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To the Graduate Council:

I am submitting herewith a dissertation written by Lisa Eckenwiler entitled "Women and the ethics of clinical research : broadening conceptions of justice." I have examined the final electronic copy of this dissertation for form and content and recommend that it be accepted in partial fulfillment of the requirements for the degree of Doctor of Philosophy, with a major in Philosophy.

James L. Nelson, Major Professor

We have read this dissertation and recommend its acceptance:

Frank Marsh, John Nolt, Mary Mahowald, Sandra Thomas

Accepted for the Council:

Carolyn R. Hodges

Vice Provost and Dean of the Graduate School

(Original signatures are on file with official student records.)

To the Graduate Council:

I am submitting herewith a dissertation written by Lisa Ann Eckenwiler entitled "Women and the Ethics of Clinical Research: Broadening Conceptions of Justice." I have examined the final copy of this dissertation for form and content and recommend that it be accepted in partial fulfillment of the requirements for the degree of Doctor of Philosophy, with a major in Philosophy.

James L. Nelson, Major Professor

We have read this dissertation and recommend its acceptance:

Accepted for the Council:

Associate Vice Chancellor and
Dean of the Graduate School

WOMEN AND THE ETHICS OF CLINICAL RESEARCH: BROADENING CONCEPTIONS OF JUSTICE

A Dissertation
Presented for the
Doctor of Philosophy
Degree
The University of Tennessee, Knoxville

Lisa Ann Eckenwiler
May 1997

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DEDICATION

This dissertation is dedicated to my mother and my grandmothers,
whose commitment to scholarship made this possible
and whose stories made it matter.

ACKNOWLEDGMENTS

The Department of Philosophy at the University of Tennessee will forever be one of my homes. The educational experiences and friendships found here have enriched my life in a way I could never have imagined. I am especially grateful to my mentors: Jim Nelson, who stepped in as Chair of my committee mid-way through this project and brought the perfect blend of caring and critique; Kathy Bohstedt, who helped me to find my voice as a philosopher; Frank Marsh, my champion, in whose footsteps I, with honor, will follow in my new position as professor; John Nolt, who first showed me the healing role philosophers can play in the world; and George Brenkert, who over the years has given me every form of support possible. I would also like to offer my warmest appreciation to Anne Beardsley and Marie Horton for their kindness and steadfast commitment, not only to me, but to us all.

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importantly, there is my husband, Thom. His unwavering devotion and encouragement make this a shared victory, indeed.

ABSTRACT

Contemporary debates concerning the participation of women in clinical research highlight the concept of social justice. In its most general sense, justice is understood to require that persons be treated fairly and that they be given what they are due. Social justice refers to society, and the manifestation of justice in its laws, institutions, moral rules, sanctions and conventions. The assertion that the knowledge sought and gained in the context of social institutions charged with promoting public health through conducting investigations with human subjects has not adequately contributed to the health of women, and the responses this has engendered, revolve around the concern that women have not received their due.

Where justice is discussed, in philosophical theories of justice generally, and in moral reflection on research with human subjects specifically, a framework focused on distribution holds privilege of place. Although it is clearly important to attend to issues of distribution, I argue here that when justice is reduced to distribution, we lack resources for illuminating all of the aspects in which research is unjust, and are greatly inhibited in the ability to envision and articulate measures crucial to the realization of justice for women. I show how an approach to social justice that integrates distributive remedies with critical attention to difference and the democratization of decision-making may guide the research

enterprise. This conception of justice draws our moral attention to the myriad social and institutional relations, processes, and structures tied to the endeavors of clinical research, and to the ways these may constrain or enhance women's development and self-determination, that is, their capacities to lead lives they regard as healthful, to determine their actions, and to realize their choices.

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CHAPTER ONE

WOMEN AND SOCIAL JUSTICE IN CLINICAL RESEARCH: THE CONTEMPORARY DEBATES

Contemporary debates concerning the participation of women in clinical research highlight the concept of social justice. In its most general sense, justice is understood to require that persons be treated fairly and that they be given what they are due. Social justice refers to society, and the manifestation of justice in its laws, institutions, moral rules, sanctions and conventions. The assertion of advocates for women's health - that the knowledge sought and gained in the context of social institutions charged with promoting public health through conducting investigations with human subjects has not adequately contributed to the health of women - and the responses they have engendered, revolve around the concern that women have not received their due.

This chapter is an introduction to the debates regarding social justice in clinical research for women. Presented here are: the specific claims put forth by advocates for women's health, examples of the evidence they have marshaled to support these claims, resolutions that have emerged in response, and, as well, the dissension that abounds. Beyond providing an overview of these contentious discussions, my aim in this beginning chapter is to delve beneath particular pronouncements in order to elucidate the conceptions of social justice embedded there.

NOT GETTING OUR DUE: THE CLAIMS OF ADVOCATES FOR WOMEN'S HEALTH

The voices of women are audible throughout the history of public scrutiny concerning the conduct of the scientific and medical community. Building upon the experience of women health activists of earlier eras, feminist scholarship, and the efforts of AIDS activists, and further, drawing strength from the ever-increasing numbers of women in science, medicine, and the legislative realm, advocates for women's health began to develop a critique of the policies and practices of clinical research in the late 1980s and early 1990s.[1] This contemporary critique encompasses two principle claims: first, the findings of many research projects are not clearly applicable to women affected by or susceptible to particular diseases, disorders or conditions that afflict both genders, and second, investigations of diseases, disorders or conditions unique to, especially prevalent or serious among women are unsatisfactory.

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[1]Resources for reviewing these various influences (in the same order as the points above) include: Ruth B. Merkatz, "Progress Notes on Women's Health," *American Journal of Nursing* 93, no. 7 (November 1993): 75-80; Boston Women's Health Course Collective, *Our Bodies, Our Selves* (Boston: New England Free Press, 1971); Sheryl Burt Ruzek, *The Women's Health Movement: Feminist Alternatives to Medical Control* (New York: Praeger Publishers, 1978); The ACT UP/New York Women and AIDS Book Group, *Women, AIDS and Activism* (Boston: South End Press, 1990); Steven Epstein, "The Construction of Lay Expertise: AIDS Activism and the Forging of Credibility in the Reform of Clinical Trials," *Science, Technology, and Human Values* 20, no. 4 (Autumn 1995): 408-437; Judith LaRosa, "Women's Health: Science and Politics," *Annals of Epidemiology* 4, no. 2 (March 1994): 84-88. Works by feminist philosophers of science and others are contained throughout this work.

Inapplicable Research Findings

In claiming that the findings of many research projects are not clearly applicable to women affected by or susceptible to particular diseases, disorders or conditions that afflict both genders, advocates for women's health point to three sorts of problems. First, they argue that women frequently have been excluded from clinical trials, particularly in the earliest phases.[2] Second, they claim that where women have been included, they have been included in insufficient numbers. What most galvanized support for these claims were the findings from a review, conducted by the General Accounting Office (GAO) at the request of the Congressional Caucus on Women's Issues, of the National Institutes of Health's (NIH) policies and practices with respect to the inclusion of women as subjects in research populations. The report, issued in 1990, argued that a policy initiated in 1986 to encourage grant applicants to include women in clinical studies, particularly in clinical trials, had been neither well understood nor well implemented.[3] Finally, according to

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[2]Phase I trials evaluate safety and are usually (but not always) conducted with healthy subjects; Phase II trials evaluate efficacy, in addition to safety and include persons with the disease or condition to be treated, diagnosed, or prevented; Phase IIIa clinical trials are conducted after efficacy has been demonstrated, but prior to regulatory submission. With investigational drugs, these clinical trials are conducted in patient populations for which a drug is intended. Here, additional data on safety and efficacy is generated. Primarily, Phase III trials are designed to evaluate an experimental intervention in comparison with a standard or control intervention, or to compare two or more existing treatments. Phase IIIb trials are clinical trials conducted after regulatory submission, but prior to an intervention's approval and launch. These trials may supplement earlier trials, complete earlier trials, or may be directed toward new types of trials or Phase IV evaluations. Phase IV is a post-marketing phase. That is to say, these studies are conducted after marketing to provide additional details about safety and efficacy, to evaluate different formulation, dosages, and durations of drug treatment, and medicine interactions. Adverse reactions and related risk factors also may be examined.

[3]United States. Congress. House. Committee on Aging. Subcommittee on Housing and

advocates for women's health, where women have been included in clinical research, gender-specific analyses of the safety and efficacy of interventions have not been performed generally.

The participation of human subjects in biomedical and behavioral research is governed by two sets of federal regulations put forth by the Department of Health, Education, and Welfare (DHEW) and its successor, the Department of Health and Human Services (DHHS).[4] The first set is DHHS's Protection of Human Subjects Regulations which apply to all biomedical and behavioral research carried out by DHHS or funded wholly or partially by a Department grant, contract, cooperative agreement, or fellowship.[5] Protections for all human subjects are set out here along with additional provisions for groups held to warrant special protection. A second set of regulations, established by the *Federal Food, Drug, and Cosmetic Act*, regulates privately funded human subjects research that aims toward the introduction of new drugs and medical devices to the market.[6] It is in large part the legacy of federal research regulations that fuels contemporary criticisms.

Consumer Interests, *Women Health Care Consumers: Short Changed on Medical Research and Treatment* (Washington, D.C.: U.S. Government Printing Office, 1991).

[4]For a history of the development of federal guidelines for human subjects research, see Advisory Committee on Human Radiation Experiments, "Government Standards for Human Experiments: The 1940s and 1950s," "Postwar Professional Standards and Practices for Human Experiments," and "Government Standards for Human Experiments: The 1960s and 1970s," in *Final Report of the Advisory Committee on Human Radiation Experiments* (New York: Oxford University Press, 1996): 45-131.

[5]National Institutes of Health, *Code of Federal Regulations Title 45 Part 46* (Washington, D.C.: U.S. Government Printing Office, 1996).

[6]*Federal Food, Drug, and Cosmetic Act*, U.S. Code Vol. 21, secs. 301-395 (1938); Food and Drug Administration, *Code of Federal Regulations Title 21 Parts 50 and 56* (Washington, D.C.: U.S. Government Printing Office, 1996).

The exclusion of certain subgroups of women was explicitly mandated by federal policy concerning research with human subjects. Indeed, the Food and Drug Administration's (FDA) 1977 *General Considerations for the Clinical Evaluation of Drugs* placed restrictions on the inclusion of women:

In general, women of childbearing potential should be excluded from the earliest dose ranging studies. If adequate information on efficacy and relative safety has been amassed during Phase II, women of childbearing potential may be included on further studies provided Segment II and the female part of Segment I of the FDA Animal Reproduction Guidelines have been completed. All three Segments should be completed before large scale clinical trials are initiated in women of childbearing potential.[7]

Although the provisions regarding animal studies are said to have effectively barred women from all but late Phase II and Phase III trials, research investigators and Institutional Review Boards tended to extend the policy to all phases of drug trials.[8] It is usually in the early stages of clinical trials that the most significant differences are found, for example, in the pharmacokinetics between men and women. These restrictions greatly limited the accumulation of knowledge about drug responses in women needed to design phase II and III trials, where knowledge is gained about relationships between dose and efficacy, and the variability of response among different populations.

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[7]Food and Drug Administration, *General Considerations for the Clinical Evaluation of Drugs* (Washington, D.C.: U.S. Government Printing Office, 1977): 10. For details regarding preclinical animal studies, see Bonnie J. Goldmann, "A Drug Company Report: What Is the Same and What Is Changing with Respect to Inclusion/Exclusion of Women in Clinical Trials," *Food and Drug Law Journal* 48, no. 2 (1993): 170-171.

[8]See Charles R. McCarthy, "Historical Background of Clinical Trials Involving Women and Minorities," *Academic Medicine* 69, no. 9 (September 1994): 697.

Moreover, while the policy defined women of childbearing potential as "premenopausal female[s] capable of becoming pregnant," it went on to state that single women, women using oral, injectable, and mechanical contraception, as well as married women whose partners had undergone vasectomies or who were using contraception, were also to be excluded.[9] The policy was interpreted even more broadly, however, so as to exclude lesbians not seeking pregnancy, and sexually inactive women such as members of cloistered religious orders. Despite the availability of women who had undergone hysterectomies, women who could prove infertility, and post-menopausal women, researchers did not generally undertake efforts to recruit them. From the perspective of many researchers, such efforts were burdensome.[10]

Going beyond drug research to investigations of particular diseases, disorders and conditions, concern has been raised regarding women's exclusion in clinical research on cardiovascular health and illness.[11] Furthermore, despite evidence since the first year in which the Acquired Immune Deficiency Syndrome (AIDS) was reported that the disease

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[9]Food and Drug Administration, *General Considerations for the Clinical Evaluation of Drugs*, 10.

[10]Jean A. Hamilton, "Women and Health Policy: On the Inclusion of Females in Clinical Trials," in *Gender and Health: An International Perspective*, ed., Carolyn F. Sargent and Caroline B. Brettell (Englewood Cliffs, NJ: Prentice Hall, 1996): 294-295.

[11]See for example, Jerry H. Gurwitz, Nananda F. Col, and Jerry Avorn, "The Exclusion of the Elderly and Women from Clinical Trials in Acute Myocardial Infarction," *Journal of the American Medical Association* 268, no. 11 (16 September 1992): 1417-1422; Bernadine Healy, "The Yentl Syndrome," *New England Journal of Medicine* 325, no. 4 (25 July 1991): 275; Nanette K. Wenger, "Exclusion of the Elderly and Women from Coronary Trials: Is Their Quality of Care Compromised?" *Journal of the American Medical Association* 268, no. 11 (16 September 1992): 1460-1461.

affected both women and men, and despite good reasons for suspecting that the disease might affect them differently, there is compelling evidence that in the early years of the epidemic women were excluded from research on the Human Immunodeficiency Virus (HIV) and AIDS.[12]

Underinclusion and underrepresentation are widely used terms that lack sufficient clarity. At least three interpretations are possible. First, the proportion of women participating in a particular study may be less than the proportion of women who suffer from the disease, disorder, or condition, or who might be expected to use a particular class of drugs or some other medical intervention under investigation. Second, analyses of effects or outcomes specific to women may not be available because women have not been included in sufficient numbers in a particular study. Third, in a program of research (as opposed to a specific study) women may be underincluded. This third interpretation warrants still further clarity. It may be that the proportion of women across studies should correspond with the proportion affected by a given health concern, or who might be expected to use a particular class of drugs or some other medical intervention. Alternatively, it may be argued that enough women should be included to allow for analyses of effects or outcomes particular to women.

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[12]Ruth Faden, Nancy Kass, and Deven McGraw, "Women as Vessels and Vectors: Lessons from the HIV Epidemic," in *Feminism and Bioethics: Beyond Reproduction*, ed., Susan M. Wolf (New York: Oxford University Press, 1996): 254. See also Gena Corea, *The Invisible Epidemic: The Story of Women and AIDS* (New York: Harper Collins, 1992); Carol Levine, "Women and HIV/AIDS Research: The Barriers to Equity," *Evaluation Review* 14, no. 5 (October 1990): 447-463.

Supporting the claim that women have faced underinclusion, Cotton and her colleagues examined enrollment and demographic data of the Aids Clinical Trials Group (ACTG) during the period from 1987 to 1990, and found that women were not enrolled in numbers proportional to the numbers of women known to be infected.[13] It has been suggested, as well, that within ACTG trials, the numbers of women have been too low to allow for gender-specific analyses.[14] In drug research, evidence supports the claim that women have been underrepresented on all of the above interpretations.[15] A review of research published in a major medical journal also found women to be underrepresented in clinical studies.[16]

A third problem affecting the applicability of research findings to women is that in clinical studies where women have participated, there has been a general failure to examine gender-specific differences. In some instances the absence of gender analyses may be a result of low numbers of women participants, but this is not the whole story. Once again, revealing

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[13]Deborah J. Cotton, Diane M. Finkelstein, Weili He et al., "Determinants of Accrual of Women to a Large, Multicenter Clinical Trials Program of Human Immunodeficiency Virus Infection," *Journal of Acquired Immune Deficiency Syndromes* 6, no. 12 (1993): 1322-1328.

[14]Faden, Kass, and McGraw, "Women as Vessels and Vectors," 271.

[15]For example, see Evlin L. Kinney, Joanne Trautman, and Jay Alexander Gold et al., "Underrepresentation of Women in New Drug Trials: Ramifications and Remedies," *Annals of Internal Medicine* 95, no. 4 (October 1981): 495-499; Kimberly A. Yonkers and Wilma Harrison, "The Inclusion of Women in Psychopharmacologic Trials," *Journal of Clinical Psychopharmacology* 13, no. 6 (December 1993): 380-382. For controversy related to this claim, see Carol Levine, "Women and HIV/AIDS Research," 454-455.

[16]Chloe E. Bird, "Women's Representation as Subjects in Clinical Studies: A Pilot Study of Research Published in JAMA in 1990 and 1992," in *Women and Health Research: Ethical and Legal Issues of Including Women in Clinical Studies*, ed., Anna C. Mastroianni, Ruth Faden, and Daniel Federman (Washington, D.C.: National Academy Press, 1994), 2: 151-173

examples come from clinical research on HIV and AIDS. In the Summer of 1992 at the VIII International Conference on AIDS, members of a panel suggested that the symptoms of HIV were the same for men and women. Advocates for women's health, however, questioned the results of the research presented as evidence for the claim. Gynecological data were not collected, nor were hormone levels, reproductive impacts, or changes in menstruation. Instead:

> the scientists categorized women as men and studied them only in accordance with their biological similarities to men ... the disease was studied as a male disease in female bodies that were in fact treated throughout the research as male bodies.[17]

Further, research has been found to be deficient with respect to gender-specific analyses in the pharmacokinetics and pharmacodynamics of drugs despite good reasons to believe that gender differences exist in absorption, distribution, and metabolism of drugs, and that taking oral contraceptives may affect drug interactions.[18]

Due to these inadequacies in the context of research, women suffer more illness, disability and death. To the extent that women are excluded or underincluded in research, or gender-specific analyses are not performed, health care providers have insufficient information on the

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[17]Mary Beth Caschetta, "The Identity Politics of Biomedical Research: Clinical Trials, Medical Knowledge, and the Female Body," *SIECUS Report* 22, no. 1 (October/November 1993): 3.

[18]Jean A. Hamilton and Barbara Parry, "Sex-Related Difference in Clinical Drug Response: Implications for Women's Health," *Journal of the American Medical Women's Association* 38, no. 5 (September/October 1983): 126-132; Ruth B. Merkatz, Robert Temple, and Solomon Sobel et al., "Women in Clinical Trials of New Drugs: A Change in Food and Drug Administration Policy," *New England Journal of Medicine* 329, no. 4 (22 July 1993): 292-296.

etiology, symptoms, and progression of particular diseases, disorders and conditions in women, and further, on preventive strategies and diagnostic testing.[19] When women are excluded or underrepresented as participants in investigations of drugs and other medical interventions, or when gender-specific differences fail to be assessed, health care providers do not have accurate and complete information on their safety and efficacy. With respect to drugs, they lack information on such specifics as appropriate dosages, timing of administration, and indications for use. When such information is absent or otherwise insufficient, health care providers may be reluctant to prescribe drugs for women, a consequence described as "residual exclusion."[20] In the event that medications not analyzed in women are prescribed for their use, potential risks are shifted outside of the research context. After marketing, women, including those who are pregnant, may use many of the same drugs that men use. Moreover, they may be the primary users of these drugs, as is the case with psychotropic drugs and those used for acute myocardial infarction.[21] There is no basis for predicting the effects of such drugs in women. Not only will side

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[19]For example, see Nora Kizer Bell, "Women and AIDS: Too Little, Too Late?" in *Feminist Perspectives in Medical Ethics*, ed., Helen Bequaert Holmes and Laura M. Purdy (Bloomington: Indiana University Press, 1992): 46-62; Nanette K. Wenger, Leon Speroff, and Barbara Packard, "Cardiovascular Health and Disease in Women," *New England Journal of Medicine* 329, no. 4 (22 July 1993): 247-256.

[20]Howard Minkoff, Jonathan Moreno, and Kathleen Powderly, "Fetal Protection and Women's Access to Clinical Trials," *Journal of Women's Health* 1, no. 2 (1992): 137.

[21]Gurwitz, Col, and Avorn, "The Exclusion of the Elderly and Women from Clinical Trials"; Allen Raskin, "Age-Sex Differences in Response to Antidepressant Drugs," *Journal of Nervous and Mental Disease* 159, no. 2 (1974): 120-130; Yonkers and Harrison, "The Inclusion of Women in Psychopharmacologic Trials."

effects inevitably occur in a certain percentage of women who take drugs, these side effects involve many more women, because the exposed population is much larger during marketing than during Phase I, II, and III clinical trials.[22] Women, in fact, have been shown to suffer more adverse side effects from pharmacotherapy than do men.[23] Furthermore, adverse effects may go undetected. When other interventions are not adequately studied in women, their medical care may be seriously compromised. On the one hand they may not receive available interventions, while on the other these interventions may present greater risks for them than for men, contributing to adverse prognoses.[24]

The consequences of research deficiencies extend even further toward inhibiting women's prospects for leading healthy lives. As Merton observes with respect to AIDS, for example, the failure to study its progression in women ultimately skewed statistics used to determine

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[22]See Kinney, Trautman, and Gold, "Underrepresentation of Women in New Drug Trials," 498-499.

[23]See L.E. Bottiger, A.K. Furhoff, and L. Holmberg, "Fatal Reactions to Drugs," *Acta Medica Scandinavia* 205, no. 6 (1979): 451-456; C. Domecq, C.A. Naranjo, I. Ruiz, and U. Busto, "Sex-Related Variations in the Frequency and Characteristics of Adverse Drug Reactions," *International Journal of Clinical Pharmacology,Therapy, and Toxicology* 18, no. 8 (August 1980): 362-366; Natalie Hurwitz, "Predisposing Factors in Adverse Reactions to Drugs," *British Medical Journal* 1, no. 5643 (1 March 1969): 536-539.

[24]John Z. Ayanian and Arnold M. Epstein, "Differences in the Use of Procedures Between Women and Men Hospitalized for Coronary Heart Disease," *New England Journal of Medicine* 325, no. 4 (25 July 1991); Jonathan N. Tobin, Sylvia Wassertheil-Smoller, John P. Wexler et al., "Sex Bias in Considering Coronary Bypass Surgery," *Annals of Internal Medicine* 107, no. 1 (July 1987): 19-25; Nanette K. Wenger, "Gender, Coronary Artery Disease, and Coronary Bypass Surgery," *Annals of Internal Medicine* 112, no. 8 (15 April 1990): 557-558. For further review of the health consequences of exclusion, underlinclusion, and the failure to perform gender-specific analyses, see Carol S. Weisman and Sandra D. Cassard, "Health Consequences of Exclusion or Underrepresentation of Women in Clinical Studies," in *Women and Health Research*, 35-50.

funding levels for services and other resources, and further, led to the denial of social security benefits for them.[25]

Inadequate Agendas for Research

The second broad claim, that investigations of diseases, disorders or conditions unique to, especially prevalent or serious among women have been unsatisfactory, is generally attributed to research agendas that historically have failed to reflect or adequately pursue many health concerns that are salient to women.[26] Women's health advocates point to such health concerns as cancers of the cervix and ovaries, to breast cancer and osteoporosis, and to the potential carcinogenic and cardiovascular effects of hormone replacement treatments. Studies on pregnant women that, for example, examine pregnancy-specific indications and the use of drugs in pregnant women with clinical problems common in pregnancy (such as asthma, hypertension, and diabetes) are also lacking. Pregnant patients have been described as "therapeutic orphans," as practitioners lack information on the safety and efficacy of drugs for this population. They are forced to extrapolate from non-pregnant patients or deny women's use of drugs altogether.[27] Furthermore, differences in age,

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[25] Vanessa Merton, "The Exclusion of Pregnant, Pregnable, and Once Pregnable People (A.K.A. Women) from Biomedical Research," *American Journal of Law and Medicine* 19, no. 4 (1993): 384.

[26] See, for example, National Institutes of Health, Task Force on Women's Health Issues, *Report of the Public Health Service Task Force on Women's Health Issues*, 2 vols. (Washington, D.C.: U.S. Government Printing Office, 1987); U.S. Congress, *Women Health Care Consumers*.

[27] Marilynn C. Frederiksen, "Clinical Trials in Pregnancy," *Food and Drug Law Journal* 48, no. 2 (1993): 195-6.

socioeconomic status, geographical location, occupation, racial and cultural background, and sexual orientation, contribute to different health concerns among women.[28] Such differences warrant the development of research agendas that more effectively capture the heterogeneity of needs among women.

This is not to say that women's issues have been altogether absent from research agendas. Reproductive matters have figured prominently in the history of research involving women.[29]

In addition to the claim that women's health has not been adequately represented in research agendas, advocates maintain that to extent that women have served as research subjects, inquiries have not been developed in accordance with their greatest concerns. Frequently they have been motivated by aims other than improving women's health. ACTG protocol 076, for instance, investigated the use of zidovudine to reduce the potential for perinatal transmission of HIV. Women were, of course, included in the study, but it was the health of the fetus that served as the central focus for research.[30] Further, early studies of HIV and AIDS

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[28]See for example, Wenger, "Exclusion of the Elderly and Women from Coronary Trials"; Cesar A. Perales and Lauren S. Young, ed., *Too Little, Too Late: Dealing with the Health Needs of Women in Poverty* (New York: Harrington Park Press, 1988); Barbara Bair and Susan Cayleff, ed., *Wings of Gauze: Women of Color and the Experience of Health and Illness* (Detroit: Wayne State University Press, 1993); Jocelyn White and Wendy Levinson, "Primary Care of Lesbian Patients," *Journal of General Internal Medicine* 8, no. 1 (January 1993): 41-47.

[29]See Susan Sherwin, *No Longer Patient: Feminist Ethics and Health Care* (Philadelphia: Temple University Press, 1992): 167-169.

[30]See Edward M. Connor, Rhoda S. Sperling, Richard Gelber et al., "Reduction of Maternal-Infant Transmission of Human Immunodeficiency Virus Type 1 with Zidovudine Treatment," *New England Journal of Medicine* 331, no. 18 (3 November 1994): 1173-1180.

involving women focused upon prostitutes.[31] Rather than investigating such questions as their risks for infection, or the progression of infection in women, research projects tended to focus upon women as potential sources of transmission to men and fetuses.[32] Now that breast cancer has emerged as an important area for research, women have argued that investigations should go beyond the focus on genetics to examine the relationship between breast cancer and toxic waste and pesticides. Commentators have noted, as well, that while much research related to treatment for this disease has focused upon the outcome of mortality, women are interested in a broader range of outcomes: the effect of various treatments on reproductive potential, sexual function, and the ability to participate in work and other daily activities.[33]

SKEPTICISM, RESOLUTIONS, AND STILL MORE SKEPTICISM: RESPONDING TO THE CLAIMS OF ADVOCATES FOR WOMEN'S HEALTH

Critiquing the Claims of Advocates for Women's Health

A variety of responses have emerged in the wake of women's health advocates' claims concerning clinical research. These responses have

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[31]See Corea, *The Invisible Epidemic*, 26-35, 82-87.

[32]This claim has been researched and substantiated by Faden and her colleagues. See Faden, Kass, and McGraw, "Women as Vessels and Vectors." As well, see Dianne Murphy, "Women in Clinical Trials: HIV-Infected Women," *Food and Drug Law Journal* 48, no. 2 (1993): 178.

[33]Kay Dickerson, "Re-inventing Health Outcomes Research Related to Breast Cancer." Paper presented at Health Outcomes Research Seminar, The University of Chicago, Chicago, IL, March 1996.

taken many forms, spanning the continuum from outright rejection to tepid acceptance and efforts at redress.

Despite findings from government and other inquiries, there are those who claim that women have been appropriately represented in clinical studies. Further, some argue that although disparities in the sex composition of study samples might exist, these are unimportant. A final assertion is that the involvement of women in clinical research is arduous and excessively expensive.

In the early 1990s, FDA offical Robert Temple repeatedly claimed that women were appropriately represented in clinical trials at meetings of the Institute of Medicine and the Pharmaceutical Manufacturers Association.[34] Similarly, physician Andrew Kadar has denied the legitimacy of the claims of exclusion and underinclusion.[35] He and other skeptics have criticized women's health advocates for failing to acknowledge studies that have included women.

To respond to these critics it is first important to acknowledge that, historically, records were not routinely kept at the NIH regarding the sex composition of study populations.[36] This clearly made it difficult to support claims of exclusion and underinclusion, and to demonstrate their extent. Nevertheless, a preponderance of the available evidence, brought

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[34]See Hamilton, "Women and Health Policy," 315.

[35]Andrew Kadar, "The Sex-Bias Myth in Medicine," *The Atlantic Monthly* 272, no. 2 (August 1994): 69.

[36]U.S. Congress, *Women Health Care Consumers*, 50-51.

forth by government and other sources, suggests that these claims do hold legitimacy. The failure to include women, as well as the failure to analyze data according to sex where they are included, have been pervasive, moreover, systemic problems in clinical research.

When skeptics assert that numerous studies have included women, they often point to samples of women that have been added on to ongoing studies. Examples include the Baltimore Study on Aging and the Framingham Heart Study.[37] In such cases "measures and procedures based on an implicit male norm remain unchallenged."[38] Kadar refers to the Nurses' Health Study, which, like the Physicians' Health Study, investigated the benefits of aspirin for the primary prevention of cardiovascular disease. Yet, as Kadar himself notes, while the Physicians' Health Study was a randomized clinical trial where participants were randomly assigned to treatment and control groups, the Nurses' Health Study was based upon recollection.[39] Thus, the latter was not of equal rigor. Indeed, "[i]n any observational study, the amount of uncontrolled confounding may be as large as the most plausible small-to-moderate benefits being sought."[40]

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[37]Hamilton, "Women and Health Policy," 296.

[38]Ibid., 315.

[39]Leslie Laurence and Beth Weinhouse, "Sex-Bias Myth," *The Atlantic Monthly* 272, no. 5 (November 1994): 16.

[40]JoAnn E. Manson, Meir J. Stampfer, Graham A. Colditz et al., "A Prospective Study of Aspirin Use and Primary Prevention of Cardiovascular Disease in Women," *Journal of the American Medical Association* 266, no. 4 (24/31 July 1991): 525.

It has been argued, further, that more funds are allocated for research on women's diseases, and thus the claim that women are inadequately represented in research agendas is unfounded. Kadar refers to a 1987 inventory of the NIH research budget which found that 80 percent went into research for the benefit of both sexes, 13.5 percent of the budget was devoted to studying diseases unique to women, and 6.5 percent to afflictions unique to men. He remarks that while the percentage for women is cited as evidence of neglect, the smaller share for men goes unmentioned.[41]

In response, women's health advocates point to the problematic methodology of the inventory. As Bemman and Johnson observe, studies on conditions that affect both sexes such as cardiovascular disease are counted in a general category instead of a sex-specific one *even if* study populations were all male. "A more accurate methodology," they suggest, "would calculate the representation of women in all NIH-sponsored research except for studies on exclusively male conditions."[42] However, such an effort would be hindered by the fact, noted above, that there is no readily accessible source of data on the demographics of past NIH study populations.

Kadar continues this line of critique by directing attention to the funding allocations for cancers of the breast, cervix, ovaries, and uterus,

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[41]Kadar, "The Sex-Bias Myth," 69.

[42]Kathryn C. Bemman and Tracy L. Johnson, "Sex-Bias in Medicine," *The Atlantic Monthly* 274, no. 6 (December 1994): 19.

which, he claims, are "substantially larger per fatality than the funding for prostate cancer."[43] Here again there is reason to approach his claims with caution. With respect to breast cancer funding, contestants put forth sharply divergent amounts. In any case it is fair to say that support for research in this area is a contemporary phenomenon. Prior to the 1980s, precious little attention was paid to the disease. It was only the efforts of breast cancer activists that brought it into the view of researchers. So, whatever figures are accurate, they reflect only a time slice in research history. Moreover, breast cancer afflicts a larger number of patients and women tend to die from breast cancer at earlier ages than do men from prostate cancer. It is not unreasonable to focus research efforts on areas that involve more persons and that lead to more premature deaths. (While Kadar makes this point, he asserts that this is a "rational, non-political explanation," thereby undermining the credibility of advocates for women's health.[44] The significance of this not uncommon tendency to regard women as emotional and irrational will be taken up in the second chapter.) With respect to those cancers that are unique to women, cervical, ovarian, and uterine, these too tend to lead to premature death. What is more, these are cancers of women's reproductive system. While crucial areas for further study, to point to them as demonstrative of a substantial

[43]Kadar, "The Sex-Bias Myth," 69.
[44]Ibid.

concern for women's health is to take a restrictive view of what women's health encompasses.

Finally, with respect to the dispute concerning the adequacy of women's inclusion, Kadar claims that the 1977 FDA policy that excluded women of childbearing potential - and most others - from clinical studies was implemented "out of concern, not out of disregard, for them."[45] As I shall argue in detail later, such restrictive policies focused on the well-being of fetuses and fears of legal liability rather than on women's health. As we have seen, women's risks were postponed until after marketing. They were shifted outside the boundaries of research, beyond the scope of regulatory attention.

A second critique of the claims of advocates for women's health concerning clinical research holds that although disparities in the sex composition of study samples might exist, on the whole these are unimportant. Is the clinical relevance of women's underinclusion, rather than being profound and pervasive, instead peripheral and spotty?

While there are significant similarities between males and females, this view discounts the relevance of such factors as hormonal changes, the use of certain contraceptives, women's characteristic physiology, and generally smaller body size for assessing the safety, efficacy, and appropriate use of interventions. Numerous examples demonstrate the speciousness of the claim that the inclusion of women is unimportant.

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[45]Ibid., 70.

First, the etiology and symptoms of a disease, disorder, or condition often differ between males and females, as investigations of cardiovascular disease and AIDS have shown.[46] Further, with respect to interventions, while data have shown that aspirin is effective as a primary preventive for cardiovascular death in men, it is not for women.[47] Pharmacotherapy for mild hypertension is known to be effective for males, but not for females.[48] There is evidence to suggest that usual treatments may be quite harmful to women.[49]

In responding to this line of criticism, yet another set of remarks by Kadar warrants comment. Considering cardiovascular illness, Kadar alleges that there are good reasons to believe that women receive better care than men, and thus that the concern that inadequate research on women contributes to inadequate care is not well founded.[50] More specifically, Kadar notes that when considering appropriate treatment, physicians take such factors as age, other medical problems, and the

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[46]Wenger, Speroff, Packard, "Cardiovascular Health and Disease in Women"; Charles C. J. Carpenter, Kenneth H. Mayer, Michael D. Stein et al., "Human Immunodeficiency Virus Infection Among North American Women: Experience with 200 Cases and a Review of the Literature," *Medicine* 70, no. 5 (September 1991): 307-325.

[47]Laura Engels McAnally, Carolyn R. Corn, and Stephen F. Hamilton, "Aspirin for the Prevention of Vascular Death in Women," *Annals of Pharmacotherapy* 26, no. 12 (December 1992): 1530-1534.

[48]Kathryn Anastos, Pamela Charney, Rita A. Charon, Ellen Cohen et al., "Hypertension in Women: What Is Really Known?" *Annals of Internal Medicine* 115, no. 4 (15 August 1991): 287-293.

