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Student Comment: Not Really a Battle of the Sexes: Women's Health Agenda Advocates Global Equality in Medical Research Trials and Drug Administration

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Not Really a Battle of the Sexes: Women's Health Agenda Advocates Global Equality in Medical Research Trials and Drug Administration

Margery R. Beltran

ABSTRACT: The New Women's Health Agenda seeks to close the discriminatory gap between men's and women's medical treatment around the world. Often, women's reproductive issues are the focus of medical studies in which women are involved; however, chronic diseases are quickly becoming a high health risk for the female population around the world. This comment explores the past, present, and future of women's global health. Throughout history, women have been prevented from participating in clinical trials for reproductive protection reasons. The problem arises after men have successfully responded to treatment because the medication is then administered to both men and women. Women are still facing numerous challenges in regards to proper healthcare today. Women today are experiencing an increase in mental health diseases and chronic diseases such as heart disease, autoimmune diseases, and HIV/AIDS. Women of color and of low socioeconomic status also face their own unique challenges. This comment argues importance of a global healthcare system in which men and women are treated as biologically different, but socially and psychologically equal.

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I. Introduction

Between lifestyle changes and the shift to a longer-living population, women's health, both reproductive and non-reproductive, has become an issue on the rise throughout the field of public health.¹ "The world still focuses very much maternal health and, more recently, family planning, which definitely reflect critical needs; [however], the predominant view today is of women as reproductive beings, which leads to neglect of women's health in other stages of life," explained Ana Langer, Professor at the Harvard T.H. Chan School of Public Health.² The *New Women's Health Agenda* ("Agenda") aims to address what Langer calls the "double burden of disease among women" in order to promote health to women of all ages around the world.³

The Agenda's double burden of disease integrates two scopes of study in women's health.⁴ The first burden and most commonly studied are the problems that still exist in the realm of reproductive health, infectious diseases, gender-based violence, and malnutrition.⁵ The second, and more recently emerging, is the epidemic of chronic diseases.⁶ There is a drastic inequality in government focus on women's reproductive and non-reproductive health around the world.⁷

The Agenda is concerned about the rise of chronic diseases and the lack of preparedness, especially in low to middle socioeconomic status countries.⁸ Langer also notes that chronic diseases and reproductive health problems are more common in the low to middle socioeconomic class countries, primarily in Europe and Africa.⁹

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1. Fiona Fleck, *The New Women's Health Agenda*, 91 BULL. WORLD HEALTH ORG. 628 (2013). Ana Langer is an advocate for women's health on the global level and has served on the boards for multiple global health organizations over the past 25 years. She is at the forefront of the Women and Health Initiative at the Harvard School of Public Health.
 2. Fleck, *supra* note 1.
 3. *Id.*
 4. *Id.*
 5. *Id.*
 6. *Id.*
 7. *Id.*
 8. Fleck, *supra* note 1 ("It seems that donors are not prepared to invest in the prevention, detection and treatment of chronic diseases affecting women unless more progress is made in the unfinished agenda of reproductive health.").
 9. *See generally id.*

This comment explores the discrimination towards women in medical research and treatment throughout the world while developing a clearer understanding of the Agenda's objectives. Through a combination of modern medical research analysis and a historical examination of gender discrimination in medical testing, this comment argues that the Agenda is a necessity in the field of global health. The Agenda, which was created in 2010 at the Harvard School of Public Health, is quickly gaining recognition among global medical researchers and academics.¹⁰ The Agenda aims to improve the outlook of women's health research and treatment in order to bring equality to women in their treatment for chronic diseases and reproductive health.¹¹

II. Historical Discrimination: A Timeline of Women's Treatment

Gender Bias and Discrimination

In the field of medicine, women fall victim to sex discrimination.¹² However, traditional treatment of women has not been without its own rationale.¹³ According to Langer, there are valid concerns in regard to including women in clinical trials, but that these concerns should not bar women from participating in the trials:

There is evidence that discrepancies exist between men and women in terms of the attention they receive for the problems they have in common... Women are not recruited to trials for the testing of drugs for chronic diseases that, once approved, are used by women. Women are often not considered "stable enough" to participate in such trials because of their menstrual cycles, because they may become pregnant during the trial and because they may be breastfeeding, which could incur risks for the baby. Therefore, women are excluded from many trials and as a result don't get proper treatment later.¹⁴

10. *Id.* at 629.

11. *Id.*

12. Anita Holdcroft, *Gender Bias in Research: How Does it Affect Evidence Based Medicine?*, 100 J. ROYAL SOC'Y OF MED. 2 (2007).

13. Fleck, *supra* note 1.

Clinical research demonstrates gender bias in a number of ways.¹⁵ A key issue in women's discrimination is the field's tendency to apply the research collected from male-dominated clinical trials to women's clinical treatment.¹⁶ While the rationale to protect the reproductive anatomy of women when collecting research is understandable, that rationale is counterintuitive on the macro-level goal of improving the overall health of women.¹⁷ There is a huge discrepancy between clinical trials and treatment.¹⁸ Women must forego testing of a drug, but if it proves successful for men, it is then prescribed to women.¹⁹

Anita Holdcroft provides the example of gender differences in the treatment of coronary artery disease between men and women in which male studies on heart disease are provided far more funding than women.²⁰ Holdcroft found coronary artery disease research funding is far more generous to studies for males; however, the risk of the disease is far higher for women.²¹ Women have a much higher chance of dying from coronary artery disease than men.²² Therefore, there should be more studies focused on either just women or the differences between men and women's symptoms and reactions to medication treating coronary artery disease.²³

The same result occurs across the medical field. For instance, research strongly suggests women have stronger immune systems than men,²⁴ thus women have a naturally higher prevention of disease.²⁵ Unfortunately, this also leaves women far more likely to de-

14. *Id.* at 629; *see also* Holdcroft, *supra* note 12 (“The evidence bases of medicine may be fundamentally flawed because there is an ongoing failure of research tools to include sex differences in study design and analysis. The supporting bias which this methodology maintains creates a situation where guidelines based on the study of one sex may be generalized and applied to both.”).

