\textsuperscript{15} The standard medical treatment for coronary disease developed for men may not
be the appropriate treatment for women. \textit{LAURENCE AND WEINHOUSE, supra} note 1, at ch. 4.
treatment them different from men due to their sex. It is important to keep in mind, however, that there are usually established medical rationales for this behavior. It is not "insidious discrimination" in violation of constitutional rights for the physician to treat the female patient in accordance with generally accepted medical practices. Thus, it is unlikely that discrimination based upon prevailing medical thought would be considered unlawful. Along with other potential litigation-blocking problems to be discussed later, the facts of each case will contribute to the ineffectiveness of any proffered litigation solution to medical gender bias's complex manifestations.

1. Section 1985

Section 1985(3) of Title 42 of the United States Code allows a right to recover damages for any conspiracy founded on a discriminatory purpose based on a person's membership in any class which deprives the person of equal protection or any rights or immunities under the law. In 1971, the Supreme Court held that for there to be a cognizable Section 1985 claim, "there must be some racial, or perhaps otherwise class-based, invidiously discriminatory animus behind the conspirators' action." A decade later the Court in Carpenters v. Scott, while reiterating its earlier hint that Section 1985 might extend beyond its (presumable) original focus on race, held that the "racial or perhaps otherwise...animus" language did not extend to economic or anti-union animus. A decade after Carpenter, the Court in Bray v. Alexandria Women's Health Clinic, was presented with the question whether Section 1985 applied to animus against women, but ducked the issue by holding that persons obstructing abortion clinics did not necessarily harbor animus against women, as such. Although Bray did not explicitly hold that gender is a cognizable class under Section 1985(3), "language from the opinion at least hints that it does." Furthermore, the

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16. Treatment of women different than men leading to injurious results is perhaps most apparent in the mental health field. Id. at ch. 11, entitled "Women's Mental Health: A Cruel Double Standard.
21. Id. at 268-74.
22. Lyes v. City of Riviera Beach, Fla., 166 F.3d 1332, 1339 (11th Cir. 1999). Furthermore, in Bray, three justices, Justices O'Connor, Souter, and Stevens, all stated
prevailing modern view among the circuits is that women can be a class for purposes of Section 1985 actions. Any conclusion that women are not a protected class under § 1985(3) would run into a solid wall of contrary precedent. However, there must still be a conspiracy or discriminatory intent to bring a Section 1985(3) action.

There is no conspiracy among the medical profession to discriminate against women. The fact that gender bias influences medical research, education, practices, diagnoses, and treatment is not a conspiracy to discriminate. Yet, gender bias might well influence the development of standard medical practice and the individual treatment of women. However, it still represents standard medical thought regarding a particular disease or condition. The motive or intent is still to properly treat the medical symptoms of women even if the standard practices have been influenced by gender bias. Furthermore, most medical decisions are based on the decisions of one person—the individual treating physician. It would be difficult to establish a conspiracy even if the treating physician’s recommendations regarding care of the female patient were influenced by preconceived notions or feelings regarding women by others within the medical community. Therefore, recovery unequivocally that women are a protected class and would outlaw conspiracies based on sex-based animus against women. Bray, 506 U.S. at 295-96; Lyes, 166 F.3d at 1339.

23. The circuits that have actually decided the issue have all unanimously held that conspiracies founded on a sex-based animus against women are actionable under 42 U.S.C. § 1985(3). Libertad v. Welch, 53 F.3d 428, 448-49 (1st Cir. 1995); Stathos v. Bowden, 728 F.2d 15, 20 (1st Cir. 1984); New York State Nat’l Org. for Women v. Terry, 886 F.2d 1339, 1359 (2d Cir. 1989); Novotny v. Great Am. Fed. Sav. & Loan Ass’n, 584 F.2d 1275, 1243 (3d Cir. 1978), vacated on other grounds, 442 U.S. 366 (1979); Nat’l Org. For Women v. Operation Rescue, 914 F.2d 582, 585 (4th Cir. 1990); Volunteer Med. Clinic, Inc. v. Operation Rescue, 948 F.2d 218 (6th Cir. 1991); Volk v. Coler, 845 F.2d 1422, 1494 (7th Cir. 1988); Conroy v. Conroy, 575 F.2d 175, 177 (8th Cir. 1978); Life Ins. Co. of N. Am. v. Reischardt, 591 F.2d 499, 505 (9th Cir. 1979); Lyes v. City of Riviera Beach, Fla., 166 F.3d 1332, 1339-40 (11th Cir. 1999); Lucero v. Operation Rescue of Birmingham, 954 F.2d 624 (11th Cir. 1992), reh’g denied, 951 F.2d 224 (11th Cir. 1992). Further, the Sixth Circuit stated in dicta that women would be included as a cognizable class under § 1985. Haverystick Enter., Inc. v. Fin. Fed. Credit, Inc., 32 F.3d 989, 994 (6th Cir. 1994). Two circuits in dicta have indicated that they would not include women as a protected class for § 1983 purposes. Deubert v. Gulf Fed. Sav. Bank, 820 F.2d 754, 757 (5th Cir. 1987); Wilhelm v. Continental Title Co., 720 F.2d 1173, 1176 (10th Cir. 1983).

24. Lyes, 166 F.3d at 1338.
under Section 1985(3) would likely be an impossible way to attack gender bias in the practice of medicine.27

2. The Equal Protection Clause

The Equal Protection Clause prohibits the government from treating similarly situated persons differently.28 Gender occupies an intermediate status for equal protection analysis. The "semi-suspect" status of gender-based classifications triggers the so-called "intermediate" standard of review, pursuant to which such classifications, where facial,29 may be sustained only where they "serve important governmental objectives and [are] substantially related to the achievement of those objectives."30 Beyond the problem of satisfying the apposite standard of review, a threshold problem with sustaining any equal-protection-based challenge arises from the fact that there is usually no state action involved in the practice of medicine.31


28. U.S. CONST. AMEND. XIX.

29. See, e.g., Pers. Adm’r. v. Feeney, 442 U.S. 256, 272-73 (1979). Where only a disparate impact on members of one gender or the other results from the application of a statute, non-heightened rational-basis scrutiny applies, absent a demonstrable intent to discriminate. Id at 273-74.


31. There must be state action involved in order to violate the equal protection clause. Shelley v. Kramer, 334 U.S. 1, 13 (1948); Life Ins. Co. of N. Am. v. Reichhardt, 591 F.2d 499 (9th Cir. 1979).
It would be difficult to argue that the provision of medical treatment is not a legitimate governmental interest. The fact that the provision of medical treatment, considered by the medical profession as an appropriate choice for a particular disease or condition, also incorporates gender bias would still serve "an important governmental objective and be substantially related to the achievements of those objectives." In many areas of practice there are no treatment alternatives except those tainted with sex bias.

Furthermore, it is hard to describe medical practices as discriminatory when in many areas gender bias reflects itself with women being treated exactly the same as men. Equal protection would unlikely strike down established medical practices without proven alternatives. But once again, the reason there are no alternatives is due to the pervasive impact of gender bias in the medical profession. Nevertheless, any equal protection analysis would likely fail. In summary, absent either any applicable constitutional or Title VII claim based upon discrimination in employment, causes of action for

33. In Geduldig v. Aiello, 417 U.S. 484 (1974), the California disability system was attacked because it did not include coverage for disability resulting from a normal pregnancy. The Court held, "We cannot agree that the exclusion of this disability from coverage amounts to invidious discrimination under the Equal Protection Clause. California does not discriminate with respect to the persons or groups which are eligible for disability insurance protection under the program." Id. at 494.

The State has a legitimate interest in maintaining the self-supporting nature of its insurance program. These policies provide an objective and wholly noninvidious basis for the State's decision not to create a more comprehensive insurance program than it has. There is no evidence in the record that the selection of the risks insured by the program worked to discriminate against any definable group or class in terms of the aggregate risk protection derived by that group or class from the program. There is no risk from which men are protected and women are not. Likewise, there is no risk from which women are protected and men are not.

Id. at 496-97. Rather, "[t]he program divides potential recipients into two groups—pregnant women and nonpregnant persons. While the first group is exclusively female, the second includes members of both sexes. The fiscal and actuarial benefits of the program thus accrue to members of both sexes." Id. at 496, n.20. Geduldig was overruled by the Pregnancy Discrimination Act, 42 U.S.C. § 2000e(k)(1988).

violation of constitutional or civil rights are not a promising approach for the elimination of medical practices inappropriately influenced by gender considerations.35

B. Personal Injury Actions

1. Medical Negligence Actions

Gender bias is ingrained in the medical profession and so it is likely reflected in the customary practice of physicians. Medical negligence actions would likely be an impossible way to attack the problem because the standard of liability is based on a violation of the standard of care of the customary practice of other physicians in the same area of medicine.36 Doctors influenced by gender bias are simply likely to comply with the standard of care required because they are following customary practice; other physicians are engaging in the same behavior. For example, one common diagnostic test for coronary disease is the


35. For a constitutional analysis of the problem of exclusion of women from medical research, see WOMEN AND HEALTH RESEARCH, supra note 14, at 149-50; Carol Jonann Bess, Gender Bias in Health Care: A Life or Death Issue for Women with Coronary Heart Disease, 6 HASTINGS WOMEN’S L.J. 41 (1995) [hereinafter Life or Death Issue]; Gender Matters, supra note 4, at 1245-55.

treadmill stress test. However, this test has limited accuracy for women since “less than half of women have accurate treadmills (versus 70% of men).”37 It could hardly be called negligence to prescribe a customary diagnostic test despite the low accuracy rate for women because it is the test doctors resort to in the diagnosis of heart disease.

Another example can be seen in the field of mental health. The Diagnostic and Statistical Manual DSM-IV38 is the bible of modern psychiatry.39 The standard practice of all psychiatrists and psychologists is to follow the DSM-IV guidelines to diagnose mental illness and personality disorders. However, many of the DSM-IV guidelines have been challenged as containing built-in sex biases, which more likely could result in women being diagnosed with a mental illness than men.40 “[I]f a woman conforms to the female role, she runs the risk of being labeled under one of the categories of ‘dependent personality disorder,’ ‘histrionic personality disorder,’ or ‘borderline personality disorder.’”41 Histrionic personality disorder consists of being “more excitable in minor crises,” “more emotional, less objective,” “more conceited about their appearance,” and “more submissive, less independent, less adventurous, more easily influenced.”42 The reader will certainly appreciate the similarity between the diagnostic criteria and the stereotype of the personality of a woman.43 “[V]ia assumptions about

37. LAURENCE & WEINHOUSE, supra note 1, at 100.
38. AMERICAN PSYCHIATRIC ASSOCIATION, DIAGNOSTIC AND STATISTICAL MANUAL OF MENTAL DISORDERS (1994) [hereinafter DSM-IV].
39. LAURENCE & WEINHOUSE, supra note 1, at 265.
40. Id. at 266-68.
41. DENISE RUSSELL, WOMEN, MADNESS & MEDICINE 37 (1995) [hereinafter WOMEN, MADNESS, & MEDICINE]; see DSM-IV, supra note 38, at §§ 301.83 (borderline personality disorder), 301.81 (histrionic personality disorder), 301.6 (dependant personality disorder).
42. WOMEN, MADNESS & MEDICINE, supra note 41, at 33.
43. Attribution of personality characteristics based upon gender probably dates back to the beginning of language. Aristotle once described the differences between men and women of all animals as follows:

In all genera in which the distinction of male and female is found, Nature makes a similar differentiation in the mental characteristics of the two sexes.

...[T]he female is softer in character, is the sooner tamed, admits more readily of caressing, is more apt in the way of learning. . . .

In all cases, excepting those of the bear and leopard, the female is less spirited than the male. . . . With all other animals the female is softer in disposition than the male, is more mischievous, less simple, more impulsive, and more
sex roles made by clinicians, a healthy woman automatically earns the
diagnosis of histrionic personality disorder.” Thus, malpractice would
be next to impossible to prove in this situation if the mental health
professional made the misdiagnosis based on the DSM-IV guidelines,
because those guidelines would similarly be followed by other
psychiatrists or psychologists in the field.

In other areas of practice, doctors are more likely to commit
malpractice against women due to the gender gap. The physician is more
likely in some medical specialties to negligently treat a woman compared
to a man by failure to comply with the standard of care required by
customary practice. There exists major disparities between men and
women in providing diagnostic and therapeutic interventions for kidney
dialysis and transplantation, diagnosis and treatment of lung cancer, and
catheterization for coronary bypass surgery. However, biological
differences cannot explain the disparity in treatment.45

Data that suggest[s] that a patient’s gender plays an
inappropriate role in medical decision making raise[s] the
question of possible gender bias in clinical decision making.
Gender bias may not necessarily manifest itself as overt

attentive to the nurture of the young; the male, on the other hand, is more
spirited than the female, more savage, more simple and less cunning. The
traces of these differentiated characteristics are more or less visible
everywhere, but they are especially visible where character is the more
developed, and most of all in man.

Hence woman is more compassionate than man, more easily moved to tears, at
the same time is more jealous, more querulous, more apt to scold and to strike.
She is, furthermore, more prone to despondency and less hopeful than the man,
more void of shame or self-respect, more false of speech, more deceptive, and
of more retentive memory. She is also more wakeful, more shrinking, more
difficult to rouse to action, and requires a smaller quantity of nutriment.

ARISTOTLE, HISTORY OF ANIMALS 608a20-30, 608b1-10 (Richard McKeon ed. & trans.
1941). For an interesting view of Aristotle, see Andrew C. Spiropoulos, Aristotle and the

44. WOMEN, MADNESS, & MEDICINE, supra note 41, at 33.

45. Council Report, Council on Ethical and Judicial Affairs, American Medical
Association, Gender Disparities in Clinical Decision Making, 266 No. 4 JAMA 559
(1991) [hereinafter Gender Disparities in Clinical Decisions]. In 1996, Suzanne Haynes,
Ph.D., assistant director for science at the U.S. Public Health Service’s Office on
Women’s Health, stated, “We’ve come almost nowhere in developing diagnostic criteria
for women” suffering from heart disease. There is still no answer to the question “why
women die more frequently than men within the first month after a heart attack.”
LAURENCE & WEINHOUSE, supra note 1, at ix.
discrimination based on sex. Rather, social attitudes, including stereotypes, prejudices, and other evaluations based on gender roles may play themselves out in a variety of subtle ways. 46

Medical malpractice would be an appropriate avenue for relief assuming a woman is injured due to delayed treatment influenced by subconscious gender bias.

Illustrative of this point is the diagnosis of lung cancer. Women have a greater risk of developing and dying from lung cancer. 47 “However, men [are] twice as likely to have cytologic studies of sputum ordered as women.” 48 Cytologic studies of sputum are cell studies of saliva. 49 Basically, the patient spits in a cup and the cells are examined for abnormality. Assuming a woman who smokes presents a doctor with the symptom of chronic cough, the customary practice of physicians acting under the same or similar circumstances should be to have her spit in a cup. If the doctor failed to do so, for whatever reason, and the failure to order the test resulted in the failure to diagnose lung cancer causing damage to the woman, a cause of action for medical malpractice would be available for failure to order the customary test. 50 However, this is more appropriately considered straight medical negligence, perhaps caused by bias in diagnostic approaches influenced by inappropriate considerations of gender. The law does not recognize the tort of gender bias. Ordinary negligence actions might provide individual relief under the unique facts of individual cases, but negligence actions will not cure the underlying problem. Medical negligence actions might provide compensation in a few cases where it can be shown by a preponderance of the evidence that the doctor deviated from established protocols causing harm to a female patient.

46. Gender Disparities in Clinical Decisions, supra note 45, at 561.
47. Catherine Guthrie, Kick Butts Now!, WebMD, at http://aolsvc.health.webmd.aol.com/content/article/1689.50430 (last visited Sept. 24, 2002). The genetic marker for lung cancer is on the X chromosome so women have two copies of the gene that could be activated compared to a man’s one. Candace Hoffmann, Genetics: One More Reason for Women to Quit Smoking: Marker May Put Female Smokers at Greater Risk of Lung Cancer, WebMD at http://aolsvc.health.webmd.aol.com/content/article/1728.53935 (last visited Sept. 24, 2002).
50. Liability could even be predicated under the reasonable prudence test of Helling v. Carey, 519 P.2d 981 (Wash. 1974). Reasonable prudence would dictate the giving of a harmless, unintrusive, inexpensive, diagnostic test even if medical custom did not dictate the test.
2. The Doctrine of Informed Consent

Another possible avenue of litigation would be the violation of a doctor’s duty of disclosure under the doctrine of informed consent. Under informed consent, physicians have a duty to disclose any material risks of treatment and alternatives, including the alternative to have no treatment at all.51 An informed consent cause of action requires the following proof: (1) the material risks that could be caused by the treatment, including any risks of non-treatment, and the failure to disclose those risks; (2) the material risk occurred causing damage to the plaintiff; and (3) the patient or reasonable person would have opted for a different type of treatment and avoided the risk of harm if proper disclosure had been made.52

Curbing sex bias by pursuing an informed consent cause of action will be explored through questioning the disclosure obligation of physicians prescribing an aspirin a day to keep heart attacks away. The standard medical preventative treatment for heart disease is an aspirin a day.53 This treatment is used for both men and women despite the fact that the research study that concluded an aspirin a day helps prevent coronary problems was performed exclusively on men. Due to the all-male control group of research participants, science does not yet know if aspirin has the same effect on women as it does on men. It may or may not; science does not know without conducting the same tests on women.54 As a preventative measure, and in accordance with standard medical practices, a physician might prescribe an aspirin a day for a woman who presents a family history of heart problems. Typically, however, doctors do not give any disclosure when they prescribe aspirin as a preventative measure for heart disease. Arguably, the physician’s disclosure obligation would be to disclose all material risks of treatment, including the risk of no treatment at all. Thus, the informed consent obligation might include advising the female patient that the medical profession has no definitive studies on women and aspirin; the scientific

52. Scott, 606 P.2d at 559.
54. Id.
data supporting its use arose from research studies conducted only on male participants. This does not mean that aspirin will not prevent heart attacks in women, they might. However, in order for there to be a material risk, there must be a potential harm caused by the prescribed dose of an aspirin a day. There may exist a greater risk in women than in men of a hemorrhagic stroke from the ingestion of fifteen or more aspirins a week. Ingestion of an aspirin a day might avoid a likely risk of such harm as a heart attack, but at the same time it might also expose the female patient to a risk of harm that is much less likely to occur, namely, a stroke. Doctors prescribe aspirin because it probably will do more good than harm in women.

In informed consent cases, the jury would decide whether the very slight risk of stroke from the aspirin was a material risk or a remote risk that did not need to be disclosed. The decision would be based on whether this information would be significant to a reasonable person in deciding whether to accept or forego treatment. Since reasonable minds could differ as to whether this presents a material risk, for the sake of discussion, it will be assumed to be a material risk.

If the female patient consumed an aspirin per day, there was no disclosure of the risk, she suffered a stroke, and evidentiary proof established that the stroke was caused by the aspirin (this alone could be an insurmountable obstacle), then there would still need to be proof of

55. Id. The Nurses' Health Study was conducted on women but it was not considered definitive because the observational study was based on self-reporting by the participants. "Aspirin now joins estrogen replacement therapy as a promising, but incompletely evaluated, primary prevention therapy in women. To clarify their roles in the prevention of coronary heart disease, additional research, specifically clinical trials, are urgently needed." Id. On the Nurses' Health Study, see Susan E. HANKINSON, ET AL., HEALTHY WOMEN, HEALTHY LIVES: A GUIDE TO PREVENTING DISEASE FROM THE LANDMARK NURSES' HEALTH STUDY (Harvard Medical School Book 2001).


57. Doctors perform a balancing test to decide whether to prescribe medication; they prescribe the medication because they have decided that the potential good from the medicine outweighs the potential harm. Discussing the underlying facts, both pro and con, that contribute to the balancing test would probably be an insurmountable barrier and no court requires full disclosure of all risks. Canterbury v. Spence, 464 F.2d 772, 786 (D.C. Cir. 1972). Arguably, a physician's failure to disclose is partially based on the idea that he or she knows what is best because they have performed the balancing test considering the benefits and risks involved. However, this paternalistic notion, "I know what is best for the patient so I will decide what is best," was at the heart of the informed consent doctrine. Id at 789. Self-autonomy protects the right of the patient to conduct the balancing test for himself or herself.

causation to prevail; that is, the patient would have opted for different treatment such as not taking the aspirin to avoid the stroke. Statistically, there is a greater chance of women having a heart attack than a stroke.59 Furthermore, there is no equivalent preventative for women. Thus, most women would still have opted to take an aspirin a day if they had a history of heart disease even with this disclosure of information. If a doctor fails to make this disclosure, a cause of action for violation of the duty of disclosure would likely not succeed for failure to establish causation. Informed consent cases require proof that the patient would decline treatment if proper disclosure had been made.60 Most patients would take the aspirin, therefore, it would be difficult to establish damages as a result of not disclosing this information.

In those jurisdictions that gauge the informational obligations of physicians by customary practice, that is what other doctor’s disclose,61 informed consent would be a very unusable cause of action because the customary practice of other doctors is likely not to disclose this information as well. It is hard to conceive that the standard adopted by the medical profession would be to inform patients of the lack of inclusion of women in research studies. Thus, failure to obtain informed consent would be a difficult and probably ineffectual cause of action to help eradicate gender bias, especially when medical custom sets the threshold for the informational obligation. Eradicating gender bias from external sources outside the medical profession, particularly through litigation,62 is virtually impossible.

59. Coronary disease is the number one killer of women, with 500,000 deaths a year caused by this illness. Debra R. Judelson, Cardiovascular Disease in Women, 49 JAMWA 180 (1994); Richard M. Steingart, et al., Sex Differences in the Management of Coronary Artery Disease, 325 No. 4 NEW ENG. J. MED. 226 (1991).

60. Canterbury, 464 F.2d at 790-91 (applying objective test: what the reasonable patient would decide); Scott v. Bradford, 606 P.2d at 558-59 (applying subjective standard: what the individual patient would decide).


62. The modern judicial system also shows evidence of gender bias in the area of health law. In cases where a court had to decide whether to discontinue life sustaining treatment when the patient was without a written directive, there is evidence in the reported cases that gender might be an important factor in the resolution of the case by the judge. Steven H. Miles & Allison August, Courts, Gender and “The Right to Die,” 18 LAW MED. & HEALTH CARE 85 (1990). “[C]ourts’ view that a man’s opinions are
Litigation may provide compensation in select cases for women who fall victim to gender bias. Indirectly, litigation may influence modification of behavior because doctors would become more careful, for example, in ordering the sputum test, if doctors were sued more often for failure to do so. Litigation could help remedy damage created by gender bias in certain areas of practice; however, litigation would be unlikely to remedy the true underlying problem, which is the subtle ways gender plays into diagnostic decision-making.

C. Legislation

Legislation has been enacted that lends support to the presence of gender bias in managed care. However, the legislation is only aimed at known problems where gender bias has resulted in extreme abuses. The cartoon depicting the initials “HMO” as standing for “Hurry Mom Out” rational and a woman’s remarks are unreflective, emotional, or immature.” *Id.* at 87. Even the legal system may take the expressed wishes of men more seriously than those of a woman. A pregnant woman, who refuses a cesarean section against the advice of her physician, stands the risk of a court-ordered procedure. *Outrageous Practices*, *supra* note 2, at 318-22.

In 1987 the *New England Journal of Medicine* reported on a review of cases where physicians went to court in order to force pregnant women to undergo cesarean sections, hospitalization, and intrauterine transfusions against their will. The study found that 86 percent of physicians’ requests were granted by the courts. In most of these cases the patients were poor, black, Asian, or Hispanic. The disenfranchisement factor is disturbing, but the legal principles used to defend the court decisions could be used against any woman, no matter what her race or socioeconomic status. *Id.* at 318.

illustrates one area of extreme abuse and legislative reaction. Solution by legislation is unlikely to reach all avenues of existing gender bias. Rather, legislation is more likely to address extreme pockets of gender bias that exist within managed care plans. This article does not attempt to solve gender bias in the practice of medicine. Instead, it only raises the question whether the efforts by the medical profession to enlighten its members in an effort toward elimination of this bias will be undone by the managed care philosophy.

III. MEDICAL GENDER BIAS

The Women’s Health Movement began over thirty years ago. The reader might immediately question why it was necessary to have a women’s health movement; after all, there is no corresponding men’s health movement. The answer lies in history. The historical treatment of women by the medical profession is frightening by today’s standards and it reflected the general social, political, and religious attitudes toward women at that time. The historical taint, including the general social attitudes toward women, and scientific ignorance perpetuated the gender

63. Since 1995, twenty-nine states have enacted statutes requiring health care plans to cover “extended hospital stays for mothers following childbirth.” HMO Regulation on Agenda for 1997 Term in State, Federal Legislatures, 1 Mealey’s Ins. L. Weekly, March 6, 1997.

64. Legislation has included patient protection acts, “any willing provider” laws, prohibition against gag clauses, and laws that allow direct access to OB/GYNs or selection of an OB/GYN as the primary health care provider. “In 1996, 447 patient protection acts were introduced in 44 states” aimed predominately at managed care organizations. Id.


66. The National Institutes of Health contains an Office of Research on Women’s Health (ORWH), but no corresponding office on men’s health. A bill was introduced in 2001 to create a new office to study and promote men’s health. One response to the creation of an office on men’s health is that the “U.S. Health Department is already one giant office of men’s health.” Sean Martin, Why Guys Die Sooner, WebMD, at http://aolsvc.health.webmd.aol.com/content/article/1685.52232 (last visited Sept. 24, 2002). “There is no office for men’s health because for many, many years men were the ones being studied in clinical research, . . . And those findings were used to treat everybody.” Charles Downey, Does Men’s Health Get Enough Care?, WebMD, at http://aolsvc.health.webmdaol.com/content/article/1685.50052 (last visited Sept. 24, 2002).
discrepancies that still persist in the modern practice of medicine. It was not until the later part of the twentieth century that the medical profession began to recognize gender bias from within its own profession.\textsuperscript{67} Recognition of a problem is the first step toward modifications of behavior and paving the way toward a solution. The women’s health movement created public awareness and spurred the medical profession toward this introspection.

\textit{A. The Genesis of Gender Bias}

The roots of gender bias grow from the historical patriarchal power structure of western civilization. One key feature of a patriarchy is that societal attitudes are shaped by institutions of power including churches, governments, disciplines of endeavor, and businesses.\textsuperscript{68} "Patriarchy is

\textsuperscript{67} Dr. Stanley West wrote in 1994,

As far as medical sexism is concerned, there is finally some realistic hope for change. The long-overdue recognition of a ‘gender gap’ in both medical research and treatment is an optimistic development that should have major repercussions for the kind of health care women can expect in the future.\textit{The Hysterectomy Hoax, supra} note 6, at 177.

\textsuperscript{68} Marilyn French, \textit{Beyond Power: On Women, Men, and Morals} 356 (1985) [hereinafter \textit{Beyond Power}]. Certainly, no one can argue with the fact that religion and the Bible helped shape society’s attitude toward women as second-class citizens. Elizabeth Cady Stanton, \textit{The Original Feminist Attack on the Bible (The Woman’s Bible)} (1974). The Woman’s Bible was first published in 1895. On page seven of the original \textit{Introduction}, Elizabeth Cady Stanton wrote,

From the inauguration of the movement for woman’s emancipation the Bible has been used to hold her in the “divinely ordained sphere,” prescribed in the Old and New Testaments.

The canon and civil law; church and state; priests and legislators; all political parties and religious denominations have alike taught that woman was made after man, of man, and for man, an inferior being, subject to man. Creeds, codes, Scriptures and statutes, are all based on this idea. The fashions, forms, ceremonies and customs of society, church ordinances and discipline all grow out of this idea.

She continued on page 13,

In criticizing the Mosaic code we would not question the wisdom of the golden rule and the fifth Commandment. Again the church claims special consecration for its cathedrals and priesthood, parts of these aristocratic churches are too holy for women to enter, boys were early introduced into the choirs for this reason, woman singing in an obscure corner closely veiled. A few of the more democratic denominations accord women some privileges, but invidious
male-dominated in that positions of authority—political, economic, legal, religious, educational, military, and domestic—are generally reserved for men.”  

Thus, great power differences are created between men and women.  

Furthermore, society becomes “male identified,” what society perceives as “good, desirable, preferable, or normal are associated with how we think about men and masculinity.”  

Because men are in positions of power in a patriarchal society, the work that is valued most, “business, politics, war, athletics, law, and medicine,” springs from qualities associated with maleness.  

Qualities such as “control, strength, efficiency, competitiveness, toughness, coolness under pressure, logic, forcefulness, decisiveness, rationality, autonomy, self-sufficiency, and control over any emotion that interferes with other core values (such as invulnerability),” are perceived by society as positive because they help assure success in the work created in a male-dominated, male-identified society.  

The focus is primarily on men in a patriarchy; it is “male-centered.”  

Evidencing the “male-identified” and “male-centered” nature of society, the first anatomical descriptions of women’s genitalia were that the “womb and vagina were the penis and scrotum turned inside out.”  

Discriminations of sex are found in all religious organizations, and the most bitter outspoken enemies of woman are found among clergymen and bishops.  


70. Id. at 130.  

71. Id.  

72. Id.  

73. Id.  

74. Id. at 132.  

Perhaps one of the deepest reasons for denying the reality of women’s oppression is that we don’t want to admit that a real basis for conflict exists between men and women. We don’t want to admit it because, unlike other groups involved in social oppression, such as whites and blacks, females and males really need each other, if only as parents and children. This can make us reluctant to see how patriarchy puts us at odds regardless of what we want or how we feel about it. Who wants to consider the role of gender oppression in everyday married and family life? Who wants to know how dependent we are on patriarchy as a system, how deeply our thoughts, feelings, and behavior are embedded in it? Men resist seeing the oppression of their mothers, wives, sisters, and daughters because we’ve participated in it, benefited from it, and developed a vested interest in it.  

Id. at 136-37 (emphasis added).  

Medical Gender Bias and Managed Care

2002] Medicine, however, was not part of the patriarchal power structure until the eighteenth century. For the vast majority of the population prior to the eighteenth century, the caregivers were unpaid women in one’s own family. 76 The eighteenth century, with the evolution of the scientific method, saw the institutionalization of the practice of medicine. As such, medicine became part of the patriarchal power structure of the time. It also excluded women from medical study. 77 As a “male-centered,” “male-identified” society, it is not surprising that medicine in the early 1800s perceived the norm as the male body, and the woman’s body as “inherently pathological.” 78 Doctors during this time frame viewed any woman’s health issue around the uterus. “[T]he Almighty, in creating the female sex, had taken the uterus and built up a woman around it.” 79 Illustrating that all female functions were viewed as “inherently pathological,” 80 Victorian doctors believed:

Menstruation in all women is supposed to give rise to mental instability which may lead on to acute mania. Pregnancy gives rise to melancholia and sometimes-moral perversion, perhaps an uncontrollable craving for stimulants. Childbirth may cause mania or melancholia. The problem that arises with menopause is that ‘the age of pleasing is past, but not always the desire.’ Menopause may result, then, in insane jealousy and a propensity to stimulants. 81

of “male-centered” science comes from Freud.

The major difference between women and men lies in the construction of their genital and procreative systems; under patriarchy, the penis and penile forms have been exalted. Freud’s theory of penis envy makes the penis the most important object of all human experience, male and female. . . . [T]he penis is: and boys and girls and women shift to accommodate themselves to it as a symbol of power.

Beyond Power, supra note 68, at 373.