[49]Peter L. Schnall, Michael H. Alderman, and Rochelle Kern, "An Analysis of the HDFP Trial: Evidence of Adverse Effects of Antihypertensive Treatment on White Women with Moderate and Severe Hypertension," *New York State Journal of Medicine* 84, no. 6 (June 1984): 299-301.

[50]Kadar, "Sex Bias Myth in Medicine," 68-69. See also Nina A. Bickell, Karen S. Pieper, Kerry L. Lee et al., "Referral Patterns for Coronary Artery Disease Treatment: Gender Bias or Good Clinical Judgment?" *Annals of Internal Medicine* 116, no. 10 (15 May 1992): 791-797; Harlan M. Krumholz, Pamela S. Douglas, Michael S. Lauer et al., "Selection of Patients for Coronary Angiography and Coronary Revascularization Early After Myocardial Infarction: Is There Evidence for a Gender Bias?" *Annals of Internal Medicine* 116, no. 10 (15 May 1992): 785-790.

likelihood that patients will benefit from testing and surgery into account. Men, he observes, tend to be afflicted by coronary disease at younger ages than are women, and further, younger patients generally have fewer additional medical problems that might indicate against aggressive, high-risk interventions. As well, smaller patients (read: women) have smaller coronary arteries, which are more likely to burst during or become obstructed after surgery. Thus, with respect to bypass surgery for patients with less severe disease, women, in being less likely to be referred than men, may be getting more appropriate care. Women's smaller coronary arteries, age, and perhaps concomitant medical conditions, according to Kadar, make less care more appropriate.

While the issues involved here are quite complex and certainly contentious, Kadar seems to ignore some crucial points. Because physicians and their female patients may delay or defer necessary procedures out of concern for the increased likelihood of complications, women may have worse outcomes after a given procedure such as bypass surgery.[51] Advocates for women's health have also remarked that Kadar and his fellow skeptics have neglected to consider the possibility that it is inadequate research for women in this area that leads to the adverse effects that ground the view among clinicians that women should not receive certain cardiovascular interventions, including in some cases bypass surgery. These adverse effects (like burst arteries) arise, they argue,

[51] Wenger, Speroff, Packard, "Cardiovascular Health and Disease in Women," 248.

because the interventions are designed on the basis of research with men. The size of the balloon devices used to inflate obstructed arteries, for example, may be modeled according to larger dimensions of male patients' hearts.[52] Any age-based rationing of care and research resources, furthermore, has a disproportionate effect on women, who comprise the majority of the elderly population.[53] Considered all together, the available evidence supports the view that women with cardiovascular disease receive suboptimal care in terms of prevention, diagnosis, intervention and prognosis, and that inadequacies in research have played a crucial role in contributing to this situtation.[54]

The third wave of criticism regarding the inclusion of women focuses on cost and claims of difficulty. Because the cost of research rises with the number of observations made, it is argued that studying women two or more times during their menstrual cycles will elevate the cost as well as increase the time needed to complete a study. Drug company representatives maintain, further, that the preclinical animal studies required for the enrollment of women add considerable time and expense to drug studies, and ultimately will increase the costs of medications.[55] Critics of women's health advocates claims also suggest that recruiting and

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[52]Bemman and Johnson, "Sex-Bias in Medicine," 19.

[53]Nancy S. Jecker, "Age-Based Rationing and Women," *Journal of the American Medical Association* 266, no. 21 (4 December 1991): 3012-3015.

[54] See Wenger, Speroff and Packard, "Cardiovascular Health and Disease in Women," 247-256, for a review of these complex issues.

[55]Goldmann, "A Drug Company Report," 171.

retaining women are challenging and costly endeavors.[56] I will respond to these issues in upcoming chapters.

There is one final matter that fundamentally concerns cost yet is often not explicitly mentioned in critiquing women's health advocates. Liability concerns figure prominently in considerations regarding the conduct of research with women. There is a persistent focus on the possible expenses of litigation and compensation in the event that a drug or device causes harm to a woman, fetus, or child of a woman included in research.[57] It is striking that those who raise the matter of liability emphasize its potential to emerge as a result of women's participation *in* research projects rather than from the use of interventions not tested for them *outside* of research. Too, it is significant that there is little concern over research conducted on fertile men. These issues will be considered extensively in subsequent chapters.

As a final point of skepticism, one might question the ultimate significance of women's representation in clinical studies and research agendas for their overall health and longevity. Why so much worry about clinical research? It might be the case that social reform in areas other than medicine would hold greater promise for women's health and longevity. Some suggestions might be: addressing the violence to which many

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[56]Hamilton, "Women and Health Policy," 299.

[57]Theresa McGovern, Martha Davis, and Mary Beth Caschetta, "Inclusion of Women in AIDS Clinical Research: A Political and Legal Analysis," *Journal of the American Medical Women's Association* 49, no. 4 (July/August 1994): 102-104; Michelle Oberman, "Real and Perceived Legal Barriers to the Inclusion of Women in Clinical Trials," in *Reframing Women's Health: Multidisciplinary Research and Practice*, ed., Alice J. Dan (Thousand Oaks, CA: Sage, 1994): 266-276.

women are subjected in patriarchal society, which leads to injury and in some cases disability and/or death; responding to sexual abuse of young girls which, among other problems, is thought to lead to an increased incidence of cancers of the reproductive system; or improving urban and rural environments in which women live by ridding areas of toxic waste, pesticides, and other contaminants that may pose significant health risks.

It is indisputable that these issues warrant reform. Their impact on the health and longevity of women, however, is better seen as existing alongside that of medicine rather than exceeding it in significance. Medicine plays an important role in responding to these and other health concerns, and research is what enables it to do so effectively, given its impact on determining health policies and standards of care. Thus, while the inclusion of women in clinical research as well as the incorporation of women's health concerns in research agendas may not by themselves fully promote the health of women, they play an integral role.

Implemented Resolutions

Despite the disputes surrounding their claims, advocates for women's health have been successful, to a degree, in eliciting resolutions. Early efforts included the establishment of offices for women's health at the NIH and the Public Health Service to ensure that women's health issues are addressed and that women are "appropriately represented" in NIH-sponsored biomedical and behavioral research, to support women

pursuing biomedical careers, and to coordinate women's health policy and programs.[58] Further, an NIH Task Force on Opportunities for Research on Women's Health set out in 1991 to determine important areas for future research.[59] In this same period the Women's Health Initiative began its ten-year undertaking to study cardiovascular disease, cancer, and osteoporosis in women.

In 1993, major changes were implemented in policies of the NIH and FDA. Revising its policy on drug research, the FDA removed the restriction regarding the inclusion of women of childbearing potential with its recent "Guidelines on the Clinical Evaluation Drugs." While not *requiring* the inclusion of women, the revised policy nevertheless urges that "numbers adequate to allow detection of clinically significant gender-related differences in drug response" be included early in drug development.[60] Companies submitting funding applications for clinical research trials who do not include sufficient numbers of women risk having their applications denied by the FDA. These revised FDA guidelines state that women must give informed consent that includes an

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[58]Vivian W. Pinn, "The Role of the NIH's Office of Research on Women's Health," *Academic Medicine* 69, no. 9 (September 1994): 698-702.

[59]National Institutes of Health, Office of Research on Women's Health, *Report of the National Institutes of Health: Opportunities for Research on Women's Health* (Washington, D.C.: U.S. Government Printing Office, 1992).

[60]Food and Drug Administration, "Guidelines for the Study and Evaluation of Gender Differences in the Clinical Evaluation of Drugs," *Federal Register* 58, no. 139 (22 July 1993): 39410. The guidelines note that although clinical or pharmacokinetic data collected from later phase 2 and phase 3 studies may provide evidence of differences between men and women, such data may emerge too late to affect the design of and dose selection in controlled trials. Hence, the point about early inclusion.

acknowledgement of fetal risks inherent in the study and of the need to take precautions against pregnancy during trial participation. The policy is unclear with respect to the inclusion of pregnant women. Although it refers to a Supreme Court decision that upheld the decision-making authority of women in employment contexts that may present risks to fetal health, it also notes that efforts will be made to ensure that women entering trials are not pregnant.[61] The other significant change in policy concerns provisions for analyzing differences between men and women in the pharmacokinetics of drugs.[62] Menstrual cycle, menopausal status, estrogen supplementation and contraceptive-related influences are acknowledged here.

Despite the fact that the NIH strengthened its policy concerning the inclusion of women in 1990, Congress passed the *NIH Revitalization Act* in 1993, legislation which established "Guidelines Concerning the Inclusion of Women and Minorities as Subjects in Clinical Research."[63] Absent a "clear and compelling rationale and justification for their exclusion," the legislation mandates the inclusion of women, along with minorities and their "subpopulations," in all NIH-supported biomedical and behavioral

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[61] Ibid., 39408. The case referred to is that of *International Union, United Automobile, Aerospace, and Agricultural Implement Workers v. Johnson Controls Inc.*, 499 U.S. 187 (1991).

[62] The new guidelines do not call for separate clinical or pharmacodynamic studies in women.

[63] *National Institutes of Health Revitalization Act*, Public Law 103-43, 103d Cong., 1st sess., (10 June 1993); National Institutes of Health, "Guidelines Concerning the Inclusion of Women and Minorities as Subjects in Clinical Research," *Federal Register* 59, no. 59 (28 March 1994): 14507-14513. The 1990 policy required all applicants for NIH support of human subjects research to include women in studies of diseases, disorders, or conditions that affect them, or to provide justification regarding why exclusion would be appropriate.

research involving human subjects, in an effort to "reaffirm NIH's commitment to the fundamental principles of inclusion ..." Where the population at risk does not refer to only one gender where the disease, disorder, or conditions are gender specific, the Guidelines call for "approximately equal numbers of both sexes in studies of populations or subpopulations at risk, *unless* [emphasis mine] different proportions are appropriate because of the known prevalence, incidence, morbidity, mortality rates, or expected intervention effect." The Guidelines state that "[w]omen of childbearing potential should not be routinely excluded from participation in clinical research." Like the FDA policy initiatives, though, they fail to address the inclusion of pregnant women.

Recognizing the significance of inclusion in the early stages of research, "when hypotheses are being formulated, baseline data are being collected, and various measurement instruments and intervention strategies are being developed," the Guidelines also broaden the definition of clinical research to include all research involving human subjects. Further, they require that Phase III clinical trials be designed so that analyses of the variables under investigation include an assessment of differential effects on women. By contrast, for Phase I and II trials the systematic inclusion and reporting of information on women is considered adequate for supplementing the scientific base of knowledge.

Along with other stipulations, the initiative states that cost is not an acceptable consideration in determinations of the appropriateness of

inclusion. Further, it expresses a commitment to form partnerships between researchers and communities identified as potential pools of research subjects in order to enhance the effort toward women's inclusion. At the heart of the FDA's revisions and the *Revitalization Act*, however, is the intention to address women's health advocates' concerns by shifting from a presumption of exclusion to one of inclusion.

Critiquing the Resolutions: Too Far or Not Far Enough?

Although a constellation of measures have emerged with the aim of responding to the concerns of exclusion, underinclusion, and historical failures to perform gender-specific analyses, many question whether these reflect optimal responses. The Women's Health Initiative has faced substantial criticism. In addition to size, complexity and cost, critics have identified problems with its premises, provisions for informed consent, statistical design, central questions, and monitoring system.[64] In a representative criticism of the *Revitalization Act*, Bennett expresses concern that government mandates are intrusions that ultimately will hinder scientific progress:

policies designed to ensure the inclusion of women ... in clinical trials of treatment efficacy might be applied so uncritically as to hamper rather

[64]See Paul Cotton, "Women's Health Initiative Leads Way As Research Begins to Fill Gender Gaps," *Journal of the American Medical Association* 267, no. 4 (22/29 January 1992): 469; Barbara J. Culliton, "Critics Condemn NIH Women's Study," *Nature* 366, no. 6450 (4 November 1993): 11. For further discussion regarding the Women's Health Initiative, see Eliot Marshall, "Women's Health Initiative Draws Flack," *Science* 262, no. 5135 (5 November 1993): 838; Ross Prentice, Maureen Henderson, Curt Furberg et al., "Women's Health and Diet," *Nature* 367, no. 6462 (3 February 1994): 404.

than enhance the advancement of scientific information ... The detection of significant differences ... generally requires clinical trials that are prohibitively large, time consuming, and expensive. Medical researchers may be caught between limited resources and their goal of answering many pressing medical questions ... The challenge will be to provide information specific to distinct population groups while collecting accurate information economically.[65]

Echoing Bennett's concern over scientific autonomy are Piantadosi and Wittes, who argue against the NIH resolutions: "we can insist on applying scientific standards and ignore the purely political ones."[66] And finally, repeating concerns over longer, more complex trials, and cost (of medicines in this case), representatives of pharmaceutical organizations have raised the specter of harm to women and unborn children if "blanket inclusion" policies are in place.[67]

Proposals to privilege women with respect to inclusion argue, by contrast, that these efforts may not go far enough. Debra DeBruin, for instance, suggests that the realization of justice for women in research may require that we adopt a policy of preferential treatment, namely, the allocation of a larger share of available resources to studies of women's health.[68]

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[65]J. Claude Bennett, "Inclusion of Women in Clinical Trials: Policies for Population Subgroups," *New England Journal of Medicine* 329, no. 4 (22 July 1993): 289.

[66]Steven Piantadosi and Janet Wittes, "Politically Correct Clinical Trials," *Controlled Clinical Trials* 14, no. 6 (December 1993): 567. For those with similar sentiments on the matter of perceived political intrusions into scientific processes, see Marcia Angell, "Caring for Women's Health - What Is the Problem?" *New England Journal of Medicine* 329, no. 4 (22 July 1993): 271-272; Traci Watson, "Affirmative Action for Clinical Trials," *Science* 260, no. 5109 (7 May 1993): 746.

[67]See Paul Cotton, "Women's Health Initiative Leads Way," 470. Here, the concerns come from a physician-representative of the Pharmaceutical Manufacturer's Association special populations committee.

[68]Debra DeBruin, "Justice and the Inclusion of Women in Clinical Studies: An Argument for Further Reform," *Kennedy Institute of Ethics Journal* 4, no. 2 (June 1994): 140-141.

SOCIAL JUSTICE IN RESEARCH FOR WOMEN: THE ASCENDANCY OF DISTRIBUTION

Underlying the discourse of commentators, skeptics, and critics, as well as the legislative and policy initiatives, are notions of what is owing in justice to women, how they might be given their due, and what sorts of concerns will have to be addressed along the way. By elucidating the frameworks that shape people's thinking about justice in research for women and that find expression in public policy, we can begin to evaluate their strengths and liabilities. The discussion presented here, though, is intended to be descriptive.

An egalitarian understanding of social justice upholds the idea that basic equalities among persons are fundamental to a just society. Within these debates and the emergent resolutions, the question concerning whether the social institutions involved in clinical research have made a fair share of resources available for women reflects such a view of social justice. In keeping with prominent policies and ethical pronouncements put forth in the history of ethical reflection upon research with human subjects, a distributive orientation prevails in these egalitarian-minded efforts.[69] That is, they support the distribution of research benefits so as to

[69]Discussions of justice in the history of research with human subjects that embrace this distributive framework include: Charles Fried, *Medical Experimentation: Personal Integrity and Social Policy* (New York: American Elsevier Publishing Co., 1974): 60-63; Karen Lebacqz, "Beyond Beneficence and Respect for Persons: Justice in Research," in *Justice and Health Care*, ed., Earl Shelp (Boston: D. Reidel, 1981): 179-191; National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, *The Belmont Report: Ethical Principles and*

equalize the net welfare of all persons. Because the knowledge that emanates from clinical research can have a profound impact on persons' health through promoting changes in health care policy and standards of care, it may greatly influence their life prospects. On this view of social justice, because resources for clinical research have not been fairly allocated and because women have not been included in sufficient numbers, they have not received a fair share of research benefits, and therefore, have suffered from inequalities of life opportunity.

A communitarian understanding of social justice is also evident, specifically in guidelines aimed at improving the recruitment and retention of women for research.[70] Central to this conception of social justice is the notion that persons' identities are fundamentally constituted by their membership in communities, and by the overall social context in which they are embedded. Rather than being conceptualized as social atoms, human beings are relational creatures whose identities and values emerge from this embeddedness. On this view, what persons are due is derivable from their community's conception of the good, determined through communal processes of decision-making.[71]

Guidelines for the Protection of Human Subjects of Research, 2 vols. (Washington, D.C.: U.S. Government Printing Office, 1978).

[70]See National Institutes of Health, Office of Research on Women's Health, *Recruitment and Retention of Women in Clinical Studies* (Washington, D.C.: National Institutes of Health, 1995); and National Institutes of Health, "Guidelines Concerning the Inclusion of Women and Minorities," 14511-14512.

[71]See, for example, Alasdair MacIntyre, *After Virtue: A Study in Moral Theory* (Notre Dame: University of Notre Dame Press, 1988); Michael Sandel, *Liberalism and the Limits of Justice* (Cambridge: Cambridge University Press, 1982).

A utilitarian understanding of social justice informs the remarks of those who, like Bennett, criticize the legislative and policy initiatives that express a commitment to women's inclusion. These utilitarians - also framing their remarks in distributive terms - advocate an allocation of research resources that will maximize public utility when they argue that "adherence to quotas," and poorly conceptualized research initiatives will expend disproportionate amounts of money and time. Their position is that less research will get done, and that the health benefits likely to emerge will therefore be diminished. While they might not object to women's inclusion in principle, here utilitarians regard the legislative and policy initiatives designed to promote it as inconsistent with social justice.

To reiterate, egalitarians and their utilitarian critics have framed the problem of social justice for women in clinical research principally in terms of the morally proper distribution of research benefits and burdens. This distributional framework underlies the focal questions of government inquiries;[72] the commentaries of some advocates for women's health;[73] the remarks of skeptics like Kadar and Bennett;[74] those who are cautious but concede that women's health advocates raise legitimate concerns;[75] and the

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[72]See the discussion on page 3.

[73]In addition to the references included throughout the chapter that focus upon exclusion and underinclusion, see the remarks by Bernadine Healy concerning disputes about the distribution of funds. See Eliot Marshall, "Big Science Enters the Clinic," *Science* 260, no. 5109 (7 May 1993): 744.

[74]See pages 14-15.

[75]For instance, Kirschstein focuses upon numbers of women in study populations as well as allocations of funds. See Ruth L. Kirschstein, "Research on Women's Health," *American Journal of Public Health* 81, no. 3 (March 1991): 291-293. Similarly Marcia Angell questions, "How many ways must we slice and dice in the interests of fairness?" Angell, "Caring for Women's Health," 272.

revised FDA "Guidelines" and the *Revitalization Act*, with their respective emphases upon numbers of women in clinical studies, and amounts of money and time allocated for women's health research.[76]

As I shall argue in the chapters ahead, although they draw our attention to important issues, the conceptions of justice that inform these debates and resolutions divert it away from and obscure others. Ultimately, they serve to hinder our ability to understand, and in turn, respond to women's concerns of justice in research in their full complexity. My aim is to show that we are compelled to embrace a quite different understanding of justice for the moral governance of research in a contemporary context, particularly for women (and perhaps for other social groups) living under conditions of domination and oppression. To begin, however, I now turn to examine the efficacy of distributively-oriented conceptions of social justice for understanding and addressing concerns of justice for women in clinical research.

[76]Kadar even focuses on distributional issues with respect to health care for women. Indeed, he argues that women have *more* health care services available to them, *more* physician contacts, and *more* organizations devoted exclusively to their health concerns. See Kadar, "The Sex Bias Myth."

CHAPTER TWO

THE DISTRIBUTIVE PARADIGM OF JUSTICE IN CLINICAL RESEARCH POLICY

In accordance with the conception that has historically prevailed in research with human subjects, the debates concerning women in clinical research and the ensuing resolutions reflect an understanding of social justice as the morally proper distribution of social benefits and burdens among persons. After examining the historical evolution of this focus on distribution for moral guidance in research, I turn here toward an evaluation of the adequacy of such a framework for addressing the concerns facing women in this context.

There is, indeed, a significant disparity between the conception of social justice to which advocates for women's health appeal, and the one that has provided the principal framework for understanding and responding to their concerns. While views of social justice that emphasize fairness in distribution clearly highlight matters of substantial concern for women's health advocates, the persistent tendency to frame the salient issues primarily in terms of distributive injustices tends to ignore or presuppose certain social and institutional processes, relations and structures related to the endeavors of clinical research. This tendency to obscure these systemic or structural matters eviscerates these advocates'

claims of injustice. Ultimately, the myriad processes, relations, and structures that contribute to the domination and oppression of women should serve as the starting point of inquiries concerning social justice for them in clinical research.

THE REIGN OF DISTRIBUTIVE JUSTICE IN HUMAN SUBJECTS RESEARCH

A distributive framework has informed discussions concerning justice in historical and contemporary contexts of clinical research. Embedded in the prominent ethical commentaries put forth since World War II to give moral guidance to research with human subjects is an understanding of justice that emphasizes distribution. *The Belmont Report* established the ethical foundations of federal regulations for human subjects research and identified justice among the central guiding principles. Justice is explained here as a principle that considers "fairness in distribution," and that calls for the question, "Who ought to receive the benefits of research and bear its burdens?"[77] Echoing this emphasis on distribution, Lebacqz writes: "Justice requires a fair distribution of burdens and benefits in a social system. It deals with the comparative treatment of persons: who should bear burdens and who should receive

[77]National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, *The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research* (Washington, D.C.: U.S. Government Printing Office, 1978), 1: 5.

benefits?"[78] According to Fried, the principle of justice compels us to consider "a clear notion of what fairness means in the distribution of risks and benefits."[79] He goes on to define injustice in research in terms of the unfair imposition of the burdens of research on those who do not fully share in its benefits, as a violation of the right of persons not to be treated as means alone, or as a resource available to others. Ultimately, he argues, justice is to be regarded as:

> a constraint upon the pursuit of the social good ... [that is] upon the optimization of policy which might lead to the sacrifice of the interests of persons, identified persons, for the sake of the good that could be done to a far greater number of a remote, more vaguely identified group.[80]

These remarks remind us that the chief concern of justice in the era that experienced the Nuremberg Trials of the late 1940s, the Tuskegee Syphilis Study, and the Willowbrook Hepatitis Study, was exploitation: some groups had been overstudied and subjected to disproportionate risks or burdens, while frequently the benefits of research accrued to others. Fairness in the selection of subjects thus gained special prominence in deliberations about justice. According to *The Belmont Report*:

> the selection of research subjects needs to be scrutinized in order to determine whether some classes ... are being systematically selected simply because of their easy availability, their compromised position, or

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[78]Karen Lebacqz "Beyond Beneficence and Respect for Persons: Justice in Research," in *Justice and Health Care,* ed., Earl Shelp (Boston: D. Reidel, 1981): 179.

[79]Charles Fried, *Medical Experimentation: Personal Integrity and Social Policy* (New York: American Elsevier Publishing Co., 1974): 63.

[80]Ibid., 60-61.

their manipulability, rather than for reasons directly related to the problem being studied. [And further,] whenever research supported by public funds leads to the development of therapeutic devices and procedures, justice demands that these not provide advantage only to those who can afford them and that such research should not unduly involve persons from groups unlikely to be among the beneficiaries of subsequent applications of the research.[81]

Some points of theory are here in order. In particular, these comments reflect concern regarding material principles of justice. Such principles give content to the minimal principle of formal justice, which holds that persons who are equal in certain respects deemed relevant must be treated equally and persons who are unequal in these respects must be treated differently, in proportion to the differences.[82] Material principles, then, specify the relevant respects in terms of which people are to be treated equally. They note a property which persons possess or fail to possess on the basis of which burdens and benefits should be distributed. Theorists have argued that certain characteristics, or properties, are not usually acceptable principles of distributive justice. To use such principles as "easy availability," "manipulability," race, social status, or physical or cognitive ability would be "to treat people differently in ways that profoundly affect their lives because of differences for which they have no responsibility."[83] According to the fair opportunity principle:

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[81]National Commission for the Protection of Human Subjects, *The Belmont Report*, 5.

[82]Tom Beauchamp, "Distributive Justice and Morally Relevant Differences," in *The Belmont Report*, Appendix 1: 6-5.

[83]William Frankena, "Some Beliefs about Justice," *The Lindley Lecture*, Department of Philosophy Pamphlet (Lawrence, KS: Universityof Kansas Press, 1966).

none should be *granted* benefits on the basis of their (let us say 'advantageous') properties when they are not responsible for those properties, and ... none should be *denied* benefits on the basis of their (let us say 'disadvantageous') properties when they are not responsible for those ... Such properties are never grounds for morally acceptable discrimination between persons based on justice *because they are not the sorts of properties that one has a fair chance to acquire or overcome.*[84]

The experiments on poor, African-American men, on Jews, and on various groups of institutionalized persons violated justice because subjects were selected on the basis of morally inappropriate properties. Research burdens were thus unjustly distributed. Moreover, in being frequently granted to persons other than the subjects, the benefits ensuing from research were unjustly distributed.

These distributively-oriented deliberations owe their framework to philosophical theories of justice, which have tended to define social justice in terms of the morally proper distribution of burdens and benefits among society's members. Rawls, for instance, defines a "conception of justice as providing in the first instance a standard whereby the distributive aspects of the basic structure of society are to be assessed."[85] Runciman defines the problem of justice as "the problem of arriving at an ethical criterion by reference to which the distribution of social goods in societies may be assessed."[86] Ackerman defines the problem of justice initially as that of determining initial entitlements of a scarce resource.[87] Other theorists who

[84]Beauchamp, "Distributive Justice," 6-17.

[85]John Rawls, *A Theory of Justice* (Cambridge: The Belknap Press of Harvard University Press, 1971): 9.

[86]W.G. Runciman, "Processes, End States, and Social Justice," *Philosophical Quarterly* 28, no. 110 (January 1978): 37.

[87]Bruce Ackerman, *Social Justice and the Liberal State* (New Haven: Yale University Press, 1980): 25.

understand justice and distribution as coextensive concepts include William Galston and David Miller.[88]

The prevailing attitude toward clinical research has shifted significantly since the decades following World War II. Instead of regarding participation as a subject as burdensome, certain constituencies have come to claim that they have been burdened by being *under*studied. In other words, they have been denied the benefits of research participation, including the knowledge that leads to changes in health policy or standards of care.[89] With respect to women, as we have seen, there is also the problem of the emphasis upon reproduction in research. One might say that in this respect women have been overstudied. The concerns raised about research agendas are tied to claims of underinclusion, yet are further related to the issue of participation in the development of research agendas. As we have seen, the primary response to women's health advocates' claims has been the development of policies that, consistent with a distributive model for assessing and addressing justice concerns, emphasize the allocation of money and positions for women. Gender has thus become a criterion for the distribution of research benefits and burdens. With these distributive measures it is

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[88]William Galston, *Justice and the Human Good* (Chicago: University of Chicago Press, 1980); David Miller, *Social Justice* (Oxford: Clarendon Press, 1976).

[89]Women have not been the only group claiming to have been understudied and denied research benefits. It is interesting to note that AIDS activists, from whom women's health advocates drew much of their impetus, had a slightly different angle. Their chief concern was securing access to experimental therapies, and in some cases, to the health care services provided in the context of research.

hoped that progress in health policy or standards of care will be achieved, thereby diminishing women's potential for illness and disability.

One way of interpreting the newly established policies is to see them as enhancing women's potential to pursue their life prospects, or their conceptions of the good. By redistributing research resources, these initiatives seem to aim toward distributing opportunity for women in society more fairly. Viewed in this way, they are informed by the work of Norman Daniels, who tailored John Rawls's liberal egalitarian theory of justice for health care. I shall argue below that these distributive efforts are too limited in scope to capture the full range of concerns of justice relevant to women's research participation. First, however, I will present Rawls's view in order to lay the foundation for that of Daniels. While there are certainly many distributive theories of justice, Rawls's contains the characteristic features of distributive conceptions of justice (that is, certain presuppositions, lines of reasoning and questioning, scope and mode of application) along, of course, with some elements uniquely his own. Moreover, Rawls and Daniels are among the most influential theorists of our time, not just in ethical theory and biomedical ethics, but also in contemporary social - and in the case of Daniels, health - policy.

Rawls's theory, "justice as fairness," centers upon the distributive aspects of the basic structure of society, and seeks to present a conception of justice which balances liberty and equality with special concern for the least advantaged. He maintains that because a well-ordered society

depends on a scheme of cooperation without which no one would have a satisfactory life, the division of advantages should be structured in such a way as to facilitate the willing cooperation of everyone, even those who are less well-situated. On his view, because many inequalities, or advantages and disadvantages among persons are undeserved, a just society should seek to render more equal the unequal situation of its disadvantaged members. According to his first principle of justice, then, each person is to have an equal right to the most extensive liberty compatible with a similar system of liberty for all. According to the second, social and economic inequalities are to be arranged so that they are both to the greatest benefit of the least advantaged and attached to positions and offices open to all under conditions of fair equality of opportunity. While his general conception of justice upholds an equal distribution of all social values unless an unequal distribution would work to the advantage of all, the special conception is formulated in such a way as to prohibit exchanges between basic liberties, and economic and social gains.[90]

This is the view of justice that would be accepted, according to Rawls, if persons were in a hypothetical situation referred to as the "original position." To ensure that no one is advantaged or disadvantaged by the outcome of natural chance or the contingency of social circumstances, and that the choosers cannot therefore design principles of justice according to personal conditions or be guided by prejudices, the

[90]Rawls, *A Theory of Justice*, 60f.

parties in this constructed moral point of view are imagined to be under a "veil of ignorance": they have no knowledge of their respective places in society, their fortune in the distribution of "natural goods" like health, strength and intelligence, nor do they know their various conceptions of the good. They do have, however, general knowledge about persons and society. That is, they know that they desire certain primary "social goods," or goods that every rational person is presumed to want because they are useful for any life plan. These include: a set of basic liberties, freedom of movement, choice of occupation with a background of diverse opportunities, powers and opportunities, income, wealth, and the social bases of self-respect.[91] Rawls remarks: "A person's prospects are improved when he can anticipate a preferred collection of these goods."[92] Further stipulations concerning the hypothetical situation in which justice as fairness would be chosen are that the parties therein are rational, pursuing the most effective means to given ends, mutually disinterested (that is, they lack concern for others), and equal. Rawls suggests that the original position may be viewed as a procedural interpretation of Kant's conception of autonomy: the veil of ignorance and the motivational assumption of mutual disinterest deprive persons in this hypothetical situation of knowledge that would lead them to choose heteronomous principles of justice.[93] In other words, the objective for this constructed

[91] Ibid., 62, 92f.
[92] Ibid., 95.
[93] Ibid., 251-7.

moral point of view is to avoid egoism, to preclude the contracting parties from choosing principles that favor themselves or their notions of the good, and instead enable them to represent the relevant interests of all persons. The theory of justice as fairness, defined from within a moral point of view modeled in accordance with an ideal of impartiality, is meant to be a case of pure procedural justice. The veil of ignorance represents a commitment to treat persons as equals without regard to "morally arbitrary" characteristics such as race, class, or religious belief.

If, as Rawls argues, it is just to use resources to counter the advantages some gain in the natural lottery, Daniels suggests it is equally important to counter disadvantages induced by disease. On his view, because meeting health care needs has an important effect on the distribution of opportunity, the moral function of the health care system is to help guarantee fair equality of opportunity by protecting people from impediments to achieving it. Daniels argues, then, that a just distribution of health care is based on the principle of needs and seeks to achieve fair equality of opportunity.[94] He begins by invoking David Braybrooke's distinction between course-of-life needs, or those that all persons have throughout life or through certain stages through which all pass, on the one hand, and adventitious needs, things we need because of particular contingent projects on which we embark, on the other.[95] Daniels links

[94]Norman Daniels, *Just Health Care* (Cambridge: Cambridge University Press, 1985).
[95]David Braybrooke, *Meeting Needs* (Princeton: Princeton University Press, 1987).

health care needs and species-typical functioning: a deficiency in course-of-life needs jeopardizes the normal functioning of the subject of need, considered as a member of a natural species.[96] Regardless of particular choices and preferences individuals might make and/or have, course-of-life needs are those necessary to achieve, restore, and maintain species-typical functioning. In turn, normal species function is necessary for persons to achieve the normal opportunity range, or "the array of life plans reasonable persons in [a society] are likely to construct for themselves."[97] Impairments in or deviations from the natural functional organization of a typical member of a species due to disease, deformity and disability thwart a person's ability to develop and pursue a conception of the good or plan of life, and thus reduce the range of opportunity open to her.[98] Shares of the normal range of opportunity will be fair, according to Daniels, when positive steps have been taken to ensure that individuals maintain normal functioning.[99]

The legislative and policy initiatives for women in clinical research noted earlier reflect such steps. Underlying them is the notion that by more fairly distributing research resources, knowledge for women's health will be developed. Normal functioning for women will, therefore, be

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[96]Daniels, *Just Health Care*, 26. Notably, Daniels suggests that it is the task of biomedical science to characterize this natural functional organization. As noted in the preceding chapter, this remains to be accomplished for women.

[97]Ibid., 33

[98]Ibid., 27-28.

[99]Ibid., 33-34.

ensured and their prospects for living healthy lives will be improved. Women, then, will get their fair share, and opportunity will be more fairly distributed.

CONCERNS OF JUSTICE FOR WOMEN IN CLINICAL RESEARCH

The tenacity of the framework of distribution for assessing and responding to claims of injustice in both historical and contemporary contexts should, by now, be evident. This framework, however, is ineffective for capturing the range of concerns relevant to women in the context of clinical research.

The model for all analyses of justice assumed by distributive theories, and holding privilege of place in the contemporary debates concerning women, suggests that "all situations in which justice is at issue are analogous to the situation of persons dividing up a stock of goods and comparing the size of the portions individuals have."[100] Yet, as Iris Young points out, when people claim that rules, practices, or other social norms are wrong and warrant change, they are often making claims - in addition to ones about resource distributions - about the ways in which social institutions dominate and oppress persons. That is to say, many claims about injustice concern the extent to which persons confront hindrances in

[100]Iris Marion Young, *Justice and the Politics of Difference* (Princeton: Princeton University Press, 1990): 18.

the potential to develop their capacities, to express their experiences, and to determine their actions and the conditions of their actions.[101]

Theories of justice that reduce social justice to distribution are characterized by several features. They tend to: emphasize end-state patterns of goods in evaluating justice; posit some procedure for making decisions about allocations; regard persons primarily as acquirers, possessors, or consumers of goods, and as externally related to these; and conceive of most social goods and values as amenable to distribution. Two general criticisms may be leveled against such conceptions of justice. First, the framework of distribution restricts the scope of justice in its propensity to ignore the institutional contexts within which distributions occur, and further, to presuppose specific institutional structures whose justice it fails to bring under evaluation. Furthermore, when the concept of distribution is extended to include non-material goods and resources, such as opportunity, they are represented as things, amenable to being assigned to persons in bundles, rather than as a function of social relations and processes.[102]

These criticisms are of the highest relevance for thinking about social justice for women in clinical research. To delve deeper beneath the claims concerning exclusion, underinclusion, and the determination of research agendas is to see that the issues raised by women's health

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[101]Ibid., 38.
[102]Ibid., 18-24.

advocates involve unquestioned social and institutional relations, norms, rules, and processes embedded in the endeavors of clinical research. They are not, therefore, reducible to matters of distribution, nor are they amenable to solutions based on a conception of social justice which has at its center the notion of an "allotment of something to persons ... goods, ... opportunities, ... and so on," in this case, money and positions for women.[103] Ultimately, they compel us to consider embracing a conception of social justice for clinical research that attends to women's experiences of domination and oppression.