15. Holdcroft, *supra* note 12.

16. Fleck, *supra* note 1.

17. Holdcroft, *supra* note 12.

18. *Id.*

19. *Id.*

20. *Id.*

21. *Id.*

22. *Id.*

23. *See generally* Holdcroft, *supra* note 12.

24. Donna E. Shalala, *Women Get Heart Disease Too: A Brief History of Gender Discrimination in Medical Research*, 10 COLUM. J. GENDER & L. 57, 59 (2000).

25. *Id.*

velop autoimmune diseases such as multiple sclerosis, lupus, scleroderma, and rheumatoid arthritis—all of which are unrelated to reproductive health issues.²⁶ The Agenda can help broaden the narrow focus of the traditional reproductive health narrative to include chronic diseases.²⁷

In the past two decades, the U.S. National Institute of Health (hereinafter “NIH”) has begun to acknowledge this lack of attention to women’s specific health problems.²⁸ In 1994, NIH implemented a set of guidelines to ensure trial drugs would be tested on a wider range of patients who would ultimately use the medication or therapy.²⁹ Before the implementation of this policy, women were often excluded from early stage drug trials as a precautionary measure.³⁰ NIH decided that this was a substantial issue because there was little information regarding how the drugs would affect women—the same battle being fought by the Agenda.³¹

By 1997, 94% of NIH research grant proposals included women as subjects.³² But, almost twenty years since 1997, there is still a discrepancy in research enrollment of men and women. To better understand the continued discriminatory research practices, it is imperative to examine the historical context of gender differences in medical research. Since the global initiative grew out of primarily U.S. policy, an examination of U.S. policy changes will be conducted henceforth to understand how the Agenda has shaped the international landscape regarding medical research for women.

26. *Id.*

27. Fleck, *supra* note 1.

28. Shalala, *supra* note 24.

29. *Id.*

30. *Id.* Holdcroft noted in 2005, eight out of ten prescription drugs were withdrawn from the U.S. prescription pharmaceuticals market due to their negative effects on women’s health. Not only is administering drugs not tested on women a dangerous gamble to women’s health, but it is also an extremely wasteful use of resources. Holdcroft, *supra* note 12.

31. Holdcroft, *supra* note 12.

32. *Id.*

a. A U.S. Historical Exploration of Women's Medical Research and Treatment

i. Guinea Pigs: Early 19th Century Clinical Trials

In the early 19th century, African-American slave women were the primary test subjects in clinical trials.³³ These tests were conducted at a time when anesthesia was non-existent.³⁴ Physicians at this time would repeat the heinous and inhumane experiments on these women in order to find the best forms of treatment.³⁵ Moving to the 1900s, researchers around the world shifted to using institutionalized populations, including mental health patients, prisoners, and concentration camp victims.³⁶

By 1949, the abuses to the institutionalized had been revealed to the global public and there was a movement formed to protect humans from unjust experimentation. This eventually culminated in the Nuremberg Code.³⁷ The code “set out ethical and legal standards for the conduct of human research aimed at protecting human research subjects from the types of experimentation practices used by the Nazis in World War II.”³⁸ According to Rothenberg, the U.S. was still slow to develop their clinical trial regulations after the code was implemented.³⁹

ii. Trial and Error: Policy Shifts in the U.S. Since the Mid-1900s

As previously stated, there has been logical rationale behind avoiding women's inclusion in new drug trial treatment.⁴⁰ Researchers do not want to be liable for potentially harming a woman's fertility or an unborn child.⁴¹ At the most primal level, the human race, like all other animals, wants to preserve its species.⁴² The Agenda

33. Karen H. Rothenberg, *Gender Matters: Implications for Clinical Research and Women's Health Care*, 32 HOUS. L. REV. 1201, 1220 (1996).

34. *Id.*

35. *Id.*

36. *Id.*

37. *Id.*

38. *Id.*

39. Rothenberg, *supra* note 33. Rothenburg believes that the U.S. changes in policy are primarily attributed to the Thalidomide tragedy in the 1960s. *Id.*

40. *See supra* Section 1.

41. Fleck, *supra* note 1.

42. *See generally id.*

does not criticize the protection and preservation of reproductive health of women; it works to find ways to preserve and protect female reproduction health issues, while also ensuring proper treatment for women with non-reproductive health problems.⁴³

There was a great deal of hesitance in the field of medicine to treat women with experimental drugs.⁴⁴ Though NIH's initiative was not implemented until 1994, there was a small increase in the late 1980s in including women in clinical trials.⁴⁵ Sarah Keitt attributes the hesitance to include women to two distinct reasons: the first, being a general neglect to women throughout history; the second, being the Thalidomide tragedy in the 1960s,⁴⁶ which caused medical researchers to be more aware of their effects on unborn children.⁴⁷ The Thalidomide tragedy sparked stricter legislative regulation for women as test subjects in the 1960s and 1970s.⁴⁸ Keitt believes that did far more harm than good.⁴⁹

Prior to this 1980's shift of female inclusion, researchers fell into one of two categories with regard to women in clinical trials; this categorization is also attributed to women's involvement in testing at the time.⁵⁰ Some researchers assumed women to simply be smaller versions of men and thus viewed women as unnecessary test sub-

43. *See generally id.*

44. *See generally* Sarah K. Keitt, *Sex & Gender: The Politics, Policy, and Practice of Medical Research*, 3 YALE J. HEALTH POL'Y L. & ETHICS 253 (2003).

45. *Id.*

46. "In 1962, the Kefauver-Harris Amendment, perhaps the most important piece of legislation regulating the conduct of clinical trials, was passed with the purpose of protecting children, pregnant women, and fetuses. The Kefauver-Harris amendment required drug manufacturers to demonstrate that new drugs were safe and effective via adequate and well-controlled clinical trials. This legislation was passed in response to the thousands of babies with severely deformed limbs as a result of utero exposure to Thalidomide (used to prevent morning sickness). Later, during the early 1970s, research revealed the daughters of women who took diethylstilbestrol during pregnancy had an increased risk of vaginal cancer. In 1977, the [FDA] responded to these events by issuing guidelines that required women of childbearing potential to be excluded from [drug trials until data from animal studies regarding development disturbances in embryonic or fetal was collected]. The only exception to these guidelines was for drugs used in treatment of life-threatening or serious diseases." *Id.* at 255.