77. Beyond Power, supra note 68, at 357.

78. Id. at 358.

79. Id. (quoting a New Haven medical professor in 1870.)

80. Id.

81. Women, Madness & Medicine, supra note 41, at 20.
The normal biological functions of women were perceived as a disorder or a diseased condition.\(^{82}\)

Doctors also perceived that all illness in women sprang from their reproductive functions, "[d]iseases of the stomach, liver, kidneys, heart, and lungs were tied to the uterus."\(^{83}\) "The Uterus, it must be remembered, is the controlling organ in the female body, being the most excitable of all, and so intimately connected by the ramifications of its numerous nerves, with every other part."\(^{84}\) As late as 1897, the Journal of the American Medical Association reported that an "inflamed or conjusted [sic] uterus" could negatively affect the voice and advised

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82. BEYOND POWER, supra note 68, at 358. In an attempt to overcome the common societal attitude toward the "curse," Erica Jong authored the following poem:

Each month

the blood sheets down

like good red rain.

I am the gardener.

Nothing grows without me.


83. BEYOND POWER, supra note 68, at 358. "Some doctors really believed that est femineo generi pars una uterus omnium morborum, 'the womb is a part of every illness of the female sex.'" GERMAINE GREER, THE FEMALE EUNUCH 40 (1971).

Thus, women are treated for diseases of the stomach, liver, kidneys, heart, lungs, etc.; yet, in most instances, these diseases will be found on due investigation, to be, in reality, no diseases at all, but merely the sympathetic reactions or the symptoms of one disease, namely, a disease of the womb.

OUTRAGEOUS PRACTICES, supra note 2, at 14, (quoting M.E. DIRIX, WOMEN'S COMPLETE GUIDE TO HEALTH 23-24 (1869)). "[We must recognize] the gigantic power and influence of the ovaries over the whole animal economy of women—that they are the most powerful agents of all the commotions of her system; that on them rest her intellectual standing in society, her physical perfection." OUTRAGEOUS PRACTICES, supra note 2, at 14, (quoting W.W. BLISS, WOMAN AND HER THIRTY-YEARS' PILGRIMAGE 96 (1870)). And, the author's personal favorite, "She has a head almost too small for intellect but just big enough for love." OUTRAGEOUS PRACTICES, supra note 2, at 14 (quoting CHARLES MEIGS, FEMALES AND THEIR DISEASES (1848)). Meigs was a medical professor at D. Jefferson Medical College in Philadelphia treating diseases of women and children. OUTRAGEOUS PRACTICES, supra note 2, at 356.

84. Id. at 14 (quoting FREDERICK HOLICK, THE DISEASES OF WOMEN, THEIR CAUSE AND CURE FAMILIARLY EXPLAINED (1849)).
women it could be hazardous to sing while menstruating. Reading romantic novels allegedly caused a diseased uterus and higher education could cause that same organ to atrophy.

If women’s health was tied to her genitalia, it stands to reason that medical attempts to cure diseases would be aimed at those same organs. At least men received treatment aimed at the right part of the body for conditions such as “indigestion, curvature of the spine, fatigue, or depression.” Treatment for women might include “leeches applied to the vulva,” “chemicals injected into the uterus,” or “white-hot iron

85. OUTFRAGEOUS PRACTICES, supra note 2, at 15 (quoting Impairment of the Voice, In Female Singers, Due to Diseased Sexual Organs, 19 JAMA 36-37 (1897)).

86. THE HYSTERECTOMY HOAX, supra note 6, at 19.

87. Medical treatment was barbaric during this time frame whether the patient was male or female. Methods of treatment during the 1800s included: (1) phlebotomy or bloodletting through the use of leeches, lancet, or scarificator (Patients might be bled until they fainted.); (2) blistering (It was felt that people could only suffer one illness at a time. Burning the patient would force the old illness out of the body. Blistering was also used as a treatment for pain. Patients would focus on the pain caused by the blister and not the preexisting pain for which treatment was sought); (3) plastering (Plasters or poultices were applied to wounds and the chest and back for colds, pneumonia, or internal pain.); (4) amputation (Anesthetics were not available until 1840. Doctors used a capital saw to cut through bone and hot tar was used so the limb would not bleed. Infections were likely because there was no knowledge of bacteria, antiseptics or sterilization techniques.); and (5) purging, puking, and sweating (Expelling illness or poisons from the body was performed through administration of laxatives, inducing vomiting, or making a patient sweat.). Victorian Era Health & Medicine—Early Methods of Treatment, Victorian Lace, at http://www.geocities.com/victorianlace16/treatments.html (last visited Oct. 1, 2002). Bloodletting was used until the twentieth century for conditions such as anemia, wounds, malaria, and childbed fever. Many times “patients were bled until the patient fainted or pulse ceased.” BARBARA EHRENREICH & DEIRDRE ENGLISH, FOR HER OWN GOOD: 150 YEARS OF THE EXPERTS’ ADVICE TO WOMEN 46 (1978) [hereinafter FOR HER OWN GOOD]. The following is an account of bloodletting performed by Dr. Benjamin Rush, a famous advocate of this practice. The described episode occurred in 1793 during a yellow fever epidemic when he “achieved Transylvanian excesses.”

Toward the end of the epidemic Rush drew from seventy to eighty ounces from a patient in five days and in some cases much more. Mr. Gribble, a cedar-cooper on Front Street, lost 100 ounces in ten bleedings; Mr. George, a carter, was bled the same quantity in five days; and Mr. Peter Mierken, 114 ounces in five days.

Id. Dr. Benjamin Rush was a very influential doctor and was referred to as the “Hippocrates of American Medicine.” Victorian Era Health & Medicine—Early Methods of Treatment, Victorian Lace, at http://www.geocities.com/victorianlace16/treatments.html (last visited Oct. 1, 2002).

88. OUTFRAGEOUS PRACTICES, supra note 2, at 15.
instruments inserted into the vagina." In the late 1800s, doctors performed ovariotomies, the removal of healthy ovaries, to cure ailments. "Among the indications were troublesomeness, eating like a ploughman, masturbation, attempted suicide, erotic tendencies, persecution mania, simple 'cussedness,' and dysmenorrhea. Most apparent in the enormous variety of symptoms doctors took to indicate castration was a strong current of sexual appetitiveness on the part of women." Surgical removal of the clitoris, clitoridectomy, or its foreskin, was performed on women to cure sexual desire or masturbation. "[Clitoridectomies] were common in the United States from the 1860s on into the twentieth century, the last well-known case occurring in 1948 on a five-year-old girl, to keep her from masturbating." Hysteria was perceived as an illness of the womb, the reproductive organs acting on an unstable nervous system, which made women irritable. It was felt that hysteria could sometimes be cured by marriage. "The word hysteria has the same root as hysterectomy, from the Greek word for 'uterus'." At first, hysteria was called "mother, and was thought to be the wandering womb that rose into the throat of a girl and choked her." Physical symptoms included "epilepsy, asthma, breathlessness, flatulence, sensus globi in abdomen se volventis, lassitude, convulsions, and painful menstruation," all caused indirectly by the uterus. It is not surprising in the context of the time period that women were thought to be frail. By the late eighteenth century, the

89. Id.
90. Id. at 17.
91. BEYOND POWER, supra note 68, at 359 (citing BARBARA EHRENREICH & DEIRDRE ENGLISH, FOR HER OWN GOOD; 150 YEARS OF THE EXPERTS' ADVICE TO WOMEN 127 (1978)).
92. WOMEN, MADNESS & MEDICINE, supra note 41, at 19.
93. Id.
94. LAURENCE & WEINHOUSE, supra note 1, at 16.

That the Mother (as they call it) gets into the throat of married women and Maids, is by thousands believed to be a truth; yea, that the string of the Mother is fast in the throat, and that the vein of the Mother is also seated there, which fancy is craftily managed by a certain Woman in this Town, who thereby deceives many innocent women, and marvelously enriches herself. Id. at 40 (quoting In libellum Hippocrates de virginum morbis 73 (1648)). Hysteria or "mother" was also known as "greensickness" at one time. Id.
96. Id. Hysteria was socially accepted, if not expected of well-bred women. FOR HER OWN GOOD, supra note 87, ch. 4.
97. See generally BARBARA EHRENREICH & DEIRDRE ENGLISH, COMPLAINTS AND
belief was “to be a woman was to be sick.” He was himself asked the question, ‘What is woman?’ and answered it in one word: ‘disease.’ In fact, many woman were frail, or in ill health. The uterus and menstrual cycle was perceived as debilitating. Diet, “[t]ight lacing of corsets, arsenic nipping, maternal mortality, repeated pregnancies, and gynecological complications at delivery [such as prolapsed uterus and irreparable pelvic tears] contributed to poor health.” Physicians believed that the uterus caused the “weaker sex” to have twice the number of illnesses compared with men.

Throughout history, midwives have helped “catch” babies. In the late 1800s, physicians convinced middle and upper class women that their health would be in jeopardy if midwives assisted in childbirth. Doctors blamed midwives for the leading cause of maternal death, called puerperal infection, or childbed fever. Further, physicians sought the

DISORDERS—THE SEXUAL POLITICS OF SICKNESS (1973). Surprisingly enough, a woman of that era that most would describe as “strong” today, perceived of herself as frail. “I know I have the body of a weak and fable woman, but I have the heart and stomach of a king, and a king of England too; and think foul scorn that Parma or Spain, or any prince of Europe, should dare to invade the borders of my realm.” Queen Elizabeth I, Speech to the Troops at Tilbury on the Approach of the Armada, 1588, in THE OXFORD DICTIONARY OF QUOTATIONS 198 (2d ed. 1966).

98. BEYOND POWER, supra note 68, at 358.
99. THE HYSTERECTOMY HOAX, supra note 6, at 18.
100. One example is the “vesicovaginal fistula, a tear from bladder to vagina that can cause urinary incontinence and considerable discomfort. The tear was a common ailment of nineteenth-century woman, and was usually the result of a complicated delivery.” LAURENCE AND WEINHOUSE, supra note 1, at 22.
101. OUTRAGEOUS PRACTICES, supra note 2, at 16.
102. BEYOND POWER, supra note 68, at 358.

Pregnancy and giving birth were the most dangerous times in a woman’s life. Victorian Era Health & Medicine: Women’s Health Issues, Victorian Lace, at http://www.geocities.com/victorianlace16/womenshealth.html (last visited Oct. 1, 2002).

104. LAURENCE & WEINHOUSE, supra note 1, at 19.
105. ld. There is no evidence that childbed fever occurred any more frequently with midwives “catching” babies as compared with doctors “delivering” babies. Hygiene of both groups were bad; physicians delivered babies with unwashed hands and instruments and unsterilized sponges. However, doctors practiced in hospitals where bacteria spread rapidly, while midwives went into homes of expectant mothers and avoided the hospital breasting ground. ld. For most of the 19th Century, physicians were ignorant about germs and the reasons causing illness and instruments used were wiped clean, but certainly not sterilized. Victorian Era Health & Medicine—Early Methods of Treatment, Victorian Lace, at http://www.geocities.com/victorianlace16/treatments.html (last visited
lucrative business of birthing and had licensing laws enacted requiring formal training which obviously midwives lacked. By 1900, midwives assisted in just half the births in this country; by 1930, midwives had been driven out of business. "Medicalizing" childbirth brought forceps to help with difficult deliveries, eye drops for infants to prevent blindness caused by gonorrhea, and ether and chloroform as anesthesia. It also brought the concept that women were ill and their pregnancy was to be "managed" instead of being looked upon as "natural." Prior to "medicalization," midwives provided information on contraception and performed abortions. Feminists contend that "[w]ith the elimination of midwifery, all women—not just those of the upper class—fell under the biological hegemony of the medical profession." When midwives disappeared, "women lost control over their own bodies." One has to

Oct. 1, 2002).

106. Laurence & Weinhouse, supra note 1, at 19. Many doctors had never seen a childbirth when they graduated from medical school. Id. Doctors still practice what is referred to as "professional birth control," meaning restricting access into the medical profession for economic benefit. Doctors remain the highest paid of any profession. The Boston Women’s Health Book Collective, Our Bodies, Ourselves—A Book By and For Women 339-40 (2d ed. 1979) [hereinafter Our Bodies, Ourselves].


108. Laurence & Weinhouse, supra note 1, at 19-20.

109. Id. at 20.

110. Id.


112. For Her Own Good, supra note 87, at 88.

113. Laurence & Weinhouse, supra note 1, at 20. Terminating pregnancy was fairly common during the 1800s.

From 1800 through 1825, approximately one in every twenty-five pregnancies was reportedly ended by abortive means. By the 1860s, the number soared to one in six births, and in some areas, even higher, due to the greater availability of and acceptance of the use of abortifacients. By the time of the Civil War, at least twenty-five different abortifacients were being sold at pharmacies and through newspaper advertisements. . . . Contrary to common belief, during the
ponder the question whether the social issue of abortion that has plagued this country would have been so divisive had midwives been incorporated into the provision of medical services instead of pushed to extinction. Certainly, "[t]he virtual extinction of the midwives at the hands of nineteenth-century male physicians is considered a devastating turning point in the history of women's health."114

B. The Gender Gap in "Modern Medicine"

The twentieth century in many ways was an era of medical enlightenment. Physicians rejected the notion that women's illnesses sprang from the uterus. Based on what appeared to be sound scientific theory, physicians instead assumed that there was very little difference between men and women in regards to how we respond to disease and treatment.115 Woman was studied as if she were a man with a vagina, ovaries, uterus, and breasts. Medical research and clinical trials for prescription drugs were conducted predominately with only white male participants and then the results of those studies were extrapolated and applied to the remainder of the population. Science assumed that women would respond to the same treatment as men, except in the area of reproductive health.116 The scientific lag in information on gender discrepancies, along with underlying societal feelings toward women, impacted the practice of medicine and perpetuated the gender gap.

The extrapolation of scientific data on white men as the primary source of information regarding women's health continued until almost

first half of the century, abortion was—for the most part—generally accepted in the early months of pregnancy. 


114. Laurence & Weinhouse, supra note 1, at 18.

115. Women and Health Research, supra note 13, at 85; Life or Death Issue, supra note 35, at 49; R. Alto Charo, Protecting Us To Death: Women, Pregnancy, and Clinical Research Trials, 38 St. Louis U. L.J. 135, 140-41 (1993) [hereinafter Protecting Us To Death]; Gender Matters, supra note 4, at nn.12-19 and accompanying text. Differences between men and women include differences in body size, women have less lean body mass, and men have a higher metabolism. All these factors can impact drug dosage and the way drugs are absorbed into the body. Hormonal differences are not just caused by the monthly cycle of women. Hormonal variations can result from pregnancy, lactation, hormonal contraceptives, menopause, and hormone replacement therapy. All hormonal variations may impact medical treatments but not necessarily in the same manner. Women and Health Research, supra note 13, at 85-95.

the turn of the century. The amendment of the Federal Drug Administration’s (FDA) mandate precluding female participation in clinical trials for prescription drugs and the National Institutes of Health’s (NIH) guidelines that require inclusion of women in research were both adopted in the 1990s.\footnote{Karen L. Baird, \textit{The New NIH and FDA Medical Research Policies: Targeting Gender, Promoting Justice}, 24 \textit{J. Health Pol. Pol’y} \& \textit{L.} 531 (1999) [hereinafter \textit{Targeting Gender}]; \textit{Pregnable People}, supra note 13, at 333-43; \textit{Gender Matters}, supra note 5, at 1229-41.} Research studies to determine if there is any difference between the reactions of men and women toward the progression of a disease, treatment, or prescription drugs are now routinely performed. Information from these changes in policy is now providing tangible evidence of gender discrepancies and has the potential to alter the customary practice of physicians in some medical fields to allow for more appropriate treatment of both men and women. Suggesting that gender bias no longer exists would be naive; however, there are many positive steps towards its elimination by the scientific and medical communities.

1. Medical and Scientific Research

"Medicine is only as good as the knowledge it’s based on, and the best doctor in the world can’t compensate for faulty research."\footnote{\textit{Gender Matters}, supra note 4 (quoting OUTRAGEOUS PRACTICES, supra note 2, at 7).} As mentioned previously, most research studies on the human condition were performed with only white men as participants with the results extrapolated and applied to women. In some studies, even females were excluded from animal studies.\footnote{\textit{Invisible Woman}, supra note 12, at 127.} Data extracted was then simply applied to the rest of the population. Examples of all male studies abound: (1) The Baltimore Longitudinal Study of Aging, the definitive study on aging in the United States, contains no data on women, even though sixty percent of the elderly population are female;\footnote{\textit{Laurence & Weinhouse}, supra note 1, at 61. There were no women in the study because the facility in which it was housed had only one toilet. \textit{Id.}} (2) Mr. Fit, the 1982 Multiple Risk Factor Intervention Trial, studying the relationship between cholesterol and heart disease, contained 13,000 men and no women;\footnote{\textit{Id.} "To this day no definitive answer exists on whether dietary change and exercise can benefit women in preventing heart disease.” \textit{Id.} "[T]he low fat diet being pushed by the National Cholesterol Education Project and the American Heart}
consumption of an aspirin a day might reduce the risk of a heart attack involved 22,000 men and no women;\textsuperscript{122} (4) A study conducted by the Harvard School of Public Health, concerning the link between heart disease and caffeine, was performed on 45,000 men and no women;\textsuperscript{123} (5) Rockefeller University conducted a study on all men on the effects of obesity on breast and uterine cancer;\textsuperscript{124} and finally, (6) "The Femininity Scale on the widely used Minnesota Multiphasic Personality Inventory was originally 'validated' on thirteen gay men."\textsuperscript{125} Lest these examples make the reader "stand up and exclaim, outrageous,"\textsuperscript{126} the scientific community did have reasons for the exclusion of women from participating in research studies and drug trials.

The first reason women were typically excluded from research studies is that the scientific community seeks "sameness" in its participants to provide the most certainty in the outcomes produced by any study.\textsuperscript{127} Validation of scientific experiments usually requires some

Association (AHA) could do more harm than good to women because it lowers the HDL cholesterol levels that seem to be protecting women.” Paul Cotton, \textit{Is There Still Too Much Extrapolation From Data on Middle-aged White Men?}, 263 No. 8 JAMA 1049, 1055 (1990) [hereinafter Extrapolation From Men].

122. \textit{Id.} The Physician’s Health Study was funded by the National Institute of Health.\textit{Invisible Woman, supra note} 12, at 126.

123. \textit{Laurence & Weinhouse, supra note} 1, at 61.

124. \textit{Id.} at 62. Reacting to this study, Congresswoman Olympia Snowe stated: "Somehow, I find it hard to believe that the male-dominated medical community would tolerate a study of prostate cancer that used only women as research subjects.” \textit{Id.} The rationale from the National Institutes of Health was that the study was on the "effects of certain nutrients on estrogen metabolism, which researchers believed to be similar in men and women.” \textit{Invisible Woman, supra note} 12, at 127.

125. \textit{Beyond Power, supra note} 68, at 382. Sex bias in psychology research was examined between 1970 and 1990. During that period, sexist language disappeared from journals, studies including only men decreased, and studies in which data collected from all men was applied to women had decreased.

We should point out, however, that many reasons provided were silly, irrelevant, unscientific, or sexist. For example, many authors rationalized their all-male samples by stating that there were either demonstrated or suspected sex differences on their dependent variable and they did not wish to bother with this complexity. Others stated that scoring took too much time to include both sexes. These may be reasons, although not particularly scientific ones, to study only one sex, but they do not justify the study of only males.


126. This phrase is borrowed from the \textit{Restatement (Second) of Torts § 46 cmt. d} (1965).

127. L. Elizabeth Bowles, \textit{The Disfranchisement of Fertile Women in Clinical Trials:}
type of baseline for comparison to determine how the variable affects
the sample population. For example, assume one wants to study the
effect of different levels of caffeine on fifty white mice. One would want
the fifty mice to be almost identical to achieve the most definitive results
when observing the effects of caffeine. The baseline is the mice and the
variable is caffeine. One would give levels of caffeine to half the mice
and observe and record the effect on the mice as compared with the
twenty-five mice who were not given the caffeine. “Sameness” of the
mice is important because the reaction to the caffeine is easier to validate
if the mice are the same because other factors cannot then be blamed for
the observed reactions: the reactions are more likely caused by the
caffeine. How does one assure all fifty mice are the same? Research
scientists were and are predominately male. So the male researcher
decides to use mice of the same weight and same sex, that is, all male
mice.

The inclusion of female mice might skew the results because
hormonal fluctuations or pregnancy\textsuperscript{128} might combine with the effects of
the caffeine and render any observed reaction less likely to be attributed
solely to the caffeine. Furthermore, the fat-to-muscle ratio of female
mice might be different from that of males. As a result, the female mice
might absorb some chemicals at different speeds and the fat might cause
the chemical to remain in the body for a longer period of time. It was, in
part, the quest for “sameness” in studies with human participants that led
to the study of the “homogeneous white male” and “filled medical
libraries with data on middle-aged white men.”\textsuperscript{129} “Typically, the

\textsuperscript{128} See supra note 27; Gender Matters, supra note 4, n.13-17 and accompanying
text; Gender Disparities in Clinical Decisions, supra note 45, at 559.

\textsuperscript{129} Extrapolation From Men, supra note 121, at 1049, 1050. Race bias in medicine
is beyond the scope of this article. However, “[e]thnic differences in drug response are
becoming more well known.” Id. at 1051. Examples include: (1) Asians differ in
metabolism and receptor sensitivity compared to whites. “Asians metabolize β-blockers
quicker, they metabolize psychotropics slower.” (2) African Americans have excessive
toxic reactions to lithium, exacerbating “blacks’ already seventeen-fold increased risk of
renal failure.” (3) African Americans’ bone remodeling is thirty-five percent slower than
whites, which protects African Americans from osteoporosis. (4) Asian Indians have low
bone density, “the equivalent of a 60 year old white lady.” Id. at 1051. The National
Institutes of Health guidelines require diverse populations among research participants in
an effort toward elimination of race bias in medical research.
paradigm patient or research model has been the seventy-kilogram male.130

The scientific communities now recognize that women must be included in research studies precisely because they are not the same as men.131

[It is precisely because medications and other therapeutic interventions have a differential effect on women according to their menstrual cycle that women should not be excluded from research. Research on the use of antidepressant agents was initially conducted entirely on men, despite apparently higher rates of clinical depression in women. Evidence is emerging that the effects of some antidepressants vary over the course of a woman’s cycle, and as a result, a constant dosage of an antidepressant may be too high at some points in a woman’s cycle, yet too low at others.132

Another example is that there is a premenstrual rise in seizures and asthma deaths.133 Thus, women will remain human guinea pigs,134 especially in the administration of pharmaceuticals, until women are included in enough research studies to understand how hormonal variations impact medical treatments.

The need for the inclusion of women in medical studies seems unquestionable.135 However, some members of the research community

130. Life or Death Issue, supra note 35, at 49.
131. Confronting Bias, supra note 116; Invisible Woman, supra note 12, at 17; Judith Rodin & Jeannette R. Ickovics, Women’s Health: Review and Research Agenda as We Approach the 21st Century, AMERICAN PSYCHOLOGIST, Sept. 1990, at 1025 [hereinafter Women’s Health]; Gender Matters, supra note 4, at 1271. “There is no principled basis on which to rationalize the systematic exclusion of women from scientific research.” The Invisible Woman, supra note 12, at 142.
132. Gender Disparities in Clinical Decisions, supra note 45, at 559; accord Confronting Bias, supra note 116.
133. Extrapolation From Men, supra note 121, at 1051. “Menstrual variations in response to drug therapy also occurs with clonidine (given for high blood pressure) and Dilantin (given for seizures). Further, research suggests that oral contraceptive pills and estrogen taken for replacement during menopause may influence the metabolism of a wide variety of other drugs.” Life or Death Issue, supra note 35, at 49-50.
134. “[P]hysicians are often left without any evidence that new scientific findings apply to their specific patients. For instance, some of our physicians are a little leery of some drugs because we can’t be certain whether minorities have been participants in clinical trials.” Extrapolation From Men, supra note 121, at 1049.
135. See supra note 131.
point to increased costs as a factor that should mitigate against inclusion. Cost of research will go up if women are included because larger populations will have to be studied to clearly ascertain the effects of hormonal changes during a woman's cycle. Research will also be more difficult to analyze.\textsuperscript{136} However, the cost factor is relative. The old adage, "you get what you pay for," bears repeating. Research that excludes women has value to men, but it has questionable value to women. If inclusion of women in research trials improves the quality of the results and makes the research more valuable to a much larger segment of the population, any cost increase may well be worth it.\textsuperscript{137} The National Institutes of Health Revitalization Act of 1993 provides that cost is not a reason to exclude women from research studies.\textsuperscript{138}

Difficulty in obtaining women in research populations is another factor that allegedly could increase costs.\textsuperscript{139} Researchers also contend that the difficulty in recruiting women as participants in research partially accounts for the all-male studies.\textsuperscript{140} This argument is rather circuitous. Because women were excluded from research, women were not recruited; therefore, women will now be difficult to recruit.\textsuperscript{141} Many volunteers come from the medical profession. The population included within the Physician's Health Study regarding consuming aspirin as a preventative to heart attacks was all male physicians.\textsuperscript{142} Women are

\begin{quote}
To condense what might be called the researcher's utilitarian and deontological arguments: The first contention is that women and men are so physiologically and biochemically different, it is slower and more expensive, if not impossible, to get "clean" data from gender-integrated trials. In the long run, everyone is better off with the "more efficient" single-gender approach, because therapies will become available sooner and cost less.
\end{quote}

This argument refutes itself.

Id.\textsuperscript{137} \textit{Protecting Us To Death}, supra note 115, at 149-44.

137. \textit{Protecting Us To Death}, supra note 115, at 149-44.


140. \textit{Id.}

141. "Blaming the scarcity of potential women subjects for the exclusionary practice is unacceptable. In effect, this adds insult to injury by building on past bias to justify its perpetuation in a different realm." \textit{Id.}

142. \textit{Id.}
more prevalent today within the medical profession; 40% of classes in medical school are comprised of women.\textsuperscript{143} Furthermore, the majority of other health care workers are women.\textsuperscript{144} The argument of difficulty in recruiting women is not considered a persuasive argument by most.\textsuperscript{145}

Compounding the difficulty in research populations is the lack of female researchers.\textsuperscript{146} Scientists in the past were predominately white men that studied other white men. They tended to develop research topics that interested themselves, so research was concentrated in areas of medicine that were more important to white men. Entry into the scientific research community by women has lagged behind entry into other fields of endeavor.\textsuperscript{147} Efforts to recruit women as researchers might help to develop research protocols that lend themselves to examination of areas with gender discrepancies. Indirectly, more women researchers might increase the amount of women in research populations and cause more diverse studies.

The last reason for excluding women from research was labeled "protectionism"\textsuperscript{148} at one time, but now is more appropriately regarded as "paternalistic." If women participated in a clinical trial, her reproductive capabilities could be unwittingly injured or, the woman could become pregnant and the fetus could be injured.\textsuperscript{149} Pregnable women were considered a "vulnerable population" that could be easily abused by medical research.\textsuperscript{150} The protective attitude toward woman certainly is

\textsuperscript{143} Gender Matters, supra note 4, at 3. Today, however, only eighteen percent of all doctors are women; by 2010, thirty percent is expected. OURSELVES FOR THE NEW CENTURY, supra note 65, at 700.

\textsuperscript{144} "The medical system in the U.S. is like a pyramid, with highly paid male doctors and administrators at the top and underpaid and undervalued women forming the vast base. While about 82% of doctors are still men, about 70% of all medical care workers are women." OURSELVES FOR THE NEW CENTURY, supra note 65, at 702.

\textsuperscript{145} Wanted: Single, White Male, supra note 127, at 4 of 10.

\textsuperscript{146} The Invisible Woman, supra note 12, at 127-25; Gender Matters, supra note 4, at 3.

\textsuperscript{147} Id.

\textsuperscript{148} Gender Matters, supra note 4, at part III.

\textsuperscript{149} See generally Targeting Gender, supra note 117; Life or Death Issue, supra note 35; Confronting Bias, supra note 116; Protecting Us To Death, supra note 115; Wanted: Single, White Male, supra note 127; Women's Health, supra note 131; Invisible Woman, supra note 12; Anna C. Mastroianni, HIV, Women, and Access to Clinical Trials: Tort Liability and Lessons From DES, 5 DUKE J. GENDER L. & POL'y 167 (1998) [hereinafter Lessons From DES]; Pregnable People, supra note 13; Gender Disparities in Clinical Decisions, supra note 45.

\textsuperscript{150} Invisible Woman, supra note 12, at 127; Gender Matters, supra note 4, at 1218-29. Some believe that protectionism entrenched the notion that women were just
ingrained in our society. Furthermore, there is some historical basis for the protective attitude toward the use of members of “vulnerable populations” in scientific research.

The protective attitude of the NIH and FDA toward “vulnerable population’s” involvement in research studies sprung from historical and then current events. The Nuremberg War Crime trials and Nazi experimentation, the disclosure of the Tuskegee study, the Thalidomide, DES, and Dalkon Shield disasters, experimentation

“walking wombs.” Invisible Woman, supra note 12, at 127. Vulnerable populations is defined in federal regulations as:

When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, additional safeguard have been included in the study to protect the rights and welfare of these subjects.


151. Human experimentation on Jews in the Dachau concentration camp included submerging “prisoners in freezing water to measure exposure thresholds to cold temperatures.” A Historical Perspective, supra note 138, at 25. Furthermore, Allied abuses were revealed as well:

Also exposed at Nuremberg were several instances of questionable Allied research practices, including a U.S. program which involved malaria experiments on 800 Illinois prisoners. To guard against future unethical research programs and practices, the trials gave rise to the Nuremberg Code, the first international policy of informed consent. Specifically, the Code required that research subjects have the “legal capacity,” “free power of choice,” “sufficient knowledge” and “sufficient comprehension” to consent to participation in research activities.

Id.

152. The infamous Tuskegee Research Study has been described, as follows:

One famous example is the Tuskegee syphilis experiment of four hundred African American males. From 1932 to 1972, the Public Health Service conducted a study of the effects of untreated syphilis on these men. Poor, illiterate, southern black men were watched for forty years to obtain data on the progression of syphilis and as many as one hundred men died. Most of the men were never told they had the disease, no drugs or treatments were given or tested in this experiment, and, in fact, most of the subjects did not even know that they were participating in the trial.

Targeting Gender, supra note 117, at 533-34. Antibiotic therapy for syphilis was available; it just was not used. A Historical Perspective, supra note 138, at 26. It is unknown the extent of injuries caused to the wives or partners of the participants.

153. Thalidomide was prescribed to pregnant women primarily in Europe as a
with slave women, and the use of “dummy pills” in studies for birth control pills fueled the flames of protectionism. The philosophy to

treatment for morning sickness during the 1950s. Over a thousand limb reduction defects and organ malformations in children were caused by maternal ingestion of Thalidomide. The manufactures ignored animal studies which indicated teratogenic effects. Targeting Gender, supra note 117, at 533; A Historical Perspective, supra note 138, at 25.

154. DES has been referred to as a “classic example of teratogenic liability on a grand scale.” Disfranchisement, supra note 127, at 907. DES was widely prescribed to pregnant women during the 1940s and 1950s to prevent miscarriages. DES causes generation-skipping cancer. Children and grandchildren of women who ingested DES develop rare forms of cancer. Numerous lawsuits were generated as a result of DES. DES was an additive for cattle food prior to its use in humans. Yet, it was not tested for teratogenic effects in humans. Furthermore, DES did not prevent miscarriages. Id. at 888-89.

155. The Dalkon Shield was an IUD (intrauterine birth control device) that caused “infection, hemorrhage, reproductive harm, and sometimes death.” The Dalkon Shield was withdrawn from the market due to “exaggerated manufacturer claims, poor research methodology, and selective presentation of results” on the part of the manufacturer. A Historical Perspective, supra note 138, at 25.

156. Surgical experimentation on African-American slave women was performed during the early 19th Century without the benefit of anesthesia. Gender Matters, supra note 4, at 1220. The most famous culprit was Dr. J. Marion Sims, a founder of modern gynecology. Slave owners brought female slaves who had fistulas to Dr. Sims. Vesicovaginal fistulas are a tear from the vagina to bladder caused by difficulty in childbirth. Dr. Sims operated on seven slaves with only their “master’s” permission.