My present project, then, is to raise issues of social and institutional context that are salient to social justice for women in clinical research, and point to the inefficacy of the distributively-oriented theories of justice, including those of Rawls and Daniels, for understanding and addressing them.

Women and Physiological Particularity

Distinctive features of women's bodies have been posed as obstacles to their participation in clinical research. First, perhaps foremost, the capacity for reproduction and, in particular, for gestation, has historically and continues currently to raise problems for women. Experiences with thalidomide, a drug that proved teratogenic, diethylstilbestrol (DES), yet

[103]William Frankena, "The Concept of Social Justice," in *Social Justice*, ed., Richard B. Brandt (Englewood Cliffs, NJ: Prentice-Hall, 1961): 9.

another drug which caused teratogenic effects, in addition to such harms as vaginal cancers and reproductive problems in the daughters of the women to whom it was given, as well as with contraceptive devices that proved harmful, had a dramatic impact upon research policy in previous decades.[104] Specifically, they fostered the development of protectionist regulations for clinical research in the 1960s and 1970s. Some of these policies were aimed directly at women.

Most notably, the Food and Drug Administration's (FDA) 1977 *General Considerations for the Clinical Evaluation of Drugs* placed restrictions on the inclusion of women.[105] As pointed out in the preceding chapter, several subgroups of women (lesbians, postmenopausal women, and celibate ones) were formally excluded from drug research through this policy. In addition, the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research began working in 1974 on informed consent guidelines for populations considered "vulnerable" to abuse and coercion, in this case prisoners, children, and the

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[104]For a brief history on the use and impact of thalidomide and DES see Carol Levine, "Women and HIV/AIDS Research: The Barriers to Equity," *Evaluation Review* 14, no. 5 (October 1990): 452-454. Other sources include: Roberta J. Apfel and Susan M. Fisher, *To Do No Harm: DES and the Dilemmas of Modern Medicine* (New Haven: Yale University Press, 1984); Ann B. Barnes, Theodore Colton, and Jerome Gunderson et al., "Fertility and Outcome of Pregnancy in Women Exposed in Utero to Diethylstilbestrol," *New England Journal of Medicine* 302, no. 11 (13 March 1980): 609-613; Arthur L. Herbst, Howard Ulfelder, and David C. Poskanzer, "Adenocarcinoma of the Vagina: Association of Maternal Stilbestrol Therapy with Tumor Appearance in Young Women," *New England Journal of Medicine* 284, no. 16 (22 April 1971): 878-881; The Insight Team of the Sunday Times of London, *Suffer the Children: The Story of Thalidomide* (New York: Viking, 1979). For discussion of the harms associated with intrauterine devices, see Sheryl Burt Ruzek, *The Women's Health Movement: Feminist Alternatives to Medical Control* (New York: Praeger Publishers, 1978): 43-44.

[105]Food and Drug Administration, *General Considerations for the Clinical Evaluation of Drugs* (Washington, D.C.: U.S. Government Printing Office, 1977): 10.

institutionalized mentally infirm, as well as for research involving fetuses. Its amended recommendations were eventually codified into the Code of Federal Regulations, or 45 CFR 46.[106] These regulations did not exclude women from research, but they placed special emphasis on potential risks to fetuses in setting out the requirements for informed consent.[107] Additional protections for research involving fetuses and pregnant women required that "appropriate studies on animals and non-pregnant individuals" be completed "except where the purpose of the activity is to meet the health needs of the mother or the particular fetus, the risk to the fetus is minimal and, in all cases, is the least possible risk for achieving the objective of the activity."[108] With respect to activities directed toward pregnant women as subjects specifically, the policy states:

(a) No pregnant woman may be involved as a subject in an activity covered by this subpart unless: (1) The purpose of the activity is to meet the health needs of the mother and the fetus will be placed at risk only to the minimum extent necessary to meet such needs, or (2) the risk to the fetus is minimal. (b) An activity permitted under paragraph (a) of this section may be conducted only if the mother and father are legally competent and have given their informed consent after having been fully informed regarding possible impact on the fetus, except that the father's informed consent need not be secured if: (1) The purpose of the activity is to meet the health needs of the mother; (2) his identity or whereabouts

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[106]National Institutes of Health, *Code of Federal Regulations Title 45 Part 46* (Washington, D.C.: U.S. Government Printing Office, 1975).

[107]45 C.F.R. § 46.116. Concern about fetal research was one of the reasons that the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research was created by Congress and that it took up such research as its first project. See Levine, "Women and HIV/AIDS Research," 454.

[108]45 C.F.R. § 46.206.

cannot reasonably be ascertained; (3) he is not reasonably available; or (4) the pregnancy resulted from rape.[109]

There is thus a two-tiered test for women's participation. Once the initial threshold test is passed, research may be carried out under the governance of stringent requirements for parental consent. As I will note below, it is significant from the standpoint of obtaining consent that the notion of "the health needs of the mother" is not defined.

These policies reflect the sexual division of labor, in this case the fact that women perform the work of gestation and birthing. In research, these distinctive physiological capacities have been transformed into disadvantage. Commentators argue that the protectionist policies reflected "an attitude of concern for the fetus that ... superseded maternal considerations."[110] Rather than present risks to actual or potential fetuses in research, women's participation was restricted. They were frequently excluded. Their risk was shifted outside research contexts, and the development of knowledge relevant to women's health was inhibited. The homogenization of women's identities, or the inattention to specific contextual features of individual women's lives is worthy of note here. Viewing women as reproductive beings first and foremost, protectionist policies were overextended in being applied to women not likely to become pregnant. While women's childbearing potential was pivotal in decisions to exclude them, the role of men in reproduction went

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[109]Ibid., § 46.207.

[110]Howard Minkoff, Jonathan Moreno, and Kathleen Powderly, "Fetal Protection and Women's Access to Clinical Trials," *Journal of Women's Health* 1, no. 2 (1992): 137.

unheeded: the policies failed to acknowledge reproductive effects of drugs on fertile men.[111]

The influence of industry on health care and the conduct of clinical research is evident here. Protectionist policies reveal a (some would say an exaggerated) fear of liability for injury in research, primarily to fetuses, but given the problems with intrauterine devices, to women as well.[112] Yet, the harms that resulted from the use of thalidomide, DES, and intrauterine devices did not occur due to women's participation in research. In the case of thalidomide, pharmaceutical companies distributed the drug to physicians, many of whom then prescribed it for their pregnant patients even though marketing approval had not been granted by the FDA. Physicians prescribed DES despite findings that the drug was ineffective.[113] With respect to intrauterine devices, the scientific and

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[111]On the potential for men to incur reproductive risks from exposure to drugs, therapies, or other substances, see Lester F. Soyka and Justin M. Joffe, "Male Mediated Drug Effects on Offspring," in *Drug and Chemical Risks in the Fetus and Newborn*, ed., R.H. Schwarz and S.J. Yaffe (New York: Alan R. Liss, 1980): 50-65. For further commentary on this point, see Theresa McGovern, Martha Davis, and Mary Beth Caschetta, "Inclusion of Women in AIDS Clinical Research: A Political and Legal Analysis," *Journal of the American Medical Women's Association* 49, no. 4 (July/August 1994): 102-103.

[112]Ibid., 103-104; Michelle Oberman, "Real and Perceived Legal Barriers to the Inclusion of Women in Clinical Trials," in *Reframing Women's Health: Multidisciplinary Research and Practice*, ed., Alice J. Dan (Thousand Oaks, CA: Sage, 1994): 266-276.

[113]Testimony from the period revealed that the practice of distributing samples of experimental drugs to physicians, who would then precribe them to patients without their knowledge or consent was common. Pharmaceutical companies would pay physicians to collect data in this loosely goverend research process. These activites, and other pharmaceutical company conduct, led to legislation aimed at injurious and inneffective drugs, specifically the 1962 Kefauver-Harris amendments to the *Food, Drug and Cosmetic Act* of 1938. This protective legislation required manufacturers to obtain FDA approval to study new drugs in humans, and to demonstrate not only drugs' efficacy, but also their safety before marketing. It also gave the FDA authority to recall drugs from the market when there were safety concerns. The Amendments here applied only to new drugs, not to those previously approved. Further, it called for informed consent in the testing of investigation drugs, a sigificant but not adequate initiative. The resolution was even more limited in effectiveness by large loopholes that gave doctors discretion in judging the appropriateness of disclosure and discussion. See Advisory Committee on Human Radiation,

medical community failed to heed reports regarding the severe complications associated with their use. Further, the FDA claimed that devices did not fall within its regulatory purview, for prior to the Medical Device Amendments of 1976, medical devices could be marketed without testing.[114] The harms perpetrated on women and children may therefore be attributed to the profit-driven efforts of industry, physicians' uncritical acceptance of promotional claims, and inadequate standards for research.[115] The marriage between industry and science served to deny women's capacity to make decisions concerning the risks of research participation. They were simply ruled out as potential subjects, precluded from exercising this ability by the hierarchical structure of decision-making processes and policy formulation. Moreover, the harms from thalidomide, DES, intrauterine devices, as well as the initial birth control pill had a chilling effect on the development of research for women.[116]

As we have seen, the protectionist policies implemented in previous decades have been revisited and substantially revised. Nevertheless, the emphasis on women's role in reproduction is a concern that remains unabated in the context of research. Above all, given the

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"Government Standards for Human Experiments: The 1960s and 1970s," 98.

[114]The harms linked to intrauterine devices led to the passage of the *Medical Device Amendments* in 1976, which gave the FDA regulatory authority over medical devices.

[115]Levine, "Women and HIV/AIDS Research," 452-453. As well, see Ruzek, *The Women's Health Movement*, 43-44.

[116]Oberman, "Real and Perceived Legal Barriers," 269-270.

relationship between industries that produce medical devices and pharmaceuticals and scientific pursuits, the extent to which liability concerns continue to define debates regarding women in research is significant. The emphasis upon fetal protection and the fear of legal liability continue to loom large in current discussions. Recall, for example, the pharmaceutical industry executive quoted in Chapter One who raised concerns regarding inclusion policies which, in his view, pose grave threats to "unborn children."[117]

Additionally, despite the revisions of protectionist policies, barriers that diminish women's capacities to make decisions persist. Within the requirement to obtain paternal consent included in section 46.208 of Subpart B of the Code of Federal Regulations, the provisions focused on research involving fetuses in utero raised concerns for pregnant women in AIDS Clinical Trials Group (ACTG) protocol 076. Picking up again on the point that the "health needs of the mother" is an undefined concept within the regulations, this example reveals the difficulties that may arise in determining when an activity aims at the health of the mother, fetus, or both. The ambiguity is problematic in that there are different standards for paternal consent for activities directed at fetuses in utero. In the 076 study, despite the potential effects on women's health, the focus on the fetus required paternal consent (except where fathers' identity was

[117]See Paul Cotton, "Women's Health Initiative Leads the Way As Research Begins to Fill Gender Gaps," *Journal of the American Medical Association* 267, no. 4 (22/29 January 1992): 470.

unknown, his whereabouts could not be ascertained, he was not reasonably available, or the pregnancy was due to rape). Many women did not want to disclose their infection status to the fathers for fear of violence. Others claimed that the fathers refused to give consent.[118] Thus, women's research participation was hindered due to assumptions about the structure of families, in particular, assumptions that women are members of nuclear, non-violent families, wherein males hold substantial if not primary decision-making authority. This policy, then, perpetuated women's subordination. The requirement for paternal consent is especially interesting in light of the aforementioned failure to acknowledge possible teratogenic effects of drugs used by fertile men. Men have not found their own research participation hindered as a result of their role in reproduction.

Women's physiological particularities, especially the potential to bear children, also have an impact upon their research participation insofar as they affect the structure of health care services. Women's health advocates note the degree to which services tend to be overspecialized in the realm of reproductive health, as well as fragmented: "even healthy women must visit two physicians, an internist and a gynecologist, to attend to their basic health needs."[119] Through the focus on women's

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[118]William L. Freeman, "IRB Feedback on the NIH Guidelines on the Inclusion of Women, and Discussion of Subpart B Issues." Paper presented at ARENA and PRIMER Meetings, October 1995, Boston, MA. As well, see McGovern, Davis and Caschetta, "Inclusion of Women in AIDS Clinical Research," 103; Karen H. Rothenberg, "Gender Matters: Implications for Clinical Research and Women's Health Care," *Houston Law Review* 32, no. 5 (Symposium 1996): 1251, note 327.

[119]Kathryn C. Bemman and Tracy L. Johnson, "Sex Bias in Medicine," *The Atlantic Monthly* 274, no.

reproductive capacities and the erection of disciplinary barriers - barriers which potentially inhibit the sharing and development of knowledge in health care institutions - the development of knowledge relevant to the full range of women's health care concerns through clinical research endeavors is inhibited.

Epistemological assumptions in research, and specifically views about how reliable knowledge is produced, have transformed the particularities of women's bodies into obstacles to their participation in research. Researchers have often argued that in a clinical trial, valid interpretation requires that subjects be as homogeneous as possible. By using uniform subjects they believe they can better determine which effects are attributable to a drug or other intervention as opposed to some other variable. Rather than taking the cyclical variation of women's hormones, their body size and composition, and the use among many of steroidal contraceptives as reasons to study women, they have been seen as confounding factors or methodological problems, and thus used as rationales for exclusion.[120] In many cases such uniquenesses have been ignored.[121] Older women have been regarded as especially problematic

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6 (December 1994): 19. As well, see Jessica A. Jonikas and Lisa Razzano, "Sex Bias in Medicine," *The Atlantic Monthly* 274, no. 6 (December 1994): 16; Leslie Laurence and Beth Weinhouse, "Sex Bias Myth," *The Atlantic Monthly* 274, no. 5 (November 1994): 16-17.

[120]See Jean A. Hamilton, "Women and Health Policy: On the Inclusion of Females in Clinical Trials," in *Gender and Health: An International Perspective*, ed., Carolyn F. Sargent and Caroline B. Brettell (Englewood Cliffs, NJ: Prentice Hall, 1996): 298-299; Ruth B. Merkatz, Robert Temple, and Solomon Sobel et al., "Women in Clinical Trials of New Drugs: A Change in Food and Drug Administration Policy," *New England Journal of Medicine* 329, no. 4 (22 July 1993): 292-296.

[121]Mary Beth Caschetta, "The Identity Politics of Biomedical Research: Clinical Trials, Medical Knowledge, and the Female Body," *SIECUS Report* 22, no. 1 (October/November 1993): 3.

because they may have multiple health conditions and take concomitant medication.[122] Women have thus been neglected and as well, defined as a highly problematic group for study.

Certain ethical notions may have served to privilege homogeneity in research populations. For instance, one of the cherished ideals of a liberal society is the view that all persons are of equal moral worth. The quest for social justice has, in part, involved attempts to eliminate certain dissimilarities as bases for difference of treatment. Such efforts are reflected in the context of research, as the ideal of the equal moral worth of all persons lies at the center of codes of ethics developed in response to the exploitation of certain groups to govern experimentation with human subjects. Yet, an ideal of equality that is blind to individual or group differences may have grounded the assumption that the interests and experiences of males were representative of the interests and experiences of all persons. As Dresser suggests:

> If all humans have equal moral value, then, in some sense, they are identical and interchangeable. If all people are identical, then it might appear that any human subject could adequately represent the general human population ...; the white male subject could stand for everyone.[123]

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[122]Jerry H. Gurwitz, Nananda F. Col, Jerry Avorn, "The Exclusion of the Elderly and Women from Clinical Trials in Acute Myocardial Infarction," *Journal of the American Medical Association* 268, no. 11 (16 September 1992): 1417-1422; Nanette K. Wenger, "Exclusion of the Elderly and Women from Coronary Trials: Is Their Quality of Care Compromised?" *Journal of the American Medical Association* 268, no. 11 (16 September 1992): 1460-1461.

[123]Rebecca Dresser, "Wanted: Single, White Male for Medical Research," *Hastings Center Report* 22, no. 1 (January-February 1992): 28.

On this reductionistic understanding of equality, not only would it be unnecessary to recruit subjects according to gender, but the failure to perform gender-specific analysis and to develop research agendas for women would not be causes for concern.

The social and institutional relations, structures and processes thus far noted to work to women's disadvantage in the context of research include the sexual division of labor, decision-making structures, and entrenched assumptions in research methods and ethical theory. Here I have noted the tenacity of the view that all women - even lesbians, postmenopausal women, and those sworn to celibacy - are potentially pregnant; the transfer of women's real or imagined childbearing labors to society without comparable remuneration (in that knowledge relevant to their health was not developed), and indeed, with considerable harm (in that risks were shifted outside of research); and the failure to attend to men's role in reproduction. Decision-making processes in research have been brought into view, particularly their hierarchical structure and key participants. Further, I have pointed out that certain research methodologies and moral concepts warrant scrutiny to the extent that their inattention to and virtual pathologization of physiological particularities disadvantage women.

Women and Cultural Pluralism

Research methods that value homogeneity and that simultaneously silence differences and regard them as deviances have proven especially problematic for women who are members of non-dominant cultural groups. Women of color have not been well represented in study populations.[124] When they have served as subjects, dominant groups have shaped research agendas.

For instance, the reproductive autonomy agenda of white, middle-class feminists was arguably applied to Hispanic and African-American women with AIDS through ACTG protocol 076. To recount a bit of history, it is important to recall that with the recognition that homosexual men were not the only affected group came a shift in focus toward HIV infection in children, particularly newborns. Early efforts to address the increasing incidence of perinatally acquired HIV infection centered on reproductive counseling and encouraged women to delay if not avoid pregnancy. These efforts proved largely ineffective. ACTG 076 reflected a transition toward attempting to reduce the incidence of perinatal transmission through administering zidovudine, or AZT, to pregnant women and investigating its efficacy. The findings that it was quite efficacious have intensified calls for prenatal counseling and testing of pregnant women.[125]

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[124]See, for example, Evelyn C. White, ed., *The Black Women's Health Book: Speaking for Ourselves* (Seattle: Seal Press, 1990).

[125]Edward M. Connor, Rhoda S. Sperling, Richard Gelber et al., "Reduction of Maternal-Infant

Through incorporating the discourse of reproductive choice - language borrowed from the rhetoric of feminists who claimed to represent the concerns of women and sought to combat their "common oppression," yet wrongly posited homogeneity among them - the 076 study ultimately served to strengthen arguments for increased surveillance of poor women of color via increasingly coercive HIV/AIDS counseling and testing proposals. Thus, feminist aims were appropriated by scientists to pursue racist and classist research agendas and health care policies. This research fits into and fuels the discourse surrounding welfare mothers, the defrauding of social service agencies, the "failure to control" pregnancy, AIDS orphans and abortion - all issues which revolve around the social relations of gender, race and culture, and class. When placed in its particular social and historical context, then, the agenda of middle-class white feminists, through the development of clinical research, indirectly contributed to the denial of the opportunity for women in non-dominant cultural groups to articulate their health concerns as they experience and understand them, and to participate in determining their actions or the conditions of their actions. Only a select

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Transmission of Human Immunodeficiency Virus Type 1 With Zidovudine Treatment," *New England Journal of Medicine* 331, no. 18 (3 November 1994): 1173-1180. Most recently, the American Medical Association's House of Delegates has chosen to advocate mandatory testing of pregnant women. Jeremy Manier, "AMA Supports HIV Tests for All Pregnant Women: Critics Fear Some Will Avoid Prenatal Care," *Chicago Tribune* (28 June 1996). Calls that preceded this decision came largely, though not exclusively, from pediatricians. See, for example: Katherine Luzuriaga and John L. Sullivan, "Pathogenesis of Vertical HIV-1 Infection: Implications for Intervention and Management," *Pediatric Annals* 23, no. 3 (1994): 159-166; Arthur J. Ammann, "Human Immunodeficiency Virus Infection/AIDS in Children: The Next Decade," *Pediatrics* 93, no. 6 (1994): 930-935.

group defined the concerns of women: pediatricians and other medical professionals, as well as white, middle-class women, all of whom have access to such dominant channels of communication as publication, teaching institutions, and legislative processes.[126] The process of formulating an agenda for research, in other words, excluded those who would bear the greater share of the consequences. Initially the subjects of inattention, women living with AIDS eventually bore the burdens of attention that was organized in accordance with partial and distorted constructions of their identities. Such constructions emerged from sites of discourse in which they were not participants.

Similarly, the assumption that all women are heterosexual tends to exclude the consideration of lesbians.[127] This assumption inhibits the potential for research projects to be developed that focus on their health concerns. Where lesbians have received attention in health policy, they have been subjected to dominant groups' definitions of their identities. Again, it is crucial to consider who has access to channels of communication and thus the potential, not just to express their experience, but to have it heard and heeded.

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[126]For discussion of the dominance of white middle-class women in shaping feminist agendas, see: bel hooks, "Black Women: Shaping Feminist Theory," and "Feminism: A Movement to End Sexist Oppression," in *Feminist Theory: From Margin to Center* (Boston: South End Press, 1984): 1-32; Maria Lugones and Elizabeth Spelman, "Have We Got a Theory for You: Cultural Imperialism and the Demand for 'The Woman's Voice,'" *Women's Studies International Forum* 6, no. 6 (1983): 573-581.

[127]See Nancy Warren, "Out of the Question: Obstacles to Research on HIV and Women Who Engage in Sexual Behaviors with Women," *SIECUS Report* 22, no. 1 (October/November 1993): 13-16; Jocelyn White and Wendy Levinson, "Primary Care of Lesbian Patients," *Journal of General Internal Medicine* 8, no. 1 (January 1993): 41-47.

Even when cultural pluralism among women is acknowledged and incorporated in research agendas, positing homogeneity among groups can prove problematic. The identification of cultural groups tends to suppress the complexity of social experience by obscuring differences within and across groups. The inexhaustibility of contemporary social relations and networks must be realized by researchers, lest they perpetuate reductionism in their endeavors. This topic will receive further attention in the following chapter.

Finally, women in certain cultural groups have served as subjects in research and borne its risks largely for the benefit of other women. The first oral contraceptive released was based on studies with Puerto Rican women. Another study examining the side effects of contraceptives involved Mexican-American women. The women in the latter study believed they were receiving effective birth control, but many were given placebos. When questioned about this, the chief investigator, Joseph Goldzieher, responded: "If you think you can explain a placebo test to women like these, you never met Mrs. Gomez from the West Side."[128]

Once again, we see the sexual division of labor reflected in the emphasis placed on reproduction-related research for women (here on

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[128]Barbara Seaman, *Free and Female* (New York: Fawcett, 1972): 180-181. To fully appreciate the force of Goldzieher's statement, it is important to understand that the West Side of San Antonio is the area of the city where more impoverished residents reside, especially Hispanics. Further, readers should note that the exploitation of certain populations of women has historical precedent, for example, in the use of slave women as research subjects in the antebellum South. See James Marion Sims, *The Story of My Life* (New York: Appleton, 1889). The use of women in underdeveloped nations as subjects is pervasive in contemporary research practice, but beyond the scope of this discussion.

contraception and on perinatal transmission of the virus that causes AIDS). In the use of poor women of color for research projects we see the links between relations of class and culture and clinical research. The inclusion of Mexican-American and Puerto Rican women in contraceptive research benefited women in dominant cultural groups in that the latter did not face research risks yet did benefit from the studies. Moreover, in the San Antonio contraceptive study, many women were harmed in having the possibility of an unwanted pregnancy imposed upon them. These women had no control over research, and furthermore, were denied respect. It is evident that where women of color have been included in clinical research, they have found themselves "defined from the outside, positioned, placed, by a network of dominant meanings they experience as arising from elsewhere, from those with whom they do not identify and who do not identify with them."[129] They have been precluded from expressing their experiences and denied respect as decision-makers. Goldzieher's remark is especially revealing in this regard, namely in his refusal to regard poor women of color as capable thinkers and decision-makers in the context of research.

Women and Work

The historical understudying of women may be attributable to biases in economic measurements. In regarding young or middle-aged

[129]Young, *Justice and the Politics of Difference*, 59.

white men as the "'normal' economic contributors," researchers may have believed them to be more worthy recipients of research resources.[130] Men were perhaps given priority over women, especially older women and women of color, based upon the judgment that it would be more detrimental to society if men were taken out of the work force due to illness or disability. Too, in the era of public support for research, the view that it was men's money that provided the primary economic base for research activities may have prevailed.[131] The notion that women did not contribute to the economy rests on the traditional family's division of labor according to gender, and the division of society into public and private spheres organized by capitalism and patriarchy.[132] Women assume primary responsibility for the care of children and the elderly. This work may inhibit their potential to participate in research because of the time and energy it requires, and because of the difficulties, including cost, associated with arranging for care on the one hand, or with transporting children and/or the elderly to a research site and caring for them there on

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[130]Dresser, "Wanted: Single, White Male," 28.

[131]Paul Starr notes that in the post World War II decades, science, including medical research, had come to be regarded as a national asset. Investment in medical research was seen as an especially appealing avenue for expansion because it promised improvements in the quality of life without, it was believed, the major social reorganization required, for example, by the implementation of national health insurance. Concerns about disturbing the medical profession loomed large in this assessment. In this historical period, funding of research shifted from being a largely private, voluntary effort to a federal one, based substantially upon public investment. Paul Starr, *The Social Transformation of American Medicine* (New York: Basic Books, 1982): 338-347.

[132]See Heidi I. Hartmann, "The Family As the Locus of Gender, Class, and Political Struggle: The Example of Housework," in *Feminism and Methodology*, ed., Sandra Harding (Bloomington: Indiana University Press, 1987): 109-134; Christine Delphy, *Close to Home: A Materialist Analysis of Women's Oppression* (Amherst: University of Massachusetts Press, 1984); Carole Pateman, *The Sexual Contract* (Stanford: Stanford University Press, 1988).

the other. Women frequently exercise their capacities according to the purposes and for the benefit of others, yet their labor goes unpaid and often unrecognized.[133]

Women who do participate in the paid labor force have seen their economic status decline over the last several years. With the U.S. economy shifting from an emphasis on manufacturing toward service and information industries, jobs tend to come with lower wages and fewer benefits. As most low wage workers are women, they are disproportionately affected by declining wages and benefits, including those that provide access to health care services. It is more difficult for women to take time away from such jobs, as they afford them less autonomy. Additionally, the disparity between the earnings of men and women, and the economic dependence of many women, has implications for power relations within a household: it contributes to the potential for domestic violence and to the tendency to deny women decision-making authority. Women, too, are more likely to be expected to account to their partners for their time. Their lower earnings further inhibit access to prestige and political power, hindering prospects for acknowledging and addressing their health concerns in clinical research.

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[133]On the biases in definitions of what constitutes economic activity, or what is considered "productive," see Julie Nelson, "Gender, Metaphor, and the Definition of Economics," *Economics and Philosophy* 8, no. 1 (Spring 1992): 103-125; Michèle Pujol, "Into the Margin!" in *Out of the Margin: Feminist Perspectives on Economics*, ed., Edith Kuiper and Jolande Sap (New York: Routledge, 1995): 17-34.

Unemployment is a growing problem for women, particularly in the wake of the economic policies of the last decade. The proliferation of mergers and acquisitions, the encouragement of "downsizing," the movement of many jobs outside the U.S., as well as a decline in unions have resulted in higher rates of unemployment for many women. Consequently, their access to health care and, through it, clinical research is undermined. Given that clinical research typically takes place in the context of health care institutions, to the extent that women have diminished access to the health care system they are restricted from participation. These concerns are especially prominent among women of color, whose jobless rates are twice those for white women.[134]

Women, Class, and Health Care Coverage

To delve further into issues of economics, it is crucial to observe that the "feminization of poverty" has contributed to the economic inaccessibility of health care for many women.[135] Especially problematic is the inverse relationship between poor persons' need for health care and their actual use of health care services.[136] Again, women of color are

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[134]For further discussion of the relationship between economic policy and women's health, see Anne S. Kasper, "An Economic Policy Primer for Women's Health." Paper presented at Urban Women's Health: Models for the Future, Health and Medicine Policy Research Group Conference, Chicago, IL, November 1996.

[135]See Diana Pearce, "The Feminization of Poverty: Women, Work and Welfare," *Urban and Social Change Review* (February 1978): 28-36. As well, see Mary Briody Mahowald, "The Feminization of Poverty: Its Impact on Women's and Children's Health," in *Women and Children in Health Care: An Unequal Majority* (New York: Oxford University Press, 1993): 217-235.

[136]Ruth Sidel, *Women and Children Last* (New York: Penguin Viking Books, 1986): 136-137.

disproportionately affected by this diminished access. In addition to finding that women were not enrolled in ACTG trials in numbers proportional to the numbers of women known to be infected, for example, Cotton and her colleagues showed that women entering these trials were significantly more likely to be white, as well as less likely to have ever used intravenous drugs than U.S. women reported to have AIDS.[137] One explanation for this is that by virtue of their socioeconomic status, along with their race and history of drug use, these women were more privileged with respect to health care access, and consequently clinical research, than the majority of women with AIDS. Here we see the significance of economic obstacles to health care, and more particularly, the biases in referral networks related to research participation.[138]

Transportation is yet another issue that has been identified as a barrier for many poor women, especially the elderly and disabled. Without it they are unable to get to locations where health care services are provided and research protocols undertaken. Further, suspicion regarding the health care system (including research), difficulty with

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[137]Deborah J. Cotton, Diane M. Finkelstein, Weili He et al., "Determinants of Accrual of Women to a Large, Multicenter Clinical Trials Program of Human Immunodeficiency Virus Infection," *Journal of Acquired Immune Deficiency Syndromes* 6, no. 12 (1993): 1322-1328.

[138]Other discussions regarding the disproportionate effect of inequities in health care for poor women and women of color include Machelle Allen, "The Dilemma for Women of Color in Clinical Trials," *Journal of the American Medical Women's Association* 49, no. 4 (July/August 1994): 105-109; Cesar A. Perales and Lauren S. Young, ed., *Too Little, Too Late*: Dealing with the Health Needs of Women in Poverty (New York: Harrington Park Press, 1988); Susan Sherwin, "Gender, Race and Class in Health Care," in *No Longer Patient: Feminist Ethics and Health Care* (Philadelphia: Temple University Press, 1992): 222-240. With respect to the problem of drug use and its impact on research participation, see Timothy F. Murphy, "Women and Drug Users: The Changing Face of HIV Clinical Trials," *QRB* 17, no. 1 (January 1991): 26-32.

meeting protocol requirements, and homelessness may preclude the participation of poor women.[139] These concerns tend to be especially salient for women of color. Speaking to such barriers, one physician was quoted as saying: "There is a kind of assent that this might be important, but the bottom line is that NIH funding is for research and not for social services."[140] Thus, to the extent that social barriers inhibit their participation, poor women are seen as a highly problematic, or especially "deviant" population to study.

In other cases, however, the relationship between the institutionalized structure of health care and persons' socioeconomic status has contributed to a greater inclusion of poor women of color in clinical research and a lesser inclusion of women privileged in terms of class and race. In one researcher's nearly unimpeded study of the potential for carcinoma in situ to progress to invasive cervical cancer at the National Women's Hospital in Auckland between 1955 and 1988, wealthier white women were deterred by their physicians while Maori women were disproportionately represented.[141]

The nature and extent of the impact of managed care on clinical research is currently a subject of debate. The emphasis on cost control

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[139]See, for example, Allen, "The Dilemma for Women of Color in Clinical Trials"; Cotton, "Determinants of Accrual of Women," 1327; Wafaa El-Sadir and Linnea Capps, "The Challenge of Minority Recruitment in Clinical Trials for AIDS," *Journal of the American Medical Association* 267, no. 7 (19 February 1992): 954-957; Murphy, "Women and Drug Users"; Christine L. Young and Marianne Dombrowski, "Psychosocial Influences on Research Subject Recruitment, Enrollment and Retention," *Social Work in Health Care* 14, no. 2 (1989): 43-57.

[140]Cotton, "Women's Health Initiative Leads Way," 470.

[141]Sandra Coney, *The Unfortunate Experiment* (Auckland and New York: Penguin Books, 1988).

within the managed care framework may erode the potential to include research costs as part of patient care. Members of managed care organizations (MCOs) may be discouraged from enrolling in trials because MCOs fear that side effects from research would necessitate hospitalization, that is, an expense. Some maintain that this will have a disproportionate effect on women.[142] Because women comprise a significant proportion of enrollees in MCOs, some suggest that more women than men will be prevented from participating in clinical trials. Therapeutic choice is a significant issue here. Whereas with a fee-for-service model, decisions to participate in research were left largely to patients and their physicians, in the managed care context, such decisions are made at the institutional level, yet another manifestation of industry's potential to deny or undermine persons' decision-making capacities.

To return to issues of particular significance for poor women, the economic inaccessibility of health care raises a further concern: the potential for coercion in efforts to recruit them for clinical research. Participation in research may become especially compelling for populations of women who have diminished access to the health care system when services including health education, monitoring, referral, and follow-up are provided.[143] Given the increasing numbers of women

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[142]Society for the Advancement of Women's Health Research, *Women's Health in a Changing Economic Environment: The Impact of Managed Care on Women's Health Research* (Washington, D.C.: Society for the Advancement of Women's Health Research, 1996). As well, see: Leslie Laurence, "Is Managed Care Good for Women's Health," *Glamour* (August 1996): 237.

[143]Carey Goldberg, "Cutting a Lifeline to AIDS Study," *New York Times* (30 January 1996): B1, B5; Murphy, "Women and Drug Users."

without health care benefits, research as an option for obtaining medical care may become more prominent.

A few final words on women living in poverty, though not specific to health care coverage, are in order. While poverty inhibits women's access to health care - and through it clinical research - in the ways noted above, it may also serve to inhibit the development of their self-esteem. A sense of self-worth grounds persons' impetus to seek out research projects that will either benefit them directly or further the development of knowledge relevant to health. As well, poverty may hinder the development of the kinds of skills that are an integral part of research participation. Important skills include the ability to make risk assessments, to project into the future, and to sufficiently comprehend information in order to make an informed choice to participate.[144] There may be factors other than poverty which inhibit women's potential to flourish in these respects: these abilities may not be highly valued by or for women, if valued at all, in some cultures, for example; or alternatively, some economically advantaged families may be quite traditional in how they opt to socialize their daughters. I raise these issues here because less privileged women are far more vulnerable to them given that their opportunities to develop requisite skills and a strong sense of self-worth are diminished.

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[144]See Allen, "The Dilemma for Women of Color in Clinical Trials."

Thus, the confluence of institutional structures, and relations of class and culture inhibit women's research participation, inhibition that is differently manifested depending upon the particularities of women's social situations.

Funding for Clinical Research

The economic structure of health research financing has historically inhibited studies of women. Above I examined the economic biases underlying the discounting of women's work in making funding decisions for research. In this section I will consider related features of research financing.