47. *Id.* at 253.

48. *Id.*

49. Keitt, *supra* note 44.

50. *Id.* at 254.

jects.⁵¹ The other group viewed women's biology as too complicated to study due to their hormonal cycles.⁵² The assumption of hormone complications draws a question of irony in that researchers were preventing women from inclusion in medical trials for medication created to treat women.⁵³ Critics have since pointed out that drugs tested on men only, were also being prescribed to women even though the researchers conducting the trials fully recognized that fluctuations of hormones affect how a woman reacts to certain kinds of drugs.⁵⁴ The risks of some of those prescriptions administered could have been very dangerous, and medical researchers at the time had very little data on what sort of reactions women could have.⁵⁵

By 1983, the then-Assistant for Secretary of Health, Dr. Edward Brandt noticed a distressing pattern in medical research.⁵⁶ Brandt found that there was a plethora of information regarding menopause, pregnancy, and menstruation, but hardly any information on chronic illnesses that affect both men and women, namely heart disease.⁵⁷ To remedy this problem, Brandt formed a national task force dedicated to analyzing women's health issues.⁵⁸

In 1985, the task force concluded that the lack of research on women's non-reproductive health issues was negatively affecting the overall healthcare of women.⁵⁹ The task force's findings prompted the official NIH guidelines for inclusion of women, particularly women of childbearing potential, in federally funded clinical research.⁶⁰ Despite the NIH's efforts for female inclusion, advocates for women's health and the task force found that since the inclusion guidelines were not "enforced," trials were still being conducted in the same way they were prior to the implementation of the guidelines.⁶¹

51. *Id.*

52. *Id.*

53. Shalala, *supra* note 24.

54. *Id.*

55. *See generally* Shalala, *supra* note 24.

56. Keitt, *supra* note 44.

57. *Id.* at 255-56.

58. *Id.* at 256.

59. Keitt, *supra* note 44, at 256.

60. *Id.*

61. *Id.* ("Women were still routinely excluded from clinical trials.").

iii. The 1990s and the Society for Women's Health Research

In 1990, the increasingly frustrated and concerned advocates for women's health formed the Society for Women's Health Research (hereinafter "Society").⁶² The Society sought to enforce the NIH clinical trial rules by placing pressure on the U.S. Congress to involve the General Accounting Office.⁶³

After a great deal of investigation, the General Accounting Office found that the "NIH policy had not been well communicated or understood within NIH or the research community, was applied inconsistently across institutes, and only applied optional research. NIH had also done little to encourage the analysis of studying sex differences in data."⁶⁴ The report found that only 13% of the NIH budget was allocated to women's health research.⁶⁵ The findings sparked a serious shift in women's health.⁶⁶ Following the findings, researchers were informed by the government that they would be held accountable if they did not follow the NIH guidelines and that policies had to be treated like mandates.⁶⁷

As the 1990s progressed, various new proposals and bills began to develop to protect women's treatment.⁶⁸ By 1995, the FDA had also proposed regulation requirements to include safety and efficacy data by gender.⁶⁹ All the changes in the 1990's provided more accessible opportunities for women.⁷⁰ By the 2000s, women were proportionally represented in clinical trials with the exception of pregnant women.⁷¹

Fortunately, abusive medical treatment is no longer an acceptable practice to any person, regardless of biological sex. There are still many discrepancies between the way men and women are treated in clinical trials. The Agenda seeks equality in the quality of

62. *Id.*

63. *Id.*

64. *Id.*

65. Caroline W. Jacobus, *Legislative Responses to Discrimination in Women's Health Care: A Report Prepared for the Commission to Study Sex Discrimination in the Statutes*, 16 WOMEN'S RTS. L. REP. 153, 174 (1995).

66. Keitt, *supra* note 44, at 257.

67. Keitt, *supra* note 44, at 257.

68. *See generally* Shalala, *supra* note 24.

69. *See generally* Shalala, *supra* note 24.

70. Keitt, *supra* note 44, at 258.

71. *Id.*

treatment towards women in medical trials because modern medicine is still discriminatory towards women.

III. Testing Positive for Unequal Treatment Towards Women in Modern Medicine

a. Biopsychosocial Differences: What really needs to be addressed?

i. Attitudes and Behaviors in the Healthcare Facility

Women tend to receive more direct health care over their life span.⁷² This is primarily attributed to their reproductive health needs and their longer life expectancy.⁷³ In one study comparing the general treatment of men versus women in healthcare facilities, researchers concluded, “women’s health care tends to be comprised of drug prescriptions and routine checks whereas major diagnostic and therapeutic interventions are more frequently performed on men.”⁷⁴

In the past twenty to thirty years, physicians have changed their notion about how women experience symptoms of illnesses and diseases.⁷⁵ It was often assumed, throughout the field, that men and women experience symptoms the same way.⁷⁶ This could contribute to the assumption that women could be prescribed the same treatments as men.⁷⁷

According to Jacobus, in 1995, men were 6.5 times more likely to be tested for common chronic diseases.⁷⁸ “Women’s ailments are more likely to be attributed to emotional rather than physical causes.”⁷⁹ According to recent social demographic research conducted by University of Michigan, both men and women develop the same types of illnesses.⁸⁰ The key differences arise in the frequency of

72. Jacobus, *supra* note 65, at 174.

73. *Id.*

74. Jacobus, *supra* note 65, at 174.

75. *Id.*

76. *Id.*

77. *Id.*

78. *Id.*

79. *Id.*

80. Megan Veith, Note, *The Continuing Gender-Health Divide: A Discussion of Free Choice, Gender Discrimination, and Gender Theory as Applied to the Affordable Care Act*, 21 GEO. J. POVERTY L. & POL’Y 341, 345 (2014).