The first woman, named Lucy, was operated on without anesthesia (although anesthesia had been developed, Sims was not aware of it). In excruciating pain, she nearly died afterward of blood poisoning—and the operation was not successful. After each of the operations the stitches became infected and the fistulas remained open. Another woman, Anarcha, endured thirty operations, all without anesthesia, until finally the fistula was repaired when Dr. Sims used silver sutures, which resisted infection.

LAURENCE & WEINHOUSE, supra note 1, at 22. As late as 1989, eight HIV-positive women were part of a study at Subic Bay Naval Base in the Philippines. The eight women were prostitutes serving military men and were not told of their disease. The study was to determine “the value of positive thinking on the course of the disease.” Id. at 23-24.

157. In 1971, Dr. Joseph Goldzieher ran a research study to ascertain if reported side-effects from oral contraceptives were real or imagined. He conducted research on 398 Mexican-American women in San Antonio Texas. “Of these women, seventy-six who thought they were getting contraceptives were given placebos instead. Ten became pregnant within months.” GENA COREA, THE HIDDEN MALPRACTICE: HOW AMERICAN MEDICINE TREATS WOMEN AS PATIENTS AND PROFESSIONALS 13 (1977) [hereinafter THE HIDDEN MALPRACTICE]. The NIH funded Dr. Goldzieher’s research until 1974. Id. at n.; See also Targeting Gender, supra note 117, at 533.
protect “vulnerable populations” grew partially from a desire to avoid prior research abuses.  

In addition, fear of liability created by extensive litigation caused by injuries from the Dalkon Shield, DES, and Thalidomide coincided with the philosophy of protection. Both protectionism and fear of liability combined to create the original NIH and FDA policies excluding women from most research studies. Certainly by today’s standards, an exclusionary policy aimed at all fertile women to protect the unborn fetuses of pregnant women is simply over broad and clearly violates modern concepts of self-autonomy.

In the 1970s, however both FDA and NIH policies reflected the attitude to protect women from research and to protect the research industry from liability to women and their children. The FDA policy in 1977 limited participation of fertile women in drug testing. Pregnable women, unless they suffered from a life-threatening disease, were only allowed to participate after phase I and II drug studies were complete. Prescription drug manufacturers though were not required to include women in phase III studies and thus women were commonly excluded. The NIH did not encourage the use of women in clinical research in applicants applying for research grants until 1986. The General Accounting Office (GAO) issued a report in 1990 stating that the NIH policy encouraging researchers to include women participants was “not implemented consistently, if at all.” The GAO report concluded that the NIH policy was ineffective in causing inclusion of more women in research as evidenced by “the larger, more expensive NIH-funded clinical studies that had included only men.”

158. “FDA officials estimate that until 1972, more than 90% of all investigational drugs were first tested on prisoners.” Gender Matters, supra note 4, at 1220.
160. Targeting Gender, supra note 117, at 533-34; A Historical Perspective, supra note 138, at 25-6; Gender Matters, supra note 4, at 1220.
162. Id.
163. Id. Large numbers of women have been included in late-phase clinical trials, but gender differences have not been evaluated routinely. Susan F. Wood, Office of Women’s Health, Food and Drug Administration: Future Directions for Women’s Health, 56 JAMWA 197 (2001). More participation “as well as analyzing data by sex and gender have the potential to improve dosing for women and prevent a variety of adverse events.” Id. at 197.
164. Women and Health Research, supra note 13, at 43.
165. Id.; see also Women and Health Research, supra note 13, at 43; A Historical Perspective, supra note 138, at 26-27; Gender Matters, supra note 4, at 1229-41.
2. Federal Regulatory Response within the NIH and FDA

In 1993, President Clinton signed the National Institutes of Health Revitalization Act\(^{166}\) "which requires the inclusion of women in sufficient numbers to ensure a 'valid analysis' in most clinical trials."\(^{167}\) The current NIH policy on the inclusion of women and minorities is as follows:

It is the policy of NIH that women and members of minority groups and their subpopulations must be included in all NIH-funded clinical research, unless a clear and compelling rationale and justification establishes to the satisfaction of the relevant Institute/Center Director that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. Exclusion under other circumstances may be made by the Director, NIH, upon the recommendation of an Institute/Center Director based on a compelling rationale and justification. Cost is not an acceptable reason for exclusion except when the study would duplicate data from other sources. Women of childbearing potential should not be routinely excluded from participation in clinical research. This policy applies to research subjects of all ages in all NIH-supported clinical research studies.\(^{168}\)


\(^{167}\) A Historical Perspective, supra note 138, at 27. President Bush had vetoed the bill in 1992. Id. The National Institutes Health Revitalization Act also mandates the inclusion of racial and ethnic groups in NIH sponsored or funded research. WOMEN AND HEALTH RESEARCH, supra note 13, at 44.

\(^{168}\) NIH Policy and Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research, National Institutes of Health, Office of Extramural Research (amended Oct. 2001), available at http://grants1.nih.gov (last visited Sept. 26, 2002) (emphasis added). The requirement to include women does not apply under the Act if it is "inappropriate with respect to the health of the subjects" or "is inappropriate under such other circumstances as the Director of NIH may designate." National Institutes of Health Revitalization Act, § 492B(b). See also NIH Guidelines on the Inclusion of Women and Minorities As Subjects in Clinical Research, National Institutes of Health, Office of Extramural Research (Updated August 1, 2000), available at http://grants1.nih.gov (last visited Sept. 26, 2002), which provides: "Since a primary aim of research is to provide scientific evidence leading to a change in health policy or a standard of care, it is imperative to determine whether the intervention or therapy being studied affects women or men or members of minority groups and their subpopulations.
Therefore, preganlable women may still be excluded if the research poses an "unacceptable risk for women of childbearing potential" and pregnancy can be used as a "clear and compelling" justification for exclusion. As previously mentioned, pregnant women and their unborn children are already protected as members of "vulnerable populations" under other federal regulations.

The FDA withdrew its restriction on the participation of women of childbearing potential in early clinical trials in 1993. However, precautions must be taken to assure that female participants are not pregnant and will avoid pregnancy during the trial. Further, the FDA did not require pharmaceutical companies to include women; rather, they expected inclusion.

We do not at this time perceive a regulatory basis for requiring routinely that women in general or women of childbearing potential be included in particular trials, such as phase I studies. However, as this guideline delineates, careful characterization of drug effects by gender is expected by the agency, and [the] FDA is determined to remove the unnecessary Federal impediment to inclusion of women in the earliest stages of drug development.


169. Gender Matters, supra note 4, at n.231.


The current policies of both the NIH and FDA can be seen as progress toward the inclusion of women as participants in research studies. However, the NIH policy to exclude women if research could injure their reproductive capabilities has been attacked because there is no similar exclusion for men. A man’s reproductive functioning can also be injured in research trials impacting the ability to father children and the health of his future children.\textsuperscript{172} The failure of the FDA to mandate women participants in early drug testing has been widely criticized.\textsuperscript{173} Drug companies are unlikely to routinely include fertile women in early drug testing due to fear of liability unless required to do so by the FDA.\textsuperscript{174}

Some believe the fear of liability for including pregnable women in research studies is overestimated. The truth is that future potential liability for inclusion of women capable of becoming pregnant is unknown due to the fact that the risk of harm cannot be calculated because women were excluded in the past.\textsuperscript{175} There are three reported cases regarding liability for including women in research trials, two involved DES.\textsuperscript{176} Liability could be based on theories of negligence,

\textsuperscript{172} The Invisible Woman, supra note 12, at 136. “In studies where there is a known risk to potential offspring and no obvious benefit to participants, sexually active fertile women and men should probably be excluded, since evidence shows many substances may damage sperm and thereby create the risk of birth defects in the male’s progeny.”

\textit{Id.}

\textsuperscript{173} Targeting Gender, supra note 117; Wanted: Single, White, Male, supra note 127; Invisible Woman, supra note 12; Pregnable People, supra note 13; Gender Matters, supra note 4.


\textsuperscript{175} WOMAN AND HEALTH RESEARCH, supra note 13, at 12-13. One solution to the problem of exposure to liability is to use only selected classes of women. “[T]here are groups of women who are at little or no risk of becoming pregnant (e.g., women with hysterectomies, women whose monogamous partner has had a vasectomy, lesbians not planning to have children, celibate women), and informed consent can protect all research subjects.” Women’s Health, supra note 131, at 1025. In response, hormonal fluctuations could be different for women with hysterectomies compared with other women. The status of the rest of the categories of women could literally change overnight; all are still quite capable of becoming pregnant.

failure to receive informed consent, and perhaps strict products liability in tort.\textsuperscript{177} However, carefully drafted consent forms and full disclosure of known, knowable, and potential unknowable risks of harm could avoid tort liability for the individual participants.\textsuperscript{178} There could very well be more exposure to tort liability for exclusion of women from clinical studies than from inclusion.

The argument for liability against pharmaceutical companies for excluding women from research is fairly straightforward.\textsuperscript{179} Assume a drug company places a drug on the market and clinical trials did not include women. Women take the drug and are injured as a result. If women had been included during the development of the drug, either the drug would not have been marketed, warnings would have been issued, or dosages would have been varied. The argument supporting negligence is that the reasonable drug manufacturer would include women in research studies if the drug was intended for use by women. Reasonable care requires gender analysis data to ascertain any side effect or dosage requirements unique to women when they take the drug. The argument for negligence is strengthened given the strong federal policy statements supporting the FDA’s “expectation” of inclusion of women. There is also arguable liability under strict products liability in tort for

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\textsuperscript{177} WOMEN AND HEALTH RESEARCH, supra note 13, at 150-65; Disfranchisement, supra note 127, at 907-11; Protecting Us To Death, supra note 115, at 144-49; Lessons from DES, supra note 149, at 175-81; Pregnable People, supra note 13, at 347-61; Gender Matters, supra note 4, at 1259-63. The author is unaware of any precedent that says a manufacturer has injected a product into the stream of commerce while it is still in the testing and development stage even if a participant is exposed to the product and is injured. A product has to be injected into the stream of commerce in order for there to be liability under strict products liability in tort.


\textsuperscript{179} Disfranchisement, supra note 127, at 911-916. For example, in West v. Johnson & Johnson Products, Inc., 220 Cal. Rptr. 437 (1985), the plaintiff suffered toxic shock syndrome from a tampon manufactured by Johnson & Johnson. “The court found that the company had failed to study the basic microbiology of the human vagina, to test for vaginal infections, and to include women with a history of vaginitis in their human studies.” WOMEN AND HEALTH RESEARCH, supra note 13, at 166.
failure to provide adequate warnings and injecting a defectively designed product into the stream of commerce.  

Furthermore, many constitutional arguments have been raised to strike down exclusionary policies of researchers including violation of equal protection (they assume state action can be found).  

The right of self-autonomy supports the idea that fertile women have the right to decide for themselves if they want to participate in research trials. The Supreme Court has strongly suggested that women have a liberty interest in deciding the course of their own medical treatment. It is a right personal to all women. Further, the Court has stated that women have the right to decide the importance of their reproductive future for themselves. Excluding women because they may become pregnant violates firmly entrenched principles of self-autonomy. “In the end, society must trust women to make decisions about their own health and a healthy future with their families. . . .[I]f we do not presume that all women can be trusted to make decisions about clinical research and

180. WOMEN AND HEALTH RESEARCH, supra note 13, at 165-67; Disfranchisement, supra note 127, at 911-16; Lessons from DES, supra note 149, at 181-83; Pregnable People, supra note 13, at 361-75; Gender Matters, supra note 4, at 1263-65. But see supra note 177 (discussing the requirement that a product must be injected into the stream of commerce before strict products liability in tort will attach).  

181. Life or Death Issue, supra note 35, at 57-61; Disfranchisement, supra note 127, at 896-907; Protecting Us To Death, supra note 115, at 149-58; Gender Matters, supra note 4, at 1242-59.  

182. The United States Supreme Court “assumed and strongly suggested” that we have a liberty interest in deciding the course of our medical treatment, including the right to decline life-prolonging care. Cruzan v. Director, Missouri Dept. of Health, 497 U.S. 261 (1990). The Court has reaffirmed the existence of the liberty interest in self-autonomy, but held that it did not include the right to physician-assisted suicide. The individual states may permit physician-assisted suicide, however, the United States Constitution does not prevent a state from prohibiting physician-assisted suicide. Washington v. Glucksburg, 521 U.S. 702 (1997); Vacco v. Quill, 521 U.S. 793 (1997).  

183. Automobile Workers v. Johnson Controls, 499 U.S. 187 (1991). In Johnson Controls, the Court decided that Johnson Controls did not have the right to exclude fertile women from the battery department due to fear of lead exposure harming a future fetus if a woman became pregnant. The Court held that fertility was not a bona fide occupational qualification under Title VII; fertile women could make batteries as well as anyone else. The Court stated: “It is no more appropriate for the courts than it is for individual employers to decide whether a woman’s reproductive role is more important to herself and her family than her economic role. Congress has left this choice to the woman as hers to make.” Although Johnson Controls was interpreting Title VII, it still lends support for the argument that it is a woman’s right to balance her reproductive health versus her other personal interests.
health care, we will never eradicate gender bias."\textsuperscript{184} Accordingly, the FDA’s "expectation" that women be included in research should be amended to require the inclusion of women of childbearing potential in phase I and II studies by pharmaceutical companies.

The resolution of the problem of participation of pregnant women in research studies is harder to resolve. Before discussion of this problem and the proposed solution, however, explanation of terminology employed is critical. Research in which pregnant women might participate can be divided into two categories, therapeutic research and research that lacks therapeutic value. This distinction has been appropriately described as "murky"\textsuperscript{185} and "illogical."\textsuperscript{186} Therapeutic research generally is assumed to be the equivalent of clinical research, meaning "[t]he doctor can combine medical research with professional care, the objective being the acquisition of new medical knowledge, only to the extent that medical research is justified by its potential diagnostic or therapeutic value for the patient."\textsuperscript{187} This definition would prove too narrow to allow meaningful research. For example, a placebo given in a double-blind drug trial (patients are not told whether they are given the placebo or the actual drug) does not have therapeutic value for the research participant, although it has value to enable effective research regarding the disease of the participant.\textsuperscript{188} Therefore, therapeutic value includes research that would further the understanding of the illness or condition of the pregnant participant or her fetus, for example, "the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of pregnant women, fetuses, or neonates."\textsuperscript{189}

Research that lacks therapeutic value is research that has an "experimental design [that] is not related to the patient’s illness,"\textsuperscript{190} even though the research contributes to development of generalized scientific

\begin{thebibliography}{9}
\bibitem{184} *Gender Matter*, supra note 4, at 1271.
\bibitem{185} *Pregnable People*, supra note 13, at 342.
\bibitem{186} ROBERT J. LEVINE, ETHICS AND REGULATION OF CLINICAL RESEARCH 8 (2d ed. 1988) [hereinafter ETHICS OF CLINICAL RESEARCH].
\bibitem{187} Id. (quoting the Declaration of Helsinki, World Medical Association Declaration of Helsinki: Recommendations Guiding Medical Doctors in Biomedical Research Involving Human Subjects, § II (6), reprinted at Appendix 4, p. 429).
\bibitem{188} ETHICS OF CLINICAL RESEARCH, supra note 186, at 9.
\bibitem{189} 45 C.F.R. § 46.207(a) (2002).
\bibitem{190} ETHICS OF CLINICAL RESEARCH, supra note 186, at 9, (quoting the Declaration of Helsinki: Recommendations Guiding Medical Doctors in Biomedical Research Involving Human Subjects, § III (2)).
\end{thebibliography}
knowledge.\textsuperscript{191} The argument can be made that participation in any research study has therapeutic value from the standpoint that the participant might be given free medicine, access to unapproved drugs or unapproved uses of drugs, an overall health assessment, and receive regular examinations and evaluations by a health care professional.\textsuperscript{192} In short, “clinical trials are the best available source of quality health care.”\textsuperscript{193} However, the inclusion of pregnant women in research studies, and appropriate modifications of existing NIH and FDA guidelines, will be discussed with the “illogical” distinction of therapeutic versus non-therapeutic value.\textsuperscript{194} Certainly, any such qualification undermines principles of self-autonomy. Pure self-autonomy means that a pregnant woman has the right to choose for herself whether to participate in a research study, with the accompanying generalized benefits, without qualification by anyone or from any regulatory body.

Some argue that the right of self-autonomy is broad enough that a pregnant woman has the right to decide for herself whether to participate in research trials and the right to decide whether to risk harm to the fetus.\textsuperscript{195} At a minimum, pregnant women should have the right to decide for themselves assuming the research trial has therapeutic value to the pregnant woman or to her fetus.\textsuperscript{196} Courts will likely decide that a pregnant woman has the right to decide whether to participate if the research might alleviate a serious condition even if participation might injure the fetus.\textsuperscript{197} The woman should have the right to either accept the

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\bibitem{191} Ethics of Clinical Research, \textit{supra} note 186, at 3.
\bibitem{192} 	extit{Pregnable People}, \textit{supra} note 13, at 318-21.
\bibitem{193} \textit{Id.} at 320.
\bibitem{194} This distinction corresponds with the intent of the Department of Health and Human Services regulations which allow, but do not require, inclusion of pregnant women in research studies. 45 C.F.R. §§ 46.201, 46.204, 46.205, 46.206, 46.207 (2002).
\bibitem{195} Protecting Us To Death, \textit{supra} note 115, at 167; Pregnable People, \textit{supra} note 13, at 375-78; Gender Matters, \textit{supra} note 4, at 1271.

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experimental treatment in hopes of improving her health or reject it for fear of injuring her unborn child. No one else can decide what is best for the future of her family. A woman suffering from AIDS should have the unquestionable right to participate in early drug testing, even if she is pregnant, if she decides that is what is best for her, her unborn child, and her family.\textsuperscript{198} This right only has meaning if the woman is not to be excluded from a research study solely because of her pregnancy. Similarly, a pregnant woman should have the right to decide to participate in research, which might benefit her fetus.\textsuperscript{199} Both the FDA and NIH guidelines should be amended to mandate that a pregnant woman should not be excluded from research studies that have a therapeutic value to the woman or to her fetus.

A pregnant woman may not have the unquestionable right to participate in any and all research that has no known or little therapeutic value to her or to her fetus.\textsuperscript{200} Some research, such as validation of the femininity scale on the Minnesota Multiphasic Personality Inventory,\textsuperscript{201} poses no danger to a fetus, but other forms or types of research may. In research that poses no possible in vivo danger, pregnant women should have the right to participate even if there is no therapeutic value. Conversely, a pregnant woman might not have the right to be a participant in research that \textit{may} cause a teratogenic harm, which could be a possibility during phase 1 or phase 2 testing of many prescription drugs.

This discussion is rather paternalistic. Women do not lose their intelligence nor common sense just because they become pregnant. I suspect, without empirical support, that few pregnant women, intending to carry their baby to term, would want to be included in a research

\textsuperscript{198} Federal regulations prohibit research on pregnant women unless animal studies and studies on nonpregnant people have been completed, the research is to meet the health needs of the mother, and the fetus will be placed at the minimal risk necessary to meet the health needs of the mother. 45 C.F.R. § 46.206(a)(1) (1975); 45 C.F.R. § 46.207(a) (1992); \textit{Pregnable People}, supra note 13, at 341-44. Research under the regulations, provided the guidelines are fulfilled, may be performed; however, the regulations do not mandate inclusion.

\textsuperscript{199} Currently, federal regulations require the consent of both the mother and father if the research is only to benefit the fetus. 45 C.F.R. § 46.204(e) (2002).

\textsuperscript{200} \textit{Pregnable People}, supra note 13; \textit{Gender Matters}, supra note 4.

\textsuperscript{201} See supra note 125.
project that lacked therapeutic value if there was any risk, whether known or unknowable, to the fetus. Therefore, federal regulations that sanction excluding pregnant women from research trials seems, at first blush, unnecessary. However, there are at least three reasons why such regulations might still be necessary. First, sanctioning exclusion might alleviate the liability concerns of research organizations that preclude pregnant women from participation.

Second, the research industry has taken advantage of women and minorities in the past. A pregnant woman, who lacks either the intelligence, educational background, or language skills, might not understand that participation in an outwardly innocuous research study with no known danger to her fetus might be subjecting her fetus to an unknowable and unforeseeable risk. Some people might lack the capacity to truly give informed consent. Some degree of protectionism might still be necessary to avoid research abuse. However, this concern applies equally to all vulnerable people, not just pregnant women.

Finally, excluding pregnant women avoids the following draconian suggestion: "[D]isasteful as it may seem, there are good policy reasons for encouraging experimentation on pregnant women whose fetuses are not destined to go to term. These reasons include preserving the health of the pregnant women, [and] minimizing unintended damage to fetuses that do go to term." Society would probably find a research study

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202. Women and Health Research, supra note 13, at 118-19; see supra notes 151-57.

203. Federal regulations require that informed consent include a statement that the "particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable." 45 C.F.R. § 46.116(b)(1)(2002).

204. 46 C.F.R. § 46.116 (2002).

205. Protecting Us To Death, supra note 115, at 167. The author continues: "Of course, this conclusion is almost certainly politically untenable, but it would appear to be a valuable example of the extreme endpoint in the discussion of the general question of the inclusion of women in research." Id. There are two types of research that are considered appropriate immediately preceding an abortion. The first is the administration of a drug to the woman before the abortion and then the examination of the fetus after the abortion to ascertain if the drug passed through the placenta and then determine the effects of the drug on the fetus. "Development of rational drug therapy for the pregnant woman and for the fetus is dependent upon the performance of such research." Ethics of Clinical Research, supra note 186, at 301. The next type of research deals with the development of a maneuver that might induce labor, such as amniocentesis or intrauterine umbilical cord blood sampling. Researchers prefer testing these type of procedures shortly before an abortion is performed. Id. at 302. DHHS regulations currently provide that under certain circumstances research not otherwise approvable may be performed if
violate of public policy that deliberately experimented with fetuses in anticipation of their abortion. Precluding pregnant women from non-therapeutic research avoids what some would consider a rather far-fetched slippery slope. However, federal regulations of the Department of Health and Human Services (DHHS) currently allow a fetus to be subjected to a risk of harm when the research provides a "direct benefit to the woman or the fetus; or, if there is no such prospect of benefit, the risk to the fetus is . . . minimal and the purpose of the research is the development of important biomedical knowledge, which cannot be obtained by any other means."\textsuperscript{206} The caveat, of course, is that the risk must be minimal. Therefore, the FDA and NIH guidelines should be amended to reflect the current guidelines of the DHHS and allow participation in non-therapeutic research when the risk of harm to the fetus is minimal.\textsuperscript{207}

However, a pregnant woman's right of self-autonomy collides, at some point, with strong well-established policies to protect unborn children from teratogenic injuries and bioethical concerns regarding experimentation on fetuses. These concerns spring from public policy and do not recognize that the fetus has an equal legal status as compared with the mother.\textsuperscript{208} One concern is that researchers might encourage

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the "research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of pregnant women, fetuses, or neonates," so long as it is conducted in accordance with sound ethical principles and informed consent is obtained. 45 C.F.R. §§ 46.207(a), 46.207(b)(2)(ii), 46.207(b)(2)(iii).

\textsuperscript{206} 45 C.F.R. § 46.204(b) (2002).

\textsuperscript{207} There appears to be few research studies that are non-therapeutic that pose a serious risk of injury. A review of 183 federally-funded research projects dealing with high-risk pregnancy found only 3 that posed even a minimal risk of injury. Two involved ultrasound and the other involved the use of a placebo-controlled trial of antibiotics in the treatment of urinary infections in pregnant women. ETHICS OF CLINICAL RESEARCH, supra note 186, at 311.

\textsuperscript{208} The legal status of a fetus is unclear. Although a fetus can be viewed as a potential person or potential life, some suggest that classification is less than helpful.

Even less relevant is the question so often raised in proposed legislation and constitutional amendments: When does life begin? There is life in a sperm, in a white blood cell, and in a fingernail. As we consider how we ought to treat the human fetus or embryo, the most constructive questions are: When does a developing human being begin to acquire the entitlements of membership in the moral (human) community? When does it begin to count as one of us? When should it become enfranchised by the Fourteenth Amendment to the United States Constitution?

ETHICS OF CLINICAL RESEARCH, supra note 186, at 300. It is clear that a pregnant woman
women to abort to have sufficient research material. Some fear that experimentation on fetuses without a tangible therapeutic benefit would relax feelings of reverence and extend to other forms of human indifference. "One would also wish to inquire whether such research would set a precedent for the performance of similar procedures on other classes of human organisms—for example, on newborns who are mortally ill or comatose elderly persons."

Further, liability concerns for including pregnant women in early clinical trials when there is no known or very little therapeutic value seem well founded. There could very well be a rational basis for exclusion of pregnant women as research participants if there is more than a minimal risk of harm to her fetus when the potential of a tangible therapeutic value is lacking.

Inclusion of any pregnable or pregnant woman in research studies raises concerns for liability. Injuries could occur to an unborn child of either a pregnant woman or a woman who becomes pregnant during the course of the trial. Better technology, birth control, and the availability of abortion lessens exposure to liability to some degree. But it would be foolhardy to suggest that exposure to liability is not present to some degree. Proper consent avoids liability exposure to any injury sustained by the female participant. However, the mother’s consent will not preclude the unborn child’s cause of action. Some suggest a legislative

has full fourteenth amendment rights while her developing fetus does not. It is precisely for that reason that a pregnant woman has a liberty interest in deciding to undergo medical treatment even if the treatment might injure her fetus.

209. ETHICS OF CLINICAL RESEARCH, supra note 186, at 303.
210. Id.
211. Id. at 304 (citation omitted).
212. Protecting Us To Death, supra note 115; Pregnable People, supra note 13; Gender Matters, supra note 4.
213. As stated by Professor Vanessa Merton:

Most lawyers will say that the parent’s consent to risk on behalf of a child is ineffective. While parents can consent to their children’s participation in all manner of fairly dangerous and nonbeneficial activities outside the medical area, generally they can consent to medical intervention for their children only if the intervention is intended and expected to be beneficial to the individual child.

The traditional view, therefore, has been that parents lack capacity to consent to their child’s participation in research not intended to be therapeutic, and therefore, ipso facto, to assumption of the risks of the child’s participation in such research.

Pregnable People, supra note 13, at 386-87.
solution. The legislature could create a system of compensation, much like worker’s compensation, to award limited recovery for injuries caused to research participants or their children who were injured in vivo. 214 However, worker’s compensation arguably benefits the employers much more than the workers it was designed to protect. 215 Society might very well be better served by leaving the tort system intact to help police the research industry.

Proposals to protect researchers by finding ways to immunize them from tort liability could, in one swoop, eliminate an important rationale for the exclusion of women from research. That is an inviting prospect. The trouble is, it could also mean that the clinical trials women would finally get to participate in would become incrementally more dangerous, and that they, their injured offspring, and the injured offspring of male subjects, would have to absorb whatever injury was entailed. It remains hard for me to see the justice of eliminating liability for those who sponsor and conduct research, unless they are willing to share their profits, in the broadest sense. Liability is an

214. Wanted: Single, White, Male, supra note 127; Invisible Woman, supra note 12; Pregnable People, supra note 13; Gender Matters, supra note 4. There is a judicial tendency to protect the prescription drug industry. Brown v. Superior Court, 44 Cal. 3d 1049, 751 P.2d 470, 245 Cal. Rptr. 412 (Cal. 1988); Feldman v. Lederle Lab., 97 N.J. 429, 479 A.2d 374 (N.J. 1984). Some courts have equated for-profit pharmaceutical companies with professional health care workers. Id. Drug companies exist for only one reason, to make money and increase dividends to shareholders. A secondary purpose, i.e., the betterment of mankind, only exists because it fosters the primary purpose, making profit. A statutory grant of immunity to the industry that gave us DES, Thalidomide, the Dalkon Shield, breast implants, benedectin, and E-Ferol seems misplaced. “E-Ferol was an untested preparation of intravenous vitamin E sold by O’Neil, Jones, and Feldman, Inc. to treat infants. Physicians assumed it had been tested and approved by the FDA. In 1984, E-Ferol killed 38 infants. In 1989, three employees of O’Neil, Jones, and Feldman, Inc. were fined $130,000 each and jail sentences of six months.” Vicki Lawrence MacDougall, Products Liability Law in the Nineties: Will Federal or State Law Control?, 49 CONSUMER FINANCE LAW QUARTERLY REPORT No. 4 327, 339 n.179 (1995) (citing Jerold F. Lucey, Do You Remember E-Ferol? The Penalty for Selling Untested Drugs in Neonatology: Fines and a Jail Sentence, 89 PEDIATRICS No. 1, 159 (1992)); Vichien Lorch, M. Dianne Murphy, Linda R. Hoersten, et al, Unusual Syndrome Among Premature Infants: Association With a New Intravenous Vitamin E Product, 75 PEDIATRICS No. 3, 598 (1985).

215. Pregnable People, supra note 13, at 384, n.287 (citing DANIEL BERMAN, DEATH ON THE JOB 54-73 (1978) (Workers’ compensation does not increase safety incentives nor make employers bear the cost of workplace hazards. It only replaces approximately 10% of lost income)).
important disincentive, and at present one of few, for the kind of
callous disregard for human health and life that has been all too
prominent a feature of drug development and other kinds of
biomedical research. Perhaps we have progressed to the point
where such deterrence is no longer necessary, but without more
evidence, to jettison this one proven mechanism of preventing
harm seems rather reckless.\textsuperscript{216}

Furthermore, liability in negligence may be avoided by simply using
reasonable care, the standard that other researchers would use under the
same or similar circumstances. For example, reasonable care includes
reasonable animal testing and reasonable collection and analysis of data
before exposing human populations. If reasonable care is used based on
the prevailing scientific knowledge available, knowable dangers should
be discovered and avoided through redesign or adequate warnings. Strict
products liability in tort attaches for failure to warn of known or
knowable dangers only. Strict products liability in tort does not apply to
unknowable dangers in the vast majority of jurisdictions.\textsuperscript{217} Again,
reasonable care in research and development would avoid liability for
failure to warn whether the cause of action was founded in either

\textsuperscript{216} Pregnable People, supra note 13, at 390.

\textsuperscript{217} Anderson v. Owen-Corning Fiberglas Corp., 53 Cal. 3d 987, 281 Cal. Rptr. 528,
810 P.2d 549 (Cal. 1991); Brown v. Superior Court, 44 Cal. 3d 1049, 245 Cal. Rptr. 412,
1998); Feldman v. Lederle Lab., 97 N.J. 429, 479 A.2d 374 (N.J. 1984); compare
Sternhagen v. Dow Company, 935 P.2d 1139 (Mont. 1997) (A manufacturer can be held
liable for an unknowable danger.). The Restatement (Third) of Torts, Products
Liability § 2, cmt. n (1997), provides as follows:

The issue of foreseeability of risk of harm is more complex in the case of
products such as prescription drugs, medical devices, and toxic chemicals.
Risks attendant to use and consumption of these products may, indeed, be
unforeseeable at the time of sale. Unforeseeable risks arising from foreseeable
product use or consumption by definition cannot specifically be warned
against. Thus, in connection with a claim of inadequate design, instruction, or
warning, plaintiff should bear the burden of establishing that the risk in
question was known or should have been known to the relevant manufacturing
company. The harms that result from unforeseeable risks—for example, in the
human body's reaction to a new drug, medical device, or chemical—are not a
basis of liability. Of course, a seller bears responsibility to perform reasonable
testing prior to marketing a product and to discover risks and risk-avoidance
measures that such testing would reveal. If testing is not undertaken, or is
performed in an inadequate manner, and this failure results in a defect that
causes harm, the seller is subject to liability for harm caused by such defect.
negligence or strict products liability in tort. Litigation from Thalidomide, DES, the Dalkon Shield,\textsuperscript{218} toxic shock syndrome,\textsuperscript{219} and breast implants\textsuperscript{220} all resulted from the glaring deficiencies of failure to use reasonable care, in the research and development of those products. Telling the research industry to avoid such deficiencies is not an exacting standard and is certainly the standard society should demand. If the research and pharmaceutical industries do their jobs the way they should, the specter of liability appears exaggerated.