The U.S. Department of Health and Human Services (DHHS), specifically through the National Institutes of Health (NIH), reviews proposals for research and assigns priority scores that determine the allocation of funds. The selection of proposals to support has been biased against women in several ways. It is considered likely that reviewers, most of whom have been men, placed less emphasis on the health concerns of women.[145] The selection process, furthermore, privileges those who have a successful record of research completion. Historically women have constituted a small number of researchers and thus have submitted fewer

[145]Consider former Representative Patricia Schroeder's now famous quote: "[Y]ou fund what you fear. When you have a male dominated group of researchers, they are more worried about prostate cancer than breast cancer." Ellen Goodman, "A Health Research Bias," *Boston Globe* (21 June 1990): 15. For a review of statistics on women in science and medicine, see Vanessa Merton, "The Exclusion of Pregnant, Pregnable, and Once Pregnable People (A.K.A. Women) from Biomedical Research," *American Journal of Law and Medicine* 19, no. 4 (1993): 373, note 15.

proposals. Those women who are researchers tend to be concentrated in the lower levels of the research hierarchy and therefore have fewer accomplishments to cite when they submit proposals.[146]

The changing economic environment attributable to the advent of managed care is having an effect on the financing of women's health research. Academic medical centers, whose missions have traditionally included carrying out biomedical research with the aid of federal and other subsidies, are increasingly unable to support research activities as they face federal spending reductions and focus more on expanding clinical market share.[147] Because research on women's health concerns has been inadequate, diminishing investment in clinical research may be especially harmful to the degree that it inhibits the development of knowledge related to women's health. In any case, changes in the health insurance market seem to be affecting the type of research that is conducted. Commentators disagree over how the shift in focus of research away from the investigation of new drugs, devices, procedures, and their safety and efficacy for various groups toward medical effectiveness studies, aimed at improving the delivery of medical care and reducing costs, will affect women. Some suggest that this trend will be quite beneficial. Others, however, maintain that the more medical effectiveness

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[146]See the discussion by L. Elizabeth Bowles, "The Disenfranchisement of Women in Clinical Trials: The Legal Ramifications of and Solutions for Rectifying the Knowledge Gap," *Vanderbilt Law Review* 45, no. 4 (May 1992): 882-883.

[147]David Blumenthal and Gregg S. Meyer, "Academic Health Centers in a Changing Environment," *Health Affairs* 15, no. 2 (Summer 1996): 200-215.

research diverts attention away from investigations of new interventions, the more severe will be the consequences for women.[148] It warrants mention that one of the options available to academic health centers trying to survive financially is to carry out research for biomedical industries and sell intellectual property resulting from investigations to industries. The prospect of increasingly dependent relationships between institutions that carry out research and industries invites special scrutiny from the standpoints of women, given the history of such partnerships.

Women and Communication

Women's experiences with communication in health care institutions help to explain ways in which the development of knowledge relevant to women's health care concerns may be inhibited. Studying the structure of dialogues during medical interviews and examinations in different kinds of clinics, Sue Fisher discovered the extent to which physicians tended to dominate the structure and content of exchanges, influence the provision of information, and direct the course and ultimate outcome of interviews, including decisions related to care, with female patients.[149] Given the variation among women in the propensity to ask questions, express concerns, and participate in decision-making, some

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[148]Society for the Advancement of Women's Health Research, *Women's Health in a Changing Economic Environment*; Laurence, "Is Managed Care Good for Women's Health."

[149]Susan M. Fisher, *In the Patient's Best Interest: Women and the Politics of Medical Decisions* (New Brunswick, NJ: Rutgers University Press, 1988).

women are especially likely to be harmed by physician control of communication. Some women are more likely to defer to physician authority and to be concerned about politeness, for instance.[150] Overall, such domination in the context of patient-physician encounters likely hinders the potential for women to express their experiences and articulate their health concerns, which in turn diminishes opportunities for the development of provocative ideas and questions for research. Moreover, even when women enter health care institutions in acute circumstances, there is evidence to suggest that health care providers frequently fail to take their concerns seriously, thereby quelling opportunities for the development of knowledge.[151] In large part, this is due to assumptions concerning expertise: health care professionals, especially physicians, have it, and lay persons, especially women, do not. Given the current restructuring of the health care system into managed care, these concerns may be exacerbated due to the time constraints with which health care providers and patients must contend. Gender socialization, the organization of health care institutions, and assumptions regarding credibility in the production of knowledge profoundly influence the development of research for women.

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[150]Although her work does not focus on health care contexts, the work of sociolinguist Deborah Tannen is relevant here, and in particular, her finding that women tend to be focused on establishing and maintaining connections, or relationships through conversation, whereas men tend to emphasize imparting information and attaining power. See Deborah Tannen, *You Just Don't Understand: Women and Men in Conversation* (New York: William Morrow and Co., 1990).

[151]Joan Lehman, "Gender Bias in Chest Pain Evaluation in the Emergency Room." Paper presented at Third Annual Congress for Women's Health, Washington, D.C., June 1995.

Women and Decision-Making

As many examples in the foregoing discussion have demonstrated, women have frequently been denied opportunities to make decisions. The institution of protectionist policies - emergent from the confluence of corporate influences, the sexual division of labor, assumptions about traditional family structures - and biases against poor women and women of color, have deprived women not just of the benefits of research. They have been deprived, further, of respect as sources of knowledge, and as intelligent persons capable of determining their actions and the conditions of their actions. The examples presented thus far have generally focused on women and decision-making with respect to particular research projects. Yet, beyond seeking recognition as participants in clinical trials who are capable of making choices, women seek participation at every step in the research process, from decisions that research for a particular concern is needed, to the review and conduct of clinical research, and the dissemination of findings. Research on breast cancer among women is a particularly striking example of this concern: women's health advocates have sought to contribute a "meaningful voice at every level where decisions are made."[152]

[152]Kay Dickerson, "Reinventing Health Outcomes Research Related to Breast Cancer." Paper presented at Health Outcomes Research Seminar, The University of Chicago, Chicago, IL, March 1996.

The pervasive assumptions that persons not trained in science - regardless of their cognitive skills and intellectual abilities - cannot understand the complexity of the research process, or the details of an idea under investigation, and further, that those affected by an illness or condition are biased and therefore likely to undermine the production of reliable knowledge, block the participation of women and other lay persons in scientific decision-making. Such assumptions rest upon circumscribed notions of scientific expertise, conventional conceptions of objectivity, and the view that emotion - especially associated with women - undermines the formulation of reliable knowledge.[153]

One final set of concerns warrants discussion. The cervical cancer study conducted by Dr. Herbert Green in Auckland, New Zealand, at the National Women's Hospital, brings forth in brilliant detail the ways in which the institutional structures of health care and clinical research, in particular decision-making processes, contribute to injustice against women.

The fact that Green was held in such high esteem in the institution, moreover, in all of New Zealand, accorded him virtually unimpeded authority in carrying out what proved to be, in many cases, lethal research on women. Regarded as the expert on cervical cancer in the nation, his

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[153]See, for example, Sandra Harding, "Rethinking Standpoint Epistemology: What is 'Strong Objectivity'?" in *Feminist Epistemologies*, ed., Linda Alcoff and Elizabeth Potter (New York: Routledge, 1993): 49-82; Alison M. Jaggar, "Love and Knowledge: Emotion in Feminist Epistemology," in *Women, Knowledge, and Reality: Explorations in Feminist Philosophy*, ed., Ann Garry and Marilyn Pearsall (Boston: Unwin Hyman, 1989): 129-155; Genevieve Lloyd, *The Man of Reason: 'Male' and 'Female' in Western Philosophy* (Minneapolis: University of Minnesota Press, 1984).

views were highly influential. Moreover, as most physicians trained at the National Women's Hospital, his impact on medical education was profound. The manner in which cases were discussed in the institution, further, precluded the ability to see the pattern of what was happening to the women included in the project. As one of the few challengers of Green remarked, regarding the institution's Tumor Panel: [because cases were only discussed individually] "we could not get everyone out of the mines as once."[154] Finally, the organization of various authoritative committees and governing bodies - including those responsible for reviewing ethical concerns in research projects - both inside and outside the institution functioned to fragment or disperse responsibility in such a way that no one person or group was held accountable.[155]

Thus far, we have seen how the sexual division of labor, the traditional structure of families, economic measurements and structures, class relations, cultural norms, epistemological assumptions underlying research methodologies, and decision-making processes - a synergistic confluence of social and institutional structures, relations, and processes - have not only served to subject women to deprivation insofar as their health is concerned, but further, hindered the development of their capacities, the expression of their experiences, and their abilities to determine their actions and the conditions of their actions. Such concerns

[154]Coney, *The Unfortunate Experiment*, 62.
[155]Ibid., 39-66

are not amenable to distributive theories of justice. In the following section I will show in explicit detail why this is so, raising criticisms applicable to distributive conceptions of justice generally, but paying particular attention to the work of Rawls.

CHALLENGING THE DOMINANCE OF THE DISTRIBUTIVE PARADIGM

To merely redistribute goods, in this case for research, fails to address concerns involving the traditional structure of families and the sexual division of labor and, therefore, cannot capture the significance these hold for women's research participation. As Young points out:

> as long as institutionalized practices and structural relations remain unaltered, the process of transfer will re-create an unequal distribution of benefits. Bringing about justice ... requires reorganization of institutions and practices of decision-making, alteration of the division of labor, and similar measures of institutional, structural, and cultural change.[156]

Distributive theories of justice, generally speaking, uncritically accept the relations of production that define an economic system, for they are concerned primarily with what constitutes a fair end-state distribution of social goods.

A Rawlsian view of justice proves especially ill-equipped to attend to the social and institutional relations and processes underlying the transfer of women's energies to men and capitalism. For one thing, the

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[156]Young, *Justice and the Politics of Difference*, 53.

parties in the original position are thought of as heads of families, and in particular, as fathers.[157] Although this assumption is intended to address the issue of justice between generations, by invoking it Rawls is "effectively trapped into the public/domestic dichotomy and with it, the conventional method of thinking that life within the family and relations between the sexes are not properly regarded as part of the subject matter of a theory of social justice."[158] In regarding families as hierarchical, headed by a male decision-maker, heterosexual, and generally organized in accordance with traditional gender roles, it seems that Rawls cannot effectively identify or challenge such issues as: the tendency to regard women fundamentally as actual or potential mothers in research; ways of socializing girls that emphasize passivity, obedience, relationships with and responsibility for others, and that in turn de-emphasize their potential for self-confidence and independence, for articulating their experiences and concerns, and for making decisions, perhaps with the counsel of others, yet not from a subordinate position; the potential for violence in domestic contexts; and inattention to lesbian relationships in research projects.[159] Because the justice of social relations involving household labor, childrearing, and caregiving is not subjected to scrutiny, the potential for these tasks to hinder women's research participation will be ignored as well. Assuming that the parties in the original position expect

[157]Rawls, *A Theory of Justice*, 128, 146, 289.
[158]Susan Moller Okin, *Justice, Gender, and the Family* (New York: Basic Books, 1989): 92.
[159]Rawls, *A Theory of Justice*, 467-468.

to be participants in the paid labor market, Rawls's theory obscures the relationship between the unpaid and frequently unacknowledged labor performed by women and their diminished research participation. Furthermore, the implications of the disparities between the earnings of men and women for power relations within a household as these affect research may be missed.[160]

Susan Moller Okin maintains that a Rawlsian view can address these concerns if it lives up to its own best insights. In particular, she sees the original position as a potent tool for criticizing social structures that perpetuate injustice against women. She follows Rawls in holding that justice can be defined through a process of reasoning from within an original position. She accepts the ideal of impartiality, but seeks to correct the gender bias in Rawls's model of moral reasoning so that principles of justice will truly function impartially, no longer perpetuating inequality. Impressed, then, by Rawls's discussion of the development of persons' capacities for moral thinking, Okin seeks to connect the ability to take up others' points of view and imagine different perspectives - capacities learned in the context of family - with the imaginative exercise performed by the parties in the original position.[161] On her reading of Rawls, these parties think from the perspective of everyone, in the sense of each in turn, with feeling, emotion, even empathy, for different others as they, as Rawls

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[160]Okin, *Justice, Gender, and the Family*, 95.

[161]Rawls, *Political Liberalism* (New York: Columbia University Press, 1993): 468-471.

puts it, "take the good of others into account."[162] Thus, if we reconstruct the original position so that sex is veiled, the contracting parties purportedly would take the situation of both sexes into account in their formulation of principles of justice. It is Rawls's second principle that holds, on her view, the greatest potential for feminist criticism:

> ... if any roles or positions analogous to our current sex roles ... were to survive the demands of the first requirement [that inequalities be to the greatest benefit of the least advantaged], the second requirement [that these be attached to offices and positions open to all] would prohibit any linkage between these roles and sex. Gender, with its ascriptive designation of positions and expectations of behavior in accordance with ... sex, could no longer form a legitimate part of the social structure, whether inside or outside the family.[163]

Standards of justice should be extended to apply to the family, as a basic social institution. Justice, she suggests, requires adoption of principles that encourage the creation of families in which the responsibilities of caregiving and other domestic work would be shared between adults, and in which girls could better develop self-respect. This would not only help to uncouple the status of the least well off with a specific sex, and to overcome unjust relations within families, but further, as inequalities in the family seep into the economy and politics, and indeed, all areas of

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[162]Okin, *Justice, Gender, and the Family*, 100; Rawls, *A Theory of Justice*, 148. Marilyn Friedman argues that this interpretation is actually closer to R.M. Hare's model of critical moral reasoning, organized around the process of universalization. Instead of suppressing knowledge of particularities that might be used to privilege oneself or others, the idea here is that impartiality is attained by taking particular knowledge about persons into account. Marilyn Friedman, "The Impracticality of Impartiality," in *What Are Friends For?: Feminist Perspectives on Personal Relationships and Moral Theory* (Ithaca, NY: Cornell University Press, 1993): 16-17, note 20. Friedman's discussion focuses on the work of R.M. Hare as it is presented in *Moral Thinking* (New York: Oxford, 1981): 91-95.

[163]Okin, *Justice, Gender, and the Family*, 103.

social life, reproducing inequalities there, it would promote the realization of justice in the public, or political realm.[164] The genderless family is part of a larger project of transformation involving all aspects of gender-structured social relations. According to Okin's Rawlsian account, justice can be realized in society only if "genderless institutions and customs" are developed. The gender structure is incompatible with the attainment of social justice, and thus, its "disappearance ... is a pre-requisite for the complete development of a non-sexist fully human theory of justice."[165]

Both Rawls and Okin hold that the original position can ensure respect for pluralism by making the principles of justice acceptable to all once the veil is lifted. This is said to be guaranteed by requiring that the principles be unanimously approved by the parties. This stipulation regarding unanimity rests on the assumption that the parties share similar motivations, psychologies, and patterns of moral development. The prospect for unanimous agreement on principles of justice is significantly diminished, however, when we take into account the substantial evidence which suggests that in this gender-structured society, women and men differ in these respects. For unanimity to be possible, Okin suggests, the contractors must truly share similar psychologies and experiences of moral development, a state of affairs that calls for the original position to

[164]Ibid., 174, 182.
[165]Ibid., 105.

incorporate the requirement of the genderless family and other social institutions and practices.[166]

As J.S. Russell points out, the crucial problem with this idea is that the parties cannot be said, then, to choose a genderless society or justice in the family in the original position:

> [T]hey are prerequisite to their (and our) deliberations ... [thus] there is no sense here in which the original position operates as a tool for feminist criticism ... the feminist principles of justice that [Okin] advances are in no sense a product of the original position. They are introduced and defended before the parties begin their deliberations about justice; they are not deliberated over or chosen within the original position.[167]

There also seems to be a problem with the coherence of Okin's use of the original position to critique gender-structured institutions and customs while at the same time using it to acknowledge respect and tolerance for certain traditional views about gender. Given that the parties in the original position recognize a personal sphere of life into which the state must not intrude, that traditionalist views about gender and family life may be held by some once the veil is lifted, and that such views may be found consistent with the principles of justice, the capacity of the original position to challenge a gender-structured society is significantly weakened.[168]

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[166]Ibid., 107.

[167]J.S. Russell, "Okin's Rawlsian Feminism: Justice in the Family and Another Liberalism," *Social Theory and Practice* 21, no. 3 (Fall 1995): 403-4.

[168]Ibid., 405-406; Okin, *Justice, Gender, and the Family,* 127, 170, 174.

Finally, even though Okin looks to Rawls's principle of fair equality of opportunity as having feminist potential, it is limited by respect for pluralism and liberty:

> For if the parties decide to tolerate gender-structured institutions, as Okin says they will, it must be because they hold that those institutions are consistent with principles of justice. It follows, then, that if the parties recognize that gender-structured institutions fall within the bounds of justice as part of their liberty of choice, Rawls's principle of fair equality of opportunity must be interpreted within this limitation and cannot itself generate an argument for a gender-free society given the priority that liberty receives in his theory.[169]

It seems quite doubtful, then, that Okin has used Rawls's framework successfully as a tool to challenge the gender structure of our society.

If there was potential in *A Theory of Justice* to subject families to principles of justice, insofar as they are part of the system of institutions that comprises the basic structure of society, in *Political Liberalism* it seems that adjusting the family to the requirements of justice may not meet with the kind of overlapping consensus that we may expect to find in a pluralistic society concerning other measures. Thus, Rawls's more recent work appears to represent a diminished commitment to issues of justice in families. Before lending support to this claim a brief overview of his project in *Political Liberalism* is in order.

Rawls acknowledges that *A Theory of Justice* did not reckon adequately with the fact of reasonable pluralism in a modern democratic society. Such a society, he notes, "is characterized not simply by a

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[169]Russell, "Okin's Rawlsian Feminism," 408.

pluralism of comprehensive religious, philosophical, and moral doctrines, but by a pluralism of incompatible yet reasonable comprehensive doctrines."[170] While he continues to propose the same two principles of justice, his central question in *Political Liberalism* becomes: "How is it possible that deeply opposed though reasonable comprehensive doctrines may live together and all affirm the political conception of a constitutional regime? What is the structure and content of a political conception that can gain the support of such an overlapping consensus?"[171] "How is a just and free society possible under conditions of deep doctrinal conflict with no prospect of resolution?"[172] In this work, justice as fairness is presented as a moral theory but not a comprehensive one. That is, it does not claim validity for all spheres of life.[173] It is a political conception, designed only for the basic structure of society and not for other moral spheres. The diverse doctrines that citizens in a pluralistic society hold apply to these other, non-political, spheres. According to Rawls, limiting the claims of justice as fairness to the political makes it a more viable conception because citizens may affirm this conception of justice as a doctrine for this structure while still affirming their own comprehensive doctrines.[174]

Yet, within political liberalism doctrines may be called reasonable, and thus not contrary to liberalism's basic political values, even if they

[170]Rawls, *Political Liberalism*, xvi.
[171]Ibid., xvii.
[172]Ibid., xviii.
[173]Ibid., 89-129.
[174]Ibid., 145.

include sexist tenets. A comprehensive doctrine that, for example, advocates the use of state power to enforce the masculine monopolization of economic power and political authority would count as unreasonable for both Rawls and Okin, because it denies the basic values of justice as fairness (such as equal opportunity) in a clearly public realm. However, those doctrines that can be party to an overlapping consensus about justice as fairness as a political doctrine, yet advocate that women exclusively take on such duties as child care, elder care, cooking, and cleaning would not be unreasonable for Rawls. They could be based on perfectly reasonable convictions about women's abilities, the benefits of female parenting, female fulfillment, or about a divinely ordained social order. For Okin, however, such doctrines effectively deny women fair equality of opportunity, given that inequality in the family seeps into and causes inequality elsewhere. As well, they deny women the maximal justice in the family that, on her view, parties in the original position would require.[175] There is reason, then, for skepticism with respect to the efficacy of a Rawlsian view in addressing injustice in the family, and thus for its potential to hinder women's research participation.

Distributive understandings of justice are not equipped to deal adequately with many of the other issues of justice identified as relevant to women in the research context due to the conception of moral reasoning

[175] Amy R. Baehr, "Toward a New Feminist Liberalism: Okin, Rawls, and Habermas," *Hypatia* 11, no. 1 (Winter 1996): 56-60.

they incorporate, namely, the ideal of impartiality. This picture of the moral point of view, characterized by detachment and dispassion, suggests that deliberators should adopt an impersonal point of view on a situation, weigh the interests of all equally, and make determinations regarding what constitutes a just course of action. Particular histories, commitments, and feelings are (purportedly) suspended, and seen as inimical to the promotion of justice.

The attainability of this ideal is, first of all, open to question, for social life is comprised of particular contexts and peopled by embedded, or situated moral agents who have affiliations, biases, emotions, and varied perspectives on and interests in specific questions of justice.

Aiming this line of critique at a Rawlsian theory of justice, Seyla Benhabib maintains (in response to Okin's account of the usefulness of the original position, in particular) that moral agents cannot possibly reason from the standpoint of everyone else while subject to the conditions of the veil of ignorance. Because the relevant criteria for individuating among selves - given their construction as disembedded and disembodied "generalized others" - are lacking, the other as distinct from the self necessarily disappears. Okin herself questions the sense of talking about "mutually disinterested selves pursuing their interests when, to the extent that their interests are distinct and differentiated, they have no knowledge of them," due to the epistemic constraints of the veil.[176] Laden with

[176]Susan Moller Okin, "Reason and Feeling in Thinking About Justice," *Ethics* 99, no. 2 (January

Kantian presuppositions, Rawls's conception of the self and the moral point of view precludes any serious acknowledgment of difference, or of the standpoints of 'concrete others,'" that is, persons considered in the complex context of their lived experience. In the original position:

> [i]nstead of thinking from the standpoint of all involved, that is, instead of reversing perspectives and asking [for example] 'what would it really be like to reason from the standpoint of a black welfare mother,' we are simply asked to think what distribution of material goods would be most rational and reasonable to adopt, if we did know in a general way that our society is such that one may be a black, welfare mother of three children ... living in a rapidly decaying urban neighborhood.[177]

The general concern, then, is that the failure to confront or engage with the 'otherness' of the other - a failure inherent to the ideal of impartial moral reasoning - leaves the prejudices and misunderstandings that permeate social relations and institutions hidden (for Rawls, behind a veil) and consequently, unaddressed.[178] Views of justice that focus on distribution tend not to be concerned with the particularities of persons' lives, save for assessments of the material inequality they experience and of what is needed for them to possess a fair share of social goods. These views give great attention to outcomes while neglecting other moral concerns, including: who makes decisions about the distributions?; upon what information and assumptions are such decisions based?

1989): 242.

[177]Seyla Benhabib, *Situating the Self: Gender, Community, and Postmodernism in Contemporary Ethics* (New York: Routledge, 1992): 166-167. Contained in this quotation are references to Benhabib's own construction of the moral point of view. I will take this up in Chapters Three and Four.

[178]Ibid.

Again considering Rawls specifically, who seeks to achieve impartiality on the contractual model, Friedman argues it is impossible to ensure that one's moral thinking is unaffected by his or her subjectivities. They can have "motivational influence" on one's thinking "even when those particulars are not specifically referred to by one's reasons or one's conclusions."[179]

Similarly, Friedman argues that the method of universalization put forward by Okin and others (like Hare) - where deliberators aspire to think from the perspective of particular others - falls prey to significant practical problems. First, the knowledge typically available to us about the standpoints of others is not sufficiently descriptive. Returning to the example of the welfare mother of four, Friedman asks us to imagine:

> What attitude will she have toward ... government decreases in welfare support? She might welcome [them] as an incentive to find a job, or she might rue them as an unwarranted penalty ... for economic circumstances beyond their control. In order to know whether or not she will adopt either of these attitudes or some other ... we must know something of what she presupposes about current economic conditions and about individual responsibility within and for those conditions. We must also know her attitudes regarding the entitlement of dependent children to certain material conditions for growth and development, and regarding the role of the state in assuring that those needs are met ... In general, one needs to grasp the conceptual organization and framework of presuppositions that she brings to her experience. Someone's view of her own moral situations is shaped by normative presuppositions about, for example, economics, politics, and social life - presuppositions pertaining to profound matters of guilt or innocence, legitimacy or illegitimacy, entitlement or its lack.[180]

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[179]Ibid., 25.

[180]Friedman, "The Impracticality of Impartiality," 20-21.

In addition to the problem of underdescription, there is the concern that another's standpoint, to the extent that it can be known, "might be very unfamiliar, alien, or even despised" from that of the impartial moral thinker.[181] Again, subjectivities can and usually do seep into our moral deliberations.

Beyond the question of whether achieving impartiality is possible, through their reverence for this concept as the "hallmark of moral reason," most views of justice (including Rawls's) perpetuate a propensity in modern ethics to deny or suppress difference, or in other words, to reduce heterogeneity to unity. Young argues that this occurs in three ways. First, in requiring that moral agents abstract from particular histories and experiences, affiliations and perspectives, interests and commitments, this model of moral reasoning denies the uniqueness of situations: all are to be treated according to the same moral rules. Impartiality's requirement of dispassion, moreover, abstracts from the particularity of bodily being, as well as from feelings that attach to the experienced particularity of things and events. Impartial reasoning is constructed in opposition to bodies and feeling, the very things which differentiate persons from one another, and which notably, are aspects of identity that tend to be associated with women.[182] Finally, it reduces the plurality of moral subjects to one subjectivity: "In its requirement of universality, the ideal of impartial

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[181] Ibid., 21-22.

[182] Young, *Justice and the Politics of Difference*, 100.

reason is supposed to represent a point of view that any and all rational subjects can adopt, precisely by abstracting from the situational particularities that individualize them."[183] According to the ideal of impartiality, all persons can engage in identical processes of moral reasoning, and all should be treated alike.

This conception of moral reasoning, as Young argues, supports cultural imperialism "by allowing the particular experiences and perspectives of privileged groups to parade as universal."[184] The ideal of impartiality:

> functions to mask the inevitable particularity of perspective from which moral deliberation actually takes place. The situated assumptions and commitments that derive from particular histories, experiences, and affiliations ... are asserted as 'objective.'

While the standpoint of the privileged is constructed as normal and neutral, difference from this dominant perspective is constructed as deviance and inferiority. Simultaneously, difference is ignored and silenced. Speaking specifically to women's exclusion from clinical research, Dresser explains:

> As individuals, we are all different from everyone else in countless ways. In society, however, certain differences are deemed relevant to how people are regarded. The choice of which differences matter inevitably reflects and reinforces existing social structures, and normality and abnormality are determined by the most powerful social group's (usually unstated) point of reference. Accordingly, women are different from men in relation to the unstated male norm. Members of the dominant group making decisions in reliance on this norm may discount or be oblivious to the

[183]Ibid., 101.
[184]Ibid., 10.

influence of their particular perspective. To the contrary, they see themselves as objective, and the existing social structure as natural.[185] Where oppressed groups challenge this situation they are seen as biased, and as advancing special interests which deviate from the impartial general interest.[186] In this way, the ideal of impartiality reproduces relations of domination and oppression.[187]

All knowledge, however, is situated. There is no universal, objective, impartial perspective from which to see and judge. In societies stratified by race, ethnicity, class, and gender, moreover, the activities of those in positions of power organize and set limits on what they may understand, both about themselves and the world around them. From the standpoints of persons who face domination and oppression in society and its institutions, the accounts of the privileged are especially partial and distorted.[188]

This leads us to a further consequence of the ideal of impartiality. In addition to denying difference and fostering cultural imperialism, it legitimates authoritarian hierarchy with the "conviction that bureaucrats

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[185]Dresser, "Wanted: Single, White Male," 27-28.

[186]Ibid., 115-116.

[187]For a related discussion on the problems posed by the ideal of impartiality, see Martha Minow, *Making All the Difference: Inclusion, Exclusion, and American Law* (Ithaca, NY: Cornell University Press, 1990).

[188]See Sandra Harding, *The Science Question in Feminism* (Ithaca, NY: Cornell University Press, 1986); *Whose Science? Whose Knowledge?: Thinking from Women's Lives* (Ithaca, NY: Cornell University Press, 1991); "Rethinking Standpoint Epistemology"; Donna J. Haraway, "Situated Knowledges: The Science Question in Feminism and the Privilege of Partial Perspective," in *Simians, Cyborgs and Women: The Reinvention of Nature* (New York: Routledge, 1991): 183-201; Nancy C.M. Hartsock, "The Feminist Standpoint: Developing the Ground for a Specifically Feminist Historical Materialism," in *Feminism and Methodology: Social Science Issues*, ed., Sandra Harding (Bloomington: Indiana University Press, 1987): 157-180.

and experts can exercise their decision-making power in an impartial manner."[189] Whereas popular decision-makers are regarded as grounded in the particular and thus likely to generate irresolvable conflicts, government administrators and persons deemed to be experts purportedly excel in the exercise of impartiality. The myth of the neutral state governed by impartial administrators and experts, indeed, helps to account for distributive justice. As most discussions of justice assume that justice is "dispensed" by some impartial authority, and that evaluations of justice concern end-state patterns, there is no compulsion to question the organization of decision-making authority, that is, to consider *its* justice. Challenges to decision-making structures and processes, and calls for democratization are defused by the ideal of impartiality.[190]

With respect to the justice of decision-making processes, Daniels' work comes to the fore in warranting critique. Recall that on his view, the health care system ought to satisfy peoples' course-of-life needs, and thereby ensure fair equality of opportunity in society. This account, however, takes for granted the justice of processes for interpreting needs. Just as contemporary debates regarding justice - including those concerning women in clinical research - tend to consider the primary questions to be whether or not the distribution of goods and positions are

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[189]Young, *Justice and the Politics of Difference*, 10.

[190]Ibid., 115. Cheshire Calhoun also notes that theories may have ideological effects independent of their logical application, focusing attention and/or shaping perception in particular ways. Cheshire Calhoun, "Justice, Care, Gender Bias," *The Journal of Philosophy* 85, no. 9 (September 1988): 452-453.

just, and whether redistributive measures are warranted, it is often assumed in discussion of needs that the crucial question concerns only whether various pre-defined needs will or will not be provided for. This line of inquiry takes the interpretation of people's needs as given and unproblematic, and thus diverts attention away from the interpretive dimension of needs politics - the fact that not just satisfactions but need interpretations are politically contested. It obscures considerations regarding who gets to establish authoritative, thick definitions of people's needs, taking who interprets the needs in question, from what perspective, and in light of what interests to be unproblematic. Furthermore, it assumes that the "socially authorized forms of public discourse" available for interpreting people's needs are adequate and fair. The issue of whether these forms of public discourse are skewed in favor of the interpretations and interests of dominant social groups and, so, work to the disadvantage of subordinate or oppositional groups is taken for granted, and therefore, not brought into explicit discussion. Important questions such as where in society and in what institutions are authoritative need interpretations developed, and what sorts of social relations are in force among the interpreters and the targeted beneficiaries, are obscured by accounts of justice that emphasize end-state distributions.[191]

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[191]Nancy Fraser, "Women, Welfare, and the Politics of Need Interpretation," and "Struggle Over Needs: Outline of a Socialist Feminist Critical Theory of Late Capitalist Political Culture," in *Unruly Practices: Power, Discourse and Gender in Contemporary Social Theory* (Minneapolis: University of Minnesota Press, 1989): 144-187.

In sum, distributive theories of justice, insofar as they invoke the ideal of impartiality, make problematic assumptions about selves and the moral point of view. The underlying understanding of who we are, of those about whom we do our critical moral thinking, of how these persons are related to one another and to social and institutional structures, relations, and processes, and of what we are capable of as beings with moral imaginations, is distorted, partial, and unrealistic. The operative conception of moral decision-making, furthermore, severely circumscribes the information deemed relevant and restricts the scope of attention in deliberations about justice.

Having said all this, what are the implications of the view of persons and the process of moral reasoning embedded in distributive theories of justice for women in clinical research? The bodily distinctiveness of women may continue to be ignored and, simultaneously, regarded as deviant. Women's hormonal cycles, their capacity for gestation and birthing, and the changes associated with their aging bodies may well persist as hindrances to their research participation. Cultural pluralism among women is also likely to be overlooked and, at the same time, constructed as deviance. Despite Rawls's self-criticism with respect to the heterogeneity that prevails in democratic society, his and other theorists' focus on the public or political sphere as the site where we come together solely as citizens and suspend our differences in public dialogue (having donned the veil) perpetuates the urge for unity and thus the potential for

exclusion. Too, as the public sphere is the only realm subject to principles of justice, much misogyny may persist unscrutinized in other contexts of social life, areas which are inextricably linked to women's research participation. Finally, incomplete and distorted formulations of women's needs may continue to emerge due to the discounting of their involvement as decision-makers in research. In part this is a consequence of the division of rationality and emotion and women's association with the latter. Above all, though, it is due to the assumption that decision-making structures and processes function fairly under the control of impartial experts and do not merit critical evaluation.

We have yet to consider the efficacy of distributive theories of justice for capturing and responding to the relationship between women's material inequality and their research participation. On this issue they fare no better. Such theories have been criticized "for presupposing at the same time they obscure the context of class inequality that the theories are unable to evaluate."[192] As Evan Simpson suggests, class and other economic relations are not brought into view or evaluated by distributive conceptions of justice due to their focus on particular individual actions and acquisitions. To the extent that distributive theories emphasize end-state patterns in evaluations of justice and the acquisition of goods among individuals, and conceive of persons primarily as possessors of goods,

[192]Young, *Justice and the Politics of Difference*, 20.

they prevent an understanding of structural phenomena.[193] Merely increasing women's share of research resources can help remedy past inequities, but as an overall strategy this fails to address the processes of naming, valuing, producing, and allocating these resources.

We have thus far examined ways in which the theories of Rawls and Daniels, as distributively-minded theories of justice, tend to ignore the institutional contexts within which resource distributions occur and to presuppose institutional structures whose justice is not subject to evaluation. These limitations render them ineffective in both illuminating and suggesting responses for the myriad concerns of justice raised for women in the context of clinical research.

Acknowledging that philosophical discussions of justice like Rawls's tend to emphasize the distribution of goods and positions and to ignore concerns related to social and institutional structures, relations, and processes, why not extend the scope of justice and include rights, opportunities and power? In other words, the failure to acknowledge and respond to the sorts of issues raised above is not, one might argue, a necessary consequence of theories of distributive justice; it is just that such theories have tended to privilege material goods and social positions in considering allocations. They can and should, however, broaden their scope to capture other issues of justice. "To do so," Young observes, "the paradigm simply formulates the issue in terms of the distribution of some

[193]Evan Simpson, "The Subject of Justice," *Ethics* 90, no. 4 (July 1980): 497.

material or non-material good among various agents. Any social value can be treated as some thing or aggregate of things that some specific agents possess in certain amounts, and alternative end-state patterns of distributions of that good among those agents can be compared."[194]

Thinking with a Rawlsian frame of mind, then, it might be suggested that we invoke the first principle of justice which holds, "Each person is to have an equal right to the most extensive basic liberty compatible with a similar liberty for others."[195] Here Rawls refers to that part of the social structure that defines and upholds the equal liberties of citizenship, including the right to vote, be eligible for public office, freedom of speech, and so on.[196] With respect to clinical research, one might suggest that all persons should have an equal right to be eligible to participate in such research. It might also be argued that all should have equal freedom to speak out about health issues that pose, for them, great concern. In a just society, indeed, all citizens are to have the same basic rights.