those illnesses and the “pace of death” among the sexes.⁸¹ Thus, both should be treated according to their biological needs.⁸² Gender-specific medicine positively impacts both men and women:

Although [the modern] field of medicine originated from feminist critiques of the current health care system’s treatment of women in the past, gender-specific medicine strives to help both women and men, especially concerning gender difference in disease susceptibility and lifespan. Gender-specific medicine is important because it seeks to recognize the differences between men and women’s health, while also ensuring that both genders are equally represented in medicine.⁸³

The issue at hand is not to advocate for a healthcare system in which women take precedence over men in clinical trials and treatment. The goal should be achieving just and fair treatment of both men and women in medical research to ensure a healthier future for all persons. Historically, research on women’s health is far less developed than that of men and thus, there may need to be an increased focus on women’s health issues in the near future.⁸⁴

ii. Women of Color in Medicine

A subcategory of disparities among women’s health is the treatment of women of color in

the healthcare system, especially with regard to clinical trials. The health concerns of women of color, who comprise a crucial percentage of the world’s population, are in need of attention from researchers.⁸⁵

Although various programs and policies throughout the world have begun to mandate the inclusion of women in clinical trials, many of the advancements fail to provide benefits to women of col-

81. Veith, *supra* note 80.

82. *Id.*

83. *Id.* at 344. In regards to the modern involvement of the U.S. in women’s health movements, “The gender-specific medicine movement has greatly benefitted women, who have been the focus of much of the new scientific studies and research of the last few decades. Thus, it may come to a surprise that the [Affordable Care Act] includes more female-specific benefits than male-specific benefits.” *Id.* at 355.

84. *See generally* Keitt, *supra* note 44.

85. *See generally* Lisa C. Ikemoto, *Deconstructing the Image Repertoire of Women of Color: In the Shadow of Race: Women of Color in Health Disparities Policy*, 39 U.C. DAVIS L. REV. 1023 (2006).

or.⁸⁶ “[T]he core failure – inattention to the intersections of categories used for social ordering – leaves the particular ways that racialized patriarchy allocates health risks to women of color out of sight and out of mind.”⁸⁷ Lisa Ikemoto argues that in the past fifty years, racism and patriarchy have been successfully addressed;⁸⁸ however, racism and patriarchy issues continue to act as completely separate entities from initiatives to promote the health needs of women of color.⁸⁹

As social health disparities continue to be acknowledged, social scientists are gathering data on how biopsychosocial factors affect a person’s health treatment.⁹⁰ Researchers found that biological race, socioeconomic status, and general lifestyle habits are the key factors fueling all health disparities and differences in mortality rates among races.⁹¹

According to Ikemoto, hardly any research has been conducted on the specific disparities and needs for women of color⁹² because they were assumed to be a subcategory of the already studied race disparities and thus need no extra examination.⁹³ Ikemoto raises her concern that researchers are only addressing the problem in a fashion that is far too narrow because they are only looking at the factor of race, while disregarding gender.⁹⁴ Ikemoto fears that “the narrowing scope of the health disparities inquiry threatens to constrain the understanding of health, as well as to push the health needs of women of color and others back into the shadows.”⁹⁵ The world is quickly recognizing health disparities among racial groups.

iii. The Flaws of Structuralism Research

In regards to the research collected and analyzed about race, Ikemoto also criticizes the primary research and implications of the

86. Ikemoto, *supra* note 85, at 1025.

87. *Id.*

88. *Id.* at 1026.

89. *Id.*

90. *Id.*

91. *Id.*

92. Ikemoto, *supra* note 85, at 1026.

93. *Id.*

94. *Id.*

95. *Id.*

structuralist school of thought.⁹⁶ In other words, the research is collected under a framework that focuses on organizational structures in society, and in this case, how those structures affect health outcomes among racial classes.⁹⁷

Structuralism analyzes how large societal influences, such as governments or global policy organizations, affect the treatment of humans.⁹⁸ Leadership organization's treatment towards groups of people, regardless of whether they are subtle or not, can have a great deal of effect on stereotypes and the way people react to one another.⁹⁹ According to Ikemoto, structuralism can be one of the most successful ways to analyze governing organizations and their effects on populations, but it should not be the only approach used.¹⁰⁰ This theory can provide insight as to what sort of policy changes or legal interventions should be implemented.¹⁰¹

Structuralism is often the theory of choice because it assumes racism is perpetuated through the operation of greater institutions.¹⁰² Under the structuralist theory, implementing strict programs and providing cross-cultural training would eventually lead to the elimination of racism in healthcare.¹⁰³ Application of this theory in program development can identify the changes in tangible practices, which has the possibility of greatly improving the treatment of the disparaged.¹⁰⁴ The problem arises when the changes in practice do not adapt with the fluid changes in ideology.¹⁰⁵ According to Ikemoto, it is not the best nor is it the only theory in addressing disparities to different races and women,¹⁰⁶ because "racism and patriarchy persist even as their forms change. As new practices and standards

96. *Id.*

97. *Id.*

98. *See generally* Ikemoto, *supra* note 85, at 1027.

99. *See generally id.*

100. Ikemoto, *supra* note 85, at 1027-28.

101. *Id.* ("While structuralist analysis is good at identifying opportunities for legal intervention. An exclusive focus on health care organizations and practices fails to fully account for how orders or power formed by racialized patriarchy can persist despite the dismantling of specific institutional structures and practices.").

102. *Id.* at 1048-49.

103. *Id.* at 1049.

104. *Id.* at 1050.