In conclusion, inclusion of more women in research is a critical prerequisite to the provision of better health care to women. Both the NIH and FDA guidelines reflect some progress, but both agencies should issue stronger guidelines promoting the inclusion of women in research studies. First, the FDA “expectation” that women be included in research and that proper gender analysis be performed should be a mandate. Next, both the NIH and FDA guidelines should reflect the policy that exclusion of women because they are pregnant is not permissible so long as there is therapeutic value to the woman or to her fetus, or the risk to the fetus is minimal and the “purpose of the research is the development of important biomedical knowledge which cannot be obtained by any other means”\textsuperscript{221} in accordance with current DHHS guidelines. This proposal will appear frightening to many. However, more frightening is the prospect of women taking medications that have been tested only on male participants. This scenario becomes more frightening when a pregnant woman is prescribed a drug because there is normally no disclosure of the foreseeable risks that could occur from

\textsuperscript{218} See supra notes 153-55.

\textsuperscript{219} See supra note 179.

\textsuperscript{220} Breast implants were first used in 1964. Until 1976, the FDA lacked authority to regulate medical devices and breast implants bypassed the approval process due to a grandfather clause in FDA regulations. The FDA did not require reports of health problems until 1984; did not classify breast implants as potentially dangerous until 1988; and did not require safety data until 1991. “The silicone gel that filled the majority of implants was first used as a sealant, then sold as Silly Putty. The polyurethane foam used to cover one type of implant was industrial grade, used in furniture, upholstery, oil filters, and carburetors.” Laurence & Weinhouse, supra note 1, at 188. A petition from the American Society of Plastic and Reconstructive Surgeons to the FDA panel regulating breast implants stated that “small breasts were a disease that required medical intervention.” Id. Breast implants cause capsular contracture, serious autoimmune reactions, and obscure mammography. Id. at 188-90. “In April 1994, lawyers representing women in a class action suit against the manufacturers of breast implants said they had discovered a 1975 Dow Corning study showing that the silicone in the implants harmed the immune system of mice.” Id. at 190. Bastards!

\textsuperscript{221} 45 C.F.R. § 46.204(b) (2002).
taking a drug that was approved without proper testing on women or pregnant women. Further, the medical community has sanctioned the treatment giving the pregnant woman a false sense of security. Amendment of the FDA and NIH guidelines is the less frightening of the two alternatives.

3. Gender Discrepancies in Treatment

Clearly, exclusionary research practices impact the treatment of women by the medical profession. For example, women are prescribed more drugs than men despite the lack of participation by women in research populations. Not surprisingly, women suffer more adverse drug consequences than men. Low fat diets have been encouraged for both men and women. Yet, low fat diets that help men fight high

222. Disfranchisement, supra note 127, at 877.
223. Overall, women have twice as many fatal drug reactions as men. A 1992 article

... noted a seventeenfold increase in the risk of fatal myocardial infarction in young women taking psychotropic drugs. Seventy percent more women than men visit emergency rooms to be treated for tranquilizer-related adverse consequences, and more than twice as many women as men enter [emergency rooms] for adverse reactions to antidepressants.”

LAURENCE & WEINHOUSE, supra note 1, at 276. Ten drugs were taken off the market between 1997 and 2001. “Eight of the 10 medications, including the allergy drug Seldane and the acid reflux drug Propulsid, put women at more risk of side effects than men.” Star Lawrence, How Drugs Affect the Sexes, WebMD, at http://aolsvc.health.webmd.aol.com/content/article/1689.53791 (last visited Sept. 24, 2002). Only two of the ten drugs withdrawn from the market carried a warning about side effects on women. Id. Many factors explain why drugs react differently in women as compared to men.

[It's not estrogen that makes women more sensitive to some drugs, but androgens possessed by the male that makes men less sensitive . . . . Many drugs achieve different blood levels and effectiveness depending on when during a menstrual cycle they are taken . . . . Some drugs work differently in postmenopausal women than in premenopausal women. In the case of one drug, blood levels are lower during menstruation—but the drug is actually more effective.

[W]omen metabolize drugs differently in their livers than men. Reproductive hormones also control the time the medicine spends in the gut and the metabolic processes that break it down. The difference in women's muscle to fat ratio is also a factor.

Id. Medication can get caught in the fat and increase side effects. Id. See also Disfranchisement, supra note 127, at 877.
224. Extrapolation From Men, supra note 121, at 1055.
cholesterol and heart disease might not be necessary for women. Further, there is some indication that low fat diets may actually hinder a woman’s natural ability to fight heart disease. In the context of medical treatment, what is good for the gander might not be good for the goose.

Another example can be seen in the treatment of women suffering from AIDS. Originally, it was believed that only homosexual men contracted the deadly virus. Women were, somewhat understandably, ignored in the early research of the disease. However, researchers continued to ignore women even after women became the largest growing class of patients with AIDS. The progression of the disease in

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225. Laurence & Weinhouse, supra note 1, at 89.

The Framingham study has found that what’s dangerous for a man may not be a problem for a woman. For instance, Framingham has found that in men, high levels of the “bad” LDL cholesterol may be most predictive of future heart trouble. In women, however, low levels of “good” HDL cholesterol may be a bigger risk. Also, high levels of triglycerides do not seem to be a risk factor for men, but may be predictive of heart trouble for women.

For women these findings call into question the current guidelines for prescribing cholesterol-lowering drugs and . . . low-fat diets. Framingham and other studies continue to discover gender differences in cholesterol risks, yet the message that physicians and the media continue to circulate is that it’s important to get cholesterol levels under 200. Women have the right to ask: Important for whom?

Id. at 89-90.

226. Low-fat diets “could do more harm than good to women because it lowers the HDL cholesterol levels that seem to be protecting women.” Extrapolation From Men, supra note 121, at 1055; see also Gender Matters, supra note 4, at n.43.

227. On the common practice of prescribing an aspirin as a preventative to heart disease despite the lack of definitive studies on its impact on women, see supra notes 53-61. There is also no evidence that drugs designed to lower cholesterol are effective when used with oral contraceptives. Extrapolation From Men, supra note 121, at 1055. Further, a study with 51,529 male participants suggested that moderate drinking may lower the risk of heart attacks. However, moderate consumption of alcohol increases the risk of breast cancer in women. Gender Matters, supra note 4, at nn.44, 45. Women who abuse alcohol are five times more likely to commit suicide than non-alcoholic women. Women’s Health, supra note 131, at 1022.


229. Women and Health Research, supra note 13, at 81.

230. Id. at 81, 66.

women differs from that of men\textsuperscript{232} and women tend to die sooner after the diagnosis of being HIV positive.\textsuperscript{233} Yet it was not until 1993 that the most common symptoms in women, cervical cancer, pelvic inflammatory disease, and vaginal yeast infections, were acknowledged by the Center for Disease Control.\textsuperscript{234} As a result, women were excluded from participation in many of the experimental treatments and many women were undiagnosed for longer periods of time causing inappropriate treatments of their conditions.\textsuperscript{235} Research on women with HIV has been glaringly deficient.\textsuperscript{236} Practitioners have not had the advantage of solid research which probably has negatively impacted thousands of female AIDS victims.\textsuperscript{237}

Similarly, women were excluded from early research on the effectiveness of autologous bone marrow transplants (ABMT) in

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"The number of AIDS cases among women in this country has increased more than 600\% since 1986. The growth rate is currently 2½ times faster among women than among men." \textit{Women's Health, supra} note 131, at 1026.
\end{quote}

\textsuperscript{232} \textit{Gender Matters, supra} note 4, at n.54.
\textsuperscript{233} \textit{Women's Health, supra} note 131, at 1027.
\textsuperscript{234} \textit{Gender Matters, supra} note 4, at n.54.
\textsuperscript{235} \textit{Women and Health Research, supra} note 13, at 66; \textit{Less Than Equal Treatment, supra} note 231, at 20 ("Because of our failure to focus on women earlier in the course of the epidemic, there are significant gaps in our knowledge about HIV disease in women."); \textit{Women's Health, supra} note 131, at 1027. "Perhaps more important, where women have been the focus of clinical research the primary research question has been how to reduce or prevent a vertical transmission of human immunodeficiency virus (HIV) from a pregnant woman to a fetus or newborn, not how to treat the female-specific manifestations of HIV diseases." \textit{Women and Health Research, supra} note 13, at 66.
\textsuperscript{236} Professor Rothenberg writes:

Of the 28 trials of drugs designed to fight HIV, only 131 of 2634 participants were women. In addition, when the FDA approved AZT in 1987, not one of the 63 federally-sponsored studies had analyzed its effects on women.

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It is not surprising that women experienced toxic side effects when given AZT dosages to treat AIDS calibrated to the ever-popular seventy-kilogram male. Physicians treating women with AIDS are still left guessing at drug dosing. When the results of the study comparing the benefits of AZT to the drug deoxyinosine were released in 1992, only four percent of the participants were female, too small a percentage to provide meaningful information to physicians about drug treatment regimens.

\textit{Gender Matters, supra} note 4, at nn.33-35, 37-39 and accompanying text.
\textsuperscript{237} \textit{Id.; Lessons from DES, supra} note 149, at 169-170.
conjunction with high-dose chemotherapy (HDC) to fight cancer. As a result, insurance companies denied coverage of ABMT with HDC as a treatment for metastatic breast cancer because its use on women was classified as experimental due to the fact that the original research populations were all male. Currently, women with metastatic breast cancer who are covered by some health insurance providers are forced to fight in court with mixed success for HDC accompanied by ABMT.

238. Invisible Woman, supra note 12, at 140. High Dose Chemotherapy (doses of cancer-fighting drugs are six to ten times higher than in standard chemotherapy) and radiation is usually considered a last-resort medical treatment to save patients who have not responded to traditional chemotherapy. A side-effect of HDC is that it kills bone marrow, which controls the immune system and produces blood cells. In ABMT, physicians remove the patients own bone marrow prior to HDC and reinfuse it after HDC is completed to rebuild the patient’s bone marrow. The cost of the treatment is over $100,000 and it is dangerous and painful. In many cases of stage IV metastatic breast cancer, HDC combined with ABMT provides the only hope for treatment. Id. at 139-40. See also Edward A. Stadtmufer, et al., Conventional-Dose Chemotherapy Compared with High-Dose Chemotherapy Plus Autologous Hematopoietic Stem-Cell Transplantation for Metastatic Breast Cancer, 342 NEW ENG J. MED. 1069 (2000).

239. Less Than Equal Treatment, supra note 231, at 21.


The cases can be difficult to reconcile. The differences can be explained, in part, based on differences in coverage provided in plans and differences in the stages of breast cancer suffered by the plaintiffs. There also appears to be more likelihood of success when the case is brought on the preliminary injunction battleground. There is less potential of winning on the merits. A preliminary injunction only requires proof of irreparable harm
Although there appears to be judicial sympathy for the plight of women denied coverage for HDC along with ABMT, courts do not always order health insurance companies to cover the treatment, which means the woman must pay for the treatment out of her own pocket or forgo HDC and ABMT.241

However, treatment disparities cannot be blamed entirely on the research industry. Preconceived notions about women by members of the medical profession negatively impact medical treatment.242 Women are perceived as being more complaining.243 Women do visit the doctor (this is easy to proof with cancer victims who might die without treatment) and a reasonable likelihood of success on the merits (statements from experts who assert the treatment is widely accepted as state-of-the-art will usually suffice). When the case is fought on the merits, the insurance company has the opportunity to present extensive testimony that HDC/ABMT is still experimental. Invisible Woman, supra note 12, at 141. In general, patients win coverage disputes in over half of the reported cases so there is judicial sympathy for the patient’s complaints. However, patients prevail less frequently in federal appellate courts. Mark A. Hall, et al., Judicial Protection of Managed Care Consumers: An Empirical Study of Insurance Coverage Disputes, 26 Seton Hall L. Rev. 1055, 1068 (1996).

Although more than 30,000 women underwent HDC with ABMT during the 1990s, Zervos, 277 F.3d at 635, the studies were not controlled nor were randomized trials performed and the studies are not considered scientifically valid. Peruzzi, 137 F. 3d at 431; Graham, 130 F.3d at 293; Reed, 197 F. Supp. 2d at 883; Glauser-Nagy, 987 F. Supp. at 1002. Thus, plans originally defined HDC with ABMT as experimental. See, e.g., Zervos, 277 F.3d at 635; Simkins, 229 F.3d at 729; Lewis, 1999 U. S. App. Lexis 15746; Peruzzi, 137 F. 3d at 431; Killian, 152 F.3d 514; Reed, 197 F. Supp. 2d at 883; Smith, 148 F. Supp. 2d at 637. Now plans might deny treatment as not medically necessary, meaning not shown to be more effective than traditional treatments. Graham, 130 F. 3d at 293; Reed, 197 F. Supp. at 883. See also Mark A. Hall & Gerald F. Anderson, Health Insurers’ Assessment of Medical Necessity, 140 U. Pa. L. Rev. 1637 (1992). Further, some plans cover HDC accompanied by ABMT for some stages of breast cancer, but not other stages. Graham, 130 F.3d 293 (coverage denied because plaintiff’s breast cancer only involved six of her lymph nodes, but the cancer had yet to metastasize); Reed, 197 F. Supp. at 2d 883 (women with Stage II breast cancer with six positive lymph nodes denied coverage because plan covered only Stages II and III cancers with 10 positive nodes or 2 metastatic organ sites); Glauser-Nagy, 987 F. Supp. 1002 (plan covered treatment for Stage IV breast cancer, but not stage III).

241. Id.
242. Laurence and Weinhouse, supra note 1, at 262-63.
243. Gender Disparities in Clinical Decisions, supra note 45, at 561 (Women are perceived to be overanxious about their health). Gena Corea describes this sexual prejudice, as follows: “When doctors were asked in 1971 to describe ‘the typical complaining patient,’ 72 percent referred spontaneously to a woman. Only 4 percent referred to a man. (The remaining 24 percent did not mention the patient’s sex.) Men describe symptoms, it seems, but women ‘complain.’” The Hidden Malpractice, supra note 157, at 81 (citations omitted).
more than men. Women also might be more descriptive in their symptoms. Further, new research indicates that women might have a lower tolerance for pain than men. For whatever reason, women's symptoms are not taken as seriously by physicians as men's. Doctors are also more likely to assume that a woman's condition is "all in her head." If a man and a woman present to a doctor with the same symptoms, a physician is more likely to search for a physical explanation for the man and is more likely to consider the disorder as psychogenic for the woman and prescribe a psychoactive drug. The origins of attributing physical conditions to psychosomatic illnesses in women can be traced to medical school as well as the personal assumptions by

244. *Life or Death Issue*, supra note 35, at 65; *Gender Disparities in Clinical Decisions*, supra note 45, at 559.

245. LAURENCE & WEINHOUSE, supra note 1, at 261. "Apparently, the more stoical the patient, the more seriously the doctor tends to regard him or her. The more expansive the patient, the less seriously the physician takes her." *The Hidden Malpractice*, supra note 157, at 85. Men's complaints are more believable to a doctor because men are more stoic. LAURENCE & WEINHOUSE, supra note 1, at 261. "The open and emotional behavioral style used by women in reporting their illnesses may prompt physicians to react to women's complaints as though they were expressions of emotional problems, whereas the more stoic style found in men reporting a similar complaint does not elicit a psychosomatic diagnosis from the physician." *Id.* (citation omitted).

246. Bob Calandra, *Gender: Some Painstaking Differences*, WebMD, at http://aolsvc.health.webmd.aol.com/content/article/1687.50940 (last visited on Sept. 24, 2002). Women are more sensitive to pain during the premenstrual phases of their cycle. *Id.* Also, men and women may react differently to pain medication. "For example, research has shown that certain pain-relieving drugs called kappa opiates, such as Stadol, are highly effective in women. They were originally thought to be ineffective, however, because they had been tested only on men." Joanie Stewart, *When It Hurts, Gender Matters*, WebMD, at http://aolsvc.health.webmd.aol.com/content/article/1689.51889 (last visited on Sept. 24, 2002).

247. BEYOND POWER, supra note 68, at 366; LAURENCE & WEINHOUSE, supra note 1, at 261-63. This has been referred to as the Yentl Syndrome. This phrase was borrowed from a story "about a woman who pretends to be a man in order to achieve equality. In the doctor's office, the Yentl syndrome means that women's complaints are not taken as seriously as men's, even when their medical symptoms are similar." *Less Than Equal Treatment*, supra note 231, at 17.

248. BEYOND POWER, supra note 68, at 366; LAURENCE & WEINHOUSE, supra note 1, at 259; *Women's Health*, supra note 131, at 1018; *Gender Disparities in Clinical Decisions*, supra note 45, at 561.

249. BEYOND POWER, supra note 68, at 366; LAURENCE & WEINHOUSE, supra note 1, at 259, 276.

250. Traditionally, medical education was not a bastion of gender enlightenment.

The medical textbooks of the 1800s may seem laughably ignorant today, but as recently as the 1970s physicians were being taught that morning sickness was
individual doctors based on subjective stereotyping. Empirical studies on the communication gap between physicians and patients show that the communication gap is at its worse when the conversation is between a male doctor and a female patient.\footnote{251}

Startling discrepancies in treatment exist for lung, heart, and kidney disease.\footnote{252} Part of the disparity is attributed to societal feelings about lung and heart disease. Historically, lung and heart disease was associated with men, not women. At one time, few women smoked and lung cancer became associated with men. As a result, women are not as likely to be properly screened for lung cancer as their male counterparts; men are more than twice as likely to have diagnostic tests ordered as compared with women.\footnote{253}

\begin{quote}
caused by a woman’s resentment at being a mother, PMS was also a psychological disorder, and menopause represented the end of a woman’s usefulness in life. And the doctors who were trained with those textbooks are still practicing medicine.
\end{quote}

Laurence & Weinhouse, supra note 1, at 30-31. "The 1970 edition of Novak’s Textbook of Gynecology has etched into its cover a picture of a naked woman walking forward, one hand covering her pubic area, the other across her breasts, and pain screaming from her face." The picture is from a 1427 painting entitled “Expulsion of Adam and Eve” and conveys the “message of Eve, the fallen woman in need of medical management.” In The Patient’s Best Interest, supra note 6, at 155-56. The anatomy textbooks of the 1990s still featured men in pictures; only nine percent of pictures were of women, other than in the reproductive arena. Laurence & Weinhouse, supra note 1, at xi. Today, the addition of a course in Women’s Health to a medical school’s curriculum is still met with resistance. Id. Lecturers normally use the neutral pronoun “he,” but automatically switch to “she” when discussing psychosomatic illness. Id. at 262. Further, anatomy lecturers have been known to refer to the female reproductive system as “inefficient, badly designed, and prone to problems.” Laurence & Weinhouse, supra note 1, at 30.

\footnote{251} Life or Death Issue, supra note 35, at 45-46; see generally In the Patient’s Best Interest, supra note 6, at ch. 3; An Unequal Majority, supra note 62, at 28-35; Ourselves for the New Century, supra note 65, at 685-86; Patricia Peppin, Power and Disadvantage in Medical Relationships, 3 Tex. J. Women & L. 221 (1994).

\footnote{252} Gender Matters, supra note 4, at 1210; Gender Disparities in Clinical Decisions, supra note 45, at 560.

\footnote{253} A detection bias favors the ordering of diagnostic testing for lung cancer inpatients who are smokers, have a recent or chronic cough, or are male.” Id. (emphasis added). See also supra notes 45-50 and accompanying text. Lung cancer surpassed breast cancer as a leading cause of death for women in 1986. Women’s Health, supra note 131, at 1022. Women may find it more difficult to stop smoking than men. Studies show that women find more subjective pleasure from smoking than men. Norra MacReady, Subjective Pleasures of Smoking Greater for Women, WebMD, at http://aolsvc.health.webmd.aol.com/content/article/1728.53553 (last visited Sept. 24, 2002). Further, women find it easier to quit during the follicular phase of their cycles, one to fourteen days after their periods. Women who quit during the luteal phase, fifteen
Similarly, heart disease became associated with men. Women were not perceived as potential victims of heart failure because of the prophylactic effects of estrogen. Although estrogen probably does provide temporary protection from heart disease for women, heart disease is, in fact, the leading cause of death for women; women just tend to die ten years later of heart disease than men.

As such, there are disturbing differences between the medical care provided to men as compared with women suffering from cardiovascular disease. Women are more likely to be misdiagnosed when suffering from heart disease, women receive fewer invasive procedures (men or more days before their periods, experience more irritability, depression, and anxiety. Gay Frankenfield, Menstrual Cycle May Affect Tobacco Withdrawal: Timing Your Quit Date Right Can Reduce Irritability, WebMD, at http://aolsvc.health.webmd.aol.com/content/article/1728.56933 (last visited Sept. 24, 2002).

254. WOMEN AND HEALTH RESEARCH, supra note 13, at 64.
255. Id. This perception is based in part on the Framingham Heart Study which followed the medical histories of both men and women over a twelve-year period. The Framingham Heart Study found that men were more vulnerable to heart disease than women. It was assumed women were protected by estrogen. Now medical science knows that women are not immune; they simply develop the disease later in life. After menopause, there is a gradual increase in heart disease until women ultimately suffer heart attacks at the same rate as men. Id. On the Framingham Heart Study, see Mahesh Bikkin, et al., Left Ventricular Mass and Risk of Stroke in an Elderly Cohort: The Framingham Heart Study, 272 JAMA 33 (1994); Trudy L. Bush, et al., More Reasons than ever for HRT, PATIENT CARE 103, Nov. 1993; Wendy Chavkin, Women and Cohort Studies, 50 JAMWA 34 (1995); Debra J. Lerner, Pattern of Coronary Heart Disease Morbidity and Mortality in the Sexes: A 26-Year Follow-up of the Framingham Population, 115 AM. HEART J. 383 (1986); Richard V. Milani, et al., Pharmacologic Prevention of Coronary Artery Disease, Symposium, Ischemic Heart Disease, 99 No. 2 POST GRADUATE MEDICINE 109 (1996); Joanne M. Murabito, Women and Cardiovascular Disease: Contributions from the Framingham Heart Study, 50 JAMWA 35 (1995).
256. Id.; Life or Death Issue, supra note 35, at 51; see also Debra R. Judelson, Cardiovascular Disease in Women, 49 JAMA 180 (1994); Nanette K. Wenger, Coronary Heart Disease in Women: Gender Differences in Diagnostic Evaluation, 49 JAMA 181 (1994). On the use of aspirin as a preventive to heart disease, see supra notes 53-60 and accompanying text; Editorial, Preventing Heart Disease in Women: Another Role for Aspirin, 266 JAMA 565 (1991). Fears existed that women might develop more stress-related disorders, including cardiovascular disease, as women moved into the male job market. In fact, women become healthier as they assume multiple roles, along with household responsibilities, so long as there is some degree of job satisfaction. Women’s Health, supra note 131, at 1023-1024.
257. Gender Disparities in Clinical Decisions, supra note 45, at 560. Of patients with abnormal nuclear scan tests, “women were more than twice as likely to have their symptoms attributed to somatic, psychiatric, or other noncardiac causes as men.” Id.; accord Less Than Equal Treatment, supra note 231, at 18.
are twice as likely to undergo a cardiac procedure),\textsuperscript{259} with poorer outcomes when invasive procedures are performed,\textsuperscript{260} and women are more likely to die sooner after they have a heart attack.\textsuperscript{261} Studies suggest that men are 6.5\textsuperscript{262} to 10 times\textsuperscript{263} more likely to be referred for cardiac catheterization after an abnormal stress test than women.

The symptoms of angina for a woman may be different than a man which could lead to improper or delayed diagnosis.\textsuperscript{264} But research studies show that “women were more than twice as likely to have their symptoms attributed to somatic, psychiatric, or other noncardiac causes as men.”\textsuperscript{265} Moreover, the lower use of invasive procedures for women, and treatment only through medications, cannot be explained by the medical conditions of women versus those of men. In other words, a man with the same condition would be treated more aggressively by the medical profession.\textsuperscript{266} Evidence suggests that there might even be


\textsuperscript{259} \textit{Sex Differences, supra} note 258, at 229.

\textsuperscript{260} \textit{Differences in the Use of Procedures, supra} note 258, at 22; \textit{Life or Death Issue, supra} note 35, at 55-56.

\textsuperscript{261} \textit{Laurence \& Weinhouse, supra} note 1, at ix; \textit{Differences in the Use of Procedures, supra} note 258, at 22. Startling new evidence exists that digoxin, medication used in the treatment of heart failure, increases the risk of death of women given the drug. Digoxin does not increase the death rate of men. The death rate of women given digoxin was 33.1% compared with 28.9% when given a placebo. No such difference appeared with men. Saif S. Rathore, \textit{et al.}, \textit{Sex-Based Differences in the Effect of Digoxin for the Treatment of Heart Failure}, 347 \textit{New Eng. J. Med.} 1403 (2002), available at http://www.nejm.org.

\textsuperscript{262} \textit{Gender Disparities in Clinical Decisions, supra} note 45, at 560.

\textsuperscript{263} \textit{Sex Differences, supra} note 258, at 229.

\textsuperscript{264} The most common description of the pain caused by a heart attack is chest pain radiating down the left arm. However, radiating chest pain is less likely to occur in women compared to men. Women are more likely to have “abdominal or mid-back pain, jaw pain, indigestion, or extreme fatigue” when suffering a heart attack. Michael Smith, \textit{News for Women: Heart Attack Symptoms May Be Different Than You Think}, WebMD, at http://aolsv.health.webmd.aol.com/content/article/1728.93421 (last visited on Sept. 24, 2002).

\textsuperscript{265} \textit{Gender Disparities in Clinical Decisions, supra} note 45, at 560.

\textsuperscript{266} \textit{Differences in the Use of Procedures, supra} note 258, at 221, 223; \textit{Less Than Equal Treatment, supra} note 231, at 18-19; \textit{Sex Differences, supra} note 258, at 229; \textit{Gender Disparities in Clinical Decisions, supra} note 45, at 560-61; David Benjamin Oppenheimer \& Marjorie M. Shultz, \textit{Gender and Race Bias in Medical Treatment}, at http://www.mmmh.com/jgsm/articles/JGSM9908/law.html (last visited on July 3, 2002).
disparities when medications are prescribed to treat cardiovascular disease. Women are less likely to receive thrombolytic therapy, intravenous drugs that dissolve blood clots.267 "Physicians prescribed nitrates (vasodilators which increase oxygen supply to the heart muscle) and anticoagulation (blood-thinning) therapy more often to men and prescribed diuretics (water pills) more often to women."268

Further, the prognosis for women is not as good as for men when an invasive procedure is performed.269 Originally, equipment was designed for men and was not as well suited for the narrower coronary arteries of women which led to poorer outcomes.270 The higher death rate can also be attributed to the delay in treatment271 and the fact that women are usually older than men when they develop heart disease.272 Again, however, men are more likely to receive coronary angiography,273 angioplasty, and bypass surgery than women when presenting the same symptoms.274

267. Life or Death Issue, supra note 35, at 55.
268. Id. at 53.
269. Differences in the Use of Procedures, supra note 258, at 22; Life or Death Issue, supra note 35, at 55-56; Less Than Equal Treatment, supra note 231, at 19.
270. Differences in the Use of Procedures, supra note 258, at 22; Life or Death Issue, supra note 35, at 56.

At one time, women had a ten-fold higher risk of dying in the hospital after undergoing coronary angioplasty, a procedure in which a tiny balloon catheter is threaded into a blocked artery and then inflated, thus flattening the blockage. The mortality difference eventually was attributed to the smaller artery size of women, a factor that was not considered when angioplasty was developed. Now . . . machines have been scaled down and the inflatable balloons used in women are smaller and more appropriate for their artery size.

Gender Matters, supra note 4, at 1264.

271. Life or Death Issue, supra note 35, at 57. "Medical research suggests women are referred later than men for all diagnostic, medical and surgical interventions." Id.
272. Life or Death Issue, supra note 35, at 51; see also Debra R. Judelson, Cardiovascular Disease in Women, 49 JAMA 180 (1994); Nanette K. Wenger, Coronary Heart Disease in Women: Gender Differences in Diagnostic Evaluation, 49 JAMA 181 (1994).
273. "The adjusted odds of undergoing angiography were 28 percent and 15 percent higher for men than women in Massachusetts and Maryland, respectively . . . . The respective adjusted odds of undergoing revascularization were 45 percent and 27 percent higher for men than for women." Differences in the Use of Procedures, supra note 258, at 221.
274. Differences in the Use of Procedures, supra note 258, at 221, 223; Sex Differences, supra note 258, at 229; Life or Death Issue, supra note 35, at 54; Less Than Equal Treatment, supra note 231, at 18; Gender Disparities in Clinical Decisions, supra note 45, at 560-61.
Similarly, a woman suffering from end-stage renal disease has a one-third\(^{275}\) to one-half chance to receive a kidney transplant compared with a man with the same medical history.\(^{276}\) The American Medical Association (AMA) cannot explain this phenomena based on any rational medical criteria. The Report of the Council on Ethical and Judicial Affairs of the AMA made the following observation:

Societal value judgments placed on gender or gender roles may also put women at a disadvantage in the context of receiving certain major diagnostic and therapeutic interventions, such as kidney transplantation and cardiac catheterization. A general perception that men's social role obligations or of their contributions to society are greater than women's may fuel these disparities. For instance, altering one's work schedule to accommodate health concerns may be viewed as more difficult for men than for women. Overall, men's financial contribution to the family may be considered more critical than women's. A kidney transplant is much less cumbersome than dialysis. Coronary bypass surgery, for which catheterization is a prerequisite, is a more efficient and immediate solution to the problem of coronary artery disease than continuous antianginal drug therapy. However, judgments based on evaluations of social worth or preconceptions about the probable roles of men and women are clearly inexcusable in the context of medical decision-making.\(^{277}\)

Conversely, the medical profession has been criticized for too quickly resorting to surgical solutions for women, particularly in the area of reproductive health.\(^{278}\)

\(^{275}\) Gender Matters, supra note 4, at n.50.
\(^{276}\) Gender Disparities in Clinical Decisions, supra note 45, at 560.
\(^{277}\) Id. at 561 (emphasis added).
\(^{278}\) On unnecessary hysterectomies, see supra note 6, and HYSTERECTOMY HOAX, supra note 6. The medical profession has no qualms about exposing women to technology during the birthing process. Only 3% to 5% of babies were born by cesarean section until the 1970s; 23% of births are by cesarean section today. It is feared that rate could exceed 50% over the course of the next twenty years. Neonatal mortality has improved by the use of cesarean sections. However, "[t]he maternal mortality rate is four times higher than in vaginal delivery, and at least one third of all cesarean section patients have some postoperative infection, . . . as well as depression and exhaustion. Women's Health, supra note 131, at 1029. Some feel technology is also overused in monitoring the progress of labor. "Overall, members of the American College of Obstetricians and
The mental health field has also been attacked for treatment discrepancies based on gender. Some of the DSM-IV guidelines are attacked as containing sex biases, which could result in a normal woman in our culture easily being misdiagnosed as having various personality disorders.279 The DSM-IV definition of premenstrual dysphoric disorder (PMDD), commonly known as PMS, is perhaps the most disturbing.280 The mere inclusion of PMS indicates that a normal biological function

Gynecologists report that rates of prenatal testing and fetal heart rate monitoring have nearly doubled ... despite their unproven value in reducing the morbidity and mortality of newborns.” Id. at 1030 (citations omitted). Clearly, the biggest consumers of plastic surgery are women. Women are perhaps responding to societal pressures in their quest for plastic surgery; however, plastic surgeons certainly reap the profits. LAURENCE & WEINHOUSE, supra note 1, at 168, 186-92; Ann Gerhart, More and More Young Women Choose Surgical “Perfection”, in RACE, CLASS, AND GENDER IN THE UNITED STATES 129 (PAULA S. ROTHENBERG, ed., 5th ed. 2001). Women are also the biggest consumers of foot surgery (Oh, those high-heeled shoes!). “More than three-quarters of all foot operations are performed on women, including 94 percent of bunion surgery, 87 percent of neuroma surgery, and 81 percent of hammertoe surgery.” LAURENCE & WEINHOUSE, supra note 1, at 168. Women can also exceed men in surgical interventions in surprising areas.