This leads us to the second broad critique of the distributive framework as a guide for thinking about justice. Rawls specifically, who conceives of the subject of justice as "the way in which major social institutions distribute fundamental rights and duties," seems guilty of a confusion regarding what is and is not amenable to distribution.[197] Are

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[194]Young, *Justice and the Politics of Difference*, 24.
[195]Rawls, *A Theory of Justice*, 60-1.
[196]Ibid.
[197]Ibid., 7.

rights, for example, properly included under the logic of distribution? "Rights," Young argues, "are not fruitfully conceived as possessions. Rights are relationships, not things; they are institutionally defined rules specifying what people can do in relation to one another. Rights refer to doing more than having, to social relationships that enable or constrain action."[198] It should be abundantly clear by the foregoing discussion how women's eligibility for research and their efforts to speak and be heard about their health concerns have been constrained. To the extent that Rawls and other justice theorists think in a distributive way about goods or social values which do not lend themselves to distribution, they overextend the logic of distribution.

With respect to the notion of distributing opportunities, the proposal put forth in the Rawls-informed view of Daniels and evidenced in the legislative and policy initiatives discussed in Chapter One, this same criticism is compelling. Recall that informing these initiatives is the notion that by more fairly distributing research resources, knowledge for women's health will be developed and therefore, normal functioning for women will be ensured and their prospects for living healthy lives improved. Women, then, will get their fair share, and opportunity will be more fairly distributed.

Quoting James Nickel, who defines opportunities as "states of affairs that combine the absence of insuperable obstacles with the presence of

[198]Young, *Justice and the Politics of Difference*, 25.

means ... that give one a chance of overcoming the obstacles that remain," Young argues that opportunity is best conceived as a condition of enablement.[199] Usually this involves "a configuration of social rules and social relations, as well as an individual's self-conception and skills." Rather than being a concept of possession, and amenable to distributive measures:

> [o]pportunity ... refers to doing more than having. A person has opportunities if he or she is not constrained from doing things, and lives under the enabling conditions for doing them. Having opportunities in this sense certainly does often entail having material possessions ... Being enabled or constrained refers more directly, however, to the rules and practices that govern one's action, the way other people treat one in the context of specific social relations, and the broader structural possibilities produced by the confluence of a multitude of actions and practices. It makes no sense to speak of opportunities as themselves things possessed.

The crucial point here is that if we are to evaluate social justice according to whether or not persons have opportunities, the key is to examine to what extent social relations, processes and structures "enable or constrain persons in relevant situations," not some outcome of distribution.[200]

One might claim that with respect to the importance of women's self-esteem for research participation, Rawls's theory offers an answer. He suggests that distributive arrangements provide the background conditions for self-respect.[201] However, self-respect and self-esteem are

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[199]James Nickel, "Equal Opportunity in a Pluralistic Society," in *Equal Opportunity*, ed., Ellen Frankel Paul, Fred D. Miller, Jeffrey Paul, and John Ahrens (Oxford: Basil Blackwell, 1988): 110; Young, *Justice and the Politics of Difference*, 26.

[200]Young, *Justice and the Politics of Difference*, 26.

[201]Rawls, *A Theory of Justice*, 148-150.

better understood as a function of social relations and processes. As Young argues, self-respect is not a material thing that can be allocated in a measurable quantity and possessed by individuals. Rather, it involves an array of non-material conditions that cannot be reduced to distributive arrangements. It involves how persons view their life situation and prospects, how they define themselves and how they are regarded by others in a society. She directs us to look instead toward the relations and processes in which persons are embedded.[202]

From the presentation here, two major problems can be seen to emerge from efforts to extend the concept of distribution to non-material goods. First, such efforts reinforce social relations and institutional rules, and reflect a concept of "individuals as social atoms, logically prior to social relations and institutions." This analytically separates individuals from distributed goods, and therefore, fails to acknowledge that persons' identities and capacities are to a significant degree the result of social processes and relations: "[s]ocieties do not simply distribute goods to persons who are what they are apart from society, but rather constitute them in their identities and capacities."

Further, this conceptualizes social justice primarily in terms of end-state patterns, thereby diverting attention away from social processes. This, in turn, supports a view of persons as fundamentally consumers of goods, or bearers of properties, whose shares may be compared. Selves, in

[202]Young, *Justice and the Politics of Difference*, 27.

a distributive framework, are not regarded as "actors with meanings and purposes," whose actions reflect and reproduce existing social and institutional structures.[203]

The significance of this for justice is that while the evaluation of distributional patterns is important, scrutiny of the "matrix of rules, attitudes, interactions, and polices as a social process that produces and reproduces" patterns is also crucial.[204] Instead of believing, then, that judgments about justice are judgments about what persons possess or consume, how much, and how this compares to what others have or consume, our attention should turn toward the consideration of:

> what people are doing, according to what institutionalized rules, how their doings and havings are structured by institutionalized relations that constitute their positions, and how the combined effect of their doings has recursive effects on their lives.[205]

Finally, it might be suggested that beyond distributing research goods to women to promote justice, decision-making power should be more fairly distributed. In other words, rather than emphasizing the fair distribution of goods, the realization of justice requires a redistribution of social power. Young points out three problems with conceptualizing power "as a kind of stuff possessed by individual agents in greater or lesser amounts [such that] a power structure or power relations [are]

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[203]Ibid., 27-29.
[204]Ibid., 29-30.
[205]Ibid., 25.

described as a pattern of the distribution of this stuff."[206] First, when power is conceived as amenable to distribution, as a possession of individuals, its relational character and function is obscured. Distributive understandings of power, moreover, are atomistic. To the extent that they do regard power as relational, they frame it in dyadic terms: particular agents or roles have power over others who do not. Such a "modeling of power misses the larger structure of agents and actions that mediates between two agents in a power relation."[207] That is to say, it is only "in the context of a network of practices" carried out by others that power relations are enabled to persist.[208] Most crucially:

> a distributive understanding of power ... misses the structural phenomena of domination [i.e.] ... the structural or systematic phenomena which exclude people from participating in determining their actions or the conditions of their actions. Domination must be understood as structural precisely because the constraints that people experience are usually the intended or unintended product of the actions of many people ...[209]

To point toward structural bases of power is not, as Young notes, to deny that individuals bear power relative to others. What is key here is the understanding of how power is enacted and reproduced:

> The structured operation of domination whose resources the powerful draw upon must be understood as a process ... conceptualizing power as relational rather than substantive, as produced and reproduced through many people outside an immediate power dyad, brings out the dynamic nature of power relations as an ongoing process.[210]

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[206]Ibid., 31.
[207]Ibid., 30.
[208]Ibid., 31.
[209]Ibid., 32.
[210]Ibid.

REALIZING SOCIAL JUSTICE FOR WOMEN IN CLINICAL RESEARCH

This discussion demonstrates that distribution is too restrictive a focus for the evaluation of the social institutions involved in research, and that those newly established policies aimed at addressing injustice that rely on this framework do not go far enough. When advocates for women's health allege that women have not been given their due in the context of clinical research - that they have faced social injustice - they appeal not only to a conception that captures issues of distribution. Such a conception narrowly construes the issues at hand, and compels resolutions, and in turn criticisms of the resolutions, that obscure underlying concerns about the justice of social institutions related to research, about the ways such institutions inhibit and/or liberate women: "[i]nsofar as this paradigm of justice limits evaluation to distribution, ignoring and obscuring questions of the justice of institutional organization, it serves an ideological function; it implicitly supports the institutional relations it assumes as given."[211]

Women's health advocates appeal to a conception of social justice that affirms the heterogeneity of persons, that attends to such values as self-development and self-determination, that is, the potential for persons to express their experiences in socially recognized contexts where others

[211] Ibid., 198.

listen, and to determine their actions as well as the conditions of their actions, and that, above all, considers the extent to which society and its institutions - here, those responsible for developing and conducting clinical research - contain and support the conditions necessary for their realization. Young describes such a conception of social justice as "enabling."[212]

What might social justice as enablement contribute to thinking about women's participation in research? Thus far we can say it would compel us to draw attention to class relations, as well as biases in economic structures and measurements. It would advocate a reorganization of the division of labor and a reformation of cultural norms and imagery. It would seek to promote social conditions that inhibit and enhance the development of women's self-esteem, their cognitive skills, and capacities to articulate their concerns. It would propose that we revisit traditional research norms and methodologies, in particular, their epistemological underpinnings, and strive to tailor research designs to accommodate the heterogeneity of bodies and social experiences. Finally, it would support the restructuring of social and institutional decision-making processes in ways that allow the health concerns of all women - poor, cultural minority, affluent, rural, urban, and beyond - and their particular needs for effective participation, to become audible as well as

[212]Ibid., 26-27, 37-39.

credible, and above all, not determined solely by persons claiming expertise or seeking profit at the expense of women's health. Following an excursion into the communitarian-minded research initiatives that have emerged of late, I will explore in far greater detail what such a conception of justice would look like and how it might be realized for women in the context of clinical research.

CHAPTER THREE

THE IDEAL OF COMMUNITY AND CLINICAL RESEARCH

Talk of community has held a prominent place in scholarly discussions as well as in contemporary political discourse.[213] The influence of the idea of community has also emerged in the realms of science and medicine.[214] Although the conception of justice that most clearly informs them is liberal and distributive, it is possible to discern the influence of communitarian ideals amidst the legislative and policy initiatives intended to guide research efforts for women. In particular, measures aimed at improving the recruitment and retention of women suggest the influence of communitarianism.

In this chapter I will outline the major tenets of communitarianism and carefully consider their influence on clinical research for women.

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[213]See the following works by academic communitarians: Benjamin Barber, *Strong Democracy: Participatory Politics for a New Age* (Berkeley: University of California Press, 1984); Seyla Benhabib, *Situating the Self: Gender, Community and Postmodernism in Contemporary Ethics* (New York: Routledge, 1992); William Galston, *Justice and the Human Good* (Chicago: University of Chicago Press, 1980); and *Liberal Purposes: Goods, Virtues, and Diversity in the Liberal State* (Cambridge: Cambridge University Press); Alasdair MacIntyre, *After Virtue: A Study in Moral Theory* (Notre Dame: University of Notre Dame Press, 1981); Michael Sandel, *Liberalism and the Limits of Justice* (Cambridge: Cambridge University Press, 1982). In the political arena, the campaigns of politicians like former President Ronald Reagan and former Governor of New York, Mario Cuomo, incorporated the idea of community as a central theme. More recently, communitarians like William Galston have been influential in the administration of President Clinton. See Allan Winkler, "Communitarianism," *Utne Reader* (November-December 1994): 107.

[214]See, for example, Ezekiel J. Emanuel, *The Ends of Human Life: Medical Ethics in a Liberal Polity* (Cambridge: Harvard University Press, 1991). Emanuel proposes that community health programs involving citizen-members determine democratically which medical benefits to provide, which care is to be prioritized, and whether or not to include expensive services. On his proposal, health services should be provided in accordance with a community-endorsed conception of social goals.

Further, I will identify concerns of social justice, understood in terms of domination and oppression, that may emerge if the application of communitarian ideals is not subjected to serious scrutiny. While it may be argued that, to some degree, these community-minded initiatives seek to attend to the social and institutional structures, processes and relations that constrain women's self-development and self-determination, my aim is to point to their shortcomings. When the idea of community is upheld, often there is not adequate criticism of the domination and oppression that may structure relations within and across communities, nor is there sufficient skepticism with respect to attempts to identify or demarcate communities, and to come to know women within them. Moreover, despite increasing attention to the ways in which the embeddedness of women in social contexts inhibits research participation, these initiatives - like those informed by distributivism - continue to conceptualize women in accordance with a consumerist model of the self. In this respect, the turn toward community seems motivated more by an emphasis upon its strategic value, here the potential to increase the numbers of women in clinical studies, than by a genuine concern for the thoughts and values of women who comprise them. For these reasons, the turn toward community in clinical research fails to fully address the domination and oppression of women. In other words, it cannot effectively promote the social and institutional conditions necessary for the realization of women's capacities to express their experience and to participate in determining

their actions and the conditions of their actions in the context of clinical research.

COMMUNITARIANISM

Communitarians hold that "the community, rather than the individual, the state, the nation, or any other entity is and should be at the center of our analysis and our value system," and that "human life would be more prosperous if communitarian, collective and public values guided and constructed our lives."[215] As an alternative to liberal individualism, this political philosophy questions liberalism's fundamental ontological and consequent moral commitments, challenging how its ideas explain the world and influence the structuring of society and its institutions. Whereas liberalism posits the self as an atomistic and self-sufficient unity, and devalues and obscures the role of communities in human life, communitarians hold that persons are fundamentally relational and that their identities and moral commitments are principally shaped by their membership in communities: "individuals understand values as intimately connected with their identification with a particular community and the social practices and roles assumed in that

[215] Elizabeth Frazer and Nicola Lacey, *The Politics of Community: A Feminist Critique of the Liberal-Communitarian Debate* (Toronto: University of Toronto Press, 1993), 1-2. For points of contrast among communitarian views, see Steven Kautz, *Liberalism and Community* (Ithaca, NY: Cornell University Press, 1995): 1-22; Frazer and Lacey, *The Politics of Community*, 101-116. These authors place the emergence of communitarianism in a social and historical context, noting its relationship to historical political themes and contemporary legal, political, and philosophical discussions.

community."[216] Communitarians, finally, emphasize participatory processes of decision-making.[217]

Perhaps the most basic tenets of communitarianism are that community is an integral feature of human life and that who we are is principally and inescapably constituted by our engagement in the way of life of a particular community. Whereas the fundamental notion at work in liberal social ontology suggests that persons are radically individualized agents, and that the uniqueness of human beings is located in the capacity for rationality and autonomy, communitarians embrace a conception of the self as embodied, and "constituted and defined by its attachments, including the particularities of its social relationships, community ties, and historical context. Its identity cannot be abstracted from community or social relationships."[218] Alasdair MacIntyre writes:

> [I]t is through his or her membership in a variety of social groups that the individual identifies himself or herself and is identified by others. I am brother, cousin and grandson, member of this household, that village, this tribe. These are not characteristics that belong to human beings accidentally, to be stripped away in order to discover 'the real me.' They are part of my substance ... Individuals inherit a particular space within an interlocking set of social relationships ...[219]

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[216]Ann Ferguson, "Feminist Communities and Moral Revolution," in *Feminism and Community*, ed., Penny Weiss and Marilyn Friedman (Philadelphia: Temple University Press, 1995): 369.

[217]Barber, *Strong Democracy*; Allen E. Buchanan, "Assessing the Communitarian Critique of Liberalism," *Ethics* 99, no. 4 (July 1989): 852-853.

[218]Marilyn Friedman, "Feminism and Modern Friendship: Dislocating the Community," in *What Are Friends For:? Feminist Perspectives on Personal Relationships and Moral Theory* (Ithaca, NY: Cornell University Press, 1993): 233.

[219]MacIntyre, *After Virtue*, 32.

Seyla Benhabib criticizes liberalism's conception of selves as "disembodied cogitos" (characteristic of the rationalist tradition) or "abstract unities" of impressions (characteristic of empiricist views), all of which are abstracted from social contexts and equal in that they share the same moral rights, capacities for reason and action, and for formulating and pursuing a conception of the good.[220] She contrasts this "generalized other" with the "concrete other," or rather, the self considered as a being with a particular history, set of needs and motivations, endowments and limitations.[221]

According to this political philosophy, communities are partially if not wholly definitive of persons' moral commitments. As MacIntyre remarks: "We all approach our own circumstances as bearers of a particular social identity," as persons who occupy various roles:

> Hence, what is good for me has to be the good for someone who inhabits these roles. As such, I inherit from the past of my family, my city, my tribe, my nation, a variety of debts, inheritances, rightful expectations and obligations. These constitute the given of my life, my moral starting point.[222]

Similarly, Michael Sandel refers to:

> ... those loyalties and convictions whose moral force consists partly in the fact that living by them is inseparable from understanding ourselves as the particular persons we are - as members of this family or community or nation or people, as bearers of this history, as sons or daughters of that revolution, as citizens of this republic. Allegiances such as these are more

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[220]Benhabib, *Situating the Self*, 9-10.

[221]Benhabib, "The Generalized and the Concrete Other: The Kohlberg-Gilligan Controversy and Moral Theory," in *Situating the Self*, 148-177.

[222]MacIntyre, *After Virtue*, 204-205.

than values I happen to have or aims I 'espouse at any given time'. They go beyond the obligations I voluntarily incur and the 'natural duties' I owe to human beings as such. They allow that to some I owe more than justice requires or even permits, not by reason of agreements I have made but instead in virtue of *those more or less enduring attachments and commitments which taken together partly define the person I am* [emphasis mine].[223]

The embeddedness of persons in communities often entails a commitment to communal or collective values. In conceptualizing the ideal of community, Sandel argues that within them, persons share a common self-understanding:

in so far as our constitutive self-understandings comprehend a wider subject than the individual alone, whether a family or tribe or city or class or nation or people, to this extent they define a community in the constitutive sense. And what marks such a community is not *merely* a spirit of benevolence, or the prevalence of communitarian values, or even certain 'shared final ends' alone, but a *common vocabulary of discourse and a background of implicit practices and understandings within which the opacity of the participants is reduced if never fully dissolved* [emphasis mine].[224]

Barber discusses the extent to which persons in community create a "common ordering of individual needs and wants into a single vision ... in which all can share." On his notion of strong democracy, the objective is to attain a "creative consensus" and through the adjustment of individual desires, to create a "common consciousness and political judgment."[225] This aim contrasts with that of liberal democracy. Rather than accepting interests as individual, pre-given, and fixed, on his view, they may be transformed in the process of deliberating about the collective good.

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[223]Sandel, *Liberalism and the Limits of Justice*, 179.

[224]Ibid., 172-173.

[225]Barber, *Strong Democracy*, 224.

Ostensibly departing from these views, Benhabib maintains that persons in community should emphasize reciprocity, understood as "a reversing of perspectives and the willingness to reason from the other's point of view ..." Such a process of thinking "demonstrates the will and the readiness to seek understanding with the other and to reach some reasonable agreement in an open-ended moral conversation."[226] While upholding a commitment to the equal moral worth of all, we are to attend to persons' particularities:

> We seek to comprehend the needs of the other, their motivations, what they search for, and what they desire. Our relation to the other is governed by the norm of complementary reciprocity: each is entitled to expect and to assume from the other forms of behavior through which the other feels recognized and affirmed as a concrete, individual being with specific needs, talents, and capacities ...[227]

According to her, the goal of moral conversation in communities should not be discovering some general interest or reaching agreement but rather the "'anticipated communication with others with whom I know I must finally come to some agreement.'"[228] Although she claims that the emphasis is upon open and fair procedures in collective, or communal decision-making, her emphasis on coming to agreement suggests that it is indeed a goal. However it is expressed, the communitarian emphasis upon shared values is related to "an enriched conception of active

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[226]Benhabib, *Situating the Self*, 9.

[227]Seyla Benhabib, *Critique, Norm and Utopia* (New York: Columbia University Press, 1986): 341. Here we see the significance of the relationship between the "generalized" and "concrete" other.

[228]Here Benhabib quotes Hannah Arendt in *Between Past and Future: Six Exercises in Political Thought* (New York: Meridian, 1961): 220-221.

citizenship as a basic component of the human good, ideally realized through public dialogue" and engagement with participatory social - especially local - institutions.[229]

COMMUNITARIAN IDEALS IN CLINICAL RESEARCH FOR WOMEN

While not embracing a communitarian philosophy in its full complexity, central features of communitarianism find expression in National Institutes of Health (NIH) research initiatives aimed at women. Demonstrating the move away from abstract individualism, these initiatives reflect the notion that persons' identities, values, and life prospects are significantly constituted by their membership in communities and by the overall social context in which they are embedded. Hence, in keeping with the communitarian conception of selves, the NIH initiatives express a commitment to understand study populations based on assessments of racial and ethnic characteristics, cultural norms, language, education and literacy levels, socioeconomic status, employment characteristics, family configuration, and community characteristics (e.g., rural or urban) and structures.[230] There is, then, an appreciation for difference and particularity - a recognition that persons

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[229]Frazer and Lacey, *The Politics of Community*, 113.

[230]National Institutes of Health, Office of Research on Women's Health, *Outreach Notebook for the NIH Guidelines Concerning the Inclusion of Women and Minorities as Subjects in Clinical Research* (Washington, D.C.: National Institutes of Health, 1994): 7-10.

are not similarly situated in social life - and concomitantly, a willingness to tailor research strategies accordingly.

Moreover, researchers are charged with ensuring that strategies for recruitment and retention "conform with the needs and values of the research participants and their communities," underscoring the communitarian commitment to shared or communal values both within communities and between them and researchers.[231] Evident here is an acknowledgment that moral perspectives may vary according to context. With these initiatives, the NIH pledges to form "partnerships based on trust and mutual respect" with communities, acknowledging that "[i]n the absence of common goals or shared recognition of the unique needs of the community, clinical studies cannot successfully coexist with a community.[232]

Finally, upholding the importance of communal participation in clinical research decision-making, the initiatives to improve recruitment and retention discuss the involvement of community members in such processes as: establishing goals for recruitment and retention and evaluating the efficacy of various strategies; achieving agreement on plans for the design, methodologies, implementation and completion of research; and establishing and maintaining communication concerning the

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[231]Ibid., 14-15.

[232]National Institutes of Health, Office of Research on Women's Health, *Recruitment and Retention of Women in Clinical Studies* (Washington, D.C.: National Institutes of Health, 1995): 20.

progress and findings of studies.[233] Such provisions reflect a departure from the (illusory) notion that impartial experts are the only appropriate decision-makers in research.

What motivates this turn toward the ideal of community is the increasing acknowledgment of barriers to women's inclusion in clinical research, especially women of color, poor women, lesbians, and older and disabled women.[234] These initiatives acknowledge that persons are not similarly situated with respect to social and institutional structures, relations and processes, and that previous processes for conducting clinical research privileged some (by virtue of gender, race and class) and disadvantaged others. They illustrate a shift from the focus on protectionism, or, on the burdens of participation, to concerns related to how persons are enabled or constrained in their abilities to participate in clinical research in the first place. Protection from harms related to research participation is thus coming to be seen as only one of several moral considerations. If unjust social relations, structures and processes, related to poverty, race and culture, and gender roles, hinder women's (especially some women's) participation in clinical research, the relevant relations, structures and processes must be addressed. Outreach to communities in order to seek information about the particular constraints

[233]National Institutes of Health, *Outreach Notebook*, 7, 12-19.

[234]Ruth Kirschstein, Foreword to *Recruitment and Retention of Women in Clinical Studies*, ii.

women face has attained privilege of place among possible measures for responding.

CRITIQUING COMMUNITARIAN IDEALS

To the extent that the NIH initiatives reflect the influence of communitarian ideals, they are subject to critiques offered by feminist and other theorists. When embraced uncritically, the ideals of communitarianism may contribute to women's domination and oppression. First, the very identification of communities may be the result of a dominant group's enforcement of certain identities. Additionally, it is argued that communitarian thinking reflects a "desire [for] social wholeness," or "an urge to see persons in unity with one another in a shared whole."[235] This may contribute to an inadequate acknowledgment of: the complexity of selves and interpersonal relations, and the reductionist and exclusionary tendencies of the impulse toward homogeneity that often characterizes communities. The relations of domination and oppression that may prevail within and between communities - as typically conceived - are not addressed in this political philosophy. The models for community usually endorsed by communitarians, indeed, present "troubling paradigms of social

[235]Iris Marion Young, *Justice and the Politics of Difference* (Princeton: Princeton University Press, 1990): 229-232.

relationship and communal life" for women.[236] A final and profound concern regarding the turn toward community in these research initiatives involves a problematic conceptualization of selves, here of the women sought as subjects for research.

Constructions of Community

The division of people into communities may be the result of a dominant group's enforcement of certain identities. Several concerns arise from dominant constructions of community. When understandings of health and illness are based on racial, cultural, and sexual orientation classifications, the genes or lifestyle choices of groups may be emphasized as opposed to examining how persons' domination and oppression are related to diseases, disorders, and conditions.[237] By virtue of their membership in a community constructed on the basis of racial, cultural and other categorizations, persons have frequently been defined as deviant and inferior.[238] Disvalued groups may be exploited by serving as subjects in research, facing its risks yet perhaps not receiving its benefits. Recall the

[236]Friedman, "Feminism and Modern Friendship," 237.

[237]Nancy Krieger and Mary Bassett, "The Health of Black Folk: Disease, Class, and Ideology in Science," in *The "Racial" Economy of Science: Toward a Democratic Future*, ed., Sandra Harding (Bloomington: Indiana University Press, 1993): 161. As well, see Elena S.H. Yu, "Ethical and Legal Issues Relating to the Inclusion of Asian/Pacific Islanders in Clinical Studies," in *Women and Health Research: Ethical and Legal Issues of Including Women in Clinical Studies*, ed., Anna C. Mastroianni, Ruth Faden, and Daniel Federman (Washington, D.C.: National Academy Press, 1994), 2: 220-222.

[238]See, for example, Stephen Jay Gould, "American Polygeny and Craniometry Before Darwin: Blacks and Indians as Separate, Inferior Species," in *The "Racial" Economy of Science*, 84-115; Krieger and Basset, "The Health of Black Folk," in *The "Racial" Economy of Science*, 161-169; Iris Marion Young, "The Scaling of Bodies and the Politics of Identity," in *Justice and the Politics of Difference*, 122-155; Paul M. McNeill, *The Ethics and Politics of Human Experimentation* (New York: Cambridge University Press, 1993): 179-180.

point made in Chapter One that Puerto Rican and Mexican-American women were primary populations for the conduct of contraceptive research.[239] Furthermore, persons may be denied the opportunity to articulate and address health concerns as they experience and understand them. Instead they are "defined from the outside, positioned, placed, by a network of dominant meanings they experience as arising from elsewhere, from those with whom they do not identify and who do not identify with them."[240]

Moreover, the identification of communities tends to suppress the complexity of social experience by obscuring differences within and across groups. Such "politically asserted categories" as "the gay community" or "community of color" ultimately functioned to obscure social inexhaustibility and the complexity of identities, and thus inhibited the development of appropriate response - including research - strategies in the context of the Human Immunodeficiency Virus (HIV)/Acquired Immune Deficiency Syndrome (AIDS) epidemic.[241]

We can examine this concern with an eye toward understanding how women were affected specifically. Patton argues that the inextricably linked concepts of 'community' and 'identity' functioned to conceal

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[239]See Sheryl Burt Ruzek, *The Women's Health Movement: Feminist Alternatives to Medical Control* (New York: Praeger, 1979): 44-46. For research undertaken in an international context, see Vimal Balasubrahmanyan, "Finger in the Dike: The Fight to Keep Injectables Out of India," in *Adverse Effects: Women and the Pharmaceutical Industry*, ed., Kathleen McDonnell (Toronto: Women's Press, 1986):137-158; Lynn Duggan, "From Birth Control to Population Control: Depo Provera in Southeast Asia," in *Adverse Effects*, 159-165.

[240]Young, *Justice and the Politics of Difference*, 59.

[241]Cindy Patton, *Inventing AIDS* (New York: Routledge, 1990): 7.

women's experiences, and in particular, their risks for infection.[242] She notes that once HIV/AIDS emerged, the central framework for understanding their spread and for organizing educational strategies linked identity, community, and risk. This was due largely to the confluence of the impact of epidemiology and of gay activism. Epidemiologists seek to find descriptive categories by drawing on ideas about social groups which seem useful in controlling a health problem. They were responsible for initially representing AIDS as a lifestyle disease and for introducing the concept of "risk groups": they identified certain social groups as facing an elevated risk of infection and as posing danger to "the rest of us." With respect to gay men, their resistance to homophobia organized around the notion of community defined in terms of a positive sexual and cultural identity. Invoking the notion of community was thus an attempt to identify themselves in their own terms instead of being identified as deviant by dominant culture.

This linkage of the concepts of community, identity, and risk affected at least four groups of women: heterosexual women, sex workers, partners of men with clotting disorders, and lesbians. Heterosexual women, first of all, did not understand themselves as members of a community - one defined in terms of sexual relationships with men. As members of the general (read: normal, heterosexual) public, they did not

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[242]Cindy Patton, *Last Served?: Gendering the HIV Pandemic* (Bristol, PA: Taylor and Francis, 1994): 48-76.

(collectively) identify themselves as a community or group, as having a particular cultural identity. They did not identify with risk reduction advice, as AIDS was thought to be a problem for deviant groups only. Further, the division between the gay and heterosexual community incorporated a particular construction of male sexuality: either men were exclusively heterosexual or exclusively homosexual. Positing sexual homogeneity, there was no blurring of constructed boundaries. This tended to perpetuate the myth that heterosexual women faced no risk from their sexual partners.

Given the initial appearance of AIDS among homosexual (that is, deviant) men, its emergence in men who claimed to be heterosexuals and not to use drugs required the identification of a vector. These heterosexual men reported having sex with sex workers. This occured at about the same time that it was discovered that women thought to be infected through needle-sharing also had sold sex. The easy conclusion was that sex workers were a source of risk to male partners. They were never regarded as a community at risk, but instead were seen as the source of transfer from deviant communities to the mainstream general public.

A third group of women were partners of men with clotting disorders. Again, the preponderance of attention on gay men's need for risk reduction diverted attention away from the sexual practices of "traditional" families who, as noted above, considered themselves safe. Interestingly, these women *were* members of an organized community.

Yet, this community was centered around the health of their male partners and the needs of their children. Women, here, were understood in terms of their role as supportive caregivers.

Finally, given that one's "identity" was supposed to suggest one's degree of risk, lesbians were viewed as exempt. While gay men's risk was tied to deviant sexuality and heterosexual women's risk was tied to sex-role conformity, lesbians were viewed as safe because they were not associated with either. Too, the behaviors which form the major risks to women who identify themselves as lesbians, namely condomless intercourse with men (a risk ignored by public health authorities given the construction of sexuality as homogeneous) and needle-sharing, are not those which frame their sense of identity and community.

As a framework for dealing with HIV/AIDS, the concepts of community and identity obscured the reality of women's experience. They revolved around assumptions about traditional family structure and sexual relationships, and failed to capture the complexity of social relations. Patton's work reveals the extent to which constructions of community, particularly dominant ones, establish boundaries and lead to exclusions. It, therefore, demonstrates the need to "identify and trace the edges of silence in discourses," to "discover vast tracts of barren land, territories whose existence remains unspoken, perhaps even - for the time

being - unspeakable," to "examine why they cannot be heard within the present discourses ..."[243]

The "desire to bring multiplicity and heterogeneity into unity" raises still further concerns, the problems of transparency, homogeneity, and exclusion: "by positing fusion rather than separation as a social ideal" proponents of community deny difference and suppress social inexhaustibility.[244]

The Ideal of Transparency

Whether expressed in terms of shared self-understanding, common consciousness, or the willingness to reason from another's point of view, the ideal of community as put forth by Sandel, Benhabib, and others, tends to suggest that each person "understands the others and recognizes the others in the same way that they understand themselves, and all recognize that the others understand them as they understand themselves." This denies the complexity of selves and in turn, their capacity for self-knowledge and potential to be understood by others:

> Subjects all have multiple desires that do not cohere; they attach layers of meanings to objects without always being aware of each layer or the connections between them. Consequently, any individual subject is a play of difference that cannot be completely comprehended. If the subject is not a unity ... [but rather] is heterogeneous process, never fully present to itself, then it follows that subjects cannot make themselves transparent,

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[243]Patton, Introduction to *Inventing AIDS*, 3.

[244]Young, *Justice and the Politics of Difference*, 229-230.

wholly present to one another. Consequently the subject also eludes sympathetic comprehension by others.

No one can ever see the world from the same perspective as another. Whenever exchanges between persons occur, words and intentions are misunderstood, meanings misinterpreted. As Young observes: "in witnessing the other's objective grasp of my body, actions, and words, I am always faced with an experience of myself different from the one I have." Thus, the ideal of the transparency of subjects to one another denies the difference, or basic asymmetry, of subjects in that it:

> seeks to collapse the temporal difference inherent in language and experience into a totality that can be comprehended in one view ... persons cease to be other, opaque, not understood, and instead become mutually sympathetic, understanding one another as they understand themselves, fused.[245]

When communitarian theorists idealize local face-to-face direct participatory democracy in their appeals to community, the problem of transparency emerges:

> theorists of community privilege face-to-face relations because they conceive of them as *immediate.* Immediacy is better than mediation because ... we [become] transparent to one another ... and nothing comes between us to obstruct our vision of one another.[246]

The problem of transparency emerges in discussions of "successful" clinical studies. Attentiveness to individuals, the development of "close personal relationships" between staff and study participants and "person-to-person communication" are upheld as key components of effective

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[245]Ibid., 231-232.

[246]Ibid., 233-234.

recruitment and retention, as is agreement concerning study plans.[247] As well, it underlies efforts to employ research team members who share similar racial, ethnic and language backgrounds, similar age, or the same gender as potential subjects in order to diminish mediation between persons and establish trust.[248]

Researchers appeal to "a metaphysical illusion" if they seek to comprehend the complexities of a study population and pursue agreement among its members and between them and investigators. The notion of understanding offered by communitarian theorists may not be the only one conceivable, however. Instead, it may be possible to develop an alternative conception that avoids the problem of denying difference.

Homogeneity and Exclusion

The ideal of community "expresses a desire for the fusion of subjects with one another which in practice operates to exclude those with whom the group does not identify."[249] When the term community is used, it most often refers to those with whom one identifies, based on a shared history, culture, or set of beliefs and values. Commitment to an ideal of community in practice functions to value and enforce homogeneity because designation as a community as well as self-identification as one of its members typically entails "an oppositional differentiation" from other

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[247]See, for example, National Institutes of Health, *Recruitment and Retention of Women*, 26-27.
[248]Ibid., 12-13, 20, 26-27. National Institutes of Health, *Outreach Notebook*, 12, 20.
[249]Young, *Justice and the Politics of Difference*, 227.

persons and groups: "Persons feel a sense of mutual identification only with some persons, feel in community only with those, and [frequently] fear the difference others confront them with because they identify with a different culture, history, and point of view on the world."[250] Thus, where the goal of the ideal of community is toward such mutual identification, moral and political agreement, or common consciousness, persons regarded as different will likely be excluded, along with their views.

Patton points out that although groups working for liberation in the HIV/AIDS epidemic "foregrounded the term community in order to create a sense of unity, where discrimination and assimilation had produced fragmentation," and to "thematize the power of collective action," exclusionary tendencies arose.[251] In the white gay community, for example, racism precluded the inclusion of non-white gay men, while in communities of color, the social stigma of homosexuality made it difficult to embrace gay members. Thus, sexism, racism, and homophobia can lead to the creation of distinct communities.

As noted, however, most people have multiple community identifications. To the extent that this holds true, persons' self-definition and moral commitments emerge from a plurality of sources. This suggests reason for caution in embracing the notion of community as an organizing concept, and further, for considering some alternative framework for

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[250]Ibid., 234-235.