105. *Id.*

106. Ikemoto, *supra* note 85, at 1050.

emerge, ideology flows in and provides context.”¹⁰⁷ As the fluidity and adaptation of racial and patriarchal issues develop, the structuralism theory is able to narrow down what the new challenges are to society and how they were shaped.¹⁰⁸

Instead, Ikemoto recommends critically analyzing cultural formation; while structuralism theory should continue to be used, Ikemoto believes that implementing the added critical analysis will greatly improve the health disparities of women of color.¹⁰⁹ Critical analysis of cultural formulation will give insight to not only the governing structure, but also to the governed.¹¹⁰ Ikemoto notes: “[C]ritical cultural inquiry is sensitive to multi-axis difference, differential subordination, and the fact that ideology, including racialized patriarchy, adapts quickly to structural changes.”¹¹¹

Structuralism theory is used by researchers to reveal issues in difference of treatment among the sexes; however, the theory rarely provides any inkling of recommendation as to how to correct the issues it discovers.¹¹² For example, if health disparities are attributed to race and gender separately and not under a holistic approach, women of color fall into one of two categories of this assumption: that they react to treatment the same way as the men in their particular race or that they will react to treatment a certain way based on research primarily conducted on white women.¹¹³

Women of color are victimized on two levels. The first is the standard biological discrimination, as addressed by the Agenda.¹¹⁴ The second is their psychosocial demographic factors including their race and socioeconomic status.¹¹⁵ Women of color have health needs that desperately need to be addressed and it is imperative that they do not become a mere subcategory in race and gender studies.¹¹⁶

107. *Id.*

108. *Id.*

109. *Id.* at 1026.

110. *Id.*

111. Ikemoto, *supra* note 85, at 1026 (Ikemoto also discusses how this theory’s study of ideology allows for “a more nuanced and complicated understanding of how inequality becomes embedded in our understanding of [health].”).

112. *Id.* at 1050.

113. *Id.*

114. *See generally id.*

115. *See generally id.*

116. *See generally id.*

iv. International Human Health Rights: HIV/AIDS Pandemic and Women

Another relatively new health concern is the rise of HIV/AIDS throughout the world. “To curb the spread of the pandemic, [we] must focus on the structural and contextual determinants shaping the course of the pandemic, especially the social or traditional practices that violate women’s human rights and leave them more vulnerable to HIV/AIDS.”¹¹⁷ The HIV/AIDS pandemic is posing challenges to the international human rights of women throughout the world, primarily in developing countries.¹¹⁸ Spectar argues that HIV/AIDS has become a global threat to the international human health rights for women and should be sparking the attention of national leaders around the world.¹¹⁹

There are numerous factors affecting the spread of HIV/AIDS among women, particularly in developing countries.¹²⁰ In general, women are deemed to be powerless and of a lower status in developing countries.¹²¹ Under this generalization, women are much more vulnerable to become victims of sexual abuse and coercion.¹²² Hence, women are far more likely to be pressured into a situation that presents an exposure to possible infection of HIV or other sexually transmitted diseases.¹²³

Other prominent factors continuing the pandemic include “barbaric cultural practices” and domestic violence.¹²⁴ Genital mutilation continues to occur in many areas around the world.¹²⁵ During the mutilation process, women run the risk of contracting HIV and possibly bleeding to death from subsequent injuries.¹²⁶ Moreover, many

117. J.M. Spectar, *The Hydra Hath but One Head: The Socio-Cultural Dimensions of the AIDs Epidemic & Women’s Right to Health*, 21 B.C. THIRD WORLD L.J. 1, 2 (2001).

118. *Id.* at 3.

119. *Id.* (“In fact, the situation in developing countries is becoming increasingly grave—to a degree that AIDS is effectively an “aggressor” or a global threat to women’s international human rights, particularly the right to health.”).

120. *Id.* at 4.

121. Spectar, *supra* note 117.

122. *Id.*

123. *Id.*

124. *Id.* at 6.

125. *See generally id.*

126. Spectar, *supra* note 117, at 6.

countries still view violence towards a woman as a man's right.¹²⁷ Domestic violence "is a major socio-cultural condition that violated women's human right to health."¹²⁸ In domestic violence situations, women are often in a position in which they cannot refuse sex and usually do not have the option of using any sort of sexual protection.¹²⁹ These factors raise serious issues in the treatment of women. Women are not only thought to be second class citizens; they are also more likely to be exposed to abusive situations in which they have no control over what happens to their bodies.¹³⁰

Many women in developing countries are afraid of the repercussions should they report any sort of abuse.¹³¹ According to Spectar, the legal systems of developing countries often side with abusers and further traumatize the victims.¹³² In fact, in many developing countries, both governing bodies and even family members discriminate against women with HIV/AIDS.¹³³ There, women are often denied jobs, housing, and healthcare.¹³⁴

To achieve the goals of the Agenda worldwide, the treatment and view of women's status throughout the world must be shifted. Women in developing countries are stigmatized as lesser beings.¹³⁵ The biopsychosocial stereotypes of women are the underlying issue in the lack of just treatment to women in healthcare.

This is not to say men's medical treatment should be neglected or ignored, but merely that both research of men and women, of all races and ages, should be on a level playing field. The goal of the women's health initiatives should be to increase recognition of women's health, without causing a complete neglect of men's health re-

127. *Id.* at 7 (It is important to note that domestic violence runs rampant through both developed and developing countries in different ways.).

128. *Id.*

129. *Id.*

130. *See generally id.*

131. Spectar, *supra* note 117, at 7.

132. *Id.* ("For example. In Tanzania, female rape victims who bring charges against their attackers are discriminated against to the extent that these women (but not their male attackers) are required to disclose their HIV-status.").