For instance, women have twice as many appendectomies as men, despite the fact that they are less likely to develop appendicitis. Approximately one in four women will have their appendixes removed, compared with just one in eight men. Yet the risk of developing appendicitis is just 6.7 percent for women and 8.6 for men.

Id. 279. See supra notes 38-44 and accompanying text; LAURENCE & WEINHOUSE, supra note 1, at 266-68; WOMEN, MADNESS, & MEDICINE, supra note 41, at 33, 36-37. On mental health and women, see generally Cate Hemmingway, Boxing Women: Regulation, Women and Mental Health, 2 CARDozo WOMEN’S L.J. 109 (1995); William Hoffman Pincus, Civil Commitment and the “Great Confinement” Revisited: Straightjacketing Individual Rights Stifling Culture, 36 WM. & MARY L. REV. 1769 (1995).

280. WOMEN, MADNESS & MEDICINE, supra note 41, at 37. PMDD is a proposed mental disorder and is listed in Appendix B, p. 715, of the DMS-IV. Premenstrual Dysphoric Disorder was originally called by the “gobbledygook” term of Late Luteal Phase Dysphoric Disorder ( LLPDD). LAURENCE & WEINHOUSE, supra note 1, at 269. Another disturbing proposed category was “self-defeating personality disorder,” formerly called “masochistic personality disorder.” The basic criteria was “a pervasive pattern of self-defeating behavior,” avoiding or “undermining pleasurable experiences,” and being drawn “to situations or relationships in which he or she will suffer,” preventing “others from helping him or her.” The fear was that this criteria would be mainly misapplied to women, our society fosters this behavior in women, and the criteria also “describes normal responses to the experience of victimization.” WOMEN, MADNESS & MEDICINE, supra note 41, at 37. Self-defeating Personality Disorder was stricken from the DSM-IV after protests by the National Organization for Women. LAURENCE & WEINHOUSE, supra note 1, at 274.
for a woman might still be perceived as a disorder.\textsuperscript{281} For many in the field of women’s health, the PMDD guideline has become a symbolic regression to the historical attitude that a woman’s reproductive function was a disease.\textsuperscript{282} In response, the mental health field claims that it is a proper criteria and is only used in extreme cases.\textsuperscript{283} The danger of abuse of the criteria is just now surfacing with the development of prescription drugs for premenstrual dysphoric disorder.\textsuperscript{284}

Concern regarding overuse of prescription drugs by the mental health field, particularly anti-depressants, is well justified.\textsuperscript{285} Historically, women and mental illness were perceived as intertwined.\textsuperscript{286} During the twentieth century, psychiatrists used surgery as a method to treat mental illness in women. Women were much more likely to have electric shock

\begin{enumerate}
\item \textsuperscript{281} Women, Madness \& Medicine, supra note 41, at 37.
\item \textsuperscript{282} See supra notes 78-114 and accompanying text. PMDD itself is a continuation of the chronic tendency in psychiatry to take a patriarchal stance toward women.” Laurence \& Weinhouse, supra note 1, at 274.
\item \textsuperscript{284} PMDD disorder has “symptoms such as markedly depressed mood, marked anxiety, marked affected liability (mood swings), and decreased interest in activities.” The development of a new disease lends itself to new pharmaceuticals to treat the disorder and the potential market is “astronomical.” Eli Lilly and Company’s response was to market Sarafem as treatment for PMDD. Sarafem is an “antidepressant fluoxetine hydrochloride—better known to millions by the brand name Prozac.” Eli Lilly’s web site states that Sarafem “helps you be more like the woman you are, every day of the month, even during your most difficult days.” Women Behaving Badly, supra note 283. The current home page for Sarafem shows a picture of a lovely, happy woman with the caption, “Doctors can treat PMDD with Sarafem, the first prescription medication for PMDD.” Sarafem, at http://www.sarafem.com (last visited on Oct. 23, 2002). You can order Sarafem on-line for a $49 consultation fee at http://www.I-shoppharmacy.com, or receive $10 off your first noninsured prescription at http://www.drugstore.com. However, Prozac was not tested for long-term use. “The tests on it were 6-8 weeks, but PMS is not a short-term syndrome.” The real motive behind marketing Sarafem for PMS, “Prozac’s patent was running out, and suddenly a new disorder appeared—PMDD—that changed the classification to mental disorders. So with that a new class was formed, a new market was formed, and a new patent was formed.” Women Behaving Badly, supra note 283. “The FDA allowed 38 percent of the approval board to have direct ties to Eli Lilly. Why? Sarafem is Prozac.” Prozac Truth, at http://www.prozactruth.com/sarafem.htm (last visited on Oct. 23, 2002).
\item \textsuperscript{285} “Women are two times more likely than men to suffer from addiction to prescription psychototropic drugs.” Women’s Health, supra note 131, at 1029.
\item \textsuperscript{286} See supra notes 89-98 and accompanying text
\end{enumerate}
treatments and lobotomies at the hands of the mental health field. It is certainly not surprising that some accuse the mental health field of much the same behavior through the use of psychotropic drugs instead of surgery.

Women are two to four times more likely to be diagnosed with depression than men and women are prescribed 70% of all tranquilizers and anti-depressants. Yet research populations were all male in the development of most of the anti-depressants in use today. There is more and more evidence that some anti-depressants might not be appropriate for women. Further, normal hormonal fluctuations during the menstrual cycle cause a woman to be overdosed at certain times during the month and under medicated at others.

287. Two-thirds of all shock therapy are applied to women. There are over 100,000 people who receive this treatment a year. One side effect is permanent memory loss. LAURENCE & WEINHOUSE, supra note 1, at 282. "The girl . . . was a gentle, generous veteran of mechanical psychiatry in a dozen other hospitals. Her memory had been ravaged, but her sickness was still intact." HANNAH GREEN, I NEVER PROMISED YOU A ROSE GARDEN, in THE QUOTABLE WOMAN 409 (ELAINE PARTNOW, ed. 1978).

288. "The first wave of lobotomies performed in the United States was aimed mainly at females—by two out of three. Fifty thousand people were lobotomized before 1962, with very little evidence that it helped and considerable evidence that it harmed them." BEYOND POWER, supra note 68, at 365.

289. BEYOND POWER, supra note 68, at 365.

290. Claudia Morain, Depression: Do Women Have a Biological Risk?, WebMD, at http://aolsvc.health.webmd.aol.com/content/article/1663.51920 (last visited on Sept. 24, 2002); see also, LAURENCE & WEINHOUSE, supra note 1, at 264.

291. LAURENCE & WEINHOUSE, supra note 1, at 275-76; Women’s Health, supra note 131, at 1018. "[A] third of all American women over thirty are given a prescription for a psychoactive drug each year." BEYOND POWER, supra note 68, at 366.

292. Women’s Health, supra note 131, at 1027. Women suffer more side effects than men and are more responsive to antidepressants. The exclusion of women from research and development could easily be the reason for this anomaly. Id.

293. Men’s brains synthesize 52% more serotonin than women’s and appear to respond better to “antidepressant drugs that affect both the norepinephrine and serotonin systems . . . while women respond better to drugs that affect the serotonin system alone.” Claudia Morain, Depression: There’s Something About Mary’s Brain, WebMD, at http://aolsvc.health.webmd.aol.com/content/article/1663.51922 (last visited on Sept. 24, 2002). “[W]omen who take birth control pills may need higher doses of tricyclic antidepressants, and . . . antidepressants in general may take longer to work in women than in men.” Id. “Antidepressants tested only on male subjects can cause hostility and violence in women.” Life or Death Issue, supra note 35, at 49. Another example of gender disparity in response to drug therapy comes from Wellbutrin, an antidepressant that caused alarmingly high seizure rates in women. The pharmaceutical company failed to perform gender analysis before releasing the drug. LAURENCE & WEINHOUSE, supra note 1, at 274-75.

294. Life or Death Issue, supra note 35, at 49-50; Extrapolation From Men, supra
use of anti-depressants has also been challenged because men are less likely to be prescribed anti-depressants when presenting with the same symptoms as a woman.\textsuperscript{295} Treatment disparities are likely to continue in the mental health field until medical research provides gender-specific drugs in this area of medicine.\textsuperscript{296} Some critics of this field of practice will not likely be pacified until the DSM-IV guidelines are reevaluated to remove the perceived taint of gender bias.\textsuperscript{297}

Gender bias has influenced medical practice. Research deficiencies are clearly reflected in the day-to-day practice of medicine. Furthermore, some areas of practice are more tainted than others, such as the treatment of AIDS, heart, lung, and kidney disease, and the mental health field. However, positive steps have been taken by the medical profession as well as the research industry. These steps should indicate a brighter future for the elimination of inappropriate treatment disparities based on gender.

\textit{C. The Future}

Positive steps attempting eradication of inappropriate gender bias have begun by both the research industry and the medical profession. The NIH’s mandate and the FDA’s “expectation” that women be included in research studies and appropriate gender analysis performed are significant developments in women’s health. Both policies can be criticized. The FDA’s “expectation” is clearly deficient. Further, both policies retain a degree of protectionism because the blanket exclusion of all pregnant women even from research studies that have some significant therapeutic benefit to a woman participant or from research that poses no unforeseeable or unknowable risk of in vivo injuries violates firmly entrenched principles of personal autonomy. Yet, the inclusion of women in research and gender analysis of results is an

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\textsuperscript{295} Laurence & Weinhouse, supra note 1, at 276; Gender Matters, supra note 4, at n.99.
\textsuperscript{296} Id. at 256-74. “One positive move in the DSM-IV would be to drop the facade of value neutrality.” Women, Madness & Medicine, supra note 41, at 35. When the Board of Trustees of the Psychiatric Association voted to include PMDD in Appendix B of the DSM-IV, an official of the National Organization of Women stated. “When a woman feels angry, the response of the medical establishment has always been to say there’s something wrong with her, that she has a psychiatric problem.” Laurence & Weinhouse, supra note 1, at 274.
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absolute prerequisite for appropriate treatment of both genders by physicians and both the NIH and the FDA are, at least, pressuring for the inclusion of women in research populations. However, research takes time and the progress is not as rapid as most would prefer. Medical science is just now beginning to understand the depth of the gender gap and research results are just now trickling into doctors’ offices and impacting physicians’ treatment protocols and their prescription pads.

Federal intervention, the NIH mandate and the FDA “expectation,” was required to jolt the research industry to commence narrowing the gender gap. The medical profession responded to gender bias voluntarily. The medical profession believed that appropriate gender-specific research, the inclusion of more women in medicine including positions of power, and heightened sensitivity of its members would eventually eliminate gender bias. The Council on Ethical and Judicial Affairs of the AMA made the following recommendations in 1991:

Physicians should examine their practices and attitudes for the influence of social or cultural biases that could affect medical care. Physicians must ensure that gender is not used inappropriately as a consideration in clinical decision-making. Assessments of need based on presumptions about the relative worth of certain social roles must be avoided. Procedures and techniques that preclude or minimize the possibility of gender bias should be developed and implemented. A gender-neutral determination for kidney transplant eligibility should be used.

More medical research on women’s health and women’s health problems should be pursued. Results of medical testing done solely on men should not be generalized to women without evidence that results can be applied safely and effectively to both sexes. Research on health problems that affect both sexes should include male and female subjects. Sound medical and scientific reasons should be required for excluding women from medical tests and studies such as that the proposed research does not or would not affect the health of women. An obvious example would be research on prostatic cancer. Also, further research into the possible causes of gender disparities should be conducted. The extent to which physician-patient interactions may be influenced by cultural and social conceptions of gender should be ascertained.
Finally, awareness of and responsiveness to sociocultural factors that could lead to gender disparities may be enhanced by increasing the number of female physicians in leadership roles and other positions of authority in teaching, research, and the practice of medicine.298

The AMA should be praised for the strong recommendations contained within the Council Report. The Council Report clearly supports inclusion of women in medical research and predates both the NIH’s mandate and FDA’s “expectation.” Unfortunately, the clear mandate to avoid treatment based on pre-conceived gender stereotypes and to examine physician-patient interactions influenced by social conceptions of gender cannot immediately modify individual physician behavior. Hopefully, sufficient AMA members are willing to heed the admonition and positively respond that there will be meaningful change in communication and treatment. Perhaps evidencing increased enlightenment is elevated awareness of the treatment of victims of domestic violence.299

The Council Report also encourages the entry of more women into the medical profession in general and in leadership roles in particular.

298. Gender Disparities in Clinical Decisions, supra note 45, at 562 (emphasis added). See also Confronting Bias, supra note 116, at 14; Less Than Equal Treatment, supra note 231, at 21.

299. Forty percent of all injury-related hospital admissions for women is the result of battering, which is more than the combined admissions from car accidents, muggings and rape. The victim was referred to a shelter in only twenty-three out of 1,600 cases studied. THE HIDDEN MALPRACTICE, supra note 157, at 90-91. The AMA and the American College of Obstetricians and Gynecologists now recommend to the medical profession to “consider domestic violence as a medical as well as a social issue, and to recognize and treat signs of abuse.” LAURENCE & WEINHOUSE, supra note 1, at xiv. Increased enlightenment is illustrated by the program for battered women at Parkland Medical Center in Dallas, Texas.

Parkland is one of the first hospitals in the United States to have an on-site center that provides women living in violent situations with support and resources. The center pairs each woman with a social worker who helps her to negotiate the legal system, document the abuse through eyewitness testimony and photographs, develop safety plans for those who decide to leave their relationships, provide emergency shelter, and help get protective orders against abusers. The center also trains staff at other hospitals to implement their own domestic violence programs. Michele Bloomquist, Violence at Home, WebMD, at http://aolsvc.health.webmd.aol.com/content/article/1689.50377 (last visited on Sept. 24, 2002).
Forty percent of current medical school classes are now women.\textsuperscript{300} Expansion of some medical-school curriculums to include a women’s health course in addition to the standard rotation in obstetrics and gynecology is concurrently educating future physicians toward gender-specific treatment and symbolically recognizing the gender gap. Some have suggested that medical schools should go further in curricular reform and have two models of education—one would educate doctors for the provision of treatment for women and another for men.\textsuperscript{301} Certainly, a proper inference from the Council Report is that medical education needs to alter instruction based on the “male-centered model of health care.”\textsuperscript{302} “When medical schools teach both the male and female model for health care, women’s health issues will no longer be an oddity, and physicians will seriously consider women’s health concerns.”\textsuperscript{303}

However, the glass ceiling is clearly present in the medical profession. Women are unlikely to gain entrance to the top reaches of the medical establishment, practice in the more lucrative specialties,\textsuperscript{304} or become research scientists.\textsuperscript{305} Hopefully, the Council Report’s mandate to increase the number of women physicians in leadership roles and positions of authority in teaching and research will help shatter the glass ceiling. The entrance of more women into the medical profession including positions of power will not in and of itself close the gender gap. Many women emerge from medical school “indistinguishable from their male counterparts,” fully indoctrinated into the male-centered ideology of that profession.\textsuperscript{306} “It is a mistake, therefore, to assume that women physicians are the answer to the inadequacies of the medical system.”\textsuperscript{307}

\textsuperscript{300} Camille Rey, \textit{The State of Women’s Health}, WebMD, at http://aolsvc.health.webmd.aol.com/content/article/1689.50122 (last visited on Sept. 24, 2002).
\textsuperscript{301} \textit{Life or Death Issue, supra} note 35, at 63.
\textsuperscript{302} \textit{Id.}
\textsuperscript{303} \textit{Id.} at 64.
\textsuperscript{304} \textit{Beyond Power, supra} note 68, at 367.
\textsuperscript{305} \textit{Invisible Woman, supra} note 12, at 127. “Of sixty thousand female physicians surveyed, less than five percent were engaged primarily in research. . . . [D]iscrimination and harassment discourage women from pursuing careers in all branches of science.” \textit{Id.} at 125.
\textsuperscript{306} \textit{Ourselves for the New Century, supra} note 65, at 701.
\textsuperscript{307} \textit{Id.} One criticism of the inroads that have made to increase the number of women physicians (currently approximately 18% of all doctors are women) is that the gains have mainly benefited upper-class white women who already reflect the patriarchal value system. \textit{Id.} at 700.
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Society has not yet reached perfection. However, the AMA's mandate to alter physician behavior to avoid gender disparities in clinical decision-making, physician-patient interactions, and increase the number of women in medicine including leadership roles combined with the efforts of women's health supporters and with the increased research efforts dictated by the NIH and encouraged by the FDA point to a possible future with a significant narrowing of the gender gap. Another possible future is simply perpetuating the status quo. Enter managed care.

IV. THE MANAGED CARE SYSTEM

The American health care system has evolved into one of managed care. Today, most health insurance policies contain some managed care components and few pure indemnity plans remain.\[308\] Traditionally,

[S]ome women do make it to positions of power. What about Margaret Thatcher, Queen Elizabeth I, Catherine the Great, Indira Gandhi, and Golda Meir? Does not their power contradict the idea that patriarchy is male-dominated? ... Indeed, part of what makes these women standout as so exceptional is their ability to embody values culturally defined as masculine: they've been tougher, more decisive, more aggressive, more calculating, and more emotionally controlled than most men around them. These women's power, however, has nothing to do with whether women in general are subordinated under patriarchy. It also does not mean that putting more women in positions of authority will by itself do much for women unless we also change the patriarchal character of the systems in which they operate. ...

Patriarchy, supra note 69, at 131-32.

medical services were provided on a fee-for-service basis, meaning that the physician received remuneration for any services provided.\textsuperscript{309} The patient would seek professional care and after its rendition, the physician would then seek payment or indemnity from the patient's insurance company for any medical care provided.\textsuperscript{310} However, the fee-for-service system was criticized because it created financial incentives for physicians to over-treat patients because physicians made more money the more treatments physicians provided to patients.\textsuperscript{311} A financial incentive exists to provide unnecessary tests, procedures, treatments, and hospital admissions, "even when the benefits of the care may not be great enough to justify its cost."\textsuperscript{312}

The quest for alternatives to the traditional fee-for-service approach was spurred by the rising cost of medicine.\textsuperscript{313} Managed care evolved to curb the costs of medicine by injecting a system of checks and balances over the practice of medicine.\textsuperscript{314} Managed care organizations (MCOs) utilize various techniques to avoid unnecessary medical costs. One

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\item[309. Maxwell J. Mehlman, Introduction, Symposium, Physician Decision Making and Managed Care, 6 HEALTH MATRIX 5 (1996).]
\item[310. Exit & Voice, supra note 65, at 1043.]
\item[312. Id. at 158. "[E]very major study indicates that physicians who make referrals to medical facilities that they either own or have a financial interest in, recommend more (or more expensive) medical tests and procedures than do physicians without a financial interest . . . . [M]any physicians perform unnecessary medical services that can harm patients." Marc A. Rodwin, MEDICINE, MONEY & MORALS: PHYSICIANS' CONFLICTS OF INTEREST 215 (1993) [hereinafter MONEY & MORALS].]
\item[Physicians] have entered into joint ventures with diagnostic imaging centers, clinical laboratories, medical equipment suppliers, free-standing surgical centers, nursing homes, pharmacies and other providers of ancillary services. Physician investment is widespread and increasing. Physicians have a financial stake in 25 to 80% of ancillary medical facilities, depending on the region and the kind of facility. And there is compelling evidence that when physicians have a financial interest in ordering services, they recommend them more frequently.]
\item[Id. at 17.]
\item[313. Tort Liability and ERISA Preemption, supra note 9, at 859.]
\item[314. Id.]
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technique is the provision of a list of preferred providers (PPO).\textsuperscript{315} A patient enrolled in this type of health insurance plan is required to use physicians from the list of preferred providers or the plan will not cover provided treatment or will reimburse for the treatment at a lower rate. The patient may see any physician from the list.\textsuperscript{316} Preferred providers are physicians who have agreed to the contractual terms of the MCO which typically means that they agree to certain fee-reducing formulas (adjusted payments)\textsuperscript{317} when treating patients enrolled within the plan. The MCO will pay the reduced amount utilizing a fee-for-service approach.\textsuperscript{318} Some plans require pre-certification for any expensive tests, surgery, or hospital admission as a prerequisite for payment.\textsuperscript{319} The more onerous forms of managed care are Health Maintenance Organizations (HMO).\textsuperscript{320}


\textsuperscript{316} Ourselves for the New Century, supra note 65, at 693.


\textsuperscript{318} Ourselves for the New Century, supra note 65, at 693.

\textsuperscript{319} Exit & Voice, supra note 65, at 1043 n.7 (citing Controlling Costs and Changing Patient Care: The Role of Utilization Management (Bradford H. Gray & Marilyn J. Fields eds., 1989)) ("providing an historical account and descriptive overview of utilization review programs").

\textsuperscript{320} Descriptions of HMOs are usually divided into four basic models: staff, group, network, and IPA. The Staff-Model owns its own medical facility and employs physicians with physicians receiving salaries directly from the HMO. A Group HMO contracts with a group of physicians, treatment is at an HMO facility, physicians are compensated by capitation but may see patients other than those enrolled in the HMO, and patients usually have limited choice regarding physicians. Network HMOs are similar to Group HMOs but the HMO contracts with many groups of physicians and care is provided at the office of the physician. Although the physician is compensated through capitation, the physician might contract with other HMOs and usually treats fee-for-service patients as well and is merely adding pre-paid components to their practice. The IPA-Model (Independent Practice Association) HMO is the most prevalent form. The HMO contracts with the IPA and the IPA contracts with doctors to provide care for enrollees at the physician's office. Tort Liability and ERISA Preemption, supra note 9, at 864-66. The IPA receives the capitated payment and then pays the physician on a fee-for-service basis. Typically, the IPA withholds a percentage of each payment and "[t]he amount withheld may equal twenty to thirty percent of the potential fee, which the physician can recover only by achieving preset cost-containment goals." Jim M. Perdue & Stephen R. Baxley, Cutting Costs—Cutting Care: Can Texas Managed Health Care
Concerns over the rising costs of medicine and the provision of medical services to larger segments of the population\textsuperscript{321} led to federal endorsement of HMOs to spur their growth.\textsuperscript{322} As a result, most states enacted HMO enabling acts.\textsuperscript{323} Various cost-containment techniques and incentives are employed by HMOs to reduce the cost of the delivery of medical care.\textsuperscript{324} One distinguishing attribute of most HMOs is the provision of comprehensive health care services for a fixed prepaid fee, called a capitated payment.\textsuperscript{325}

An HMO is defined as an alternative system of health care delivery, whereby health care providers . . . enter into contracts with or are employed by a health care entity to provide comprehensive health care to voluntarily enrolled patients. The most distinguishing characteristic of membership in an HMO is that an enrolled patient pays a prepaid, fixed fee for medical services. . . . The patient pays a one-time charge for subsequent

\textit{Systems and HMOs Be Liable for the Medical Malpractice of Physicians?}, 27 St. Mary's L.J. 23, 28 (1995) [hereinafter \textit{Cutting Costs -- Cutting Care}]. "Managed-care plans, particularly HMOs, have complex systems for selecting, paying, and monitoring their physicians. Hybrid forms are common, and the differences between group or staff HMOs and network or IPA HMOs are less extensive than is commonly assumed." Gold, supra note 317, at 1678. "[M]any of the differences between specific HMOs cannot be explained by their classification as group or staff HMOs or as network or IPA HMOs." \textit{Id.} at 1682.


322. Sarnacki, supra note 308, at 120.

323. HEALTH LAW, supra note 10, at § 8-1.


325. Jack R. Bierig, \textit{Physician-Sponsored Managed Care Networks: Two Suggestions for Antitrust Reform}, 6 Health Matrix 115, 115 (1996); Greely, supra note 324, at 57. Capitated payments and incentive pools can be very lucrative for physicians as well as the HMO. For example, in Jones v. Chicago HMO Ltd. of Illinois, 191 Ill. 2d 278, 246 Ill. Dec. 654, 730 N.E. 2d 1159 (Ill. 2000), the physician, Dr. Jordan, was paid $34.19 per month per patient whether he treated the patient or not. The HMO also had an incentive fund that reserved funds for specialized care, diagnostic tests or hospitalizations. Dr. Jordan received 60% of the unused balance of the incentive fund at the end of the year. Dr. Jordan treated 4,527 patients enrolled with the HMO. Therefore, Dr. Jordan received a total of $154,778.13 per month, or $1,857,337.50 per year, in capitated payments. The case does not reveal how much Dr. Jordan received at the end of the year from the incentive fund.
complete health care services. The prepaid fee is paid without regard to the actual amount of services provided to the enrolled patients.326

However, the form of compensation for physicians may vary. In some HMOs, physicians are salaried employees.327 In other forms, the physician is paid a fixed pre-set fee to treat the patient and the physician is paid the same whether the physician treats the patient multiple times, or not at all, during the payment period.328

Other distinguishing characteristics include the use of a primary care provider, prospective utilization review, and physician risk-sharing.329 In some forms of HMOs, the patients selects their primary care provider from a list of available physician members; some lists can be quite small. In other forms, the primary care provider is assigned to the patient. Primary care providers are referred to as “gatekeepers” because they control access to any specialized care. The patient must see the primary care physician first and the gatekeeper decides whether to refer the patient to a specialist. In some systems, the patient has no control over the selection of the specialist.330 Certainly, HMOs restrict patient choice of physicians and access to specialized care.

327. For a description of staff-model HMOs, see supra note 320.

There is one important difference between salary and capitation with regard to a physician’s personal incentives. With capitation, physicians have an incentive to increase the number of patients for whom they have responsibility while, with salary, physicians have an incentive to reduce the number of patients for whom they have responsibility. Accordingly, salaried physicians are often assigned a certain number of patients for whom they are expected to provide care. Orentlicher, supra note 311, at 159.

329. Gold, supra note 317, at 1678-82.
HMOs use prospective utilization review,\textsuperscript{331} which is a more extreme form of pre-certification.\textsuperscript{332} The traditional fee-for-service system used retrospective utilization review meaning the physician or hospital provided services to the patient and the plan was subsequently billed. The plan then reviewed the charges and either paid the bill minus any copayment and deductibles or coverage would be denied if the services were not covered by the plan.\textsuperscript{333} The key to retrospective review was that the patient still received the medical treatment; any dispute concerned who would pay for the resulting medical bill. Under prospective utilization review, a plan administrator reviews services prior to the rendition of the medical care and either grants or denies coverage.\textsuperscript{334} A negative decision by the plan administrator results in no treatment provided to the patient.\textsuperscript{335} The danger posed by prospective utilization

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\item \textsuperscript{331} Virtually all HMOs use some type of prospective utilization review; written quality assurance plans were present in 95\% of plans, and 75\% used formal practice guidelines. Gold, \textit{supra} note 317, at 1681. Utilization review examines health care services "to ensure that the services provided are both necessary and cost-efficient." Cheryalyn E. Schessler, \textit{Liability Implications for Utilization Review as a Cost Containment Mechanism}, 8 J. CONTEMP. HEALTH L. & POL'Y 379, 380 (1992). The utilization review may be conducted by an outside utilization-review corporation, or a physician employed by the HMO or a non-physician employee of the HMO. \textit{Id.} at 390. See also Thomas M. Wickizer, \textit{The Effects of Utilization Review on Hospital Use and Expenditures: A Covariance Analysis}, 27 HEALTH SERVICES RES. 103 (1992).
\item \textsuperscript{332} Orentlicher, \textit{supra} note 311, at 182-83. "Utilization review is essentially a type of cost containment in which rationing decisions are made by persons other than physicians." \textit{Id.} at 183.
\item \textsuperscript{333} \textit{Exit & Voice, supra} note 65, at 1043.
\item \textsuperscript{334} See \textit{supra} note 331. Utilization review is a cost-containment measure. However, there has yet to be any proven reduction in the cost of medical care from the use of prospective utilization review. Studies of Medicare found that there was reduction in hospital use but no net savings from the use of utilization review. Private health insurers have shown one-time savings resulting from utilization review without reduction of the rate of growth of the overall cost of health care. Orentlicher, \textit{supra} note 311, at 183. A study from the New England Journal of Medicine indicated that utilization review reduces hospital admission by 12.3\%, hospital inpatient days by 8\%, and overall hospital costs by 11.9\%. At the same time, utilization review increases "outpatient costs as it reduces inpatient costs." One study revealed that the total reduction of cost was 8.3\%; however, utilization review is "most effective in the short run and has less effect on long-term cost increases." Furrow et al., \textit{Cases & Materials, supra} note 308, at 592 (citing \textit{Institute of Medicine, Controlling Costs and Changing Patient Care: The Role of Utilization Management} (1989)); Paul Feldstein, \textit{et al.}, \textit{Private Cost Containment}, 318 NEW ENG. J. MED. 1310 (1988).
\item \textsuperscript{335} On utilization review, see generally Thomas Bodenheimer, \textit{The HMO Backlash—Righteous or Reactionary?}, 355 NEW ENG. J. MED. 1601 (1996); Robert J. Conrad, Jr. & Patrick D. Seiter, \textit{Health Plan Liability in the Age of Managed Care}, 62 DEF. COUNS. J.
review is that a "mistaken conclusion about medical necessity following retrospective review will result in the wrongful withholding of payment. An erroneous decision in a prospective review process, on the other hand, in practical consequences, results in the withholding of necessary care, potentially leading to a patient's permanent disability or death." All forms of HMOs use some form of prospective utilization review. Another cost-saving maneuver is physician risk-sharing. Physician risk-sharing utilizes what is referred to by the various names of hospital, ancillary, referral, or shared-risk pools, whereby participating physicians share in the profits enjoyed by the HMO or share in the risk of a negative balance sheet. Risk-sharing by physicians institutionalizes direct financial incentives for physicians to withhold expensive care. In most HMOs, the insured pays the premium, and the HMO dispenses the capitated payments to physicians and retains a portion of the premium in the ancillary, referral, hospitalization, or shared-risk pool. This separate fund is intended to cover the cost of specialist referrals, diagnostic tests, hospitalizations, and surgical procedures. Any unused funds at the end of the premium period are divided between the HMO corporate entity and the participating physicians on a previously established ratio. Thus, the less the primary care physician refers patients to specialists, orders expensive tests, orders surgical procedures, or admits patients to the hospital, the more the physician will make. The arguable conflict of interest under a fee-for-service plan is that the physician makes more money as the physician provides more services to the patient. The conflict of interest within an HMO is that the


337. Gold, supra note 317, at 1681.
338. Tort Liability and ERISA Preemption, supra note 9, at 891.
339. The amount withheld may be 20 to 30% of the capitated payments. Cutting Costs—Cutting Care, supra note 320, at 28.
342. Greely, supra note 324, at 56.
physician makes more money as the physician provides fewer services to the patient.\textsuperscript{343}

Furthermore, physicians under their contractual arrangement with the HMO are required to meet certain cost-containment goals.\textsuperscript{344} The physician's status as an approved provider of health care under the plan can be jeopardized by failure to meet the cost-containment goals. This failure can occur by the physician ordering too many hospital admissions or by referring patients too often to specialists or for diagnostic tests or procedures.\textsuperscript{345} If the plan removes the physician as a plan provider, the physician can lose his base of patients. Treatment provided will not be covered by the plan and patients are forced to seek treatment elsewhere from other plan doctors. Doctors confront devastating financial consequences if they are terminated as a plan provider because they have substantially fewer paying customers.\textsuperscript{346} Therefore, HMOs not only utilize direct financial incentives to mold physician behavior to cut costs, they also employ a financial disincentive with the promise of termination if physicians do not follow the basic premise of the plan.\textsuperscript{347}


\textsuperscript{344} Greely, supra note 324, at 58-59.