[251]Patton, *Inventing AIDS*, 8.

defining social relations. In clinical research, the tendency toward homogeneity may create an illusion of agreement regarding a problem, its causes and possible solutions when, instead, multiple interpretations are available.[252] The urge toward homogeneity - so long as it includes the assumption that difference means "otherness," and is inherently divisive and strife-producing - is likely to lead to the silencing of diverse perspectives, perspectives which may prove to be valuable resources for understanding social issues, and here, research needs. These concerns are closely related to the problem of power between communities, to be taken up below. For now it will suffice to say that if communitarianism and those influenced by its ideals neglect to recognize these concerns, communitarian views and their applications may have "little relevance for our radically heterogeneous modern society."[253]

Domination and Oppression Within Communities

In discussing those communities in which persons are embedded, the contexts that influence identity formation and ground persons' moral commitments, most often communitarians refer to families, workplaces, churches, neighborhoods, social and civic organizations, tribes, and nations. These same models are embraced by the NIH initiatives for improving the recruitment and retention of women in clinical studies. In

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[252]See the discussion by Jennifer Keck, Henriette Dauphinais and John Lewko, *Critical Paths: Organizing on Health Issues in the Community* (Toronto: Between the Lines, 1989): 28-29.
[253]Young, *Justice and the Politics of Difference*, 227.

elaborating on the goal of developing partnerships with communities, NIH maintains that the intention is to "work with existing community structures." Outreach documents refer to health care institutions, community businesses and organizations, churches and other spiritual organizations, social service agencies including public welfare offices, public housing offices, and neighborhood and tenant associations. Further, researchers are advised to identify "gatekeepers," "decision-makers," "community leaders," and other "influential members" like health care decision-makers, religious and tribal leaders, schoolteachers, business and workplace leaders, as well as family and friend networks for possible enlistment as recruitment agents.[254] As well, they are called to identify "communication networks" within communities.[255]

The models of community identified here represent problematic models of social relationship and communal life for women. For women of color, lesbians, the disabled, and other women in non-dominant groups this is especially likely to be the case. Not only do relations of domination and oppression such as sexism, racism, homophobia and disability biases "create distinct communities ... [they] also establish relations which pervade and structure all communities ..."[256]

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[254]National Institutes of Health, *Recruitment and Retention of Women*, 12-13, 18, 20-21; National Institutes of Health, *Outreach Notebook*, 10-11.

[255]National Institutes of Health, *Recruitment and Retention of Women*, 22.

[256]Penny A. Weiss, *Gendered Community: Rousseau, Sex, and Politics* (New York: New York University Press, 1993): 127.

Families are usually considered contexts for nurturing and self-development. The family provides for "intimacy and security," functions as a "social form that helps people make sense of their lives," and further, can "stand as one barrier between human beings and the flattening out of their social world ..."[257] Yet, families may also serve to reproduce and reinforce a coercive heterosexist culture and the sexual division of labor, and to perpetrate violence against women.[258] Moreover, definitions of family can be restrictive to the extent that diverse forms of domestic arrangements are excluded. Workplaces are often contexts of racism, sexism, and homophobia. Sexual harassment, for example, may render "it difficult for [women] to speak or changes the meaning of [their] speech in a way that renders it less effective."[259] Although church congregations are comprised primarily of women, they are not found in positions of formal leadership in many denominations.[260] What is more, the doctrines of religious communities may make moral claims upon women that contribute to their domination and oppression.[261] While communitarians

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[257]Jean Bethke Elshtain, "Feminism, Family, and Community," in *Feminism and Community*, 260-267.

[258]See Barbara Ehrenreich, "On Feminism, Family and Community," *Dissent* 30 (Winter 1983): 103-106; Heidi I. Hartmann, "The Family as the Locus of Gender, Class, and Political Struggle," in *Feminism and Methodology*, ed., Sandra Harding (Bloomington: Indiana University Press, 1987): 109-134; Del Martin, "A Letter From a Battered Wife," in *Feminism and Community*, 45-50.

[259]Frazer and Lacey, *The Politics of Community*, 146.

[260]See, for example, Jacquelyn Grant, "Black Theology and the Black Woman," *Black Theology: A Documentary History, 1966-1979*, ed., Gayraud Wilmore and James Cone (New York: Orbis Books, 1979): 418-433. Grant further discusses the psychological and political strategizing that keeps women from realizing their own potential power in the church.

[261]See Susan Brooks Thistlethwaite, "Every Two Minutes: Battered Women and Feminist Interpretation," in *Weaving the Visions: New Patterns in Feminist Spirituality*, ed., Judith Plaskow and Carol Christ (San Francisco: Harper Collins, 1989): 302-313.

refer to neighborhoods as models of community, some urbanologists argue that these have been designed in ways that disadvantage women.[262] Social service agencies and the legal system - contexts which might seem ideal contexts for enhancing women's self-development and self-determination - often represent troubling models of community. Women who enter them are frequently stereotyped and subjected to contestable interpretations of their needs.[263] In nations and tribes, women have often been excluded from conceptions of communal good and from participation in governing bodies.[264]

Along with the dangers of embracing traditional models of community, the reliance upon "influential" community members may result in the exclusion of women's voices. This is not to say that women are not influential, only that they frequently are not found in recognized positions of leadership. Even where women are recognized as leaders, they frequently face the perpetuation of their subordination through

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[262]See, for example, Dolores Hayden, *The Grand Domestic Revolution: A History of Feminist Designs for American Homes, Neighborhoods, and Cities* (Cambridge: MIT Press, 1981), and *Redesigning the American Dream* (New York: Norton, 1983).

[263]See Nancy Fraser, "Women, Welfare and the Politics of Need Interpretation," and "Struggle Over Needs: Outline of a Socialist Feminist Critical Theory of Late Capitalist Political Culture," in *Unruly Practices: Power, Discourse and Gender in Contemporary Social Theory* (Minneapolis: University of Minnesota Press, 1989): 144-187; Wahneema Lubiano, "Black Ladies, Welfare Queens, and State Minstrels: Ideological War By Narrative Means," in *Race-ing Justice, En-gendering Power*, ed., Toni Morrison (New York: Pantheon Books, 1992): 323-363. Dohrn's analysis of the fragmentated and frequently conflicting legal systems for addressing domestic violence and child abuse, and the misogynist nature of the juvenile court system provides further support for this point. See Bernadine Dohrn, "Bad Mothers, Good Mothers, and the State: Children on the Margins," *Roundtable: A Journal of Interdisciplinary Legal Studies* 2, no. 1 (1995): 1-12.

[264]Some Aboriginal women's groups in Canada, for example, have expressed an experience of isolation within their given community, and thus sought external review of Aboriginal self-goverment. See Will Kymlicka, *Multicultural Citizenship: A Liberal Theory of Rights* (New York: Oxford University Press, 1995).

norms, moral rules, and laws.[265] As a consequence, impoverished and distorted assessments of women's research needs may emerge. Moreover, injustice is perpetuated on this model of community consultation in that opportunities for women to develop and/or exercise their capacities for expression and decision-making are inhibited.

While not denying the potential for these models of community to support the conditions necessary for the enhancement of women's capacities for self-development and self-determination - the conditions necessary for the elimination of domination and oppression - it is evident that "the mere switch of focus from individual to collective values ... does not guarantee progress towards the ending of women's subordination."[266] To recognize that communities are constitutive of identities, that they serve as persons' moral starting points, does not entail an endorsement of those moral claims they make upon them. Beyond recognizing that selves are embedded in and constituted by communities, it is crucial to consider "*how* social selves are constituted, toward what ends, and with what costs and benefits for various individuals, groups and relations."[267] There is a need for an assessment of communities that attends to their interrelationships, to the relations of dominance, and oppression within

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[265]See Diane LeBow, "Rethinking Matriliny Among the Hopi," in *Women in Search of Utopia*, ed., Ruby Rohrlich and Elaine Hoffman Baruch (New York: Schocken Books, 1984): 8-20; Mary L. Shanley and Carole Pateman, ed., *Feminist Interpretations and Political Theory* (Oxford: Polity Press, 1991).

[266]Frazer and Lacey, *The Politics of Community*, 139.

[267]Weiss, *Gendered Community*, 130.

and among them. If researchers rely uncritically upon the notions of what is good for women that emerge from these sorts of communities, they risk developing and conducting research projects that perpetuate their domination and oppression.

Having noted concerns with several models of community, the health care institution considered as a community warrants particular examination.[268] In Chapter Two it was noted that health care institutions are increasingly inaccessible to women, and the implications of this inaccessibility for the inclusion of women in clinical research were discussed. The Community Research Initiative (CRI), an effort to integrate the knowledge of community members, physicians, and researchers in designing, reviewing and conducting AIDS research, demonstrates the limitations of community-oriented initiatives for women to the extent that they are tied to the health care system and its "decision-makers."[269]

Women have not been significantly helped by the CRI, in part due to its structure of referring persons to trials.[270] More specifically, reliance on physician referral contributed to the underinclusion of women. It has taken a shift in focus from private physicians to those located in clinics and other public health care institutions serving poor women to get more

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[268]See National Institutes of Health, *Outreach Notebook*, 8, for this notion of the health care institution as a community.

[269]See Carol Levine, Nancy Neveloff Dubler, and Robert J. Levine "Building a New Consensus: Ethical Principles and Policies for Clinical Research on HIV/AIDS," *IRB: A Review of Human Subjects Research* 13, nos. 1-2 (January-April 1991): 1-17; Vanessa Merton, "Community-Based AIDS Research," *Evaluation Review* 14, no. 5 (October 1990): 502-537.

[270]Merton, "Community-Based AIDS Research," 516-517.

women with HIV/AIDS into studies. The history of community-based AIDS research also reveals the ways in which "community leaders" come to be identified and how this leads to exclusions. Because they tended to be well-educated, had pre-established political and financial networks, and familiarized themselves with the language of biomedicine, AIDS activists - for the most part gay white men - were successful in attaining credibility from the perspective of scientists. Unlike the women disproportionately affected by AIDS, they were able to play a significant role in developing ideas and strategies for research.[271]

Ultimately, communitarians and their followers in science and medicine have failed to analyze and critique the institutions typically regarded as central to women's lives, and thus to their inclusion in clinical research. Reliance upon typical models of community risks the perpetuation of women's domination and oppression in the context of clinical research insofar as the need for significant changes in underlying social arrangements is ignored.

Domination and Oppression Among Communities

It is important to consider how some communities come to define meaning concerning an issue and/or appropriate action to address it. Even communities that pay explicit attention to the empowerment of

[271]See Steven Epstein, "The Construction of Lay Expertise: AIDS Activism and the Forging of Credibility in the Reform of Clinical Trials," *Science, Technology, and Human Values* 20, no. 4 (Autumn 1995): 408-437.

women may manifest social injustice. Sexism, racism, homophobia, class relations and disability bias may ultimately divide women.[272] Late nineteenth and early twentieth century Southern women's clubs, while advancing the women's movement through developing social, economic and political opportunities for women, were among the most influential groups in the movement for the eugenic segregation and sterilization of mentally retarded females.[273] These clubs contributed to the domination and oppression of disabled women through undermining their potential to express their experiences and to make decisions regarding reproduction. Moreover, the disability bias of these women's clubs represented the aforementioned urge toward homogeneity. The views of these women, given their close ties to the medical profession and Southern legislatures, prevailed over the concerns that might have been raised by disabled women themselves.

The point made in the preceding chapter about the application of white, middle-class feminists' reproductive autonomy agenda to Hispanic and African-American women with AIDS, through ACTG protocol 076, is also relevant here. Recall that liberal theories of justice like Rawls's are ill-equipped to address such problems. First, assumptions about selves preclude acknowledgment of others' particular standpoints; and second,

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[272]Martha A. Ackelsberg, "Communities, Resistance, and Women's Activism: Some Implications for Democratic Theory," in *Women and the Politics of Empowerment*, ed., Ann Bookman and Sandra Morgen (Philadelphia: Temple University Press): 304; bel hooks, "Sisterhood: Political Solidarity Between Women," in *Feminist Theory: From Margin to Center* (Boston: South End Press, 1984): 43-66.

[273]Edward J. Larson, *Sex, Race, and Science: Eugenics in the Deep South* (Baltimore: Johns Hopkins University Press, 1995): 71-79.

the reverence for impartiality denies the uniqueness of situations and suggests that all reason with the same assumptions and from the same point of view, thus affording the experiences and perspectives of dominant groups the pretension of universality. Communitarians, by contrast, acknowledge that selves are constituted by membership in communities and affirm processes of decision-making that are grounded in the values of particular communities. They neglect, however, to provide ways to mitigate the problems that arise when some communities are more organized, confident that their perspective is worth hearing, and connected to and "fluent" within dominant channels of communication, and therefore, more audible than others when it comes to defining needs and proposing strategies to address them. When coupled with the "urge toward unity," that is, the tendency toward homogeneity, this effectively denies women in non-dominant communities voice. Although for different reasons, both sorts of theories neglect to consider the complexities concerning justice in decision-making processes.

Similarly, the white gay male community was dominant in defining the nature of "the AIDS problem" and in articulating response strategies. Beyond the fact that HIV/AIDS were seen early on as a matter of concern solely for this group, the assumption of rough equality between sexual partners in gay male culture led to response strategies that promoted a discourse of collective responsibility and choice that was not applicable to women's lives. In addition, the emphasis on empowerment was at odds

with the framework adopted by some African-American organizers.[274] Further, the white gay male community advocated "coming out" with an AIDS diagnosis. This strategy was not appealing to many women, given their fear of facing violence.[275] Finally, as noted above, the "gay community" was successful in securing access to the dominant channels of communication and interpretation, attaining scientific credibility, and becoming integrally involved in the research process while communities of women were not.[276] To the extent that they cannot express their experiences and gain a hearing, women live within a context of oppression. As well, they face domination insofar as social and institutional conditions inhibit their capacities for participating in determining their actions or the conditions of their actions.

Conceptualizations of Selves in the Turn Toward Community

As a final point, the emphasis upon community involvement for the purpose of improving recruitment and retention reflects a problematic conceptualization of selves. While acknowledging women's embeddedness and the role of community in determining their moral starting points and constraints with respect to research participation, these

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[274]Patton, *Inventing AIDS*, 15-16.

[275]Ibid., 9; Karen Rothenberg, Stephen J. Paskey, "The Risk of Domestic Violence and Women with HIV Infection: Implications for Partner Notification, Public Policy, and the Law," *American Journal of Public Health* 85, no. 11 (November 1995): 1569-1576.

[276]Epstein, "The Construction of Lay Expertise."

initiatives reveal a view of women as consumers, or receptacles of clinical research resources.

This conceptualization comes forth in a variety of ways. It is evident in the very objectives of the initiatives: to promote successful accrual of women in clinical studies. Moreover, the emphases on the dissemination of information about studies through marketing strategies, on getting women enrolled and keeping them enrolled is clearly primary.[277] It is possible, indeed, to glean from the initiatives the goal of "successful" community involvement in clinical studies: "maximized local acceptance of the program."[278] Discussions of the involvement of community in designing research plans, when examined in the context of these initiatives, ultimately amount to efforts to maintain the enrollment of women. Women, as they live in communities, are thus posited primarily as recipients or consumers of clinical research resources.[279] Contemporary efforts aimed at community participation do not represent a significant advance from historical approaches to community involvement.[280]

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[277]For example, see the strategies discussed in National Institutes of Health, *Recruitment and Retention of Women*, 23-27.

[278]Ibid., 28.

[279]For an explicit statement of this view, see Ruth B. Merkatz, "Women in Clinical Trials: An Introduction," *Food and Drug Law Journal* 48, no. 2 (1993): 164.

[280]See Robert J. Levine, *Ethics and Regulation of Clinical Research* (Baltimore: Urban and Schwarzenberg, 1986): 90-91; and "Appropriate Guidelines for the Selection of Human Subjects for Participation in Biomedical and Behavioral Research," in *The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research*, National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (Washington, D.C.: U.S. Government Printing Office, 1978), 1: 4-18.

Even when women have facilitated, or even re-focused scientific inquiry, this consumerist conceptualization of selves endures. Feminist writers, scientists and activists have demanded inquiries into the relationship between breast cancer rates and environmental contamination. In serving on policy panels, however, they have been cast in the role of "consumer" representatives.[281]

Underlying this conceptualization of selves as consumers is the tenacious influence of a distributive framework for viewing the concerns of justice for women in clinical studies. With underinclusion posed as the central problem, attention to recruitment and retention emerges as a primary solution. These efforts acknowledge the role of community in women's lives, then, primarily as it pertains to recruitment and retention efforts. Operating within the turn toward community is an ethic that does acknowledge the constitutive role played by communities, but there is, further, significant appeal to their strategic value. Recognizing women's roles as mothers as well as the implications for women of the separation of homes, health care institutions, and workplaces, for example, these community initiatives make provisions for child care and transportation. Further, they provide health care services and even insurance coverage to

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[281]Sandra Steingraber, "Women, Cancer and the Environment: A Preview of *Rachel's Daughters*." Reading at The Center for Research on Women and Gender, University of Illinois-Chicago, Chicago, IL, May 1996; Kay Dickerson, "Reinventing Health Outcomes Research and Breast Cancer." Paper presented at Health Outcomes Research Seminar, The University of Chicago, Chicago, IL, March 1996. Finally, see National Institutes of Health, Office of the Director, Office of Medical Applications of Research, *Guidelines for the Planning and Management of NIH Consensus Development Conferences* (Bethesda, MD: National Institutes of Health, 1995): 9.

maintain women's inclusion until the completion of studies.[282] Such measures are a crucial first step toward acknowledging the sorts of social arrangements that constrain women's participation in clinical research. Yet, by failing to critique such issues as the moral claims made upon women through gender role expectations or the structure of the health care system and how these may influence the development and design of clinical research (for example, focusing upon women as mothers or as childbearing beings, or ignoring the possibility of exploiting the most disadvantaged women), these initiatives ultimately fall short of eliminating social injustice as it is likely to be manifested in clinical research.

TOWARD SOCIAL JUSTICE AS ENABLEMENT IN CLINICAL RESEARCH FOR WOMEN

Responding to the constraints women face with respect to research participation is necessary if justice is to be realized. Outreach to communities is, for the most part, a praiseworthy venture in the overall effort to promote women's development and self-determination in clinical research. Yet, the liabilities of the influence of the ideal of community on clinical research for women - as currently conceived - are formidable ones. Although it has attained eminence in contemporary discourse, community may fail as an analytic concept, for, as Patton argues, "it cannot illuminate

[282]National Institutes of Health, *Recruitment and Retention of Women*, 27.

the shifting personal or network allegiances lived by individuals in face-to-face relations."[283] In its urge toward unity, it is unable to capture social inexhaustibility, including the pervasiveness and indeed, the value of difference, and the sorts of relations that characterize persons' social experience. Further, as the ideals of communitarianism tend to ignore the need for major structural economic and political transformations, so their seedlings in the context of clinical research obscure the social and institutional arrangements that subject women to domination and oppression. To the extent that these ideals fail to challenge existing social structures, relations, and processes, they risk perpetuating social injustice against women in the context of clinical research.

The concept of community may well take us further toward realizing justice however, if, mindful of these critiques, we can seek out those social locations where women challenge the status quo, including the identities and moral claims imposed upon them by traditional conceptions of community. Attempts to increase their participation, moreover, should be understood as including women at all levels of decision-making, rather than merely seeking their assent to preconceived projects, which have been formulated in accordance with incomplete and possibly distorted understandings of women and their needs. As I shall argue in the next two chapters, reconceptualizing the notion of community

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[283]Patton, *Inventing AIDS*, 7.

participation in this way supports women's development and self-determination, and therefore, promotes social justice.

CHAPTER FOUR

SOCIAL JUSTICE AS ENABLEMENT: AN INTEGRATIVE APPROACH

By displacing, but not altogether abandoning, an understanding that focuses upon patterned outcomes of goods, positions, and other social values, we can make way for a conception of justice that seeks to illuminate the ways economic analyses and structures, cultural norms and relations, and decision-making processes reflect and reproduce injustice, and begin to envision and create other social and institutional forms that will enable women and others to develop and to exercise self determination. Social justice as enablement shares with communitarianism a picture of selves as relational, informed in their knowledge and moral commitments by group membership, and as integral players in a participatory public. It departs from communitarianism, however, by reckoning seriously with social inexhaustibility and incorporating a conception of selves as modified, moreover, constructed by complex and often oppressive social relations and processes. Embracing diverse models of community and communication instead of relying on traditional ones that have proved to perpetuate injustice against women and other oppressed groups, this understanding of justice envisions a more decentered political process,

where formal institutional structures and processes are conjoined with other sites of discourse and deliberation. Lacking an urge for unity, this model holds less potential for exclusion when it comes to understanding social problems and making decisions that aim to address them. Social pluralism emerges as a resource rather than a weighty impediment in the quest to establish justice.

In contrast to views of justice that presuppose a model of moral encounters involving self-interested and disinterested acquisitive individuals, social justice as enablement understands moral engagement as largely dialogical, and decisions about social issues as ideally formulated from the fruits of interactions with a plurality of subjects under conditions of parity. Instead of adhering to the notion of a "unified public realm in which citizens can leave behind their particular group affiliations, histories, and needs to discuss a mythical 'common good'," critical moral thinking on this view requires "real participatory structures in which actual people, with their geographical, ethnic, gender, and occupational differences, assert their perspectives" on all aspects of public policy, institutional organization, social norms, and cultural meanings.[284] An enabling conception of justice:

> coincides with the concept of the political ...[it] includes all aspects of institutional organization, public action, social practices and habits, and cultural meanings insofar as they are potentially subject to collective evaluation and decision-making ... [it] concerns the policies and actions of

[284]Iris Marion Young, *Justice and the Politics of Difference* (Princeton: Princeton University Press, 1990): 116, 119

government and the state, but in principle can also concern rules, practices, and actions in any other institutional context.[285]

This view of justice is clearly aided by discourse theory in its understanding of the formation of social identities and social groups, and the attainment and renegotiation of cultural authority to make meaning and assign value. Thus, it reflects the shift in philosophy and social theory from epistemological issues to a discursive problematic, in which cultural meanings are constructed and contested.[286]

The purpose of this penultimate chapter is to lay the groundwork for the incorporation of social justice as enablement in clinical research for women. I will argue for an approach that integrates attention to difference in social policy with supportive mechanisms for the representation of oppressed social groups in a participatory democracy. Going beyond the rich analysis provided by Young, I shall also give the matter of fair resource distribution its due consideration.

EQUALITY, DIFFERENCE, AND GROUP CONSCIOUS SOCIAL POLICY

A goal of social justice, social equality refers in part to "socially supported substantive opportunit[ies] for all to develop and exercise their

[285]Ibid., 34.

[286]Delving into the debates surrounding the best conceptions of discourse for feminist aims is beyond the scope of my ambitions here. Where discourse theory is discussed in these pages, then, it is a cursory overview of what are rich and highly contentious debates in feminist theory, for example, about the virtues of structuralist or pragmatist discourse theories. For additional discussion, see Nancy Fraser, "Structuralism or Pragmatics: On Discourse Theory and Feminist Politics," in *Justice Interruptus: Critical Reflections on the "Postsocialist" Condition* (New York: Routledge, 1997): 151-170.

capacities and realize their choices."[287] Social equality, according to social justice as enablement, must be grounded in the public affirmation of particularity.

Another view, of course, is that the best way to promote social equality is to highlight commonalties among persons.[288] A good example of this view prevailing in the policy realm can be found in *The Pregnancy Discrimination Act of 1978* (PDA), which held that pregnancy should be treated like other "similar" conditions, in this case, those that affect persons' abilities to work.[289] While the PDA encouraged employers to include pregnancy in their sickness and disability plans, the emphasis on male-female commonalties caused some to reduce maternity provisions like leaves that were lengthier than those available for other conditions.[290] Notions of justice that avow the equal treatment of persons, but which understand equality as sameness and call for the elimination, suppression, or transcendence of group differences, and treatment of all according to the same principles, rules, and standards, hold oppressive consequences for women and others. Inattention to difference, or naming it as deviant, denies the uniqueness of persons and allows the views and experiences of the privileged to prevail, and to be seen as universal.

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[287]Young, *Justice and the Politics of Difference* , 173.

[288]See, for example, Wendy W. Williams, "Equality's Riddle: Pregnancy and the Equal Treatment/Special Treatment Debate," in *Feminist Legal Theory: Foundations*, ed., D. Kelly Weisberg (Philadelphia: Temple University Press, 1993): 128-155.

[289]*The Pregnancy Discrimination Act of 1978*, U.S. Code 42 § 2000e(k) (1982).

[290]Lucinda M. Finley, "Transcending Equality Theory: A Way Out of the Maternity and the Workplace Debate," in *Feminist Legal Theory: Foundations*, 196.

Policies that attend to the particularity, or specific situatedness of oppressed groups and their members can help offset, or counteract oppression and disadvantage, and promote social equality and justice. Instead of ignoring, or defining it as deviance or otherness, the meaning of difference may be reclaimed and redefined in relational terms, as naming:

> relations of similarity and dissimilarity that can be reduced to neither coextensive identity nor nonoverlapping otherness. [Thus] group differences [may be] conceived as relational rather than defined by substantive categories and attributes. A relational understanding of difference relativizes the previously universal position of privileged groups, which allows only the oppressed to be marked as different. When group difference appears as a function of comparison between groups, whites are just as specific as Blacks or Latinos, men just as specific as women, able-bodied people just as specific as disabled people. Difference thus emerges not as a description of the attributes of a group, but as a function of the relations between groups and the interaction of groups with institutions. [As well], the meaning of difference ... becomes contextualized. Group differences will be more or less salient depending on the groups compared, the purposes of the comparison, and the point of view of the comparers.[291]

This way of conceptualizing difference acknowledges that the process of identifying and evaluating differences is political, value laden, situational, and perspectival, that males and other dominant groups do not properly provide the sole standards for comparison, and the role of society and institutions in constructing and using differences, assigning them density and weight in ways that create and perpetuate disadvantage.

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[291] Young, *Justice and the Politics of Difference*, 171-172.

Operative here is a conceptualization of social identities as discursively constructed in historically specific social contexts; they are complex and plural; and they shift over time:

> social identities are complexes of meanings, networks of interpretation. To have a social identity, to be a woman or a man, for example, just is to live and to act under a set of descriptions ... drawn from the fund of interpretive possibilities available to agents in specific societies.[292]

Identities, then, arise from the multiple descriptions made available by different signifying practices, which take on different degrees of salience in different contexts, and change over time.

This view of justice finds a middle path between those that would leave the content of existing identities and group differentiations intact, and those that would support total deconstruction. By understanding difference in relational and contextual terms, we can allow for the revaluing of unjustly devalued identities and, simultaneously, aspire to challenge and destabilize "given" essentialized identities and differentiations. Through participatory decision-making processes - to be discussed below - the structures that assign value to them will undergo transformation. This approach enables groups to achieve collective empowerment (something likely left behind by strong deconstructionist approaches). Moreover, it changes *everyone's* sense of self.[293]

Having stressed the need for frameworks and policies that are sensitive to specificity and difference, we must also note the necessity of

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[292]Fraser, "Structuralism or Pragmatics," 152.

[293]See Fraser, *Justice Interruptus*, 23-24, 27.

grasping large objects of inquiry, like the global economy and the sexual division of labor. Moral thought that emphasizes relations and context should be adept at understanding features of the social totality in terms of mutual interconnection and integration.[294] Gender oppression intersects with class, "race" and ethnicity, and thus takes different forms for different women in different contexts. Still, we need to be able to capture how women's oppression is:

> imbricated in the political economy and in political culture, in state apparatuses and public spheres ... [how] it traverses households, kinship networks, and the range of institutions in civil society ... operates at all sites of cultural and ideological production, including mass cultures, high cultures, academic cultures, oppositional cultures, and counter cultures ... infuses personal identities and collective identities, social affinities and social antagonisms, and more-or-less shared common sense.[295]

We need ways of understanding and articulating the social pervasiveness of domination and oppression.

THE HETEROGENEOUS PUBLIC AND PARTICIPATORY DEMOCRACY

Participatory democracy is a second key element and condition of social justice. When decision-making is understood as a process of need interpretation, the development of social and institutional structures that invite the participation of a heterogeneous public becomes an integral part

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[294]Nancy Fraser, "Pragmatism, Feminism, and the Linguistic Turn," in *Feminist Contentions: A Philosophical Exchange*, by Seyla Benhabib, Judith Butler, Drucilla Cornell, and Nancy Fraser (New York: Routledge, 1995): 159.

[295]Ibid.

of promoting justice.[296] Participants in the formulation of public policy should include a range of civic associations as well as social groups. Young argues that for those social groups with histories of oppression, the following measures should be implemented to support their special representation: differential resource allocation to promote their self-organization, so they can understand themselves better, preserve and continually interpret the meaning of experienced injustices, and achieve the collective empowerment that will enable them to realize their aims; group analysis and generation of policy proposals, which are presented with the understanding that they will be duly considered and perhaps incorporated; and the institution of group veto power over policies that affect a group directly.[297]

Supporting the public expression of the needs of those who have faced domination and oppression promotes justice better than leaving these processes under the control of purportedly impartial experts or other commonly privileged spokespersons in numerous ways. Procedurally, it encourages fairness in the formulation of agendas and deliberations regarding their contents. It also makes it more likely that a richer assessment of needs and interests - one that more accurately reflects

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[296]Nancy Fraser, "Women, Welfare, and the Politics of Need Interpretation," and "Struggle Over Needs: Outline for a Socialist Feminist Critical Theory of Late Capitalist Political Culture," in *Unruly Practices: Power, Discourse, and Gender in Contemporary Social Theory* (Minneapolis: University of Minnesota Press, 1988): 144-187;Young, *Justice and the Politics of Difference*, 184-185.

[297]Young, *Justice and the Politics of Difference*, 184; and "Social Groups in Associative Democracy," *Politics and Society* 20, no. 4 (December 1992): 532-533. Compare Jane Mansbridge, "Using Power/Fighting Power: The Polity," in *Democracy and Difference: Contesting the Boundaries of the Political*, ed., Seyla Benhabib (Princeton: Princeton University Press, 1996): 46-66.

a pluralistic society differentiated by social groups, occupations, regions, and differences of privilege - will emerge and be supported. The perspectives of the privileged are less likely to dominate.

Such support for members of oppressed groups, then, helps in the realization of justice by enhancing persons' capacities for deliberation and articulation. It mitigates the relations of domination and oppression that may prevail within groups, *along* with those that structure the wider society. Perhaps most important, social knowledge may be increased as individuals come to appreciate the diversity of persons' experience as well as how their own is situated within a broad social context. "This greater social objectivity increases their wisdom for arriving at just solutions to collective problems."[298] In other words, providing mechanisms and supporting structures that promote the inclusion of heterogeneous standpoints - particularly those with experiences of domination and oppression - makes it more likely that decision-making processes will yield outcomes that uphold social justice.

This idea of maximized social objectivity is a crucial component of feminist standpoint theory.[299] Whereas in conventional accounts credible knowledge is to be free of particularity, standpoint theorists maintain that all knowing is grounded in the standpoint of particular knowers. They are

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[298]Iris Marion Young, "Communication and the Other: Beyond Deliberative Democracy," in *Democracy and Difference*, 128. See, as well, *Justice and the Politics of Difference*, 186. John Stuart Mill is clearly on point here. See his "Of the Liberty of Thought and Discussion," in *On Liberty*, ed., David Spitz (New York: W.W. Norton and Co., 1975): 17-52. As well, see Amélie Oksenberg Rorty, "The Advantages of Moral Diversity," *Social Philosophy and Policy* 9, no. 2 (Summer 1992): 38-62.

[299]Harding, "Rethinking Standpoint Epistemology," 49-82.

not giving up objectivity and embracing relativism in making this claim. The argument is that knowledge grounded in particular standpoints strengthens our ability to achieve objectivity. Not only do these theorists regard social situatedness as inevitable but, further, they aspire to transform this into a scientific resource.[300] They explain how research that is directed by social values and political agendas - as opposed to that which is purportedly guided by norms of impartiality and universality - can produce results that are less partial and distorted and that, moreover, promote social justice.

Similarly, Marilyn Friedman (not a self-identified standpoint theorist) proposes that critical moral thinking on social issues should be oriented around the affirmation of partialities instead of the ideal of impartiality. Rather than seeking to suppress knowledge about subjectivities (à la Rawls), or to imagine the standpoints of different others (à la Okin's Rawlsian feminism), improved moral reasoning and thinking about social issues calls for attending to "named biases whose distorting effects on moral thinking we recognize, and whose manifestations in moral attitudes and behavior can be specifically identified," and *incorporating* these into our interpersonal and public dialogue.[301]

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[300]Ibid., 58.

[301]Marilyn Friedman, "The Impracticality of Impartiality," in *What Are Friends For?: Feminist Perspectives on Personal Relationships and Moral Theory* (Ithaca, NY: Cornell University Press, 1993): 31.

Standpoint theory and social justice as enablement take a step beyond the mere inclusion of the ideas and concerns of the oppressed and suggest that these should be privileged (as opposed to receiving equal time) in the development of knowledge projects. While these have been devalued or ignored as a source of objectivity-maximizing questions, they are actually better equipped for generating critical insights than dominant ones. The social position of the privileged constrains their abilities to understand the interests of those subjected to injustice. Their privilege, moreover, depends partly on the oppression of others, and thus they have an interest in maintaining the status quo.[302] The latter are less able - because of their social situations - and less likely - because of their interest in preserving status quo relations of privilege - to generate critical questions about received belief or to provide significant problems in need of explanation. Thus:

> ... it is reasonable to think that the socially situated grounds and subjects of standpoint epistemologies require and generate stronger standards of objectivity than do those that turn away from providing systematic methods for locating knowledge in history. The problem with the conventional conception of objectivity is not that it is too rigorous or too 'objectifying,' ... but that it is *not rigorous or objectifying enough* ...[303]

In contrast to the view that difference is inherently divisive - a notion embedded in theories that avow impartiality and unity as key elements or objectives of critical moral thinking - the idea here is that:

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[302]Young, *Justice and the Politics of Difference*, 185. As well, see Sandra Harding, "Rethinking Standpoint Epistemology: What Is 'Strong Objectivity'?" in *Feminist Epistemologies*, ed., Linda Alcoff and Elizabeth Potter (New York: Routledge, 1993): 54.

[303]Harding, "Rethinking Standpoint Epistemology," 50-51.

[t]here is ... something to be learned from the other perspectives as they communicate their meanings ... precisely because [these] are beyond one another and not reducible to a common good ... The plural standpoints in the public enable each participant to understand more of what the society means or what the possible consequences of a policy will be by each situating his or her own experience and interest in a wider context of understanding something in other social locations.[304]

Rather than arriving at a point of mutual identification, having transcended differentiation and come to share beliefs, understanding refers to persons' "successful expression of experience and perspective" so that those who are differently situated can learn. Through processes of "speaking across differences of culture, social position, and need" where differences are preserved rather than suppressed or transcended, transformation of knowledge and even preferences can occur. Persons may come to recognize their own partiality and provide for others in their distinctive situations.