133. *Id.*

134. Women with HIV/AIDS tend to be more stigmatized if they are monogamous wives. Their in-laws often blame these women for exposing their son and his fate. Sometimes widows of men who died of AIDS are thrown out of their home and lose their children to their in-laws. *Id.*

135. *See generally id.*

search. The mindset must shift to recognize that men and women are biologically different, yet socially equal. Modern medicine can use this knowledge to alter its practice accordingly in order to promote the healthiest population possible. There are numerous ways researchers can work towards this goal.

b. Clinical Trials

i. Varied Biological Responses

One of the key ways to advocate this issue is through changes in gender treatment of clinical trials. It has been well established that biological reactions to medical treatments vary depending on the subgroup of humans being tested.¹³⁶ A major concern in clinical trials is what researchers call a “directional difference.”¹³⁷ Directional differences occur in research outcomes when one trial group benefits from the treatment, while the other is harmed by the treatment.¹³⁸

Jesse Berlin and Susan Ellenberg found there is no question that men and women respond differently to treatments and that the differences in response have hardly been studied and are relatively unknown.¹³⁹ Berlin and Ellenberg attribute this lack of data primarily to the difference in genetics between men and women; “the broader issue really centers on the biological factors, possibly defined by genes or gene expression, that may directly or indirectly modify the effect of specific treatments on specific individuals.”¹⁴⁰

ii. Mental Health and Substance Abuse Trials

Mental Health is a rapidly growing concern in the modern world of medicine, and substance abuse is a growing trend among

136. Jesse A. Berlin & Susan S. Ellenberg, *Inclusion of Women in Clinical Trials*, 7 BMC MED. 1, 2 (2009).

137. Berlin & Ellenberg, *supra* note 136.

138. *Id.* Berlin and Ellenberg provide an example of a recent medication trial for a heart failure drug. The medication was successful and effective on black test subjects and ineffective on white test subjects. If men of different races and the (assumed) same biological make-up can react differently to a drug, then women can most definitely react differently to drugs than men. *Id.*

139. *Id.* at 3.

140. Berlin and Ellenberg anticipate a rise in genetic profiling that could possibly lead to major discoveries in personalized medicine. *Id.*

women.¹⁴¹ Shelly Greenfield found that women trying to enter substance abuse treatment face many barriers.¹⁴² They also found evidence that women preferred participating in women-only, as opposed to mixed-gender, treatment programs.¹⁴³ Women tended to perceive women-only treatment programs as safer and more comfortable environments where they can focus on rehabilitation.¹⁴⁴ Greenfield attributes this perception to the fact that women and men have differed risk factors in substance abuse, including but not limited to medical consequences, reasons for relapse, and co-occurring mental disorders.¹⁴⁵

Upon thorough investigation, Greenfield found there are no empirical studies on women-only treatment groups for substance abuse.¹⁴⁶ “There is [no empirical research] of a manual-based recovery group for women that is not specific for type of substance abuse, co-occurring psychiatric disorders, or stages of the lifecycle.”¹⁴⁷ Nor were there any studies on generic recovery groups for women.¹⁴⁸ Greenfield found this to be disconcerting because the majority of substance abuse treatment is conducted in a group setting, so they conducted a comparative treatment between women-only substance abuse treatment groups and mixed-gender treatment groups to provide empirical data on women in a clinical group setting.¹⁴⁹

Greenfield predicted that participants in the all-women test group would have higher rates of post-treatment satisfaction than the

141. Shelly F. Greenfield et al., *The Women's Recovery Group Study: A Stage I Trial of Women-Focused Group Therapy for Substance Use Disorders Versus Mixed-Gender Group Drug Counseling*, 9 DRUG & ALCOHOL DEPENDENCE 39 (2007).

142. *Id.*

143. *Id.*

144. *Id.*

145. *Id.*

146. Greenfield et al., *supra* note 141. They found the studies researching women-only groups were largely based on parenting or pregnancy with substance abuse issues. *Id.*

147. *Id.* The Greenfield study, conducted in the mid-2000s found that there had never been any evidence collected regarding women in a substance abuse group therapy setting in general. Most often, the groups related to pregnancy and parenting for women who were substance abusers. In fact, they found there had been no studies conducted comparing women-only substance abuse groups to mixed-gender groups. *Id.*

148. *Id.*

149. *Id.*

participants in the mixed-gender group.¹⁵⁰ The research provided evidence that participants in the all-women group reported significantly higher levels of satisfaction after treatment, supporting the hypothesis.¹⁵¹ The study suggests that the participants of the all-women group were more satisfied due to enhanced satisfaction of the session content, as well as their overall experiences in the group process in an all-woman group.¹⁵² This could provide evidence that women may be more comfortable in clinical treatments without the inclusion of men, particularly in studies treating mental health diseases.

iii. Menopause and Hormone Therapy

Menopause, though a natural biological process, is not generally an event women eagerly anticipate over the course of their lives. Around the 1900s, women were beginning to be offered pharmaceutical options to suppress the symptoms of menopause, such as hot flashes and mood swings.¹⁵³ These original forms of medications included women ingesting extracts of other animals' ovaries.¹⁵⁴ Various other hormone therapies were attempted throughout the 1960s, when the anti-menopause culture made a sociological shift.¹⁵⁵

Starting in the 1960s, pharmaceutical hormone therapy became a mass produced answer to the prevention of menopause itself as opposed to suppression of the symptoms.¹⁵⁶ Famous gynecologist Dr. Robert Wilson published the 1966 novel *Feminine Forever* in which he predicted that the use of pharmaceutical hormone replacement therapy could curb the effects of aging in women.¹⁵⁷ Dr. Wilson believed that "[t]hrough hormone therapy, a woman could simulate the hormones of reproduction and thereby stay youthful and attractive

150. Greenfield et al., *supra* note 141 ("The initial hypothesis of this study was that more favorable outcomes of the [all-women] group than [mixed-gender] group would result from a synergy between gender-specific content [and] enhanced group processes, including comfort and cohesion.")

151. *Id.* at 46.