\textsuperscript{345} “The more the physician fights for the patient to receive appropriate treatment, the less the physician might be paid, and the more the physician might be threatened with the removal of his or her name from the list of approved physicians.” Tort Liability and ERISA Preemption, supra note 9, at 889. “Quite frequently MCOs shift financial risk for medical decisions to doctors.” Marc A. Rodwin, Consumer Protection and Managed Care: Issues, Reform Proposals, and Trade-Offs, 32 HOUS. L. REV. 1319, 1379 (1996).


\textsuperscript{347} Aynah V. Askanas, Physician Terminations in Managed Care: Why Are They
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Empirical data reported in the New England Journal of Medicine supports the proposition that financial incentives and cost-containment mechanisms do influence the behavior of physicians and compromise care received by patients. Physicians participating in managed care were surveyed by the prestigious journal. “Fifty-seven percent of the physicians reported that they felt pressure from the managed care organization to limit referrals (17 percent said they believed such pressure compromised patient care), and 75 percent felt pressure to see more patients per day (24 percent believed such pressure compromised patient care).” Furthermore, 30% of the primary care physicians, the gatekeepers, and 50% of the specialists responding believed that the scope of the services provided by primary care physicians had increased. Both groups, including one out of four primary care providers, believed that the care expected to be provided by the primary care provider was greater than it should be in managed care systems.

The Association of American Physicians and Surgeons conducted a survey to ascertain the impact of managed care on physician behavior and their practice. Seventy percent of responding physicians reported that they feared de-selection under their managed care contract; 62.7% did not believe managed care decreased the cost per patient of providing services; 65% did not believe their medical judgment was respected by managed care officials; 60.7% did not believe their plan administrators were knowledgeable and well-qualified; and 62.7% believed the overall quality of medical care was deteriorating. The survey of primary care providers revealed the following: 54.6% did not feel they provided better preventative care to managed care patients compared with fee-for-service.

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350. Id.
351. Id.
352. Robert F. St. Peter, Changes in the Scope of Care Provided by Primary Care Physicians, 341 NEW ENG. J. MED. 1980 (1999). Interviews were conducted with 12,385 physicians including 7015 primary care providers and 5092 specialists. Id.
353. Association to American Physicians and Surgeons, Inc., Results of 1997 Arizona Managed Care Survey, at http://www.aapsonline.org/surveys/survey.htm (last visited on November 3, 2002). Eighty-two percent of physicians surveyed stated that managed care had reduced the efficiency of their office. Eighty-eight percent stated that their patients did not have a good understanding of their managed care contract. Id.
patients; 40.8% stated that financial incentives impacted their decisions to recommend referrals or order diagnostic tests; 36.9% felt uncomfortable with some of the procedures they were required to perform; and 53.8% believed that time spent per patient was either marginal or severely limited.\footnote{354}

Specialists were surveyed as well and 70% stated that following the progress of their patients was harder under managed care as compared with fee-for-service.\footnote{355} Thirty-three percent of specialists revealed that financial incentives did impact their treatment decisions; 70.4% believed that needed procedures were sometimes or often denied under managed care; 60.2% believed that diagnostic tests were somewhat limited; and 84.9% opined that referrals were sometimes unreasonably delayed by managed care.\footnote{356}

Proponents of managed care contend that there is little incentive provided for physicians to weigh the “cost versus the benefit of the wide range of health services available” under fee-for-service plans.\footnote{357} Many medical risks are very remote, might not cause appreciable harm, or might not be treatable.\footnote{358} Further, any treatment may expose the patient to additional risks. In contrast, HMOs must provide comprehensive care from the limited funds provided by capitation payments and are “motivated to scrutinize the effectiveness of every risk-reducing measure they take,” “weigh the medical effectiveness and value of their expenditures and . . . curb . . . superfluous . . . tests.”\footnote{359} HMOs avoid depletion of the fixed budget by concentrating on preventative medicine,\footnote{360} which attempts to treat illness before it becomes acute.\footnote{361}

\footnote{354} Id.
\footnote{355} Id.
\footnote{356} Id.
\footnote{357} Randall Bovbjerg, \textit{The Medical Malpractice Standard of Care: HMOs and Customary Practice}, 1975 \textit{Duke L.J.} 1375, 1376 [hereinafter \textit{HMOs and Customary Practice}].
\footnote{358} Id.
\footnote{359} Id.
\footnote{360} Id. at 1379.
\footnote{361} Patients enrolled in managed care do receive more preventative treatment than under a traditional fee-for-service approach. Furthermore, some studies have shown that patients receive the same quality of overall care with HMOs. Maxwell J. Mehlman, \textit{Medical Advocates: A Call for a New Profession}, 1 \textit{Widener L. Symp. J.} 299, 301 (1996) [hereinafter \textit{Medical Advocates}]. \textit{See also} Philip R. Alper, \textit{Learning to Accentuate the Positive in Managed Care}, 336 \textit{New Eng. J. Med.} 508 (1997) [hereinafter \textit{Accentuate the Positive}].
\footnote{362} \textit{HMOs and Customary Practice}, supra note 357, at 1379.
with the ultimate goal of better care for lower costs. Critics of HMOs point to the capitation and ancillary-risk-pool systems and contend that both provide incentives not to treat patients and not to refer patients to specialists, order expensive tests, procedures, or hospital admissions. The physician, therefore, is given financial incentives not to do his or her best and is no longer the advocate of the patient, but may become the patient’s adversary. . . . [W]hen financial

363. Health Maintenance Organizations do cost less. Generally, younger people elect enrollment with HMOs when offered a choice of plans through their employment. Therefore, statistics compiled thus far showing fewer visits to the hospital and doctor are based on the provision of health care to generally healthier groups of people. Medical Advocates, supra note 361, at 301 n.7. Furthermore, HMOs have been accused of “cherry picking,” meaning they solicit healthier patient groups to avoid costlier care. “Cherry picking by Medicare HMOs is now well documented.” Steffie Woolhandler, Managed Care and Women’s Health, 52 JAMWA 50 (1997). “Excellence at prevention is trumpeted to woo healthy (and profitable) enrollees. But the good care that many HMO physicians offer for acquired immune deficiency syndrome, depression, cancer or victims of domestic violence is best kept quiet lest it attract too many of those (expensive) patients.” Id. at 50. Physicians who attract more expensive patients “risk being redlined.” Id. Medicare enrollees with HMOs were 15 to 30% less likely to have health histories of stroke, cancer, or heart disease. Furthermore, “more than a quarter of sick HMO disenrollees say they were urged to leave.” Id. at 50. It is feared that monetary pressures might force HMOs to withhold proven treatments to save money. “[T]he incentive to provide preventive services disappears once prevention has failed and the enrollee becomes ill. Even if managed care providers are willing to make short-term expenditures to reduce long-term costs, they still have an incentive to withhold services from enrollees who become chronically or seriously ill and require extensive, costly care.” Id. at 302. There is considerable support for the proposition that the considerable growth of managed care in the 1990s was responsible, at least in part, for the dramatically slower rate of health care cost increases during the mid-1990s. There is also evidence that greater numbers of HMOs cause “moderation of cost growth through the entire market.” Others contend that there is less evidence of the assumed causal relationship between the expansion of managed care and reduced increases in the rate of health care cost in the 1990s. Furthermore, administrative costs are higher in managed care than fee-for-service plans. However, the rate of increase of the cost of health care has so far been slower in the 2000s compared with figures from the previous decade. Furrow et al., Cases & Materials, supra note 308, at 502.

364. Tort Liability and ERISA Preemption, supra note 9, at 860. Enrollees of managed care are admitted to the hospital 40% less, use 40% fewer hospital days, and pay 10-40% less for coverage than patients using a fee-for-service plan. Health Law, supra note 10, at § 8-1.

365. Tort Liability and ERISA Preemption, supra note 9, at 861.
incentives are provided to physicians to limit costs, the interests of patients and physicians become diametrically opposed. The more the physician attempts to help the patient, the less the physician is compensated.\textsuperscript{366}

The primary purpose of performance-based incentives and cost-containment mechanisms is to reduce the cost of medical care.\textsuperscript{367}

The secondary effect of these financial incentives and mechanisms is that they may create disincentives for physicians to refer patients to specialists, to order hospitalizations, or to order diagnostic tests. The question [is] whether the financial incentives contained within the HMO structure cause[s] negligent medical care or inappropriate denial of services.\textsuperscript{368}

Although studies generally show that HMO enrollees receive the same or better quality of care compared with other patients,\textsuperscript{369} there are several reasons why patients might receive substandard care. First, physicians have an “incentive to make frugal use of diagnostic tests, referrals, and hospitalization. Physician risk-sharing can bias physician judgment and lead doctors to deny appropriate services.”\textsuperscript{370} Medical ethics demand that the best interest of the patient is the first consideration of medical practice, even when the patient’s welfare conflicts with the doctor’s own financial interests.\textsuperscript{371} “However strong or weak the past

\textsuperscript{366} Shared Risk Pools, supra note 341, at 9, 11. See also Medical Advocates, supra note 361, at 303, 314, 315, 320; Orentlicher, supra note 311, at 155.

\textsuperscript{367} Tort Liability and ERISA Preemption, supra note 9, at 862. Some contend that managed care had no impact on the cost of medicine in the 1980s and 1990s. Id. However, others contend that managed care has reduced the rate of increase in health care costs. Id. at n.30, (citing David F. Drake, Managed Care: A Product of Market Dynamics, 277 JAMA 560 (1997)).


\textsuperscript{369} Fred J. Hellinger, The Effect of Managed Care on Quality: A Review of Recent Evidence, 158 Archives of Internal Med. 833 (1998); Accentuate the Positive, supra note 361, at 508; Medical Advocates, supra note 361, at 301.

\textsuperscript{370} Marc A. Rodwin, Managed Care and Consumer Protection: What Are the Issues?, 26 Seton Hall L. Rev. 1007, 1011-14 (1996) [hereinafter What Are the Issues?]

\textsuperscript{371} Money & Morals, supra note 312, at 8.
fidelity of physicians to patients, patients confront greater risks from conflicts of interest in their doctors today. Historically, physicians practiced mainly on their own. Today, physicians are economically tied to MCOs and HMOs linking “the physician’s financial well-being to that of these groups.” Performance-based incentives and cost-containment mechanisms have “reduced the independence and autonomy of doctors” and, at times, have placed the best interest of the patient on a collision course with the financial interest of the physician. Obviously, “[c]onflicts of interest can cloud physicians’ judgment and affect their assessment of whether a medical service is needed.” Physicians might not consciously refrain from recommending treatment due to cost-containment and financial incentives. Rather, a physician might “internalize the need to consider cost in treatment decisions; in other words, they will still make treatment decisions based on medical necessity, but couched within the definition of medical necessity is a consideration of how much the treatment may personally cost the physician.”

Secondly, HMOs are “complex organizations” and are “vulnerable to organizational pathologies. . . . [L]arge organizations can impede change, become unresponsive, and limit the appropriate use of discretion by professionals. They can diffuse authority and diminish personal responsibility, thereby reducing accountability.” Next, HMOs “restrict choice: an escape valve for consumers if doctors or MCOs perform poorly.”

372. Id. at 6.
373. Id. at 17.
374. Id.
375. Id. at 215.
378. Id. “The consumer is sovereign only at the point of choosing between managed care plans. Once enrolled, choices that consumers traditionally would make are mediated by the organization and subject to its approval. For instance, consumers usually must get a referral from a primary care physician to see a specialist, and primary care physicians have financial incentives to limit such referrals. Furthermore, consumers frequently must obtain approval from the organization to receive many specialty services and non-emergency procedures.” Marc A. Rodwin, Consumer Protection and Managed Care: Issues, Reform Proposals, and Trade-Offs, 32 HOUS. L. REV. 1319, 1330-31 (1996).
Lastly, HMOs’ restriction of access to specialists might be founded upon an erroneous premise that specialized care is more expensive and that specialists order unnecessary tests.

However, the lack of referral to specialists might cause several results: increased medical costs due to improper diagnosis and delayed treatment, additional visits to the primary care provider, potentially inappropriate treatment and improper diagnosis at the hands of the “gatekeeper,” danger to the patient’s health and increased costs due to delayed treatment, and additionally, more expensive medications and tests when specialized treatment is finally received.\(^{379}\)

All of these factors combine to create legitimate concerns that consumers\(^{380}\) will not receive the quality of care required under managed care.

Managed care plans set minimum standards, or floors, for purposes of health care delivery and to comply with legal standards. Since managed care sets up economic incentives (motivations) to do less rather than more, or to keep as close to the minimum standards as possible, the goal of managed care organizations (MCOs) seems more to achieve adequacy and not necessarily quality in the delivery of health care services. Managed care, particularly capitation, is perverse to quality when health care providers are motivated to provide minimal

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379. *Tort Liability and ERISA Preemption*, supra note 9, at 863, (citing *Shared Risks Pools*, supra note 341, at 11). For example, one study compared the ability of primary care physicians to diagnose skin conditions frequently encountered by dermatologists. Primary care physicians diagnosed the condition in only 54% of the cases; dermatologists, in over 90% of the cases. *Shared Risk Pools*, supra note 341, at 11.

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(and thus less expensive care) or face sanctions or expulsion from the managed care organization.381

Considering the multifarious incarnations of gender bias within the medical profession, the haunting question is whether managed care, with its financial and performance incentives to reduce medical costs, will have a disproportionate impact on the care provided to women compared to their male counterparts. A legitimate fear is that managed care will perpetuate, rather than alleviate, gender bias in the practice of medicine.

V. MANAGED CARE’S IMPACT ON WOMEN

Women are the largest group of consumers of health care in America.382 Women outnumber men. Women outlive men. Women use more health services than men—they visit doctors more often, undergo more complex procedures, have more laboratory tests, take more medications, and spend more time in hospitals.”383 Any drastic change in the delivery of health care systems will, from a demographic standpoint alone, impact women more than men. Accordingly, any reduction in the quantity or quality of care received as a result of managed care plans will, by definition, impact women’s health more than men’s health.

A. Demographics

Many complex factors intertwine to explain why women consume disproportionately more health care services. The mere fact that women utilize medical services during the reproductive process is not a significant factor in the equation. Women consume more medical resources in part due to the “feminization of poverty.”384 The term feminization of poverty refers to the fact that two-thirds of the poor in

381. Health Law Section of the American Bar Association, Achieving Quality in Managed Care: The Role of Law 13 (John D. Blum, ed. 1997).
383. Invisible Woman, supra note 12, at 127.
384. The term feminization of poverty was first used in 1978 by Diana Pearce. Diana Pearce, “The Feminization of Poverty,” 2 J. For Peace and Justice Studies 1 (Spring 1990).
this country are women.\textsuperscript{385} This phenomena was partially caused by the increases in households headed by single women, which are disproportionately poorer than families with both parents.\textsuperscript{386} The feminization of poverty has also resulted in the “pauperization of children” who live in female-headed households with single mothers who lack the earning power to support themselves and their children above the poverty line.\textsuperscript{387} The “pauperization” extends to older women as well because women live longer than men.\textsuperscript{388} “At both ends of life’s spectrum, women are reduced to poverty through living costs that escalate in the absence or loss of male support. Regardless of whether their income is supplemented by transfer payments (government benefits [or child support]), the poverty persists.”\textsuperscript{389}

The feminization of poverty increases health care costs because health problems are caused by “workplace dangers, inadequate sanitation and housing, joblessness, environmental pollution, excessive stress, malnutrition, or violence.”\textsuperscript{390} Furthermore, “[p]eople with low incomes have more illnesses and die in greater numbers and earlier than people with more income and education.”\textsuperscript{391} However, poverty is only a partial answer to the question why women consume more health care resources than men.

Women outlive men by approximately seven years, but women also have greater morbidity than men, \textit{i.e.}, more generalized poor health.\textsuperscript{392}

Although women are more frequently ill, they suffer from problems that are serious but not life threatening; these conditions lead to symptoms, disability, and medical care, but not death. Men are sick less often, but their illnesses and injuries are more severe; men have higher rates of chronic diseases that are the leading causes of death.\textsuperscript{393}

In other words, women live longer sicker lives; men live shorter healthier lives. Furthermore, some diseases, such as Alzheimer’s, are more likely

\textsuperscript{385} \textsc{An Unequal Majority}, \textit{supra} note 62, at 219.
\textsuperscript{386} \textit{Id.}
\textsuperscript{387} \textit{Id.} at 220.
\textsuperscript{388} \textit{Id.}
\textsuperscript{389} \textit{Id.}
\textsuperscript{390} \textsc{Ourselves for the New Century, supra} note 65, at 683.
\textsuperscript{391} \textit{Id.}
\textsuperscript{392} \textit{Women’s Health, supra} note 131, at 1021.
\textsuperscript{393} \textit{Id.}
to affect women because they live to an older age.\textsuperscript{394} As Medicare and Medicaid systems embrace capitated-managed care systems, women will be more affected than men because women are more likely to be beneficiaries under both systems from a purely demographic standpoint.\textsuperscript{395}

B. The Potential HMO Fix for the “Feminization of Poverty”

The government provided incentives for the growth of HMOs to provide health care coverage to larger segments of the population for less money.\textsuperscript{396} If more people became insured versus uninsured, health care would improve for society as a whole particularly for the largest class of impoverished and underinsured people, women.\textsuperscript{397} Providing coverage to more people which would allow in turn more access to a broader range of health care services, particularly preventative medicine and prenatal care, would benefit women collectively even if individual treatment was not the ultimate medical science would allow.

Originally, managed care was perceived as a partial solution to the “feminization of poverty.” In addition to the provision of comprehensive and coordinated care and focusing on prevention and health promotion, premiums and out-of-pocket expenses are usually lower for coverage

\textsuperscript{394} Id. at 1028.
\textsuperscript{395} On the impact of managed care on medicare and medicaid, see generally Carol S. Jiminez, Medicare HMOs: A Consumer Perspective, 26 SETON HALL L. REV. 1195 (1996); Eleanor D. Kinney, Medicare Managed Care From the Beneficiary’s Perspective, 26 SETON HALL L. REV. 1163 (1996); Vernelia Randall, Section 1155 Medicaid Waivers: Critiquing the State Applications, 26 SETON HALL L. REV. 1069 (1996); Louis G. Trubek, The Social HMO for Low-Income Families: Consumer Protection and Community Participation, 26 SETON HALL L. REV. 1149 (1996). All expressed concern regarding the impact financial incentives and cost-containment mechanisms would have on the rendition of the quality of care to medicare and medicaid beneficiaries.
\textsuperscript{396} See supra notes 313, 314, 321, 322, and 323.
\textsuperscript{397} The number of uninsured men is greater than the number of uninsured women; 16.5% of men lack health insurance versus 14.6% of women. This difference could result from the fact that there are more women in the sixty-five or older age bracket who are on medicare and the fact that women are more likely to be on medicaid because as a class women are poorer than men. Furthermore, women are more likely to be underinsured if they have private health insurance and women must also pay a larger proportion of their income for health insurance coverage. Damon M. Seils, et al., Sex Difference in the Referral Process for Invasion Cardiac Procedures, 56 JAMWA 151, 152 (2001).
through an HMO compared with a fee-for-service plan. 398 Furthermore, Medicaid and Medicare beneficiaries under fee-for-service plans often confronted nonfinancial barriers to care, including “inadequate payment levels resulting in low physician participation, a scarcity of physicians in the impoverished communities where many Medicaid beneficiaries reside, and heavy reliance of fragmented care in hospitals that are often overcrowded and understaffed.” 399 Many hoped that Medicare and Medicaid HMOs would curb the rising costs of these programs while mitigating the nonfinancial barriers to access to health care. 400 “Though women consumers have had mixed experiences with nonprofit HMOs, research has shown health outcomes to be quite good. The financial incentives to physician-managers to skimp on care have mostly been balanced by nonprofit HMOs’ commitment to reducing costs by keeping people healthy.” 401

However, nonprofit HMOs are no longer the norm and for-profit HMOs have rapidly besieged the market. For-profit HMOs, with their cost-containment mechanisms and performance-based incentives, have the arguable propensity to “offer lower quality and fewer services to make larger profits.” 402 If the fear that cost-saving techniques will result in denial of or inadequate coverage for important services including specialized care, mental health services, and long-term care for those suffering from disabling or chronic illness is true, 403 then women as a class will suffer from the for-profit structure of HMOs more than men. “Not surprisingly, critics have dubbed these new for-profit managed care systems ‘mangled care.’ Another name could be ‘management care’ for a system that provides top management and the doctor-managers of health care corporations with optimum care and compensation, largely at the expense of women.” 404

However, managed care might still have the propensity to help women as a general class. “Managed care has the potential to offer

398. Roberta Wyn, et al., Women and Managed Care: Satisfaction with Provider Choice, Assess to Care, Plan Costs and Coverage, 52 JAMWA 60, 60 (1997).
399. Alina Salganicoff, Medicaid and Managed Care: Implications for Low-Income Women, 52 JAMWA 78, 79 (1997).
400. Id.
401. OURSELVES FOR THE NEW CENTURY, supra note 65, at 696.
402. Id. at 697.
403. Id. at 697. Concerns over the impact of managed care on the health care women would receive was raised in the 1970s as part of the Women’s Health Movement. OUR BODIES, OURSELVES, supra note 106, at 347-48.
404. OURSELVES FOR THE NEW CENTURY, supra note 65, at 697.
women what they have long desired: comprehensive, coordinated care and an emphasis on preventive services. Studies, for instance, show that women who are HMO members are more likely than women with traditional insurance to receive pap smears and mammograms. However, these are statutorily mandated in some jurisdictions. Managed care is also beginning to routinely screen women for Chlamydia infection. In the one-year period between 1999 and 2000, 72,500 more women than in the previous year were screened for Chlamydia, which if left untreated can cause pelvic inflammatory disease (PID), infertility, ectopic pregnancy, and HIV infection. The same one-year period saw a one-percent increase in breast-cancer screening, saving 130 lives, and an 8% increase in pap smears, saving 610 lives. Moreover, many of the larger managed care corporations are promoting investments they are making in women’s health.

Kaiser Permanente in northern California has a program to identify women at high risk for breast cancer and has contributed to studies on the relationship between hormone replacement therapy and breast cancer. Two of its centers are participating in the Women’s Health Initiative, the $625 million study of postmenopausal women’s health. U.S. Healthcare is taking part in studies of bone marrow transplants for advanced breast

405. Laurence & Weinhouse, supra note 1, at xiv; see also Ridgely Benjamin, Women Enrolled in Managed Care Receive More Gender-Specific Preventive Services, at Jacobs Institute of Women’s Health (June 25, 2001), at http://www.jiwh.org. One-third of all women did not receive pap smears, breast exams or mammograms, pelvic exams, or physicals in 1985. Eileen Hoffman & Karen Johnson, Women’s Health & Managed Care: Implications for the Training of Primary Care Physicians, 50 JAMWA 17 (1995) [hereinafter Primary Care Physicians]. Moreover, recent studies show that enrollees in Medicaid managed care “were just as or only slightly more likely to have received timely preventive services such as Pap smears and breast exams than those in traditional Medicaid.” Alina Saltanovich, Medicaid and Managed Care: Implications for Low-Income Women, 52 JAMWA 78, 79 (1997).

406. See infra notes 582-83.


408. Id. Another interesting figure is that more than 38,000 more children enrolled in managed care received the Varicella (chicken pox) vaccination in 2000 as compared with 1999. Id. The National Committee for Quality Assurance is a private, not-for-profit organization and is the leading accreditor of managed-care plans. John K. Iglehart, Health Policy Report, The National Committee for Quality Assurance, 335 New Eng. J. Med. 995 (1996).
cancer. A handful of plans, including Group Health Cooperative of Puget Sound and Harvard Pilgrim Health Care, are teaching their doctors how to screen women for domestic violence. And Oxford Health Plan is covering a wide range of alternative therapies, an area of special interest to women, and intends to introduce a women’s health program [in 1997].

C. The Provision of Health Care Services to Women Enrollees

The public promotion of women’s health might not be for purely altruistic reasons; MCOs and HMOs are for-profit organizations who realize women are their largest customers. Despite efforts to survey to women, women in managed care plans still report lower satisfaction with the care provided than women enrolled in other types of plans.

Assuming managed care might have the propensity to further the health needs of women generally (including better preventative services for breast and cervical cancer), fulfillment of the needs of the broader societal interest in women does not necessarily equate to the provision of better care to the majority of individual women within the plan in the treatment or diagnosis of conditions or disease. The managed care system inherited the gender bias that was prevalent within the medical profession and treatment and diagnostic decisions will likely reflect the same biases that were present under the fee-for-service system once prevention fails and a woman-enrollee becomes ill. Any ingrained

409. Laurence & Weinhouse, supra note 1, at xiv. At one time, 90% of MCOs paid for oral contraceptives compared with one-third of fee-for-service plans. However, only 39% of MCOs or HMOs covered all five types of birth control, the IUD, Norplant, Depo-Provera, and the diaphragm in addition to the pill. Id. at xv. For current developments regarding insurance coverage of oral contraceptives, see supra note 34.

410. Ridgely Benjamin, Women Enrolled in Managed Care Receive More Gender-Specific Preventive Services, Jacobs Institute of Women’s Health (June 25, 2001), available at www.jiwm.org. One category of managed care patients might feel as if they are receiving better care even before they receive any treatment.

One clear improvement in some of the managed care Medicaid programs is that they do designate a physician and hospital for the patients to have access to care. This is a clear departure from Medicaid non-managed care programs where patients are left to “shop” for a physician who will take Medicaid. By virtue of the fact that they do have an identifiable physician, patients may feel that they are more satisfied with their care, even if they haven’t yet received care.

Paul J. Schilling, Patient Satisfaction with Medicaid Managed Care, 272 JAMA 1297, 1297 (1996).
gender bias would likely become more accentuated because managed care uses cost-containment incentives and physician risk-sharing to curtail specialized services, diagnostic tests, and hospital admissions.

As previously established, gender bias is reflected in the provision of diagnostic tests in the screening for lung \(^{411}\) and heart disease and in the use of kidney transplantation \(^{412}\) and invasive procedures to treat cardiovascular disease. \(^{413}\) Much of this information was compiled while the fee-for-service system predominated. Under a fee-for-service system, physicians make money by ordering diagnostic tests and invasive procedures. The gender bias was sufficiently ingrained to overcome any personal interest in compensation. The AMA opined that the gender disparity in treatment of lung, heart, and kidney disease could not be explained by differences in the clinical presentation of women versus men patients and was most likely explained by subconscious inappropriate gender stereotyping. \(^{414}\) Under a managed care system with cost-containment incentives and physician risk-sharing, physicians make more money the less doctors order diagnostic tests and costly procedures. Inappropriate subconscious gender stereotyping would likely be more pronounced when combined with institutional pressures to save money and a subconscious or conscious desire to earn more money by the physician. In other words, women are the likely class of patients that physicians under managed care would be likely to not refer for specialized care, diagnostic, or invasive procedures because women are

411. See supra notes 47-50, 253 and accompanying text.
412. See supra notes 275-76 and accompanying text.
413. See supra notes 254-74 and accompanying text. “In cases of suspected myocardial ischemia [obstruction of blood circulation causing blood supply deficiency], some primary care physicians refer patients immediately to a cardiac specialists, and others make such referrals only when exercise test results are positive.” Damon M. Seils, et al., Sex Differences in the Referral Process for Invasive Cardiac Procedures, 56 JAMWA 151, 153 (2001). See also Julie C. Will, Reducing Risk for Cardiovascular Disease in Uninsured Women: Combined Results from Two WISEWOMAN Projects, 56 JAMWA 161 (2001). The Health Plan Employer Data and Information Set (HEDIS) is a standardized performance measure for health plans which includes twelve out of seventy process and outcome measures aimed at women’s health. The Foundation for Accountability (FACCT) provides information regarding the protocols that result in the best outcome. Mary Jane England, et al., Women and Managed Care, 52 JAMWA 81, 81 (1997). “Over time, HEDIS and FACCT, both of which have developed sex-specific protocols, will help address inequalities in diagnosis and treatment” of cardiovascular disease in women.” Id. at 82. On heart disease in women, see generally NIECA GOLDBERG, WOMEN ARE NOT SMALL MEN: LIFE-SAVING STRATEGIES FOR PREVENTING AND HEALING HEART DISEASE IN WOMEN (2002).
414. See supra note 268 and accompanying text.
already not referred for this type of care as a result of the preexisting gender bias prevalent in this area. In fact, one study “found that primary care physicians referred women to specialists less often overall than they did men.”

Diagnostic decisions based on physician-patient communication is very likely to be problematic to women-enrollees of HMOs. Women in managed care are more likely than women in fee-for-service systems to assert that their doctor does not spend sufficient time with them.

Quota systems requiring physicians to see a minimum number of patients per day are another aspect of managed care that will affect women’s health. Given that forty-one percent of women report changing their physicians because of dissatisfaction about not being heard or taken seriously, volume-based measures of doctors’ performance are likely to compromise women’s experiences even further.

Physicians are less likely to take a woman’s physical complaints as serious as a man’s even without consideration of “volume-based measures” of doctors’ performance. Studies have shown that men are more stoic in their communicative style; women are more descriptive. Studies also show that physicians are much more likely to take complaints more seriously if they are delivered in a stoic, non-emotional manner. Presentation of symptoms of disease in a stoic fashion is much more compatible with a system where time is limited with patients as in many managed care systems. Seventy-five percent of physicians in managed care feel pressure to see more patients per day (24% believed the pressure comprises patient care) and 53.8% believe that time spent per patient was either marginal or severely limited.

415. Damon M. Seils, et al., Sex Differences in the Referral Process for Invasive Cardiac Procedures, 56 JAMWA 151, 153 (2001), (citing Franks P. Clancy, et al., Referrals of Adult Patients from Primary Care: Demographic Disparities and their Relationship to HMO Insurance, 45 J. FAM. PRACT. 47 (1997)). This was an overall figure regarding the behavior of primary care physicians. This disparity was not observed between HMO enrollees as compared with self-pay, fee-for-service, or Medicaid, or Medicare patients in this study. Id.
416. Laurence & Weinhouse, supra note 1, at xv.
417. Primary Care Physicians, supra note 405, at 18.
418. See supra notes 242-47 and accompanying text.
419. See supra note 245 and accompanying text.
420. See supra notes 242-47 and accompanying text.
421. Kevin Grumbach, et al., Primary Care Physicians' Experience of Financial
In a time-restrictive system, physicians are likely to perpetuate the bias that a woman’s illness is “all in her head.” If a man and a woman present to a doctor with the same physical symptoms, the physician is much more likely to prescribe a psychoactive drug to the woman, assuming her complaint is psychogenic, but will perform diagnostic tests on the man in quest of a physical explanation.  

Women with symptoms of heart disease are more than “twice as likely to have their symptoms attributed to somatic, psychiatric, or other non-cardiac causes as men.”

Thus, physicians within managed care systems that are designed with cost-savings disincentives toward specialized care and diagnostic services coupled with a time crunch caused by patient quotas would appear much more likely to misdiagnose women patients due to their non-stoic communicative styles and the preexisting ill-founded bias that women suffer from more psychosomatic illnesses.

D. The Primary Care Physician and Access to Specialized Treatment

Arguably, the predominate features of most HMOs, the cost-containment and physician-performance incentives of capitation, prospective utilization review, and physician risk-sharing, have the built-in potential to impact women more than men because the goals of all are furthered by gender bias. Further, managed care is designed to limit patient choice and women’s health needs might not be furthered by requiring treatment by primary care providers within managed care.