Frye's characterization of loving perception (in contrast to that which is arrogant, or, imperialistic) conveys such a model of moral engagement:

The loving eye knows the independence of the other ... It is they eye of one who knows that to know the seen, one must consult something other than its own will and interests and fears and imagination ... The loving eye is one that pays a certain sort of attention. This attention can require a discipline but *not* a self-denial. The discipline is one of self-knowledge, knowledge of the scope and boundary of the self. What is required is that one know what are one's interests, desires and loathings, one's projects, hungers, fears and wishes, and that one know what is and what is not

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[304]Young, "Communication and the Other," 127. Also, see *Justice and the Politics of Difference*, 119. Similar insights are offered by Lorraine Code, "Experience, Knowledge, and Responsibility," in *Women, Knowledge, and Reality: Explorations in Feminist Philosophy*, ed., Ann Garry and Marilyn Pearsall (Boston: Unwin Hyman, 1989): 165.

determined by these. In particular, it is a matter of being able to tell one's own interests from those of others and of knowing where one's self leaves off and another begins.[305]

When decision-making processes are organized in this way, the aim is to avoid such constraining influences" as "epistemic indolence" - manifested in the conviction that one knows what she is talking about and is absolved of any need to know better - and "epistemic imperialism" - the belief that others are "summed up," labeled for what they are. To allow such epistemically irresponsible ways of claiming to know to pass for knowledge is "to grant one's cultural tradition undue authority and to abandon the critical perspective characteristic of responsible knowing."[306]

Others are less willing to embrace social justice as enablement's approach to the special representation of oppressed social groups, with its commitment to resource allocation to support their self-organization, group-generated policy proposals and veto power. Concurring that group consultation is necessary to justice and that disadvantaged groups warrant increased political participation, Phillips, for example, supports the alternative of group quotas.[307]

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[305]Marilyn Frye, *The Politics of Reality: Essays in Feminist Theory* (Freedom, CA: The Crossing Press, 1983): 75. Others who discuss the significance of acute attention to detail in the context of moral engagement include: Lawrence A. Blum, "Iris Murdoch and the Domain of the Moral," and "Moral Perception and Particularity," in *Moral Perception and Particularity* (Cambridge: Cambridge University Press, 1994): 12-61; and Martha C. Nussbaum, "'Finely Aware and Richly Responsible': Literature and the Moral Imagination," in *Love's Knowledge: Essays on Philosophy and Literature* (New York: Oxford University Press, 1990): 148-167.

[306]Code, "Experience, Knowledge, and Responsibility," 159-162.

[307]Anne Phillips, *Democracy and Difference* (University Park, PA: The Pennsylvania State University Press, 1993): 96-101.

Given that most persons have cross-cutting affiliations, she is concerned that special representation for oppressed groups leaves open the problem of establishing which group is most pertinent to one's identity. For example, in her participation, should a Native American lesbian represent women, Native Americans, lesbians, or some combination of these groupings? The conception of difference as relational assists us in making such determinations. The answer, in other words, is that it is context- and issue-specific.

A second challenge Phillips levels against special representation is that it risks making multiple and shifting identities fixed, or essentialized. Stated differently, the worry is that members of groups might find themselves consistently defined according to specific attributes and interests. This second concern - over "freezing" group identities - is also answerable with a relational conception of difference, particularly when accompanied by a commitment to the participation of a pluralistic public, some of whom aim to resist their domination and oppression, including dominant constructions of their identities. Conjoined, these protect against the potential for essentializing identities.

It is, indeed, Phillips' proposal that holds the greater potential for such essentialization: the suggestion of quotas does nothing to challenge the content of identities formed under conditions of domination and oppression but instead reifies these. This is especially interesting in light of her later discussion of the fact that to the extent that women have seen

political participation, their contributions have often been construed in terms of their roles as wives and mothers, legitimating the sexual division of labor and risking the fixation of women's identities organized around the interests of men and capitalism.[308] The quota system proposal, finally, affirms existing political and other decision-making structures rather than transforming them, and going further still, to broaden the scope of contexts for policy formulation in order to undermine domination and oppression.

Relying on discourse theory to help explain how relations of domination and oppression in society affect the production and circulation of social meanings, or how cultural authority is attained, maintained, and renegotiated, according to social justice as enablement, societies contain a plurality of communicative forms, discourses, and discursive sites. Undermining domination and oppression demands attention to this plurality of positions and perspectives from which persons may speak, not all of which have equal authority, or for that matter, are equally audible.

In thinking further about the development of participatory decision-making structures, and especially ways of creating conditions of parity to support the renegotiation of social meanings, broadening accounts of what deliberative processes amount to emerges as important. As an alternative to an interest-based theory of democracy, where persons pursue their own perceived interests primarily through voting processes,

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[308]Ibid., 107-109.

deliberative democracy usually refers to a discussion-based ideal aimed at realizing the common good.[309] Contemporary theorists of deliberative democracy - critics of the interest-based model - object to what they regard as privatized consumer-oriented political processes.[310] Competing for the expression and satisfaction of their own private goods, individuals are not inclined to recognize others or their particular points of view. Further, this model of democratic decision-making is said to be irrational. Ultimate outcomes are not determined through processes of reasoning, but by the desires of a majority of voters and by the influence of money and social power. The deliberative conception of democracy, by contrast, understands politics as people coming together to deliberate rationally over social goals and public policies. According to this more inclusive, egalitarian model:

> [d]emocratic processes are oriented around discussing [a] common good rather than competing for the promotion of the private good of each. Instead of reasoning from the point of view of the private utility maximizer, through public deliberation citizens transform their preferences according to public-minded ends, and reason together about the nature of those ends and the best means to realize them. In free and open dialogue others test and challenge these assertions and reasons ... The interlocutors properly discount bad reasons and speeches that are not well argued ... Putting forward and criticizing claims and arguments, participants in deliberations do not rest until the 'force of the better argument' compels them all to accept a conclusion.[311]

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[309]The presentation here is owed to the discussion by Young, "Communication and the Other," 121-135.

[310]Ibid., 121.

[311]Ibid.

While much of what has been said about social justice as enablement thus far concurs with the central insights of deliberative democracy, there are nevertheless some major liabilities of this model, as it is usually articulated. Concerns about presupposing or aiming for unity have already been amply discussed and so I shall leave these aside. Most important here is the point that, to the extent that critical argument is the privileged form of discussion, conceptions of deliberative democracy reflect a culturally biased understanding of deliberation. Although theorists claim to be "bracketing political and economic power," thereby making participants equal, they are in fact promoting ideals that are exclusionary, for:

> the social power that can prevent people from being equal speakers derives not only from economic dependence or political domination but also from an internalized sense of the right one has to speak or not to speak, and from the devaluation of some people's style of speech [most notably women and cultural minorities] and the elevation of others [typically white middle-class men].[312]

If we are serious about the notion of a heterogeneous public engaged in decision- making processes concerning matters of social policy, we must not ignore or seek to eliminate social differences related to speech. Rather we must recognize and accord respect to specificity in deliberative processes by attending to structural inequalities in discussion and

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[312]Ibid., 122. See, as well, Lucie E. White, "Subordination, Rhetorical Survival Skills, and Sunday Shoes: Notes on the Hearing of Mrs. G," in *Feminist Legal Theory: Readings in Law and Gender*, ed., Katherine T. Bartlett and Roseanne Kennedy (Boulder, CO: Westview Press, 1991): 404-428.

broadening our understanding of what constitutes communication in democratic decision-making.

Young argues that instead of privileging speech that is dispassionate, assertive, formal and general to the exclusion or disvaluing of some, we ought to eliminate biases against speech that incorporates expressions of emotion and bodily gestures, is "tentative, exploratory, or conciliatory," "halting and circuitous," or that refers to particularities.[313] Moreover, she embraces greeting (e.g., smiles, handshakes, hugs), storytelling, and rhetoric as forms of communication that can serve to strengthen political discussion. The virtues of these modes of expression are that they attend to the embodiment of participants and affirm their particularity, thus "providing ways of [communicating] across difference..."[314] According to Young, an ideal of *communicative* democracy best capture this respect for diverse "forms of communicative interaction where people aim to reach understanding."[315]

We can also note that taking difference seriously demands acknowledgment that there may be different understandings of what it is to cooperate, to agree, or to justify decisions.[316] Affirming pluralism calls,

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[313]Young, "Communication and the Other," 123-124.

[314]Ibid., 129.

[315]Ibid., 125. Others who consider mechanisms for addressing inequalities in speech include: Alison Jaggar, "Toward a Feminist Conception of Moral Reasoning," in *Morality and Social Justice: Point/ Counterpoint*, by James P. Sterba, Tibor R. Machan, Alison M. Jaggar, William A. Galston, Carol C. Gould, Milton Fisk, and Robert C. Solomon (Lanham, MD: Rowman and Littlefield, 1995): 115-146.

[316]See the discussion of pluralizing public reason by James Bohman, "Public Deliberation and Cultural Pluralism," in *Public Deliberation: Pluralism, Complexity, and Democracy* (Cambridge: The MIT Press, 1996): 71-105. Also, see Amy Guttman and Dennis Thompson, "Moral Conflict and

furthermore, for a recognition that individuals and groups differ in the degree to which they *value* such activities as deliberation and communication.

With respect to those who place little value in processes of deliberation and communication across difference, it seems that a conception of social justice grounded in attention to domination and oppression would require us (that is, those who are committed to such activities and who aspire to incorporate them into research processes aimed at improving the health of women) to pose a series of questions: What is the basis for their rejection of such activities? Is a cultural defense available? In other words, is it grounded in the accurately understood beliefs of a non-dominant cultural community? Is this a widely held view or only the position of some within the community? Does the aversion to deliberation and communication perpetuate the domination and oppression of members of the community (for instance, women) as evaluated by *them* rather than the dominant culture?[317] If women, to continue with the example, in a non-dominant cultural group do not consider themselves to be oppressed by group norms of non-deliberation and reticence, do such norms perpetuate the domination and oppression of women in the broader social context, that is, those who are not members of the particular community? Does the group have other mechanisms for

Political Consensus," *Ethics* 101, no. 1 (October 1990): 64-88.

[317]Recall the point from Chapter Three concerning Aboriginal women's groups in Canada. See Will Kymlicka, *Multicultural Citizenship: A Liberal Theory of Rights* (New York: Oxford University Press, 1995).

decision-making that are not well captured or understood by dominant frameworks? As we find answers to such questions, we will be better poised to avoid marginalizing such groups but also to elicit the concerns of those who wish to express them but have yet to find a welcoming forum.

To the extent that people are not always wise nor their decisions just and worthy of respect, it seems that some constraints may be placed on what might emerge (and be respected) from discussions involving heterogeneous standpoints. According to a conception of social justice as enablement, ideas and proposals that perpetuate domination and oppression - that inhibit persons' abilities to express their experiences and determine their actions and the conditions of their actions - should not necessarily be constrained in dialogue, but they cannot prevail in policy. We might hope that the views of participating misogynists, for example, would be transformed through engagement with others in decision-making processes that privilege the standpoints of the oppressed. But if not, group veto power over policies that affect them disproportionately provides a safety net for justice.

To grant respect for pluralism, in sum, it is appropriate to respect diverse values, to broaden understandings of what constitute relevant forms of communication and fair procedures for decision and justification, with the qualification that these can neither preclude continued discussion nor hinder the development of others and the exercise of their capacities to realize their choices and determine their

actions. These ideals help to ensure that the socially authorized forms of public discourse available for interpreting people's needs are adequate and fair, not skewed in favor of the interpretations and interests of dominant social groups. A polity can flourish as a democracy only to the extent that it upholds equal respect for all as well as rules for fair discussion and decision-making. It must contain at least this degree of unity among members. Where it is not possible to find the right blend of respect for things like human rights, constitutional guarantees such as freedom of speech, and for contesting pluralisms, we may have to turn to alternatives like self-governance for those who consistently come up as marginalized. All together, though, these conditions function as a foundation for processes of decision-making that views difference among persons as "a resource for public reason rather than as divisions that public reason transcends."[318]

If justice is to be realized for dominated and oppressed groups, attending to inequalities in communication, broadening our understanding of what constitutes cooperation and legitimation, and - through reconceptualizing principles like objectivity - including and privileging the insights of the oppressed in moral deliberations are all vital pursuits. We must also consider what are ideal *sites* for generating emancipatory discourse, and through it, justice-promoting ideas. If we recognize that relations of domination and oppression affect the

[318]Young, "Communication and the Other," 127.

production and circulation of social meanings and that these may be renegotiated, yet another level of supporting participatory democracy and seeing social justice realized involves considering where to develop authoritative need interpretations. In our case, what contexts best support the realization of women's development and self-determination?

Thinking back to the discussion above and in Chapter Three, it is possible to discern a commonalty underlying those communities cited by communitarian theorists and others as constitutive of self-identity and definitive of our moral starting points. According to Sandel, for example, the notion of community describes "not a relationship [people] choose (as in a voluntary association) but an attachment they discover, not merely an attribute but a constituent of their identity."[319] According to this view, the communities and social relationships persons find themselves in, those which are given, or in other words, persons' communities of origin, are most important for self-definition.

Yet, as Marilyn Friedman points out, for women the given identity constituted by one's original communities may "harbor ambiguities, ambivalences, contradictions, and oppressions which complicate as well as constitute identity and which have to be sorted out, critically scrutinized." While these "found" communities are indisputably constitutive of one's "given" identity, Friedman argues that when we

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[319]Michael Sandel, *Liberalism and the Limits of Justice* (Cambridge: Cambridge University Press, 1982): 150.

develop and gain experience to reflect further on our identities, we may be compelled to seek out, to create, to discover new attachments and commitments, to embrace "communities of choice" beyond those from which our selves first originate and develop, and which "may equally well contribute to the constitution of identity."[320] Rather than relying on locations where we are compelled to conform to others' images of who we should be, social justice as enablement suggests that we identify places where we can reinvent ourselves. Indeed:

> The constitution of identity and moral particularity, for the modern self, may well require the contribution of radically different communities from those invoked by communitarians. [Indeed t]he whole tenor of communitarian thinking would change if we opened up the conception of the social self to encompass chosen communities, especially those that lie beyond the typical original community of family-neighborhood-school-church.[321]

Similarly, Ferguson describes "alternative supporting communal frameworks," or, "oppositional communities."[322] Minimally, what characterizes such communities is that their norms are established by women, and their emphasis is upon enhancing women's self-development and self-determination, that is, upon building their capacities for self-understanding, critical analysis, and for expressing their experience. A

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[320]Marilyn Friedman, "Feminism and Modern Friendship: Dislocating the Community," in *What Are Friends For?: Feminist Perspectives on Personal Relationships and Moral Theory* (Ithaca, NY: Cornell University Press, 1993): 246.

[321]Ibid., 246-247. As well, see 252-253. There will, of course, be families, churches, schools, and so on that promote liberatory ideals. Consider bel hooks on the emancipatory classroom. See bel hooks, *Teaching to Transgress: Education as the Practice of Freedom* (New York: Routledge, 1994).

[322]Ann Ferguson, "Feminist Communities and Moral Revolution," in *Feminism and Community*, ed., Penny A. Weiss and Marilyn Friedman (Philadelphia: Temple University Press, 1995): 367-397.

stronger view would suggest that they incorporate a commitment to challenging dominant social and institutional structures, relations, and processes - even if inexplicitly.[323]

Such contexts are ideal sites for the development and exercise of what Walker calls "strong moral self-definition," that is, the process of affirming and repudiating various identity-constitutive features of our lives to construct a moral persona, set courses for ourselves, and make decisions.[324] It is within these sorts of social spaces that women may come to understand themselves better, interpret the meaning of injustices, and achieve collective empowerment through learning about processes of deliberation and communication for the purpose of participation in processes of decision-making and policy formulation. They are thus strengthened in their abilities to overcome the inequalities of capacities that arise from material and educational deprivation and from processes of socialization that undermine their potential to have an audible voice.[325]

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[323]Certainly not all oppositional communities are feminist or organized around norms established by women. For the purposes of this project, I confine the discussion to those that are.

[324]Margaret Urban Walker, "Moral Particularity," *Metaphilosophy* 18, no. 3/4 (July/October 1987): 42, 108-109, 134.

[325]See Deborah Tannen, *You Just Don't Understand: Women and Men in Conversation* (New York: William Morrow and Co., Inc., 1990), along with the following analyses of women's difficulties in speaking without interruption and successfully shifting discussion to another subject: Candace West and Don H. Zimmerman, "Sex Roles, Interruptions and Silences in Conversation," in *Language and Sex: Difference and Dominance*, ed., Barrie Thorne and Nancy Henley (Rowley, MA: Newbury House, 1975): 105-129; Candace West and Angela Garcia, "Conversational Shift Work: A Study of Topical Transition Between Women and Men," *Social Problems* 35, no. 5 (December 1988): 551-575. Finally, for a discussion of studies that show that female legislators speak less than male legislators, and that in public meetings women generally give information and ask questions while men state their views and are more confrontational, see Jane Mansbridge, "Feminism and Democratic Community," in *Feminism and Community*, 341-365.

Discourse theory, which again helps us to understand how social identities are developed and modified, how dominant groups come to achieve and secure authority and how this may be contested, and thus, how the transformation of relations of domination and oppression may be undermined and transformed, reminds us that as identities shift over time, their relationship to discourse also changes.[326] To a significant extent, social groups emerge from the contestation of social discourse. As Fraser notes: "many of us who had previously been 'women' in some taken-for-granted way have now become 'women' in the very different sense of a discursively self-constituted political collectivity."[327] We have developed new ways of describing social experience ("date and marital rape" for example), imagined and participated in new social practices (consider consciousness-raising) and carved out new public spheres (like the Society for Women in Philosophy and the American Medical Women's Association). In that it is "in the medium of discourse that each of us encounters and interpretation of what it is to be a person, as well as a menu of possible descriptions specifying the particular sort of person each is to be," such contexts provide potential for innovation.[328] Ferguson, moreover, points to the necessity of participation in multiple relational networks. If women are to successfully "deconstruct our internalized

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[326]The discussion here relies heavily on the analysis provided by Fraser in "Structuralism or Pragmatics."
[327]Ibid., 153.
[328]Ibid., 167, note 4.

sexism, racism, heterosexism, and class attitudes ... [t]o reconstitute ourselves," and "to reassess the values to which [we are] committed," it will be necessary to engage in activities with different others.[329]

One way of thinking about such oppositional communities in relation to discourse theory is to imagine these as opening up spaces for what Judith Butler calls "resignification," where received meanings and values are contested and innovations produced. With society comprised of a plurality of subject positions, which are themselves grounded in various "discursive regimes," innovation - albeit under conditions of imaginative and performative constraint - is possible.[330] Individuals are taken to be capable of innovation, not merely comprised of static and essentialist identities, which are themselves artifacts of social structures and systems. The category "woman," marked by some for elimination, at minimum will be redefined and accorded new meanings from within the fund of interpretive possibilities available to us at particular times, in particular contexts, in specific societies.

The possibility of making such discursive moves aimed at undermining domination and oppression helps to avoid essentializations of women's experience. It also strengthens efforts to maneuver away from

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[329]Ferguson, Feminist Communities and Moral Revolution," 370-372. For further reading on this problem of associative democracy, see David Theo Goldberg, "'Polluting the Body Politic': Racist Discourse and Urban Location," in *Racism, the City and the State*, ed., Malcolm Gross and Michael Keith (New York: Routledge, 1993): 45-60.

[330]Judith Butler, "Contingent Foundations," in *Feminist Contentions*, 35-58.

the pull of the gaze of the "arrogant eye," the urge to define ourselves in terms of patriarchal interests and frameworks:

> [T]here is in the fabric of our lives, not always visible but always affecting its texture and strength, a mortal dread of being outside the field of vision of the arrogant eye. That eye gives all things meaning by connecting all things to each other by way of their reference to one point - Man. We fear that if we are not in that web of meaning there will be no meaning: our work will be meaningless, our lives of no value, our accomplishments empty, our identities illusory. The reason for this dread ... is that for most of us, including the exceptional, a woman existing outside the field of vision of man's arrogant eye is really inconceivable.[331]

The challenge is to identify and make audible the standpoints of women while avoiding tendencies to "reset the trap of gender identities, deny the real differences between women ... and reflect the history of oppression and discrimination rather than an ideal ... to which we can aspire.[332] We must acknowledge the ineradicable and irreducible differences along with the intersections among us, strive to reimagine and construct feminist voices beyond the gender system in order that we may undermine it, all the while recognizing that the existing constructs in our language and psyches make this incredibly difficult. Indeed:

> [i]f we have no intuition of ourselves as independent, unmediated beings in the world, then we cannot conceive ourselves surviving our liberation; for what our liberation will do is dissolve the structures and dismantle the mechanisms by which Woman is mediated ... If we cannot imagine ourselves surviving this, we certainly will not make it happen.[333]

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[331] Frye, *The Politics of Reality*, 80.

[332] Drucilla Cornell, *Beyond Accomodation: Ethical Feminism, Deconstruction and the Law* (New York: Routledge, 1991): 3.

[333] Frye, *The Politics of Reality*, 80.

To think in terms of multiple oppositional networks and cross-cutting relations among them, then, addresses the concerns raised in Chapter Three regarding the implications of the ideal of community. This largely avoids the problem of community identification being the result of a dominant group's enforcement of certain identities. As Butler would put it, practices of resignification (innovation) are performed from and enabled by subject positions that are constructed by the discursive regimes they contest. Nevertheless, the aspiration of oppositional communities is to aid women in constructing their own meanings of their lived experience. Moreover, this model avoids the problems of exclusion that arise from the urge toward unity within many communities, along with those tied to the relations of domination and oppression that often prevail between communities. Furthermore, it acknowledges that segregation, due to the organization of space in society, structures social relations and impedes communication among persons. By seeking out networks of oppositional communities, we may begin to chart, or attune ourselves to the heretofore silenced or obscured "territories," Patton describes.[334] It may be possible, ultimately, to remove decision-making processes, including needs interpretation, from more dominant channels of communication, from the mouths of experts and other previously privileged decision-makers, and from contexts that have historically contributed to women's domination and oppression. Envisioned here is a

[334]Cindy Patton, *Inventing AIDS* (New York: Routledge, 1990): 3

hybrid solution, where policy formulation emerges from the confluence of oppositional discursive sites and the decision-making processes of more formal institutional structures. The concepts of the social group and the community, as typically conceived, then, provide useful guideposts for reenvisioning justice for women by drawing attention first, to the fact that it is as members of social groups that people face injustice, and second, to the organization of persons' social experience and relations. But in themselves they fail to provide the precision necessary for organizing policy formulation and other decision processes in a complex heterogeneous society.

What ultimately emerges from participatory democratic decision-making processes are local knowledges, or situated questions, social criticisms, ideas, and proposals which may be ultimately be conjoined with larger scale non-foundational, fallible narratives.[335] The proposal here combines more formal, institutionalized bodies with decentralized informal networks. In a symbiotic relation, these can reimagine and rearticulate visions of selves and social life, and transform social and institutional relations, processes, and structures so that they enhance, rather than inhibit, persons' capacities for development and self-determination.

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[335]See Fraser, "False Antitheses," in *Feminist Contentions*, 59-74; and Sandra Harding, "Is Science Multicultural?" Paper presented at International Social Philosophy Conference, Saint Norbert College, August 1996, De Pere, WI.

FAIR DISTRIBUTION AND SOCIAL JUSTICE

Contemporary efforts to attend to difference in social policy and to restructure decision making-processes in ways that allow for the representation of a heterogeneous public, particularly those with histories of domination and oppression, take place amidst serious material inequality. As we saw in Chapter Two, many of the injustices to which women are subjected take root in the economic structure of society. Going further than historical accounts of justice that focused on the need for redistribution as well as more recent ones that emphasize the necessity of cultural recognition and effective political participation for all, we need a conception that regards economic and cultural injustices (including gender bias) as linked and mutually reinforcing. As Fraser observes:

> Cultural norms that are unfairly biased against some are institutionalized in the state and the economy; meanwhile, economic disadvantage impedes equal participation in the making of culture ... The result is often a vicious circle of cultural and economic subordination.[336]

What makes addressing these forms of injustice all the more difficult to address is that people who are subject to both of them need to claim, and simultaneously, to deny their specificity. In the case of women, gender bias is institutionalized in the state and the economy, and their economic disadvantage hinders their ability to participate in the shaping of culture, through policy formulation processes and other means. In one respect, then, they need to undermine gender differentiation, and for

[336]Fraser, *Justice Interruptus*, 15, 20-21.

example, eradicate the gendered division of labor between paid and unpaid work as well as within paid work. Yet they also need recognition of and respect for differences.

The remedy of merely reallocating resources fails to promote justice by not attending to the social and institutional relations, processes, and structures that contribute to their and others' domination and oppression. Simply increasing shares for consumption to already existing groups fails to restructure the system for naming, valuing, producing, and distributing goods, and contributes to groups' oppression by reifying identities. Furthermore, redistributive efforts often lead to further stigmatization, making oppressed groups appear privileged and insatiable.[337]

On the other hand are approaches that seek to transform social and institutional relations, processes, and structures. This may include redistribution, but it goes further to democratize decision-making, including the setting or priorities for allocations, determinations of who shall be the beneficiaries, and how exactly goods are to be received. Such decision-making efforts should incorporate the processes outlined in the above discussion of participatory communicative democracy.

Appreciation and reconceptualization of difference, transformative distributivism, and public participation in decision-making under conditions of equalized communication combine to undermine the social and institutional relations, processes, and structures that contain and give

[337]Ibid., 25.

rise to domination and oppression. In the fifth and final chapter, I shall consider the potential such an approach to social justice holds for women in the context of clinical research.

CHAPTER FIVE

SOCIAL JUSTICE IN CLINICAL RESEARCH FOR WOMEN

An integrative approach to social justice as enablement combines distributive remedies with critical attention to difference and the democratization of decision-making. This conception is ideally suited for the moral governance of the funding, development, conduct, and review of research.

RECOGNITION AND RESISTANCE: DIFFERENCE IN RESEARCH POLICY AND PRACTICE

By ignoring and/or degrading the heterogeneity of bodies along with experiences of social condition and culture, research ventures have functioned to hinder the development and exercise of women's capacities and the expression of their experiences, and to restrict their participation in decisions concerning their actions. National Institutes of Health (NIH) and Food and Drug Administration (FDA) policies now formally acknowledge women's menstrual cycles, contraceptive use, and so on as reasons to study them. Yet major loopholes and lingering pockets of resistance continue to constrain women's inclusion.

First of all, while the *NIH Revitalization Act* requires that women be included in research that is conducted or supported by the NIH, a policy

more consistent with justice also would include research that is regulated by federal agencies and departments. Perhaps the greatest escape from a commitment to uphold justice, though, comes from the set of stipulations that allows women's exclusion from research when it is deemed appropriate. The requirement to include women, in other words, shall not apply when this is considered "inappropriate with respect to the health of the subjects; ... the purposes of research; or ... under such circumstances as the Director of the NIH may designate."[338] It is not hard to imagine researchers citing homogeneity as important to research purposes, or concern for the health of the "vulnerable," that is, the pregnant or potentially so, and arguing for women's exclusion. What is more, because the appropriateness of inclusion is partly a matter of what is known about the significance of a condition for women, the fact that previous studies have not included women may ultimately serve as grounds for their continued exclusion. Nor is it beyond the realm of possibility that NIH Directors, pressured by powerful constituencies and/or uncommitted to justice for women, could erode the possible efficacy of the initiatives. It is also possible to rebut the presumption of inclusion by providing some "clear and compelling rationale and justification" for exclusion.[339] Again, a pronounced commitment to respecting women and promoting justice is easily tarnished in practice.

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[338]National Institutes of Health, "NIH Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research," *Federal Register* 59, no. 59 (28 March 1994): 14509.
[339]Ibid.

With a relational conception of difference, male bodies are just as different as female ones, and women's bodies cease to figure as deviant or problematic for research purposes. When the meaning of difference becomes contextualized, it is possible to make distinctions between women who can and cannot bear children and those who do and do not expect to do so. Instead of emphasizing the physiological attributes of women and treating them universally as potential childbearers - and then excluding or underincluding them - on this view women's particular circumstances come forth as salient in developing research protocols. To enrich the presumption of inclusion, then, different provisions for the participation of differently situated women can be established. Are prospective subjects, for example, committed to celibacy, or to not reproducing? Are they post-menopausal? While there may be reason to identify and assess differences for *other* purposes, these women do not warrant special treatment related to childbearing. They should be included without restraint.

For women who anticipate pregnancy, the realization of social justice in research processes calls for a quite different sort of attention, but decidedly not of the variety that has thus far been paid to childbearing capacity. When research participation appears to offer them the best chance for life-saving or life-prolonging treatment, or for symptom relief, restrictions on inclusion are unjust because they inhibit self-development and self-determination, here, women's abilities to develop as healthy

persons and to exercise their decision-making capacities. Upholding social equality in the research context requires respect for women's bodily integrity and decisional privacy concerning their health.[340] Justice, in sum, requires that women, not courts, research institutions, or industry, have dominion over their health, reproductive and otherwise.[341] Because the conception of justice invoked here can support a demedicalized definition of health benefit, in accordance with the commitment to pluralism, benefits beyond personal symptom relief and increased longevity also might be considered.

An enabling approach to social justice suggests that within their role as research subjects, women with childbearing potential they expect to employ in the future warrant differential treatment of the sort that helps them develop and exercise their capacities and participate in determining their actions and the conditions of their actions. In the research context this could mean tailoring the informed consent process in ways that highlight risks to all persons' reproductive health (the relational understanding of

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[340]The following Supreme Court cases also support this view: *Cruzan v. Director, Missouri Department of Health*, 497 U.S. 261 (1990); *Griswold v. Connecticut*, 381 U.S. 479 (1965); *Roe v. Wade*, 410 U.S. 113 (1973). For detailed discussions of the relevance of the Fourteenth Amendment to the U.S. Constitution to the inclusion of women in clinical research, see: Hayley Gorenberg and Amanda White, "Off the Pedestal and Into the Arena: Toward Including Women in Experimental Protocols," *N.Y.U. Review of Law and Social Change* 19, no. 1 (1991-1992): 233-235; Karen Rothenberg, "Gender Matters: Implications for Clinical Research and Women's Health Care," *Houston Law Review* 32, no. 5 (Symposium 1996): 1246-1248.

[341]Legal commentators point to *International Union, United Automobile, Aerospace, and Agricultural Implement Workers v. Johnson Controls Inc.*, 499 U.S. 187 (1991) as supporting the removal of barriers to women's participation in clinical research. The case involved a fetal protection policy used by the company to exclude pregnant women and women who did not provide medical documentation asserting their inability to bear children from jobs involving lead exposure exceeding Occupational Health and Safety Administration (OSHA) standards.

difference importantly allows us to highlight men's role in reproduction), and providing participants with information on known and anticipated risks of the experimental intervention, the unknown potential for harm, along with the non-experimental alternatives available if any.[342] At minimum, federal regulations and state tort law should be upheld, but the stronger the standard for disclosure the greater the prospects for promoting women's self-determination. Attention to particularity here might also mean performing pregnancy tests prior to and during the protocol. While this strategy might seem to imply that women cannot be trusted to practice contraception, it is, for the most part, an unrestrictive way of taking morally relevant differences into account.

When research participation appears to offer them the best chance for life-saving or prolonging treatment, or for symptom relief, restrictions on pregnant women's inclusion are also unjust. Women, according to social justice as enablement, are the proper guardians over their health and that of their potential children. Upholding the conditions necessary for the realization of justice in research requires, then, that the requirement to obtain paternal consent included in federal regulations be abolished, as it undermines women's self-determination.[343] In cases where a pregnant woman seeks inclusion and there is no prospect of benefit to her, and the

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[342]Rothenberg, "Gender Matters," 1259-1261; Gorenberg and White, "Off the Pedestal," 223-227.

[343]This position has legal as well as moral support. See *Planned Parenthood v. Casey*, 505 U.S. 833 (1992); *Planned Parenthood v. Danforth*, 428 U.S. 52 (1976).

experimental intervention in question is likely to present more than minimal harm to a fetus, other approaches may be appropriate. Determinations regarding inclusion may be made on a case by case basis, weighing the benefit she seeks and her justification for its pursuit in relation to the likelihood and magnitude of risk to the fetus. Under some circumstances the commitment to women's self-development and self-determination might go unchallenged, while others would call for a privileging of fetal beneficence. The aim is to respect pluralism, avoiding standardless policies on the one hand, and moral absolutism on the other.

Influenced by industries driven by goals of production and capital accumulation, research for women has been thwarted. Concern for legal liability has permeated the research process for at least three decades. Close inspection of legal doctrines, however, reveals that undue attention is focused here. The doctrine of parental immunity, which protects parents from suits by future children for alleged fetal damage, may serve to shield women from tort claims tied to previous research participation through the principle of respect for the exercise of ordinary discretion regarding medical care.[344] When a case concerns pre-conceptual conduct and the person harmed did not exist, for example, when a woman is *not pregnant* at the time of the research, the difficulty of establishing causal links makes the success of liability claims unlikely.[345] Such causal links,

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[344]Gorenberg and White, "Off the Pedestal," 228.

[345]See Vanessa Merton, "The Exclusion of Pregnant, Pregnable, and Once Pregnable People (A.K.A. Women) from Biomedical Research," *American Journal of Law and Medicine* 19, no. 4 (1993):

indeed, may be broken by the consent process. Where a women is pregnant, on the other hand, and she seeks out research to gain access to an intervention of anticipated benefit to her or her fetus, adherence to high standards for informed consent again most likely will insulate her, researchers, institutions and manufacturers from liability.[346] What promotes justice, then, also reduces the likelihood of successful claims.

There are compelling reasons to shift our focus, as some legal commentators try to do, toward the potential for liability claims arising from women's diminished participation. They point out that legal precedent exists for finding liability for inadequate testing of drugs and devices prior to marketing, for the failure to warn, and for the failure to provide safe products. The duty to provide safe products supports liability claims for physical harm to users if a product is flawed, either in the manufacture of one item or in the design of an entire product line.[347] Drug manufacturer liability may be found where physiological differences exist between men's and women's responses to a particular drug, causation between use of the drug or device and injury can be established and the manufacturer failed to test it on women, when they are among the group of anticipated consumers.[348] All male trials may also

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406-407.

[346]Gorenberg and White, "Off the Pedestal," 223-227; Rothenberg, "Gender Matters," 1259-1262; Lucinda M. Finley, "The Impact of Tort Law on the Development of Products for Women's Health." Paper presented at The Center for Research on Women and Gender, The University of Illinois at Chicago, Chicago, IL, December 1996.

[347]See Merton, "The Exclusion of Pregnant, Pregnable, and Once Pregnable People," 416-417.

[348]Ibid., 419-422. Legal commentators note that there are formidable problems in sorting out the relationship between legal and medical causation. See Finley, "The Impact of Tort Law."

lead to liability claims based upon a failure to warn, especially when evidence of risk to women is available. Under negligence theory of product liability, manufacturers have a duty to warn about the known risks of a drug or device as well as foreseeable risks that should have been known. If there is evidence that a drug or device might be unsafe for women (based on animal studies or physiological differences), or if the manufacturer chose not to perform studies that would ascertain dangers it should have anticipated, the failure to determine and warn against the risks that were reasonably foreseeable at the time the drug was prescribed and used would support a product liability claim, regardless of compliance with FDA standards. There is no duty to warn of unknown, unforeseeable, or possible risks, although if a manufacturer realizes that knowledge of potential adverse effects is limited, it should at minimum warn customers that the product is experimental and may present unknown hazards.[349] It is also possible, finally, that a medical malpractice claim could result from the application of a treatment regimen that has been developed through research solely on men.[350] What these deliberations suggest is that adequate testing of drugs and devices for women's use and adherence to high standards for consent should not only promote women's self-development and self-determination, they should also make conditions less favorable for liability claims.