152. *Id.*

153. Lisa Faigman, *The "M Word" Symposium: An Interdisciplinary Adventure*, 23 HASTINGS WOMEN'S L.J. 3, 15 (2012).

154. *Id.*

155. *Id.*

156. Jay Schulkin, *Hormone Therapy, Dilemmas, Medical Decisions*, 36 J.L. MED. & ETHICS 73, 74 (2008).

157. *Id.*

throughout the lifespan. All the right words were in place: youth, vigor, and sex.”¹⁵⁸ Dr. Wilson understood the use of estrogen in hormone therapy was a way to stay youthful.¹⁵⁹ He felt strongly that physical signs of aging, such as wrinkles, should be avoided.¹⁶⁰

Dr. Wilson’s progressive answers to the crisis of aging opened the floodgates to the business of ending the aging process for women.¹⁶¹ By the early 1970s, hormone therapy had become a popular treatment among women throughout Western Europe and the United States.¹⁶² In the 1990s, NIH researchers completed a study on women who used hormone therapy in the 1970s—when it was first administered to women with relatively little clinical trial research.¹⁶³ Researchers noticed a correlation between hormone use and the development of breast cancer; concluding that the risk of breast cancer increases with the frequency of hormone therapy.¹⁶⁴ Around the same time, Great Britain also produced a study that followed 828,923 post-menopausal women and found the same correlation as NIH.¹⁶⁵

By 2002, NIH researchers found that the risks associated with women’s hormone therapy far exceeded the benefits.¹⁶⁶ In 2004, after about forty years of administering a risky form of hormone therapy, researchers attempted to develop a safer form of hormone therapy for women.¹⁶⁷ This attempt to find safer alternatives has been successful in modern medicine; however, researchers are continuing to find numerous correlations between use of hormone therapy and increased risk of cancer.¹⁶⁸

It is concerning that this pharmaceutical revolution was developed about fifty years ago based on an opinion by a male gynecol-

158. *Id.*

159. *Id.*

160. *Id.*

161. Schulkin, *supra* note 156. “In other words, women were sold the prospect of staying young forever. For the pharmaceutical companies this was a homerun, or at least potential homerun, since advertising from pharmaceutical companies significantly contributed to hormone therapy use.” *Id.*

162. *Id.* at 74-75.

163. *Id.* at 77.

164. *Id.*

165. *Id.*

166. Cynthia A. Stuenkel, *Hormone Therapy for Postmenopausal Women: A Brief History of Time*, 23 HASTINGS WOMEN’S L.J. 45, 47 (2012).

167. *Id.* at 57.

168. *Id.* at 61.

ogist trying to prevent the physical changes of menopause because the changes were deemed unbecoming.¹⁶⁹ Aside from that, women were being treated with hormone therapy without clinical research regarding the risks and negative effects hormone therapy could cause. Women's health initiatives are actively working to prevent administration of medical treatments that are not tested. There are still many who critique the mission of women's health initiatives.

c. Criticisms of Women's Health Initiatives and the Neglect of Men

According to Megan Veith, this shift to women's health concerns in the recent past has left developments in male health neglected.¹⁷⁰ Veith concludes that men are instead the most discriminated against.¹⁷¹ She finds men to be far more burdened with illnesses than women throughout their lifespan, and this is reflected by their shorter projected lifespan.¹⁷² Veith argues that men are in much greater need of medical attention than women and that men's health should really be the focus in modern medical treatment.¹⁷³

She offers intensive research to support her conclusion that men are at a much higher risk of chronic disease and injury.¹⁷⁴ Veith notes men lead much riskier lifestyles; they are more likely to engage in activities such as binge drinking alcohol, driving without a seat-belt, and playing riskier sports.¹⁷⁵ Veith argues that men's sexual activity is much riskier than women's, yet she makes no counterargument in regards to instances against women in powerless situations, such as genital mutilation and domestic violence.¹⁷⁶ She emphasizes

169. Schulkin, *supra* note 156.

170. Veith, *supra* note 80, at 352.

171. *Id.*

172. *Id.* at 354.

173. *Id.* at 353.

174. *Id.* at 352.

175. Schulkin, *supra* note 156, at 353. "Regarding risky behaviors and health, men also 'abuse alcohol and other drugs at least twice as often [as women] and commit 86% of all violent crimes.' Moreover, males participate in riskier sports and recreational activities than females. In terms of mental health such as depression, men may be underdiagnosed and under-treated. Finally, in the most recent US military operations, many more men died than did women." *Id.*

176. *Id.*

that men reported remarkably higher rates of syphilis and HIV.¹⁷⁷ Finally Veith found, “men are also more likely than women to develop some forms of cancer including lung, colorectal, throat, stomach, pancreas, bladder, non-Hodgkin’s lymphoma and leukemia.”¹⁷⁸

It is entirely possible that resources have not been spread equally among gender-based medical treatments. However, Veith fails to take a more holistic look at society. There is little in response to the psychological and sociological treatment of women throughout the world. She eloquently states, “a more progressive and beneficial way to look at gender and medicine is not to look to whether men or women are more entitled to healthcare, but to look at how medicine can be used to benefit both genders.”¹⁷⁹

The purpose of this comment is not to present evidence to steer healthcare away from developing men’s health, but to ensure genders are recognized for their biological differences and thus seek the most optimum healthcare for all people throughout the world. It is important to look at both genders as different biological beings in order to shape medical treatments to improve the lives of everyone. This comment is meant to provide a holistic representation of women in society, how they are faced with different challenges and barriers than men, and how this affects women’s healthcare.

IV. The Future for Women Around the World

a. Women and Health Initiative and a Global Perspective

It is imperative that all people around the world, no matter their biological sex, are provided with the best healthcare possible. The Agenda is working to accomplish well-rounded healthcare for all women.¹⁸⁰ Through the primary collection of research on non-reproductive chronic diseases in women and finding ways to include women in clinical trials, global public health will improve greatly.

177. *Id.*

178. *Id.* at 354. She does attribute some of these numbers to men being less likely to engage in any sort of preventative health treatments or screenings than women. She mentions that when men have breast cancer, about 1% of the cases, they are much more likely die from the cancer than women. *Id.*

179. Schulkin, *supra* note 156, at 352.

180. Fleck, *supra* note 1, at 629.

From the structuralism perspective, women have been treated as lesser citizens in the realm of medical research and clinical trials. Since the Thalidomide tragedy, the consideration to exclude women who are pregnant or are trying to get pregnant from clinical trials is understandable. Clinical trials involve the risk of at least one human, and thus it is justifiable to exclude a person carrying an even more vulnerable person. The key problem, however, is that these medications, once approved in trials using men, are then administered to women. This appears to be an even riskier way to test female responses to drugs.