Recent studies suggest that enrollees of managed care are more satisfied with out-of-pocket costs, preventive treatments, and the range of services provided than members of fee-for-service plans. Generally, however, managed care’s patients are less satisfied with their choice of doctors, ease of changing physicians, and access to specialized care than

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423. See supra notes 248-50 and accompanying text.
424. Gender Disparities in Clinical Decisions, supra note 45, at 560; see supra notes 257, 265 and accompanying text.
425. Psychosomatic illnesses are “disorders that have a physiological component but are thought to originate in the emotional state of the patient.” Taber’s Cyclopedic Medical Dictionary (F. A. Davis, ed., 14 ed. 1981).
426. Roberta Wyn, et al., Women and Managed Care: Satisfaction with Provider Choice, Access to Care, Plan Costs and Coverage, 52 JAMWA 60, 63 & 64 (1997).
fee-for-service patients. Managed care enrollees are six times more likely to be dissatisfied with choice of doctors and the ability to change physicians, and four out of ten women in fair or poor health "were not satisfied with the availability of advice by phone, an area that is particularly important for people in poor health." Further, studies have also established a causal link between poorer health outcomes and enrollment by the chronically ill poor and elderly in managed care plans compared with those in fee-for-service systems.

Many plans allow women to designate obstetrician/gynecologist (OB/GYNs) as their family care provider. However, many times this accommodation was a direct result of state statutes that dictated that women could choose an OB/GYN as their primary care provider. "[M]ost patients of obstetrician/gynecologists see no other practitioner for primary care," yet OB/GYNs are not trained in a quarter of the skills necessary to deliver primary care. Family practitioners have, in fact, the greatest training in delivering the broad range of services required for a "gatekeeper" compared with the training of other specialists, including internists. The training for family practice covers comprehensive care, but its curriculum is based on the male-only model.

Currently, no primary care specialty trains physicians to deliver high-quality comprehensive care to women based on research and clinical training with women. A 1992 survey showed that only twenty-five percent of medical schools offered training in women's health beyond obstetrics/gynecology, and what was offered was elective, rather than mandatory. Consequently, most of the primary care physicians women will visit under managed

427. Id. at 63.
428. Id. at 62.
429. Id. at 63.
430. Id. at 64 (citing Ware J. Bayliss, et al., Differences in 4-Year Health Outcomes for Elderly and Poor, Chronically Ill Patients Treated In HMO and Fee-for-Service Systems: Results from the Medical Outcomes Study, 276 JAMA 1039 (1996)).
431. See infra notes 580-81 and accompanying text.
432. Primary Care Physicians, supra note 405, at 17.
433. Id.
434. Id.
435. Id.
care plans will have had little or no training in women's health.\(^{436}\)

Evidence exists that currently primary care providers are neither sufficiently trained in women's health needs nor trained to overcome established practices where gender bias is reflected. "One study found that primary care physicians judged sixty-five percent of women's symptoms, versus fifty-one percent of men's, to be influenced by emotional factors. Perhaps, not surprisingly, women's complaints were more than twice as likely as men's to be identified as psychosomatic."\(^{437}\)

The Institute of Medicine issued a report in 1996 that concluded that family practitioners and internists did not have some of the skills necessary to perform the myriad of duties they are expected to perform in managed care.\(^{438}\) The New England Journal of Medicine reported that one in four primary care physicians believed that the scope of services they were expected to provide was inappropriate\(^{439}\) and another study revealed that over one-third felt uncomfortable with some of the procedures they performed in managed care.\(^{440}\) "Internal medicine residents, for instance, lacked experience in such areas as gynecology and preventive medicine, the supposed bedrock of managed care."\(^{441}\) A study conducted at Cook County Hospital in Chicago found that 40% of internal medicine and family practice residents would not think about providing information regarding family planning or German measles immunizations to a healthy woman.\(^{442}\) Furthermore, "[g]eneralists were also remiss in counseling women about sexually transmitted diseases, safer sex, and preconception care."\(^{443}\)

Primary care physicians are also insufficiently trained to render obstetrical/gynecological care. "[S]tudies clearly document that non-gynecologist physicians do an inadequate job of providing pap smears

\(^{436}\) Id. at 18.

\(^{437}\) LAURENCE & WEINHOUSE, supra note 1, at 259.

\(^{438}\) Id. at xvi.

\(^{439}\) Robert F. St. Peter, Changes in the Scope of Care Provided by Primary Care Physicians, 341 NEW ENG. J. MED. 1980 (1999). See supra note 352 and accompanying text.


\(^{441}\) LAURENCE & WEINHOUSE, supra note 1, at xvi.

\(^{442}\) Id. at xv & xvi. The mother's contraction of German measles during pregnancy causes seven birth defects in the child. Id.

\(^{443}\) Id. at xvi.
and pelvic and breast exams."\textsuperscript{444} Women are allowed to see their OB/GYNs without a referral in about three-quarters of the plans; however, women still need a referral in about half of these plans unless the appointment is for the one "well-woman" check-up allowed per year.\textsuperscript{445} Access to OB/GYNs without referrals, even as limited as it is, has been incorporated into plans as a direct response to statutory mandates throughout the country in many instances.\textsuperscript{446} "Women whose plans do not designate obstetrician/gynecologists as primary care providers, will need referrals for basic reproductive services. When systems discourage referral, however, doctors designated as primary care providers may take on functions for which they are inadequately trained."\textsuperscript{447} Or, a woman with a gynecological or obstetrical problem must first see the primary care provider for a referral and then make another appointment with the OB/GYN, causing delay that in some instances can cause serious harm.\textsuperscript{448}

"[P]rimary care is more than just the absence of specialization. It is a specific set of skills that requires appropriate education and training."\textsuperscript{449} However, 56.8\% of primary care physicians responding to one survey reported that participation in managed care did not encourage them to acquire new skills or keep old skills sharp. Further, 67.4\% did not believe that managed care had increased their interest in keeping up with new developments in their field.\textsuperscript{450}

Furthermore, it is feared that HMOs are susceptible to "organizational pathologies" inherent in large organizations that can "impede change, become unresponsive, and limit the appropriate use of discretion by professionals," thereby diminishing personal responsibility and accountability.\textsuperscript{451} Again, the structure of the HMO does not appear to be conducive to self-monitoring of proficiency. HMOs do participate in clinical research; however, the research tends to concentrate on effectiveness studies to improve the delivery of health care, not research

\textsuperscript{444} Primary Care Physicians, supra note 405, at 17.
\textsuperscript{445} Laurence & Weinhouse, supra note 1, at xv.
\textsuperscript{446} See infra notes 580-81 and accompanying text.
\textsuperscript{447} Primary Care Physicians, supra note 405, at 18.
\textsuperscript{448} Laurence & Weinhouse, supra note 1, at xv.
\textsuperscript{449} Primary Care Physicians, supra note 405, at 18.
\textsuperscript{451} What Are the Issues?, supra note 370, at 1013.
designed to acquire new medical technologies for providing care. Research is typically designed for short-term benefits for "potential application in that particular MCO and its business objectives." Thus, the research focuses on renovation, not innovation.

Obviously, new discoveries are constantly being made in medicine. In the area of women's health, science is just beginning to appreciate the depth of the gender gap. Research results from including women in research populations with gender analysis of data is likely to increase given the NIH's guidelines and FDA's expectation that women should participate in research studies. The inherent nature of managed care with its tendency to pressure physicians to treat more patients daily would seem to be the antithesis of an environment to remain abreast of current developments.

One danger to women's health is the primary care physicians remaining ignorant of new discoveries particularly in the administering of prescription drugs. It would appear from a layperson's standpoint that primary care physicians have an incredible task as they perform the duties of a full-service physician and must remember from the "all-male model" of medical training the appropriate treatment and medication for the myriad of diseases and conditions they confront on a day-to-day basis. Now, science is injecting the two-model approach with discoveries of differences in the way men and women respond to medications and treatments. Women have more adverse side effects from prescription drugs. Men and women react to some prescription drugs very differently, such as antidepressants and medications for seizures, asthma, allergies, high blood pressure, pain, and heart failure. Furthermore, low fat diets may be appropriate for men, but unnecessary for women. Treatment of cholesterol levels might

453. Id. at 84.
454. Id.
455. See supra note 223 and accompanying text.
456. See supra notes 132, 290-94 and accompanying text.
457. See supra note 133.
458. Extrapolation From Men, supra note 121, at 1051.
459. See supra note 223 and accompanying text.
460. See supra note 133.
461. See supra note 246.
463. See supra notes 224-25 and accompanying text.
differ drastically depending on whether the patient is male or female.\textsuperscript{464} Further, some studies suggest that moderate consumption of alcohol might help prevent men from having a heart attack, but moderate consumption by women might increase the risk of breast cancer.\textsuperscript{465} One has to wonder whether primary care physicians within the managed care system can adapt to the two-model approach to medicine if managed care does not encourage them to keep abreast of new discoveries in their field or acquire new skills as the survey of primary care physicians suggest.

E. Mental Health Concerns

Overall, women use more mental health services than men.\textsuperscript{466} Family practitioners do receive some training in behavioral medicine, which includes problems such as substance abuse, depression, incest, violence, and eating disorders. Once again, however, the training is based on the male model, not a female one.\textsuperscript{467} Physicians will likely misdiagnose and mistreat secondary physical illness resulting from violence and sexism if they are untrained in the female model of behavior medicine.\textsuperscript{468} In most HMOs,\textsuperscript{469} women, in order to receive care from a mental health specialist, must first see the primary care physician in his or her role as gatekeeper who must refer patients, typically following established institutional protocols, for all specialized care, including psychiatric care.\textsuperscript{470} But, family care providers are expected to

\textsuperscript{464} Id.
\textsuperscript{465} See supra note 227.
\textsuperscript{466} Laurence & Weinhouse, supra note 1, at xv.
\textsuperscript{467} Primary Care Physicians, supra note 405, at 17.
\textsuperscript{468} Id. at 18. On domestic violence, see supra note 299 and accompanying text.
\textsuperscript{469} Some managed care and fee-for-service plans began to use mental health “carve outs” in the 1990s.

In carve-out contracts, managed mental health companies accept capitated payments to cover all mental health services provided to enrollees, thereby assuming the risk of cost overruns. When HMOs use mental health carve-outs, they essentially replace one overall capitation system for all services with two more specific systems—one for mental health, the other for remaining health services.

\textsuperscript{470} See, e.g., Haller v. Kaiser Foundation Health Plan of the Northwest, 184 F. Supp. 2d 1040 (D. Oregon 2001). In Haller, The plaintiff alleged that Kaiser was negligent to treat plaintiff with lithium over a several-year period without properly monitoring blood levels. The plaintiff also alleged that Kaiser was negligent in providing “inadequate
treat rather than refer patients with many psychiatric disorders.\textsuperscript{471} However, the primary care physician has insufficient formal training in psychiatry and treatment by the family practitioner could easily result in misdiagnosis or undertreatment.\textsuperscript{472} Seventy-three percent of all prescriptions for psychotropic medications are written for women; however, that figures jumps to “an incredible ninety percent when the prescribing physician is not a psychiatrist.”\textsuperscript{473} Generalists prescribe over seventy percent of anti-depressants.\textsuperscript{474}

[S]tudies suggest that they’re more likely than psychiatrists to prescribe these drugs at suboptimal doses. They’re also more likely than mental health specialists to rely on medication alone—and the wrong medication in many cases. \ldots As a result, women with depression who are denied therapy and pushed to use inappropriate drugs won’t get the relief they need.\textsuperscript{475}

There is also substantial evidence that HMOs have a significant negative impact on the quality of mental health care services received by enrollees.\textsuperscript{476} For example, seriously ill patients with depression and schizophrenics treated within an HMO have an additional functional limitation than those treated within a fee-for-service plan. This means that the patient within the HMO might not be able to work around the house or keep a job whereas their fee-for-service counterpart would be able to do so.\textsuperscript{477} Furthermore, utilization management has greatly reduced the length of in-patient hospital stays and the number of outpatient treatment sessions.\textsuperscript{478} Many plans only cover twenty sessions of outpatient therapy per year, and some will attempt to limit the numbers of sessions even further despite the explicit coverage

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\begin{itemize}
\item \textsuperscript{471} Laurence & Weinhouse, supra note 1, at xv.
\item \textsuperscript{472} Id.
\item \textsuperscript{473} Id. at 276. On the overuse of antidepressants, see supra notes 276, 286. See also Women's Health, supra note 131, at 1018.
\item \textsuperscript{474} Laurence & Weinhouse, supra note 1, at xv.
\item \textsuperscript{475} Id.
\item \textsuperscript{476} Audrey R. Newell & Gregory M. Saltzman, The Impact of Managed Mental Health Care on Women, 52 JAMWA 69, 69 (1997).
\item \textsuperscript{477} Id. at 69.
\item \textsuperscript{478} Id. at 70.
\end{itemize}
provision.\textsuperscript{479} "[A]lthough men and women have the same rates of psychiatric disorders in any given year, women seek assistance from the health care system more frequently than men and are therefore more affected by policies limiting such care."\textsuperscript{480} Further, some mental health concerns predominately effect women.\textsuperscript{481}

Many plans, for example, limit coverage to "acute" conditions that are "amenable to short-term resolution."\textsuperscript{482} Accordingly, the plans might exclude treatment for bulimia or anorexia, a condition that primarily affects women, because it requires long-term treatment, for example more than twenty sessions, and thus patients with these conditions are not eligible for the benefits under the plan.\textsuperscript{483} Further, women are much more likely to be victims of abuse than men. Yet, "victims of rape, incest, or physical abuse require considerably more than a few sessions in order to recover, particularly if they endured prolonged, repeated, or childhood abuse."\textsuperscript{484}

It has been suggested that limiting reimbursement to only a small number of sessions per year "makes no sense clinically."\textsuperscript{485} One proposed solution combines restricting cost by limiting in-patient care to those patients who are truly a danger to themselves or others while at the same time expanding outpatient plan coverage to a minimum of fifty sessions per year.\textsuperscript{486} Further, patients would be required to perform two hours of self-help work per one hour of outpatient treatment to supplement and foster any therapy provided. Appropriate self-help work might include reading appropriate material, participation in self-help groups, viewing educational videotapes, or completing interactive learning computer programs or workbooks.\textsuperscript{487} "The challenge of meeting

\textsuperscript{479} Id.
\textsuperscript{480} Id.
\textsuperscript{481} Id. Men are more likely to be effected by "antisocial personality disorder, substance abuse, attention deficit hyperactivity disorder (ADHD), early onset schizophrenia, autism, and learning disabilities (LD)." Id. The fact that the treatment for most of the illnesses suffered by men, ADHA, autism, and LD, are carried out by the schools helps explains why men use less mental health care services than women. Id.
\textsuperscript{482} Id.
\textsuperscript{483} Id.
\textsuperscript{484} Id. at 71.
\textsuperscript{485} Id.
\textsuperscript{486} Id. at 73.
\textsuperscript{487} Id. The suggestion is that the patient and therapist would enter into a treatment contract which would specify the type of work the patient could do on his or her own to further treatment and individual responsibility toward their condition. "Not all therapeutic power comes from the therapist." Id. Indirectly, a therapist/patient contract
women's mental health needs within a budget can be solved by a combination of focusing managed care interventions more appropriately, using new treatments methods, and enacting legislation to mandate a clinically appropriate standard of fifty hours of outpatient treatment that would be required of all health care plans.\footnote{488}

F. Surgery and Hospitalization

Managed care companies frequently assert that they are protecting women by limiting access to the surgical procedures that were performed unnecessarily in the past under pay-for-service plans, for example, hysterectomies, and cesarean sections.\footnote{489}

What these companies don't say is that while unnecessary or unproven surgeries are being reduced, so are necessary ones. Some managed care companies, for instance, define reconstructive surgery after mastectomy as cosmetic rather than medically necessary and refuse to cover it. Or they pay for the first part of the procedure—the operation to recreate the breast mound—but not subsequent procedures, such as the nipple reconstruction or surgery to adjust the opposite breast so it

which places burdens on the patient to help themselves achieve mental health might also help reduce the number of "worried well." Arguably, the "worried well" might not be willing to invest their own time and effort in mental health. Managed care organizations fear increasing the number of allowable session hours because the "worried well" use a substantial portion of mental health resources instead of seriously ill patients. \textit{Id.} at 72. However, proper screening of patients to cull the "worried well" from prolonged therapy and denying coverage for patients that do not need fifty hours of therapy session a year might avoid the problem of the "worried well" needlessly consuming limited mental health resources. The author does not know if the "worried well" are truly a serious problem in the mental health field or simply a minor problem used to argue against expanding plan coverage to include more sessions. The author also assumes that a trained health care professional could distinguish between a "worried well" patient compared to one with a serious mental health problem, such as depression, abuse, or anorexia, that would require prolonged therapy to alleviate patient suffering.

\footnote{488} \textit{Id.} Such legislative action is very similar to other areas of statutory reform aimed at perceived unfair restrictions to care within managed care plans, such as statutes that prescribe that plans must cover a minimum period of time for postnatal care. \textit{See infra} notes 561-85.

\footnote{489} Laurence & Weinhouse, \textit{supra} note 1, at xvi. On unnecessary surgical procedures, see \textit{supra} notes 6, 278 and accompanying text. Again, many women suffering from various conditions might not agree with the classification of a hysterectomy as unnecessary just because the condition made their life miserable, but the condition would not kill them. \textit{See supra} note 6.
matches the new one. Even more galling, the same managed care companies that deny breast reconstruction sometimes cover penile implant surgery.\textsuperscript{490}

Managed care has been relentless in the reduction of the number of in-patient hospital days. There has been a reduction in in-patient days of forty percent per thousand patients.\textsuperscript{491} Notable examples are the famous “drive-by deliveries,”\textsuperscript{492} outpatient mastectomies,\textsuperscript{493} and discharging women after gynecological procedures with catheters in place.\textsuperscript{494} However, performance of less-renowned surgical procedures on an outpatient basis or reduction of the recuperative time spent within the hospital will also have a disproportionate impact on women inasmuch as surgery is performed on women 50\% more often than on men.\textsuperscript{495}

The trend toward outpatient care, lowering hospital admissions, combined with the reduction of the amount of in-patient days caused a financial crunch in many hospitals. Many hospitals responded by reductions in staff which resulted in registered nurses no longer delivering care, but instead supervising less-trained personnel.\textsuperscript{496} Nurses fear the reduction of staff and delivery of care by personnel other than nurses impacts the quality of care delivered within hospitals.\textsuperscript{497} One survey reported that 57\% of registered nurses believed that the quality of nursing care did not meet professional standards.\textsuperscript{498}

One hidden cost of shortening the length of time spent in hospitals is the cost to family members who become surrogate nurses when patients are discharged.\textsuperscript{499} Most people who provide surrogate nursing will be women.

\textsuperscript{490} LAURENCE \& WEINHOUSE, supra note 1, at xvi. Close to one-half of all jurisdictions statutorily mandate coverage for reconstructive surgery or prosthetic devices following a mastectomy. See infra note 585.

\textsuperscript{491} Suzanne Gordon, The Impact of Managed Care on Female Caregivers in the Hospital and Home, 52 JAMWA 75 (1997) [hereinafter Impact on Caregivers].

\textsuperscript{492} See infra notes 561-79.

\textsuperscript{493} LAURENCE \& WEINHOUSE, supra note 1, at xvi. “Women can have a breast surgically removed in the morning and be home in time to cook dinner that evening.” Id.

\textsuperscript{494} Id.

\textsuperscript{495} Id.

\textsuperscript{496} Impact on Caregivers, supra note 491, at 76.

\textsuperscript{497} Id.

\textsuperscript{498} Id. For example, non-nurse health care workers now insert catheters and suction tracheotomy tubes. Nurses must deliver care to not only more patients, but usually sicker patients. Due to early discharge practices, only the very ill remain for very long in hospitals. A nurse also must supervise various aids who are caring for other patients. Id.

\textsuperscript{499} Id.
Interestingly, however, studies advocating early discharge fail to consider the impact—financial or otherwise—on family caregivers. When studies suggest that reducing length of stay saves money, costs incurred by family caregivers are almost never factored into cost-benefit analyses. These costs are very real and include time taken off work, job losses related to family caregiving burdens, emotional stress, and physical illnesses that may result from shouldering this burden.500

Managed care’s quest to reduce cost through limiting length of hospital stays and increasing outpatient treatment has directly impacted more women than men because women are the largest consumers of health and surgical care.501 Furthermore, women are just as importantly impacted indirectly by virtue of the fact they are forced to assume surrogate-nursing duties as the usual caregivers when patients are discharged earlier than in the past.502

G. Impact on Sub-Populations

There is no definitive study that shows a reduction in the overall quality or effectiveness of medical care in managed care systems. Yet “evidence suggests that managed care may adversely affect the health of some vulnerable subpopulations,”503 based on socioeconomic, racial, and ethnic disparities.504 Moreover, institutional quality control has inadequately invested in efforts to collect data, monitor, and address disparities in the health care of subpopulations.505

The progression of disease can differ drastically between different subpopulations.506 For example, Caucasian women have the greatest incidence of breast cancer, but African-American women have higher mortality rates.507 Native Hawaiian women have an unusually high death rate, while American Indian women in New Mexico have the lowest rate

500. Id.
501. See supra notes 382-83 and accompanying text.
502. Impact on Caregivers, supra note 491, at 76.
505. Id.
507. Id.
of incidence of breast cancer and the lowest death rate.\(^{508}\) Asian-American women have a higher incident rate of invasive cervical cancer than Caucasian women, with Vietnamese women having a five times higher rate of incidence than in Caucasian women.\(^{509}\) African-American women are the most at risk for death from heart disease (there are 147 deaths per 100,000 compared to 88 for Caucasian women).\(^{510}\) Asian-American/Pacific Islander women age sixty-five or older have the highest suicide rate of all women.\(^{511}\) African-American women have the highest rate of obesity, while Alaska Native women have the highest smoking rate.\(^{512}\) Seventy-seven percent of all women with AIDS are African-American or Hispanic, with AIDS being the second leading cause of death of twenty-five to forty-four year-old African-American women.\(^{513}\)

These disparities could indicate difference in rates of early detection of disease, treatment protocols, cultural, or lifestyle factors. In addition, there could exist an undiscovered physiological explanation for some of these disparities,\(^{514}\) that science has yet to discover. The exclusion of women from research studies created a large void of information regarding women’s health, but it also created a similar void for racial/ethnic and socioeconomic subpopulations. Both the NIH and FDA have addressed racial/ethnic analysis of data as well as gender analysis.\(^{515}\) Research clearly reveals a racial/ethnic/socioeconomic disparity in the treatment and progression of some diseases\(^{516}\) and that some subpopulations require tailored support plans to allow effective

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\(^{508}\) *Id.*

\(^{509}\) *Id.*

\(^{510}\) *Id.*

\(^{511}\) *Id.*

\(^{512}\) *Id.*

\(^{513}\) *Id.*

\(^{514}\) *Id.*

\(^{515}\) See *supra* notes 129, 168, 170 and accompanying text. See also Guidelines for the Study and Evaluation of Gender Differences in the Clinical Evaluation of Drugs, Food and Drug Administration, 58 Fed. Reg. 39406 (July 22, 1993).

treatment of their diseases. Compared to more affluent women, lower-income women have a “higher incidence of chronic conditions such as arthritis, hypertension, diabetes, or limitations in activities” and are more “likely to report anxiety or depression, suicidal thoughts, and dissatisfaction with their lives or have low self-esteem,” compounding their health problems. As a result, access to specialized care is more important to lower-income women as a class because they usually have more chronic health needs.

Yet, studies of managed care systems establish that lower-income women have low levels of satisfaction with their plans in key areas. One-third of low-income women and women in fair to poor health rated their access to specialty care as fair to poor, an area that particularly affects these subpopulations because their need might be greater overall for specialized care due to their chronic health needs. “Women with incomes below $25,000 were more likely to be dissatisfied with the clinic hours, waiting time to get a routine appointment, availability of emergency care, waiting time to get care in an emergency, and access to specialty care.” Low-income women, despite generally poorer health status and lower access rates than higher-income women, were “more susceptible to access constraints,” meaning that lower-income women might have more difficulty maneuvering utilization controls within managed care systems or those constraints create an undue burden to access for lower-income women. Further, studies have shown differences in the quality of care of subpopulations within the managed care system; for example, poorer health outcomes for the elderly and

517. Julie C. Will, Reducing Risk for Cardiovascular Disease in Uninsured Women: Combined Results from Two WISEWOMAN Projects, 56 JAMWA 161 (2001). Health promotion efforts in disadvantaged communities present unique problems. First, health promotion efforts clash with the more immediate needs of the disadvantaged for transportation and income. Second, there may be only limited selection of food available in neighborhood grocery stores and neighborhoods may be unsafe. Thirdly, counseling regarding diet, life-style and physical activities is difficult because of inadequate staff, rapid turnover and limited time. Id. at 165.


519. Id.

520. Steffie Woolhandler, Managed Care and Women’s Health, 52 JAMWA 50, 51 (1997); Roberta Wyn, Women and Managed Care: Satisfaction with Provider Choice, Access to Care, Plan Costs and Coverage, 52 JAMWA 60, 63 (1997).

521. Id. at 62.

522. Id. at 64.

523. See supra notes 503-04.
the chronically ill poor have been linked to enrollment in managed care plans as compared with more traditional health care plans. If managed care has the propensity to perpetuate gender bias and if the cost-containment efforts and performance incentives impact the health of women enrollees more than men, the negative impact of managed care might be magnified toward vulnerable subpopulations, as recent studies suggest, resulting in a decrease in the quality of services rendered with corresponding negative health outcomes.

H. Potential Litigation to Curb Gender Bias Blocked by ERISA Preemption

Arguably, the tentacles of gender bias run throughout the managed care system. As discussed previously in Part II of this article, litigation is not an effective way to redress injuries caused by gender bias within the managed care system. There is no tort of gender bias and any recovery would hinge on establishing substandard care measured by the performance of other doctors within the same area of practice. Clonidine, for example, is used to rapidly reduce stroke-level high blood pressure. It would not be considered negligence to prescribe clonidine to a women with dangerously high blood pressure if other reasonably competent physicians in the same or similar circumstances would also prescribe clonidine even though there are menstrual variations in response to clonidine. If scientific research has yet to develop a gender-specific drug to rapidly reduce high blood pressure, then physicians have no options but to prescribe the drug developed using all-male research populations. Further, it would most likely be negligent not to resort to clonidine, even with its menstrual variations, to avoid a potential stroke.

Another barrier to recovery against most MCOs stems from the fact that most are part of an employee benefit plan and subject to the Employee Retirement Income Security Act of 1974 (ERISA).

524. Roberta Wyn, et al., Women and Managed Care: Satisfaction with Provider Choice, Access to Care, Plan Costs and Coverage, 52 JAMWA 69, 64 (1997)
525. See supra notes 133, 223.
526. Tort Liability and ERISA Preemption, supra note 9, at 857. Approximately 75% of all HMO coverage, which includes an estimated 150 million people, is purchased through employment benefit plans governed by ERISA. Wendy K. Mariner, State Regulation of Managed Care and the Employee Retirement Income Security Act, 335 NEW ENG. J. MED. 1986 (1996).
Congress enacted ERISA to provide uniform laws regarding the administration of employee benefit plans and curtail abuses in the administration of those plans. In an effort to provide uniform laws, ERISA preempts conflicting state laws that “relate to” employee benefit plans, and the “relates to” preemption clause is “the most expansive preemption provision contained in federal law.” Originally, there was much conflicting authority in the federal courts on the issue of whether ERISA preempted state law tort claims when an injured patient sued an HMO for substandard care.

State law tort claims against HMOs or MCOs for substandard care that results in injury can be based on either vicarious liability, including ostensible or apparent agency, or corporate or direct liability of the institution. The MCO is vicariously liable for the negligent actions of its employees. Thus, the MCO would be vicariously liable under the doctrine of respondeat superior for physicians who commit negligent acts causing injury who are either actually employed by the MCO or who are

531. Tort Liability and ERISA Preemption, supra note 9, at 898-917.
the ostensible or apparent agents of the MCO. Corporate negligence consists of institutional negligence such as negligence in the selection of the participating physicians of the MCO, negligence in the supervision of participating physicians, negligence in the administration of utilization review, and negligence in the administration of cost containment incentives.

Originally, some federal courts held that ERISA preempted both vicarious liability and corporate negligence, leaving only the ERISA allowed remedies which are very limited. In 1988, the Supreme Court observed that “run-of-the-mill state-law claims” including “torts committed by an ERISA plan” are not preempted by ERISA even though they affect the ERISA plan. Subsequently, the Supreme Court noted that ERISA does not preempt state law just because the law has “only an


535. See, e.g., Dunn v. Praiss, 606 A.2d 862 (N.J. Super. Ct. App. Div. 1992); McClellan v. Health Maintenance Org., 660 A.2d 97 (Pa. Super. Ct. 1995); Thornton v. Shah & Humana Health Plan, Inc., No. 1-00-4121, 2002 Ill. App. LEXIS 692 (August 8, 2002). In Thornton, negligence was alleged in the administration of the plan that required patients to call their primary care physician prior to seeking emergency care. A Humana nurse lost the notes to a telephone conversation wherein the nine-month expectant plaintiff called regarding excessive bleeding and contractions. Case was dismissed because there was no allegation of how the missing notes would establish plaintiff’s prima facie case for the death of the fetus from strangulation from the umbilical cord. Id.


538. Tort Liability and ERISA Preemption, supra note 9, at 905-06 nn.271, 272, 274.

539. ERISA remedies are basically the recovery of any benefits due under the plan (meaning the cost of treatment), or injunctive or declaratory relief to obtain or clarify benefits. 29 U.S.C. § 1132 (A)(1)(B).

indirect economic effect on the relative costs of various health insurance packages in a given state."\(^541\) Vicarious liability causes of actions pursued against HMOs (cases dealing with the quality of the benefits provided to a beneficiary as compared with cases that attack the quantity of benefits allowable under the plan)\(^542\) are clearly run-of-the-mill state-law claims and most federal courts allow vicarious liability claims based on state law to proceed (they are not subject to ERISA preemption) even though recovery by an injured patient might have an indirect economic impact on the cost of the plan.\(^543\)

Corporate negligence causes of action are more likely to be subject to ERISA preemption because negligence in the selection or supervision of participating physicians or negligence in the administration of utilization review or cost-containment incentives “relates to” the administration of the benefit plan and falls within the preemptionary language of ERISA.\(^544\) However, the Supreme Court noted in 2000 that

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plan administrators make two different types of eligibility decisions. A decision regarding eligibility for benefits would clearly be an action of an ERISA fiduciary and any legal challenge of the pure eligibility decision would be subject to ERISA preemption. However, if the plan administrator makes a "mixed eligibility" decision, one that is thoroughly mixed with medical judgment, any claim for injury arising out of the mixed eligibility/treatment decision is not subject to ERISA preemption and the malpractice claim must be pursued in state court.545

In summary, the prevailing view currently in the federal courts is that ERISA does not preempt claims for vicarious liability, or claims that deal with the quality, as compared to the quantity, of benefits allowed under the plan.546 ERISA will generally preempt corporate negligence claims,547 unless the negligence consists of a mixed eligibility/treatment decision.548 In the context of structural problems that perpetuate or foster underlying gender bias, the major roadblock to recovery for injuries that might be inflicted as a result is the potential of ERISA preemption if the allegation of negligence is institutional negligence as compared with an allegation of vicarious liability or a denial of benefits that results from a mixed eligibility/treatment decision. An example of an allegation of vicarious liability would be where a primary care physician employed by an HMO negligently diagnoses a woman’s heart problems as psychogenic,549 fails to refer her to a cardiologist, and she suffers a heart attack as a result. The HMO would face potential vicarious liability for the negligence of its employee-physician.

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546. See supra note 543.


548. Pegram, 530 U.S. 211; Pappas, 768 A.2d 1089.

549. See supra notes 265, 412-15 and accompanying text.
If a woman was denied coverage for ABMT with accompanying HDC,\textsuperscript{550} because the plan did not consider ABMT with HDC as medically necessary,\textsuperscript{551} any state law claim for death caused by the denial would probably be preempted because the decision “relates to” the administration of the plan and the claim deals with the quantity of benefits provided by the plan.\textsuperscript{552} As the Supreme Court stated, “any legal principle purporting to draw a line between good and bad HMOs would embody, in effect, a judgment about socially acceptable medical risk.”\textsuperscript{553} If the plan allowed ABMT with HDC for stage IV breast cancer, but not stage III,\textsuperscript{554} and the administrator negligently makes a diagnosis of stage III and a woman with stage IV breast cancer was treated with only traditional chemotherapy, recovery would arguably be allowed for the resulting wrongful death under state law because the decision was a mixed eligibility/treatment decision and, as such, is not subject to ERISA preemption. If a woman tried to sue a plan alleging that the administration of the plan was negligent because cost-containment measures, physician performance incentives, and prospective utilization review had a greater impact on women than on men, the cause of action would most likely be preempted by ERISA because the allegation of negligence “relates to” the administration of the employee benefit plan.\textsuperscript{555} ERISA combines with the problems discussed previously in Section II to restrict the viability of personal injury litigation as a tool to reduce gender bias within the managed care system.

\textsuperscript{550} See supra notes 238-41.

\textsuperscript{551} Originally, plans denied coverage for ABMT with HDC because the plan considered the treatment experimental. Now, some plans deny coverage because they contend that ABMT with HDC is not medically necessary, meaning the results of ABMT with HDC has not been proven to be more effective than traditional treatments. See supra note 240. On the definition of medically necessary, see Mark A. Hall & Gerald F. Anderson, Health Insurers' Assessment of Medical Necessity, 140 U. PA. L. REV. 1637 (1992).


\textsuperscript{553} Pegram v. Herdrich, 530 U.S. 211 (2000).


I. Legislative Approaches

Managed care's propensity to save money at the expense of women is reflected in the type of legislation adopted to remedy extreme cost-saving measures that were not in the public welfare. Reduction of coverage for conditions unique to women was one method employed by some MCOs to curtail the rising cost of medicine. Effective lobbying by women's health and consumer advocates remedied some of the more glaring examples of gender bias through legislation. The presence of legislation in the area of women's health, without corresponding legislation for issues dealing with men's health, is proof that gender bias can have a significant impact on coverage decisions by health care providers. "One study demonstrated that Medicare offers superior coverage for the acute conditions that more frequently appear in older men—such as lung cancer, prostate disorders, and heart attacks—than for the chronic medical problems that commonly afflict elderly women—for example, breast cancer, depression, and arthritis." Further, another study from Texas found that "female-specific surgery reimbursements average thirty-two percent less than other equivalent procedures." Overall, "women spend sixty-eight percent more in out-of-pocket expenses for health care than men." "Drive-by deliveries" provide another example of restrictive coverage practices impacting women. Reducing the length of

556. See infra notes 561-85 and accompanying text.
557. Throughout the country, many states passed or introduced legislation to address consumer problems with managed care. In the year 1996 alone, "447 patient protection acts were introduced in 44 states." HMO Regulation on Agenda For 1997 Term in State, Federal Legislatures, 1 MEALEY'S INS. LAW WEEKLY, March 6, 1997. There are many statutes that address problems that affect all consumers of managed care, men and women alike. For example, the Patient Right to Know Act of 1996 prohibited gag clause within provider/physician contracts. H.R. 2976, 104th Cong., 2nd Sess. (Feb. 1996). Another example is the Patient's Bill of Rights. See generally David A. Hyman, Regulating Managed Care: What's Wrong with a Patient Bill of Rights, 73 S. CAL. L. REV. 221 (2000).
558. Invisible Woman, supra note 12, at 139.
hospitalization following obstetrical delivery appealed to health insurance carriers because the most frequent cause of hospital admission in the United States is for the birth of a child.\textsuperscript{562} Coverage for childbirth was restricted to an overnight hospital stay for a vaginal birth and two nights for a cesarean birth under many health insurance policies.\textsuperscript{563} "Perhaps not coincidentally, as hospital stays decreased, the number of infants re-hospitalized with jaundice and dehydration increased."\textsuperscript{564}

Responding to public outrage and effective lobbying efforts, President Clinton signed into law federal requirements for minimum hospital stays following delivery in 1996.\textsuperscript{565} Federal law prohibits group health plans from restricting coverage to less than forty-eight hours for the mother and child following a normal vaginal delivery or ninety-six hours following a cesarean section.\textsuperscript{566} The minimum requirement does not apply if the discharge decision under the plan is made by the attending physician in consultation with the mother\textsuperscript{567} (provided there are no financial incentives provided to the physician to encourage early discharges)\textsuperscript{568} or if state law regulates such coverage.\textsuperscript{569} In order for state law to preempt the federal mandate, the state law must have the same minimal requirements (48 hours/96 hours),\textsuperscript{570} state law must require coverage according to standards adopted by professional medical associations such as the American College of Obstetricians and Gynecologists or the American Academy of Pediatrics,\textsuperscript{571} or state law requires the decision for length of stay be made by the attending health care provider in consultation with the mother.\textsuperscript{572} Accordingly, the majority of states enacted statutes addressing minimum lengths of stay following childbirth. Twenty-one adopted the 48/96 hour rule;\textsuperscript{573} three


\textsuperscript{562} \textit{Id.}

\textsuperscript{563} LAURENCE & WEINHOUSE, \textit{supra} note 1, at xvi.

\textsuperscript{564} \textit{Id.}


\textsuperscript{566} \textit{Id.} at § 300gg-4(a)(1).

\textsuperscript{567} \textit{Id.} at § 300gg-4(a)(2).

\textsuperscript{568} \textit{Id.} at § 300gg-4(b)(4).

\textsuperscript{569} \textit{Id.} at § 300gg-4(f)(1).

\textsuperscript{570} \textit{Id.} at § 300gg-4(f)(1)(A).

\textsuperscript{571} \textit{Id.} at § 300gg-4(f)(1)(B).

\textsuperscript{572} \textit{Id.} at § 300gg-4(f)(1)(C).

\textsuperscript{573} ARIZONA, ARIZ. REV. STAT. ANN. § 20-826 (West 2001); ARKANSAS, ARK. CODE
placed any discharge decision within the discretion of the physician or after consultation between the doctor and patient;\(^574\) and two states mandated a follow-up visit within forty-eight hours if there is an early discharge.\(^575\) All states that have legislation allow early discharge decisions; however, early discharge must be made after consultation between the doctor and patient,\(^576\) the early discharge decision is made by the physician exercising professional judgment\(^577\) (often with the proviso that any discharge decision must comply with standards established by professional medical associations),\(^578\) or early discharge must be accompanied by a prompt follow-up visit (usually within forty-eight hours) or an in-home visit.\(^579\)


Other legislative reactions to managed care’s restrictive coverage practices in the area of women’s health include provisions that mandate plans offer the enrollee the option of having an OB/GYN as their primary care provider$^{580}$ or require that plans allow direct access to an OB/GYN without a referral from a primary care physician.$^{581}$ Seventeen states legislatively dictate that pap smears must be covered by health care plans and provide that pap smears will be administered annually, or as recommended by the physician, or as provided for within the American Cancer Society’s guidelines.$^{582}$ More than half of the states have addressed mammograms and legislate the coverage and the frequency that mammograms be offered by plans (typically according to the age of the patient, upon referral by the physician, or as determined by the


Eight jurisdictions have statutes that set forth a minimum hospital stay for plan enrollees following a mastectomy and almost half of the states dictate by statute that plans must cover prosthetic devices and reconstructive surgery following a mastectomy. All these statutes represent solutions to egregious examples of coverage decisions that significantly impacted women’s health by managed care. The legislative cure for gender bias.


alleviates pockets of abuse where there appears to be a definitive solution. Obviously, legislatures could not, nor do they attempt to, rid managed care of all the varied manifestation of gender bias.

Critics of legislation aimed at managed care suggest that public concern over managed care caused the legislative enactments.586 “Today’s backlash against managed care is fully warranted by the failure of health plans to market themselves honestly and to accept appropriate legal responsibility both for honoring their contracts and for the quality of services provided under their auspices.”587 However, the various statutes enacted as a result might not necessarily be in the public good.588 The legislation has focused attention on specific areas of treatment, instead of fostering responsibility of managed care to adjust to market demands. Arguably, better accountability requires more candid disclosure of health care benefits, legal accountability for errors in health-coverage administration, and vicarious liability for the negligence of the various subcontractors of the managed care systems.589 Answering consumer backlash through the legislation described above was good politics, but detracted from any meaningful long-term improvement to the system as a whole.590 The legislation also arguably failed to consider the additional cost of requiring the enumerated services from the standpoint of the larger public need for the provision of health coverage

587. Id.
588. Professor Marc Rodwin offered the following observations:

The cynical view of the managed care backlash runs something like this. First, the media misled the public about how managed care works with sensational, inaccurate, and unrepresentative new stories, mostly anecdotes. Providers then masqueraded as consumer representatives to protect their own turf. Finally, legislatures practiced medicine without a license and enacted “legislation by body part.” Such legislation micro-managed clinical decision making by requiring unnecessary hospital use which prevented cost-savings innovations and locked in the status quo. Other legislation, such as bans on “gag rules” that prevent physicians from communicating with patients, addressed problems that had no basis in fact. Summed up, the backlash was interest group politics at its worst and produced bad policy.

Marc A. Rodwin, Backlash as Prelude to Managing Managed Care, 24 J. OF HEALTH POLITICS, POL’Y & L. 1155, 1155 (1999) (emphasis original; citations and references omitted.) [hereinafter Managing Managed Care].
590. Managing Managed Care, supra note 588.
to larger segments of the population for reduced prices. Further, the legislatures can be criticized in much the same way that managed care is criticized from the standpoint that the legislatures, to a certain degree, crossed over the line of regulation into the arena of the practice of medicine. In response, legislatures throughout the country were reacting to crisis situations created by coverage practices by MCOs and HMOs and appropriately dictated medically sound coverage that market forces had failed to provide, and showed no intent to provide in the future, to protect women enrolled in managed care plans.

J. Proposed Solutions

The managed care revolution swept through the country with the managed care industry attempting to balance the societal need to curtail the rising cost of medicine with consumers’ concerns for quality of the medical care rendered. The managed care approach has been described as an “economic success but a political failure.” Certainly, “[m]anaged care is not yet as good as it gets. It will improve as it is subject to consumer pressure. Backlash is unlikely to disappear until the industry matures and thoughtful regulatory authority protects the public, and the industry from itself.” Physician’s incentives, including risk-sharing and cost-containment mechanisms, cause all consumers concern because the physician earns more compensation as less treatment is offered to patients. The conflict of interest created by the financial pressure, both direct and indirect, within managed care systems can result in the physician not placing the patient’s welfare above the physician’s financial well-being.

Arguably, the concerns of all consumers with managed care become more acute for women enrolled within such plans. “While managed care has the potential to improve women’s health, its restrictive policies and hidden biases will continue to hit women hardest.” The managed care system, although at times publicly solicitous to women as the largest consumers of health care, appears to be perpetuating, if not entrenching, medical gender bias. One possible solution is simply to prohibit or restrict some of the extreme applications of cost-containment

592. Managing Managed Care, supra note 588, at 1159-20.
594. Managing Managed Care, supra note 588, at 1124.
595. LAURENCE & WEINHOUSE, supra note 1, at xvii.
mechanisms, including capitated payments, physician risk-sharing, and draconian prospective utilization review, and allow direct access to more specialists. However, any such suggestion would be myopic without a full public discussion of all the multifarious issues and societal ramifications of the virtual obliteration of MCOs or HMOs. Another solution is nationalized universal health care coverage.\textsuperscript{596}

Neither extreme solution, however, addresses the problem of gender bias nor moves toward its elimination. Instead, the status quo would be likely preserved and gender bias would be left intact. Further, the larger public need for health care at lower prices must be considered in any proffered solution. Managed care has brought needed innovation into the health care arena. Realistically, the days of unbridled health care spending and unlimited physician discretion under a fee-for-service approach are gone forever. Society is simply not willing to foot the bill. Further, there is no definitive study that shows that the overall quality of medical care has declined within managed care systems.\textsuperscript{597} Thus, any solution should be politically attainable, keeping in mind the very strong public interest in controlling the cost of medical care and the realistic view that managed care is here to stay. "It is probably politically more realistic...to focus on incremental reforms within the framework of the existing U.S. reimbursement system."\textsuperscript{598}

Two such "incremental reforms" will be suggested by this article instead of any attempt to solve all problems, perceived or real, within managed care systems. The first reform is increasing mental health coverage of plans. The second is assuring proper training of primary care physicians in women's health. In this context, a primary care provider including any physicians providing primary health care services to women enrollees of MCOs, including internists and OB-GYNs acting in that capacity.

\textsuperscript{596} We need universal coverage paid for by cuts in health care bureaucracy and a ban on for-profit care. We need a balanced way of paying doctors that rewards good work, but neither excessive interventions (as under fee-for-service) nor under-care (as in risk-sharing). We need a health care system that views patients as afflicted human beings in need of caring and compassion, not as industrial commodities. In short, we need single-payer national health insurance."

Steffie Woolhandler, \textit{Managed Care and Women's Health}, 52 JAMWA 50, 51 (1997).

\textsuperscript{597} Fred J. Hellinger, \textit{The Effect of Managed Care on Quality: A Review of Recent Evidence}, 158 ARCHIVES OF INTERNAL MED. 833 (1998) [hereinafter Hellinger].

\textsuperscript{598} Audrey R. Newell & Gregory M. Saltzman, \textit{The Impact of Managed Mental Health Care on Women}, 52 JAMWA 69, 73 (1997) [hereinafter Newell & Saltzman].
Doctors Newell and Saltzman proposed legislation that would require “managed care companies to provide fifty outpatient sessions per year for therapy or medication adjustment at the patient’s request.” Women’s health would clearly benefit from expanded outpatient coverage. Significantly more women than men use mental health services. Primary care physicians are more likely compared to mental health care professionals to over-prescribe antidepressants, many times relying on the wrong medication or using sub-optimal dosages. Women are much more likely to have physical symptoms diagnosed as psychosomatic than men. Further, women are much more likely than men to be victims of abuse or suffer from conditions, such as severe depression, anorexia, or bulimia, that require expanded outpatient therapy.

Limited mental health coverage, such as twenty hours of outpatient treatment per year, “makes no sense clinically” and could be perceived as deceptive medical marketing. Managed care promotes itself and solicits subscribers based, in part, on mental health coverage. Yet, the coverage provided does not provide sufficient sessions to alleviate the suffering of the more chronically ill patients. One research study found that “that it took an average of eleven sessions of weekly psychotherapy to achieve clinically significant improvements in fifty percent of patients,” yet “[i]t took an average of fifty-eight sessions to achieve such improvement in seventy-five percent of patients.” Expansion of coverage to fifty outpatient sessions per year would allow weekly more effective treatment of the seriously ill.

However, the availability of fifty sessions per year at the “patients request” might be ill advised. Probably only a minority of patients need fifty sessions per year. Therefore, two modifications of the Newell/Saltzman proposal would appear appropriate. First, the requirement of fifty outpatient sessions per year would only apply if a plan provides mental health outpatient coverage. Plans would not be

599. Id. at 73.
600. See supra note 466 and accompanying text.
601. See supra notes 285, 295, 470-75 and accompanying text.
602. See supra notes 257, 265, 424 and accompanying text.
603. See supra notes 299, 480-84 and accompanying text.
605. Id.
606. Id. at 71.
607. The proposal to require plan coverage of fifty sessions would allow weekly coverage with two weeks vacation.
forced to provide mental health coverage. Second, the amount of outpatient sessions required would be left within the discretion of mental health care professionals based on professional standards, not at the patient’s request. The second modification would lessen the fear that the “worried well” would consume the lion’s share of scarce medical resources. Expansion of outpatient treatment to allow more effective treatment might be consistent with cost-containment objectives. Granted, the measurement of the success of cost-containment incentives within managed care systems is typically on a yearly basis when profits are distributed. However, more effective immediate treatment (even if it is more expensive in the first year) might be cheaper in the long run than ineffective outpatient treatment than could span the course of years.

The second “incremental reform” is training the primary care physician in women’s health. Most cost-containment measures are aimed at the gatekeeper. The primary care physician is often given financial incentives to not order diagnostic tests, not refer patients for specialized care, and lower hospital admissions. Women’s health can be particularly jeopardized because in many areas women traditionally are not referred for specialized treatment, such as in the diagnosis and treatment of heart, lung, and kidney disease, are not receiving as many diagnostic tests as men, and are much more likely to have physical conditions attributed to being “all in her head.” The pressure to spend less time per patient is at odds with the descriptive, as compared with stoic, communicative styles of most women. Quite frankly, the innovative managed care system appears to foster gender bias and the structural propensity to further sex bias needs a counterbalancing influence. Better training of primary care physicians in women’s health would be a starting point to alleviate the tension between managed care and gender bias.

Members of the medical community have proposed an “interdisciplinary primary care specialty in women’s health . . . as the best way for medicine to focus on women as whole people, analogous to pediatrics’ focus on children.”

By integrating sex and gender effects into a consolidated curriculum and postgraduate training program, health and illness in women could be approached in a manner analogous to how growth and development are applied by pediatricians. An integrated, sex and gender-informed database would facilitate physicians’ understanding of how sex steroids affect the cardiovascular, musculoskeletal, neurological, and immune systems as well as reproduction.

....

An interdisciplinary primary care specialty in women’s health would bring women’s health from the periphery to the core of physician training and allow physicians to develop clinical skills that transcend arbitrary professional boundaries.

....

Furthermore, the genitalized focus that tends to equate women’s health with reproductive health compromises services to women. . . . Until we transform women’s health from its current focus on reproductive health to total women’s health care, women’s individual health concerns, whether osteoporosis, abortion, or eating disorders will remain vulnerable to marginalization.

All doctors need to know how to take better care of women, but the knowledge and skills primary care specialists in women’s health would acquire will be crucial in gatekeeper dependent managed care plans if women’s health is not to be compromised.609

The medical profession might eventually evolve into a two-model approach instead of the current all-male model. It would appear from an outsider’s viewpoint that we could be decades away from “women’s health primary care providers.” Research is just beginning to appreciate the nuances of women’s health compared to men’s. Science has yet to provide us with sufficient information to understand the depth of the differences. Science, for example, knows some pharmaceuticals react

609. Primary Care Physicians, supra note 405, at 18 (emphasis added).
differently depending on the sex of the patient. However, it is still possible that most react the same regardless of the sex of the recipient. Unfortunately, society must wait for science to provide us with information. Although a women’s health primary care provider might be the long-term solution, development of a specialty in women’s health might arguably be premature. It might also be currently impossible inasmuch as only one-quarter of all medical schools offered a course in women’s health in 1995 and the course was offered only as an elective.

A more appropriate starting point would be to require physicians who want to be primary care providers in a managed care system to successfully complete a course in women’s health before they can be eligible to participate as a provider within the plan and/or eligible to treat women enrollees of the plan. If managed care organizations required physicians to have a course in women’s health, medical educational institutions lacking such a course would quickly respond with the addition of women’s health to the curriculum lest their graduates face unemployment. An appropriate grandfather clause could be added to provider contracts for those physicians already participating within the plan with the proviso that the physician must attend sufficient continuing medical education courses in women’s health that would allow the same amount of medical training as the women’s health course in medical school. Again, continuing medical education courses would appear if a market was created by the managed care industry. Managed care could also require periodic continuing medical education courses to assure that primary care physicians are familiar with new research in the area of women’s health that will likely be generated and provide incentives that most primary care physicians feel is lacking within managed care systems to keep abreast of new developments in their fields of medicine.

Managed care organizations are businesses and have responded to consumerism to some degree. Some even contend that managed care is responding to the demands of consumers and “are in full retreat, broadening physician panels, removing restrictions, and reverting to fee-for-service payment.” Women need to become more assertive about their own health needs and demand primary care physicians complete a course in women’s health before providing professional services to women. Effective lobbying by consumer groups and women’s health

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611. Primary Care Physicians, supra note 405, at 18 (emphasis added).
advocates could bring to fruition the two suggested proposals. The requirement that plans cover fifty hours of outpatient mental health sessions and require primary care providers who treat women enrollees to complete a course in women's health are small first steps that might help to reduce gender bias within the managed care system. Managed care organizations appreciate that their largest group of consumers are women and solicit women at times through their advertising techniques. A good medical marketing strategy would be to advertise a plan promoting primary care physicians certified in women's health. It is possible managed care could see a business opportunity and respond voluntarily to consumer demands in the area. If not, lobbying efforts could be directed at legislatures to intervene and once again practice medicine without a license.

VI. CONCLUSION

The genesis of medical gender bias can be traced to scientific ignorance and the patriarchal structure of our society. The male-centeredness of our society caused physicians, during the primal period of the development of medicine as a science, to perceive women as inherently pathological with all illness springing from her reproductive organs. The early practitioners also created the perception that normal biological functions of women were diseases causing illness and mental instability. As science and society matured, twentieth-century doctors abandoned the concept that the uterus, as the root of all disease, was the controlling organ in a woman's anatomy. Instead, "modern medicine" gave us the male model of treatment with the assumption that men and women were biologically the same, with the exception of reproductive organs, and the progression of disease, responses to pharmaceuticals, and diagnostic and treatment decisions would be the same for both men and women. The health needs of women were studied and approached as if women were small men with breasts, uteruses, and vaginas.

Research until the last decade of the twentieth century was conducted on all-male research populations due to protectionism of women and their unborn children, to enable more readily validated research by having research populations as homogeneous as possible, and as a result of the fear of liability if an unborn child was unwittingly injured as a result of the mother's participation in a research study. Research results derived from all-male research participants were simply extrapolated and applied to the remainder of the population under the assumption that women would respond to disease and treatment the same
as men. The women’s health movement brought awareness of medical gender bias to the forefront which caused the medical and scientific communities to acknowledge its presence and the resulting negative impact upon women’s health.\textsuperscript{613}

Science is now awakening to the disparity in differences of the health needs of men and women as more and more evidence of the gender gap is revealed. However, medicine is only as good as the science on which it is based. Prior to 1993, federal regulatory policy excluded fertile people from participation in research studies to protect women and their potential fetuses from research and protect the research industry from liability to women and their children. Although NIH guidelines in 1986 encouraged researchers to include woman participants, the guideline was rarely implemented nor enforced. The NIH’s Revitalization Act of 1993 requires the inclusion of sufficient women to assure valid gender analysis of data in most clinical trials unless the inclusion is inappropriate from the standpoint of the health of the participant, the nature of the research, or there is a clear and compelling rationale for the exclusion. Thus, research studies funded by the NIH can still exclude pregnant women or preganble women if the research poses an “unacceptable risk for women of childbearing potential.” The FDA removed the federal impediment to the inclusion of women in clinical trials in 1993; however, FDA guidelines still require that female participants are not pregnant and will avoid pregnancy during the trial.

Both the NIH and FDA policies are positive moves for women’s health. However, both can easily be criticized as not going far enough to provide sufficient meaningful data of gender differences. The FDA policy expects that women be included in clinical trials with proper gender analysis of data but does not mandate inclusion. The FDA should mandate the inclusion of women in clinical trials. Arguably, pharmaceutical companies face more liability for excluding women from research and subsequently injecting a product without sufficient testing on women into the stream of commerce than for inclusion of women in research studies. Further, firmly established principles of self-autonomy support the principle that a woman, even if she is biologically capable of becoming pregnant, has the right to decide for herself whether to participate in a research study with acceptance of any accompanying unknown or unknowable risk of harm to her future reproductive

\textsuperscript{613} For a description of the women’s health movement, see Exit & Voice, supra note 65, at 1046-49.
capabilities or her future progeny, as men currently have the right to accept.

Participation by pregnant women in research trials is more controversial. However, courts would probably decide that a pregnant woman has the right to consent to experimental treatment if the treatment has therapeutic value to herself or her fetus, even if the treatment is accompanied by a potential risk of harm. The right of self-autonomy supports the right for the pregnant woman to weigh the therapeutic value of any treatment against the potential harm to her fetus and decide whether the treatment is in the best interest of herself and the future of her family. Accordingly, pregnant women should not be excluded from research trials assuming the research has therapeutic value, to herself or to her fetus. Some non-therapeutic research poses no danger to a pregnant woman or to her fetus. Exclusion of pregnant women from participation in any non-therapeutic research is simply over-broad and the NIH and FDA guidelines should not exclude pregnant women from non-therapeutic research if the risk of in-vivo injuries is minimal.

Inclusion of women in research is essential to the provision of improved medical care for women. Granted, the thought of women of childbearing potential, especially pregnant women, participating in clinical research is a frightening prospect to many in our society. More frightening, however, is the continued practice of women consuming prescription drugs when neither the medical profession nor the pharmaceutical industry knows the true impact on women due to clinical testing on only male participants.\footnote{614}{There is another available tool to spur the pharmaceutical industry to include more women as research participants and conduct gender analysis of data. If a woman was injured by a prescription drug and brought suit against the manufacturer for injuries sustained thereby, counsel for the plaintiff should depose the manufacturer and investigate whether women were included in the clinical trials of the product and if proper gender analysis was performed as currently expected by the FDA before the drug manufacturer injected the product into the stream of commerce with the expectation that a substantial portion of the drug's market would be women users. As established previously, there are strong arguments for liability for the act of excluding women as research participants when manufacturers know their products are intended for use by women. Plaintiffs' attorneys need to push that argument in litigation. To date, this theory of culpability has been virtually ignored in prescription drug litigation.}

Research deficiencies regarding women's health clearly impacts the treatment provided by physicians. However, the research industry cannot be blamed entirely for the treatment disparities. Preconceived biases possessed by some members of the medical community also perpetuate gender bias. Women are perceived differently from men by
physicians. Women’s complaints are not taken as seriously and physicians are more likely to consider a woman’s physical symptoms as having a psychogenic origin than a man presenting the same physical symptoms. Women are more likely to be prescribed a psychoactive drug than a man with the same symptoms. In some areas of practice, doctors are much more likely to mis-diagnose women and are much less likely to order diagnostic tests or invasive procedures for a woman as compared with a man. There is no medical explanation for the treatment differences. The AMA has recognized the presence of gender bias within the medical profession and encouraged doctors to examine their own attitudes to assure that biases did not impact treatment and that gender was not used as an inappropriate criteria for clinical decision-making.

Managed care entered the forefront of the health care arena at approximately the same time as significant inroads were being made in the area of women’s health. Managed care utilizes capitated payments, prospective utilization review, physician risk-sharing, and primary care providers to screen referrals for diagnostic tests, hospitalization, and specialized care. Performance-based incentives and cost-containment mechanisms are designed to reduce the rising cost of medical care. However, there is growing consumer concern regarding the quality of care rendered and the impact of managed care on women’s health.

Women are the largest consumers of health care in this country and any impact that managed care has on quality will impact women more than men from a demographic standpoint. Originally, managed care was perceived as a partial solution to the “feminization of poverty” because managed care had the potential to provide health-care coverage to broader segments of the population for less money and offered ostensibly better preventative and prenatal care. Today there is some evidence that managed care is having a negative impact on women enrollees, especially socioeconomic or ethnic subpopulations, despite the lack of empirical support that managed care has eroded the overall quality of care. The legislative response to the quality of care rendered by MCOs and HMOs indirectly acknowledges that quality issues dealing with managed care are more likely to impact women. Evidencing the presence of gender bias within managed care systems is the fact that legislation was perceived as necessary to allow a sufficient hospital stay for childbirth, assure pap smears and mammograms would be provided,

615. Hellinger, supra note 597, at 833.
allow sufficient recuperative time following a mastectomy, and assure
that the resulting reconstructive surgery would be provided.

Subconscious gender stereotyping, already proven to influence
diagnostic decisions and referrals for diagnostic tests and invasive
procedures, are likely to become more pronounced in managed care
given the institutional pressures created by physician risk-sharing, cost-
containment measures, and prospective utilization review to save money.
Quota systems designed to force physicians to treat more patients per day
might impact women more than men because of differences in
communicative styles. Indeed, recent studies of women enrollees of
managed care show that women are not as satisfied with their choice of
physicians or access to specialized care as fee-for-service patients.

The primary care physician acts as a gatekeeper to the managed care
system. Specialized care, hospitalization, and diagnostic testing must
first be approved by the primary care physician. Yet, very few primary
care physicians have training in women’s health other than a basic course
in obstetrics and gynecology. Studies suggest that primary care
providers are not sufficiently trained in the myriad of duties they are
expected to perform and might not be sufficiently schooled in women’s
health to overcome the built-in gender biases of attributing a woman’s
physical symptoms as psychosomatic and not treating women the same
as men in referring women for diagnostic tests and invasive procedures
to treat certain conditions. Concern is also raised that the primary care
physician will not be able to readily adapt as the research industry
provides new information of gender differences in response to disease
and treatment in a system that has been criticized by physicians as not
fostering physicians to keep abreast of new developments.

One reform of the managed care system to assure women’s health is
not sacrificed by the performance-based incentives and cost-containment
mechanisms is to require primary care physicians to receive formal
educational training in women’s health. Primary care providers should
include all physicians who provide primary health care services to
women enrolled in managed care plans, including internists and OB-
GYNs. Managed care could require that primary care physicians
complete a medical school course in women’s health as a condition of
the provider contract. Primary care providers already within the system
could be required to participate in continuing medical education courses
regarding women’s health. Managed care setting the requirement would
have the added byproduct of forcing the addition of women’s health
courses in all medical schools and the creation of a more extensive market in continuing medical education courses.616

Primary care physicians are not sufficiently trained in mental illness, yet many times they treat patients suffering from mental illness typically with a heavier reliance on the use of antidepressants, often prescribing lower doses than needed. Further, primary care providers may act as a gatekeeper to mental health services within the system. Women are the largest consumers of mental health services and any restriction to mental health services impacts women as a class more than men. Coverage of outpatient sessions is restricted to only a limited number of sessions by the terms of some plans or by de facto prospective utilization review in other plans. Expanding outpatient sessions to fifty outpatient sessions per year is clinically sound and would allow more effective treatment of the serious conditions that need more prolonged therapy. Expansion of mental health outpatient coverage would benefit women because women are more likely to suffer from conditions necessitating prolonged outpatient treatment.

The eradication of gender bias within the medical community will take years. The litigation system will not be a very likely method to indirectly attack the problem of gender bias, particularly given the presence of ERISA, although certainly the legal system might provide compensation for women who were treated by physicians who failed to use the standard of care other doctors would have used under the same circumstances. If litigation is probably not an effective way to attack the problem, the only other avenues would appear to be consumerism and legislation.

Women need to become more aggressive in demanding medical research, medical treatment, and health plans consider women’s health a top priority. Expanding research and the inclusion of more women in clinical trials is critical to the development of a mode of practice that is clinically sound for women and to bypass the traditional all-male model to the practice of medicine. Further, women need to be more vocal in their demands of managed care. Most cost-containment measures revolve around the primary care provider. The starting point to avoid the preservation of the status quo with its inherent gender bias is enlightening primary care physicians in women’s health. Consumerism is one avenue of change. Managed care might respond to consumer pressure from women because women are the largest consumers of

616. Then, the next logical step could easily become a required course in women’s health for all medical school graduates which would help narrow the gender gap.
health care and managed care has been solicitous to women in the past. If managed care fails to respond and if “customers become sufficiently discontented, they will eventually call on legislatures to act on their behalf.”§17

617. Exit & Voice, supra note 65, at 1067.