Though reproductive protection is vital to the survival of mankind, it is not the only health risk for which women need protection. In fact, HIV/AIDS is currently the leading cause of death among women around the world between the ages of fifteen and forty-nine, followed by maternal complications.¹⁸¹ The third is self-harm and mental health disorders.¹⁸² Melinda Gates notes that women's health is facing a fast-growing epidemic of chronic diseases among women, such as cancer, diabetes, and cardiovascular diseases, and that non-communicable diseases are rapidly rising in rank.¹⁸³

Gates states, "[t]hese findings raise important questions for government leaders, health experts, and parents. How are underlying social detriments of women's health affecting life options of girls and women? Are government policies sufficiently focused on these critical stages in the life course to ensure that girls grow into healthy, productive women?"¹⁸⁴ These important questions are what the Agenda seeks to answer.

Throughout the world, options remain limited for women's health. This is attributed to biological, psychological, and sociological factors often barring equal access to women's healthcare. The Agenda seeks to understand how women fit into society, not simply as reproductive beings.¹⁸⁵ Richard Horton and Audrey Ceschia are hopeful that modern globalization is shrinking the gaps of inequality

181. Melinda Gates, *Valuing the Health and Contribution of Women is Central to Global Development*, 386 THE LANCET e11, e12 (2015).

182. *Id.*

183. *Id.*

184. *Id.*

185. Richard Horton & Audrey Ceschia, *Making Women Count*, 386 THE LANCET 1112, 1113 (2015).

between countries.¹⁸⁶ However, they are fearful that globalization has aggravated inequalities within countries.¹⁸⁷ With increased communication and travel, all countries have been pulled into the limelight and are being watched by their fellow countries.¹⁸⁸ Globalization has produced social tensions that are negatively affecting the stability of societies.¹⁸⁹ Treatment outside of direct biological needs can raise the esteem of women, thus preventing mental health issues and improving overall physical health.¹⁹⁰

At the most primitive, without healthy women, there is an unsustainable society. If women's health is neglected around the world, then as a society, about half of the world's population is being neglected.¹⁹¹ In both Western society and developing countries, lack of healthcare feeds into endless cycles of poverty and violence.¹⁹²

b. The Future for Gender and Medicine

There is hope for the future of gender and medicine. "Western society has seen women gain the right to vote, receive higher education, and continue on to careers in similar positions of authority as their male counterparts. Thus...why would something so fundamental and essential as women's health continue to be constrained by male-oriented and male-dominated clinical trials?"¹⁹³

There may be critics to the shift of focusing on women's health, and though some arguments have merit, it is not a battle to eliminate male healthcare research. The key to a well-balanced healthcare system is to treat every person in the best and safest way possible. Numerous trials have provided evidence that recognizes the need for distinguishing effects based on gender.

Chronic and non-communicable diseases are on the rise among the female population. In a study produced by Niewada in Warsaw,

186. *Id.*

187. *Id.*

188. *Id.*

189. *Id.*

190. *See generally* Jim Yong Kim & Timothy Evans, *Promoting Women's Health for Sustainable Development*, 386 THE LANCET e9 (2015).

191. *Id.* at e10.

192. *Id.*

193. Breanna Sergent, *To Include or to Exclude? The Policy Question Plaguing Women's Role in Clinical Trials*, 34 J. LEG. MED. 235 (2013).

Poland, the researchers studied over 17,000 stroke patients.¹⁹⁴ Their conclusion stressed the differences in reactions between the male and female patients and that “further research to explore the underlying biological mechanism is justified [to] improve [health] outcomes of female patients.”¹⁹⁵ Around the world, medical researchers are finding differences between genders, which will hopefully be implemented in future medical treatments and clinical trials. The question of including pregnant women in clinical trials continues to be addressed by researchers and will likely be an ethical dilemma addressed in the foreseeable future.¹⁹⁶

There have been numerous laws enacted by governments to protect vulnerable populations such as prisoners, children, and pregnant women.¹⁹⁷ According to Barbara Noah, the research culture is very much against the inclusion of pregnant women.¹⁹⁸ However, there have been great strides in clinical trials towards women and this mentality may change. Some have suggested that when there is a potential risk to the fetus in a clinical trial, consent from both the mother and father should be required to create a fail-safe system for the research liability.¹⁹⁹ Over the past decade, numerous arguments have been presented in favor of including women who are pregnant or can become pregnant in trials.²⁰⁰ To develop further understanding of the overall health of women, the inclusion of this population, while risky, could continue to close the discrimination gap being fought by the Agenda.

The future for gender recognition is seemingly positive. There are still health concerns for women, but history has shown quite a shift in the past fifty years in regard to the treatment of women in at least Western society. For developing countries, this may unfortunately take quite a bit longer. The Agenda will continue to close this

194. Maciej Niewada et al., *Influence of Gender on Baseline Features and Clinical Outcomes among 17,370 Patients with Confirmed Ischaemic Stroke in the International Stroke Trial*, 24 NEUROEPIDEMIOLOGY 123 (2004).

195. *Id.*

196. Barbara A. Noah, *The Future of Health Law: Exemplary Insight Into Trending Topics: The Inclusion of Pregnant Women in Clinical Research*, 7 ST. LOUIS U. J. HEALTH L. & POL'Y 353, 372 (2014).

197. *Id.*

198. *Id.*

199. *Id.* at 376.

200. *Id.*

gap in treatment. It is an essential human right to all people to benefit from global health developments.

V. Conclusion

The Agenda will hopefully improve the global health of women. Their mission is to better understand the biology of women and how it differs from the biology of men. There is a great deal of evidence suggesting that there are marked differences between the sexes and they produce differed reactions to treatment. As the new health agenda continues advocating against the discrimination of women, global health will improve.

History has shown that women have not had their needs met to the extent that men have in the realm of healthcare around the world. In the twenty-first century, it is time to change the conversation. The improvement of global health is not only a moral duty in order to grant this essential human right, but a way to work towards ending worldwide poverty and crime. For survival, health is a fundamental need—not only for women, but for mankind in general. All people deserve to have that need met. The *New Women's Health Agenda* will have a positive impact on women and the world.