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[349]Rothenberg, "Gender Matters," 1264; Merton, "The Exclusion of Pregnant, Pregnable, and Once Pregnable People," 417-418.

[350]Rothenberg, "Gender Matters," 1264.

Another strategy is preferred by industrial interests, however. Contemporary calls for tort reform seek to undermine persons' abilities to make liability claims. Efforts to prevent suits based on manufacturers' and others' claims of compliance with FDA regulations and proposals to cap non-economic loss claims, two reforms under consideration, would disproportionately harm women. As noted in Chapter One, many injuries to women's health occur in the context of *post-marketing* activity, which falls outside the scope of FDA control. Furthermore, just as employment law regards the typical worker as male, tort law defines injuries and measures compensation primarily in relation to marketplace activities, or, what keeps people out of paid work and what this is worth.[351] In this framework, structured in accordance with male experience, non-economic damages such as pain, suffering, and emotional harm due to fertility loss, menstrual cycle chaos - harms suffered by women from drugs and devices - "are deemed suspect and expendable."[352] Women's health advocates have responded to calls for tort reform by cautioning that products liability law has played a salutary role in protecting women's health and recognizing claims of injury from their use of products.[353]

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[351]With respect to the point that employment law tends to conceive of typical workers as male, Alta Charo cites the Johnson Controls case: "How else," she asks, "could lead exposure in amounts dangerous to a developing fetus be considered acceptable under OSHA standards?" R. Alta Charo, "Protecting Us to Death: Women, Pregnancy, and Clinical Research Trials," *Saint Louis Law Journal* 38, no. 1 (Fall 1993): 141-142.

[352]Lucinda M. Finley, "Breaking Women's Silence in Law: The Dilemma of the Gendered Nature of Legal Reasoning," in *Feminist Legal Theory: Foundations*, ed., D. Kelly Weisberg (Philadelphia: Temple University Press, 1993): 575.

[353]Finley, "The Impact of Tort Law."

While the law may help in resolving injustices in research, it is ill-suited for the task of promoting women's development and self-determination. The structures, processes, and norms that guide it serve, overall, to constrain the realization of justice for women. More specifically, its reasoning structure, like the liberal philosophical and scientific tradition, privileges rationality and abstraction over passion and particularity. Too, the law presupposes a model of social life permeated by conflict among self-interested individuals. Where they address research, legal frameworks tend to construct a view of women as emotional and litigious receptacles of drugs and devices (developed, of course, by impartial experts) who are presumptively pregnant and adversarially related to their offspring. Such conceptions present a myopic and distorted view of persons and social relationships, and foster a polarized understanding of issues. Social justice as enablement places no such confines on our moral imaginations or on women's speech. It encourages us to envision and create the ideal arrangement of social and institutional structures and processes for the purpose of realizing social needs and persons' full potential, not for containing costs and averting conflict. It aspires to uphold the kinds of institutional conditions that enhance women's abilities to speak and to be heard with minimized distortion, that support their conceptions of their identities, relationships, and aims, as well as those that promote their capacity to pursue them.

Social justice also calls for substantive opportunities enabling women from varied social conditions and cultures to have access to clinical research. What this entails should be determined for the most part through the democratization of decision-making processes, a matter to be taken up below. For now, however, we can say that upholding the conditions necessary for the realization of social justice in research requires attention to such issues as the ways "women's work," the feminization of poverty, and specifics of culture and/or sexual orientation influence prospects for inclusion and treatment within specific protocols.

With respect to the participation of women who lack access to health care services, for instance, some comment on the notion of voluntariness in research is warranted. When these women, whether they face life-threatening conditions or need basic care, consider their best chance for obtaining services to be through research, the ideal of voluntary participation cannot possibly be realized. According to *The Belmont Report*, at most this would constitute a situation of undue influence: an excessive, unwarranted, or inappropriate or improper award is offered in order to secure compliance. This is contrasted with coercion, which is defined as a situation where an overt threat of harm is intentionally presented by one to another for the purpose of obtaining compliance.[354]

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[354]National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, *The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research* (Washington, D.C.: U.S. Goverment Printing Office, 1978): 6.

On an understanding of coercion that takes account of social and institutional structures and processes, women who lack access to health care and pursue research to secure basic services are in a coercive context, for:

> [t]he elements of coercion lie in the manipulation of the circumstances and manipulation of the options ... to coerce someone into doing something, one has to manipulate the situation so that the world as perceived by the victim presents [her] with a range of options the least unattractive of which (or the most attractive of which) in the judgment of the victim is the act one wants the victim to do.[355]

Some particulars of this definition warrant revision: for example, the reference to an individual person manipulating the environment. Yet, the insight that integral to the process of coercion is the *structuring* of the options accessible to persons underlines the need for contextualizing this concept for poor women in research. Social justice as enablement, with its requirement of attention to how social structures differently constrain persons' abilities to realize their choices, to determine their actions and the conditions of their actions, at minimum requires special protections for these women in the consent process. They merit mechanisms that will enable them to make reasonable decisions under conditions of domination and oppression. Better, of course, for the realization of social justice would be universal health care access. Without it research will be still another social venue for exploitation: the disenfranchised will be subject to

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[355]Marilyn Frye, *The Politics of Reality: Essays in Feminist Theory* (Freedom, CA: The Crossing Press, 1983): 56-57.

the risks of research, transferring their labors for the benefit of others who are able to avail themselves of the best science and medicine have to offer.

The informed consent process is a critical place for incorporating attention to particularity within research. Existing research guidelines and regulations already address the need for such attention when they note the importance of disclosing information in a manner that is understandable to the individual prospective subject, that is, of adapting the presentation to a person's capacities. According to social justice as enablement, though, previous standards for judging disclosure are inadequate. Finding the "local practice" and "reasonable person" standards inappropriate for the research context, *The Belmont Report* puts forth the notion of the "reasonable volunteer" as a possible guide for providing information regarding research:

> the extent and nature of information should be such that persons, knowing that the procedure is neither necessary for their care nor perhaps fully understood, can decide whether they wish to participate in the furthering of knowledge. Even when some direct benefit to them is anticipated, the subjects should understand clearly the range of risk and the voluntary nature of participation.[356]

The reasonable person standard has its origin in tort negligence law and reflects an effort to establish a universally applicable measure for conduct. This standard, originally articulated as the reasonable man standard, was revised to correct its blatant gender bias. Nevertheless, as in the legal world that generated this standard, the realm of research has been

[356]National Commission, *The Belmont Report*, 5-6.

a predominantly male environment where women's capacities to comprehend information and to make decisions have been systematically denied. The reasonable person, or the reasonable volunteer, tends to mean the male volunteer who is reasonable according to the standards of a male judge or, for our purposes, researcher.

Rather than using reasonableness as a measure, we might invoke a standard that focuses on what a responsible researcher with conscious care and concern for a concrete other with meanings and purposes in life should disclose.[357] In keeping with attention to particularity, consent policies also should give attention to the ways women *as a social group* tend to face domination and oppression. Instead of merely emphasizing differences among women, in other words, standards for disclosure and evaluating comprehension should respond to possible commonalties among women. They might, for instance, incorporate attention to socialization processes that encourage them to be subordinate. Consent practices, as well, should address educational attainment, health care access, in some cases drug use, and living conditions. Women who defer to authority, who are poor and uneducated, and who are members of non-dominant cultural groups, especially recent immigrants and refugees, warrant special provisions in the consent process. Immigrants and

[357]This proposal reflects a confluence of the views of Seyla Benhabib and Leslie Bender. See Seyla Benhabib, *Situating the Self: Gender, Community, and Postmodernism in Contemporary Ethics* (New York: Routledge, 1992); Leslie Bender, "A Lawyer's Primer on Feminist Theory and Tort," in *Feminist Legal Theory: Foundations*, 58-74. Substantial insights may also be gleaned from Margaret Urban Walker, "Picking Up Pieces: Lives, Stories, and Integrity," in *Feminists Rethink the Self*, ed., Diana Tietjens Meyers (Boulder, CO: Westview Press, 1997): 62-84.

refugees may lack knowledge about their basic human rights in the U.S. and come from countries that restrict freedom of expression. The older among them are least likely to ask questions, state their concerns, or assert themselves.[358]

Investigators and Institutional Review Boards (IRBs) are responsible for determining the adequacy of the consent process. An understanding of social justice that begins with the concepts of domination and oppression calls for aiding investigators in carrying out this moral responsibility by including members of the subjects' social groups, both with and without scientific backgrounds, who might serve as guardians of a just consent process. The evidence that "racial" matches in such efforts in themselves are ineffective suggests that age, level of assimilation in the case of immigrants, education, and so on should be considered in the selection process.[359] Such provisions would strengthen women's abilities to exercise reasonable choices even under conditions of oppression. Further discussion and recommendations regarding the composition and work of IRBs are offered below.

Despite the value of informed consent in promoting justice, this process has been overemphasized as a primary protective mechanism. Although it ideally provides participants a process in which to develop

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[358]See Elena S.H. Yu, "Ethical and Legal Issues Relating to the Inclusion of Asian/Pacific Islanders in Clinical Studies," in *Women and Health Research: Ethical and Legal Issues of Including Women in Clinical Studies*, ed., Anna C. Mastroianni, Ruth Faden, and Daniel Federman (Washington, D.C.: National Academy Press, 1994), 2: 216-231.
[359]Ibid.

and exercise self-determination, the background of dominating and oppressive relations and structures in research prohibits the realization of social justice. Not engaged in focusing, designing, and reviewing research, and frequently deferential to physician/ researcher authority (in the belief that their sole aim is to protect patient/subject interests), subjects, especially those who are members of oppressed social groups, can face substantial risk of harm in the context of research. Mitigating this requires a commitment to supporting a more encompasing conception of justice than currently prevails.

We need to be cautious in crafting policies that attend to women's particularities with the aim of promoting social equality. More specifically, it is crucial to take seriously the potential for essentialization and reification of women's identities. Merely affirming so called "women's differences," be they in relation to men, to other women, or both, is too simplistic an approach to promoting justice. It reduces treatment of difference to a universal prescription: all variations should be affirmed and enjoyed. A richer, more complex position is that there are different *kinds* of differences. While many variations should be recognized and incorporated in research (women's menstrual cycles and the capacity of some to conceive and bear children, for example), others surely warrant a different response. We must be careful to sort out the extent to which differences evinced by oppressed groups are manifestations of oppression, and then consider whether their eventual elimination or something else,

like revaluation, is the appropriate objective, and whether, in the meantime, recognition and incorporation should be accompanied by efforts at undermining or differently valuing them. We would want, for example, to eradicate cultural norms that regard women as appropriately passive, silent, and obedient to male authority on the grounds that they prevent women from exercising their capacities, expressing their experience and determining their actions. Yet with respect to something like the caregiving activities most often performed by women, we might want to challenge their undervalued status and virtually exclusive association with women, but still give them attention in research processes. In other words, we may aspire to eliminate the sexual division of labor to the extent that there is inequity between men's and women's unpaid as well as paid work, and a social norm that holds women to be proper primary caregivers. We can work to undermine the social and institutional relations, processes, and structures that support the transfer of women's labor to men and capitalism while acknowledging that in the world we inhabit this hinders women's research participation. By critically recognizing difference here and making appropriate accommodations, we can provide socially supported substantive opportunities for women to engage in clinical research - thereby enhancing their development and self-determination - without condoning, but rather *resisting*, the broader social processes subjecting them to injustice. Doing this requires that we cultivate conditions for reflecting on

the meaning of "women" and critically inquiring into their needs. The aim of attending to difference, then, is:

> not to solidify a [women's] identity but to deconstruct the [male-female] dichotomy [as well as others, like homosexual-heterosexual] so as to destabilize all fixed identities. The point is ... to sustain a ... field of multiple, debinarized, fluid, ever-shifting differences.[360]

This allows for limitless regroupments and supports women's efforts at "resignification," thus avoiding the reification of existing identities and differentiations.

The enablement view of justice, in addition to recognizing and responding appropriately to differences in and among people, might also be invoked for clarifying distinctions among activities. Distinctions between research, non-validated practices, and established therapies, in particular, hold tremendous import for women.

Research, of course, refers to activities that aim to test a hypothesis, permit conclusions to be drawn and thereby to develop or add to generalizable knowledge. By contrast, the term "practice" designates interventions that are intended to enhance the well-being of a particular patient or client - by diagnosing, or providing preventive treatment or therapy - and that are anticipated to be successful. Non-validated practices are procedures that aim to benefit a specific individual but that have not been tested to the degree that they meet the standard of having "a

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[360]Nancy Fraser, *Justice Interruptus: Critical Reflections on the "Postsocialist" Condition* (New York: Routledge, 1997): 24.

reasonable expectation of success."[361] An activity that belongs to this class of practices does not constitute research, but rather, should be made the object of research.

These distinctions are particularly relevant in the realm of women's health care. Patients generally assume that unless they are formally enrolled as participants in research, they are receiving proven therapies. In numerous instances, without warning or explanation, women have been subjected to non-validated practices, including contraceptives and infertility treatments, which have been falsely represented as safe and effective established practices.[362] This history highlights the need to carefully research interventions aimed at women. It, further, calls for stricter scrutiny of those provided under the guise of established practice, but which in fact, are non-validated practices, untested for their use. Because they will enable them to make informed choices and exercise self-determination when under the care of clinicians and researchers, such measures are an integral part of treating women justly.

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[361]These definitions come from National Commission, *The Belmont Report*, 3. I prefer the use of the term "non-validated practice" to "innovative therapies" or "innovative practices." As Levine notes, "[n]ovelty is not the attribute that defines this class of practices; rather it is the lack of suitable validation of the safety or efficacy of the practice." Robert J. Levine, "Clarifying the Concepts of Research Ethics," *Hastings Center Report* 9, no. 3 (June 1979): 22.

[362]Susan Sherwin, *No Longer Patient: Feminist Ethics and Health Care* (Philadelphia: Temple University Press, 1992): 168-170.

COLLECTIVE EMPOWERMENT AND DEMOCRATIZING RESEARCH

Institutions embedded within welfare capitalist societies serve to preserve capitalism and its economic growth imperative both structurally and politically. They create favorable conditions for production and expanding markets for goods; and by delivering material goods, they cultivate peoples' loyalties.[363] The configuration of social institutions involved in research collude against women in accordance with this welfare capitalist framework. Much like the relationship between workers and capitalists, where the former got substantial material benefits and the latter maintained control over decisions concerning, among other things, the structure and goals of production, researchers argue for independence in scientific inquiry and expect the public to be satisfied by emergent benefits, in the form of health care services and products. Government institutions, also governed by an economic growth mandate, look toward distributing resources for social consumption.[364] Attention, in this political structure, is diverted away from issues of structure and process.

To the extent that women have questioned the social and institutional processes and structures that condition scientific endeavors and sought to be participants in deliberations, they have been constructed as a consumer interest group seeking their fair share of the goods, and, to a significant degree, reproached as insubordinates. Forcing them into

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[363]Iris Marion Young, *Justice and the Politics of Difference* (Princeton: Princeton University Press, 1990): 69.
[364]Ibid., 70-71.

identity categories they might not choose otherwise, policy formulation processes pit women and other groups against one another in competition for distributive shares. Cultural minorities, including women, moreover, often end up appearing insatiable and as dominating public policy by asserting their special needs. Even researchers "become supplicants at the welfare state and corporate table" as they confront constraint in their pursuits by the structure of funding projects.[365] Rather than engaging a heterogeneous public in deliberation, distinguishing between selfish interests and claims of justice, and evaluating the justice of both patterns of distribution and the processes by which these are determined, on this model those with vested interests - in our case industries - influence policy by working through channels of communication not subject to public view, with the aim of increasing profit.[366] This usually results not only in distributive unfairness - privileging the already privileged - but also in fragmented, depoliticized decision-making processes.

The triumphs of United States scientists over the Nazis, who had centralized control of research, were taken, in the post World War II era as testament for the independence of science from politics, for making a *structural* choice in favor of scientific autonomy in order that "free" inquiry might flourish.[367] The best science, so the argument still goes, is unfettered

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[365]Ibid., 70.

[366]Ibid., 72-73.

[367]Paul Starr, *The Social Transformation of American Medicine* (New York: Basic Books, 1982): 341-344. For further discussion of this issue see, Edward A. Shils, "The Autonomy of Science," in *The Sociology of Science*, ed., Bernard Barber and Walter Hirsch (New York: Free Press, 1962): 610-614.

science.[368] The claim that it can be carried out free from the influence of politics fails to recognize that science, including experimentation with human subjects, is a political process:

> The pretense that science is objective, apolitical, and value-neutral is profoundly political because it obscures the political role that science and technology play in underwriting the existing distribution of power in society. Science and technology always operate in somebody's interest and serve someone or some group of people. To the extent that scientists are 'neutral' that merely means that they support the existing distribution of power.[369]

The idea that science may be abstracted from social relations and political processes is a myth, a pernicious one, that has perpetuated the domination and oppression of certain groups. To affirm the political nature of science opens the door for broadening the scope of collaboration to include those who have been and will be affected by its endeavors, particularly those who have faced injustice.[370]

Achieving social justice for women demands that efforts to formulate research agendas, to fund design and perform the ethical review of projects, involve many models of community, from traditional to chosen and oppositional ones. Examples might include women's civic and cultural organizations, women's bookstores and business

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[368]See Steven Piantadosi and Janet Wittes, "Politically Correct Clinical Trials," *Controlled Clinical Trials* 14, no. 6 (December 1993): 567.

[369]Ruth Hubbard, "Science, Facts, and Feminism," in *Feminism and Science*, ed., Nancy Tuana (Bloomington: Indiana University Press, 1989): 128. As well, see Bill Zimmerman, "People's Science," in *The "Racial" Economy of Science: Toward a Democratic Future*, ed., Sandra Harding (Bloomington: Indiana University Press, 1993): 440-455.

[370]For additional discussion of democratizing scientific processes, see David Dickson, "Towards a Democratic Strategy for Science: The New Politics of Science," in *The "Racial" Economy of Science*, 472-483.

development centers, emancipatory educational settings, art galleries, dance ensembles, and theaters showcasing women's work. We might even work to organize women in laundromats and shelters. While some of these contexts are sites organized around the sexual division of labor or women's experience of injustice, they are nevertheless places where women gather and exchange ideas. Others might well be categorized as oppositional communities, as they more clearly provide women opportunities to reassess and perhaps reconstitute themselves, their norms are established by women, and their goals are self-development and self-determination. Prominent oppositional communities focused on women's health include the National Black Women's Health Project, the Boston Women's Health Collective, and the Lesbian Community Cancer Project.[371] A particularly choice example here is the play *My Virginia*, about women exposed to diethlystilbestrol (DES). Darci Picoult, a DES daughter, as writer and performer gives voice to women's health concerns and properly chastises the configuration of experts and institutions who conspired to keep them silent.

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[371]See, for example, Byllye Y. Avery, "Breathing Life into Ourselves: The Evolution of the National Black Women's Health Project," in *Feminism and Community*, ed., Penny Weiss and Marilyn Friedman (Philadelphia: Temple University Press, 1995): 147-154. Alison Jaggar describes the Boston Women's Health Collective in "Toward a Feminist Conception of Moral Reasoning," in *Morality and Social Justice: Point/Counterpoint*, by James P. Sterba, Tibor R. Machan, Alison M. Jaggar, William A. Galston, Carol C. Gould, Milton Fisk, and Robert C. Solomon (Lanhamn, MD: Rowman and Littlefield, 1995): 115-146. As well, see Sandra Morgen, "Its the Whole Power of the City Against Us!: The Developmment of Political Consciousness in a Women's Health Care Coalition," in *Women and the Politics of Empowerment*, ed., Ann Bookman and Sandra Morgen (Philadelphia: Temple University Press, 1988): 97-115.

Supporting the self-organization of women for purposes of group analysis and generation of research proposals, eliciting the insights of women not formally organized around research processes in varied social contexts, and implementing veto power for women or subgroups of them over policies that disproportionately affect them promotes justice by enabling heterogeneous groups of women to decide the telos, or purposes around which health research shall be organized. To cultivate forums for idea-formulation and to seek out existing ones is to displace the conception of women as consumers. It is to recognize that their participation increases cognitive diversity, as women of diverse cultures and social groups bring different resources to bear on conceptualizations of selves, "women," bodies, nature, and on organizing the production of knowledge. Restructuring decision-making in these ways should yield research agendas and projects that reflect the heterogeneity of women and promote social justice.

The contention that those untrained in the methods of science cannot offer information that is credible and/or useful for formulating research agendas and for designing and reviewing particular projects is based on restrictive notions of expertise. Indeed:

> [t]he very nature of the problems to be resolved and the values to be balanced are usually beyond the expertise of the scientific experts who so value expertise. In defense of a free science, a scientist often protests the intrusion of the public who is not trained to understand his methodologies in an area in which he himself [may be] untrained to understand the moral and political implications of his work ... if the argument of expertise is to be used at all, it will be used to insist on a

broader representation in the control of science than merely from within the scientific community.[372]

Whereas early accounts understood the phrase as referring to the impoverished state of lay persons' knowledge about science, those examining the relationship between science's regressive and progressive tendencies have shifted the focus in conceptions of "scientific illiteracy." They argue that the failure among scientists to acknowledge that science is a social process is appropriately described as scientific illiteracy.[373]

The ideals of communicative participatory democracy, with their commitment to fairness in communicative interactions, suggest that the development of ideas for research from within *clinical* contexts requires attending to the institutionally-conditioned potential for dominating and oppressive exchanges between caregivers and patients. In part this requires educational efforts aimed at enabling health care professionals to see their patients with "loving" as opposed to "arrogant perception," teaching them to elicit and take women's concerns under consideration. Given that the aim of justice as enablement is to organize institutions and practices in ways that help persons to achieve their full potential, going beyond the economic growth and corresponding cost-containment imperative to reckon with structural constraints, like reduced visit times

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[372]Willard Gaylin, "Scientific Research and Public Regulation," *Hastings Center Report* 5, no. 3 (June 1975): 6.

[373]Far from blaming them for this myopia, these theorists consider it an artifact of scientific education. Sandra Harding, "Introduction: Eurocentric Scientific Illiteracy - A Challenge for the World Community," in *The "Racial" Economy of Science*, 1.

in the managed care framework, which hinder the potential for discussion, also falls within the scope of justice.

Yet another way to see social justice realized in health care institutions is to restructure communication processes among specialties. Just as I argued for formulating research ideas from within complex configurations of communities and social groups, and for women's participation in different groups for the purpose of reassessing their identities, values, and aspirations, health care professionals should cross disciplinary boundaries to avoid the fragmentation and obscuring of knowledge that, if integrated, might advance women's health. Experience with the human immunodeficiency virus (HIV) and acquired immune deficiency syndrome (AIDS), and more recently with breast cancer demonstrates the hindrances and harmful consequences of discipline dominance.[374]

The ethical review of specific projects is now carried out by IRBs. Within institutions that carry out federally supported research with human subjects, IRBs determine, among other things, whether: risks to subjects are minimized and reasonable in relation to anticipated benefits to subjects, and the importance of the knowledge that may reasonably be expected to result; provisions for securing informed consent are sufficient;

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[374]See Cindy Patton, "What 'Science' Knows About AIDS: The Formation of AIDS Knowledges," in *Inventing AIDS* (New York: Routledge, 1990): 51-76; and Gina Kolata, "New View Sees Breast Cancer as Three Diseases," *New York Times* (1 April 1997): B 9-10.

subject selection is equitable; and appropriate safeguards are incorporated for vulnerable subjects (a category that includes pregnant women).[375]

The spirit of communicative participatory democracy in a heterogeneous society suggests first, that the composition of ethics review panels should reflect the demographics of the potential pool of subjects rather than "the professional competence necessary to review specific research activities" with "consideration" given to "race, gender, and cultural backgrounds" of members and to ... "community attitudes."[376] Review boards can determine whether research is consistent with group goals and what are the proposed project's implications for justice. Given the discussion above as well as the demonstrated tendency of health care institutions and professionals to perpetuate injustice against women, these review boards, further, should be removed from the exclusive purview of such institutions and their personnel. Instead, they should be situated in accessible non-institutional locations and have considerably more lay representation, perhaps even a non-scientist chair and representation from the subject pool. Reports that informed consent forms used in trials investigating the use of tamoxifen to prevent breast cancer contained serious omissions of risk data are the sorts of occurrences that support this

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[375]National Institutes of Health, *Code of Federal Regulations, Title 45 Part 46,* § 111. National Institutes of Health, "NIH Guidelines on the Inclusion of Women and Minorities," 14510. The Institute of Medicine's Committee on the Ethical and Legal Issues of Including Women in Clinical Studies gave additional recommendations for IRBs. See Mastroianni, Faden, and Federman, ed., *Women and Health Research.* For further discussion see Karen H. Rothenberg, Eugene G. Hayunga, Joyce E. Ruddick, and Vivian W. Pinn, "The NIH Inclusion Guidelines: Challenges for the Future," *IRB: A Review of Human Subjects Research* 18, no. 3 (May-June 1996): 1-4, 12.

[376]National Institutes of Health, 45 CFR 46, §107.

claim. Clinical investigators with vested interests in recruiting women for the study tended to emphasize benefits and underemphasize risks in the disclosure process.[377] Current guidelines merely mandate the inclusion of one member whose "primary concerns are in non-scientific areas," and one member who is not affiliated with the particular institution. Finally, IRBs should incorporate a model of moral decision-making that accords with the ideal of communicative democracy, privileging the concerns of the oppressed and respecting diverse forms of communication, not just the dispassionate argumentation based on evidence characteristic of scientists.[378] Like the "unified view" NIH takes to be the objective of deliberations, the IRB's goal of majority approval may support an oppressive process.[379] The goal under a conception of social justice as enablement would be to emphasize the fairness of the process of deliberation *as well as* its outcome.

Although McCarthy argues that the strength of the current system for research review is that board members "are aware of the attitudes and mores of the local community," and "[t]here is little opportunity for abuse of Government power [with respect to] the ethics of research," it is

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[377]See Janet Raloff, "Tamoxifen and Informed Consent/Dissent: Congress, Outside Advisors Cite Reservations About NIH Cancer Prevention Trial," *Science News* 142, no. 21 (21 November 1992): 378-380.

[378]For an earlier but interesting discussion of the "identity crisis" of IRBS and consequent confusion about their function, requisite skills, participants, and so on, see Robert M. Veatch, "Human Experimentation Committees: Professional or Representative?" *Hastings Center Report* 5, no. 5 (October 1975): 31-40.

[379]National Institutes of Health, Office of the Director, Office of Medical Applications of Research, *Guidelines for the Planning and Management of NIH Consensus Development Conferences* (Bethesda, MD: National Institutes of Health, 1995): 2. National Institutes of Health, 45 CFR 46, §108.

important to recall the discussion about power from Chapters Two and Three. It is wrong to frame this concept in dyadic terms, that is, in terms of particular agents who have power over others who do not, or even in terms of specific places where power is located.[380] Power is best understood as structural, as a function of complex processes, not as a top-down tyranny by a ruling group. Again, it is "in the context of a network of practices" carried out by persons that power relations persist.[381] This view of power allows us to see that the injustice of the IRB system lies in its tendency - by virtue of its composition, placement, and deliberative aims - to reduce heterogeneity to unity and to constrain the capacities of those who are potentially subject to the consequences of research to express their experiences and determine their actions and the conditions of their actions. Despite aiming at subjects' protection, the decision-making process of the current system for ethical review perpetuates domination and oppression.

We are compelled, indeed, to question whether the IRB system is the mechanism best suited to play a principle role in the promotion of social justice, the quest to uphold the institutional conditions for the realization of self-development and self-determination in research. Despite its salutary role in advancing ethics in research, it reflects a quite different view of justice and of the process of critical moral thinking than that

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[380]Charles R. McCarthy, "Experience with Boards and Commissions Concerned with Research Ethics in the United States," in *Research Ethics*, ed., Kare Berg and Knut E. Tranoy (New York: Alan R. Liss, Inc., 1983): 112.

[381]Young, *Justice and the Politics of Difference*, 30-31.

offered by the understanding of social justice as enablement. With the displacement of impartiality as the hallmark of moral reason, ethical review of human subjects research - particularly that which includes and/or focuses upon oppressed groups - requires alternative forums and procedures for deliberation.

TRANSFORMATIVE DISTRIBUTION AND JUSTICE IN RESEARCH

In Chapter Two I explored the relationship between the socioeconomic injustices to which women, particularly women of color, are subjected, and their access to and treatment within clinical research. The gendered division of labor between paid and unpaid work, and women's frequent joblessness and underemployment affect health care coverage, which in turn, has consequences for research participation. The history of and persistent potential for exploitation of poor women and women of color in research is yet another face of socioeconomic injustice. Such injustices are inextricably linked to cultural or symbolic ones: gender bias, racism, and other cultural regulatory norms are institutionalized in the economy, and the economic deprivation of cultural minorities inhibits their abilities to shape social and institutional norms and practices, make decisions and formulate policies. Diminished access to dominant channels of communication and inhibited self-esteem perpetuate both economic and cultural injustices.

The legislative and policy initiatives aimed at women's participation in research aspire to correct inequitable outcomes by allocating money for women's health research and mandating equitable numbers of positions for women in clinical trials. Such affirmative action efforts narrowly construe the requirements for justice in failing to attend to the social and institutional relations, processes, and structures that generate inequitable outcomes. They also underline existing differentiations, ostensibly revaluing women and other cultural minorities. Yet, in not challenging existing identities and differentiations formed under injustice, redistributive strategies perpetuate their stigmatization. As we have seen, many critics of women's health advocates' claims and the policy resolutions adopted argue that women have been and continue to be privileged in health care and research.

Social justice as enablement calls for a radical transformation of the very nature of the research enterprise, including its underlying systems of production and distribution. While its commitment to promoting self-development and self-determination certainly supports the allocation of subject positions for women in protocols and more equitable distributions of research funds, it also avows democratization and demedicalization of distributive structures, along with a restructured relation between the division of labor and research participation.

Reconceptualizing difference in a way that shows their bodies and social conditions to be no more unique than those of men allows us to

grant women the substantive opportunity to develop and exercise their self-determination within and beyond research. The proportion of women participating in particular studies or in programs of research should approximate the proportion of women who suffer from the disease, disorder, or condition, or who might be expected to use a particular class of drugs or some other medical intervention under investigation. In addition, sufficient numbers of women should be included to allow for analyses of effects or outcomes particular to women. Current initiatives aim for this ideal.

We have seen that the division of labor in society has profound implications for women's research participation. While challenging the gendered division of labor is a long term political effort, in the meantime it is possible to change the nature of the relationship between it and research participation. With respect to the division of labor between paid and unpaid labor, undermining the hindrances caregiving can place on women's access to research entails making provisions to support child care. Referral structures, furthermore, might be transformed so that there is less of a link between having a job with health benefits and getting into a clinical trial. Along with locations for conducting trials, referral pathways might become increasingly demedicalized, that is, organized so that they are not tied exclusively to health care institutions, but instead located in diverse contexts, like traditional and oppositional communities. In this way the mechanisms for distributing subject positions undergo

transformation. The community outreach efforts for recruitment and retention are premised on this idea, seeking women who do not present through the usual channels. Not accompanied by the democratization of decision-making, though, these efforts fail to challenge injustice. Given the potential for coercion among poor women to seek out clinical trials to obtain health care services, it is particularly important for the realization of justice to follow stringent consent guidelines and to involve them at all levels of decision-making. This will undermine the potential for exploitation and make it more likely that the research they are engaged in (and not just the care provided therein) will be of specific benefit to them.

In keeping with the ideal of communicative democracy, structures for investment in clinical research warrant democratization. Within public institutions, women - not just those who are scientifically trained and credentialled, but also representatives of diverse communities and social groups - should participate in decisions concerning research funding. Moreover, broadened conceptions of what constitutes credibility should be invoked to avoid privileging only career scientists. Even further, grants from collaborative researchers should receive more recognition. Private industries, including those producing medical drugs and devices and managed care organizations should also include divergent communities of women in their efforts to develop and finance research that affects them.

The response to industry representatives and researchers who maintain that the inclusion of women is a risky and excessively costly

venture is a reminder of the purpose of research: to establish what are safe and effective therapeutic interventions for the public. While time and cost-effective drug and device development surely serve the public interest, neglecting to obtain the information necessary for determining if interventions are safe and efficacious do not. To exclude women at any phase of research is to fail, then, in upholding the commitment made by research institutions, and ultimately, to deny what is owed to women.

We might further invite these critics to consider the cost savings that might accrue from the conduct of research that, through studying women, more effectively promotes their health, and thus decreases morbidity and mortality. When the knowledge that emerges from research is not clearly applicable to women, in other words, society may incur more costs, in terms of health care services, disability benefits, as well as loss of time away from work, be it caregiving, work in the paid labor force, or more likely, both.

Too, other ways of cutting costs can be pursued. Evidence suggests, for example, that research institutions sometimes seek to increase their share of Federal funds by providing inflated assessments of what it costs them in overhead to conduct projects.[382]

Yet another redistributive step is to transform the basic structures that deliver the results of clinical research. Not only can collaboration

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[382]Elisabeth Rosenthal, "N.Y.U. Hospital Settles Case on Research Billing Charges," *New York Times* (8 April 1997): A 1, 11.

between researchers and members of the lay public for generating research ideas occur in non-institutional contexts, but a conception of social justice aspiring to promote self-development and self-determination further supports the dissemination of research findings to non-scientific audiences in non-scientific media and social contexts. The sorts of communities discussed above as venues for the formulation of research agendas and projects may also serve as sites for discussion about and demonstration of new interventions.

A contemporary example of such efforts comes from debates over the distribution of AIDS drugs known as protease inhibitors (PIs). Found to inhibit the maturation of HIV and thus improve prognoses, PIs are under consideration for widespread use. Decisions about candidacy for the use of the drugs have sparked vitriolic debates among researchers, health care professionals and social service agencies, in light of the requirements for efficacy. The homeless and transient, and persons with mental illness, often called "non-compliant," may be hindered in the ability to take, over a prolonged period, multiple medications at different times, which variously require high fat meals, large quantities of water, and refrigeration. Public health departments and others have argued that the just course of action involves giving PIs to all those in need of treatment, and not just those under the care of a personal physician who have ample social amenities. Rather than excluding the so-called "non-compliant" from the pool of potential recipients, public health officials

and others are considering the conditions of their lives, and making provisions to enhance their potential to see a delay in the progression of infection, a reduction of symptoms, and possibly enjoy longer lives. Drug therapy is combined with efforts to secure housing, food, and, through using lay people and social institutions other than clinics and hospitals, the mechanisms for drug distribution are demedicalized.[383]

For women, particularly those who are similarly constrained by the social conditions of their lives, such strategies can serve as a model for strengthening adherence to the requirements for research participation or benefiting from emergent drugs and devices. The provision of social supports and the demedicalization of research sites and knowledge dissemination settings, while requiring additional resources, can better enable women to participate in clinical trials, reap the benefits of results, and promote their self-development and self-determination. The ideals of social justice as enablement suggest that we come to regard the sphere of research as interrelated with the contexts of women's lived experience, as mutually reinforcing and not in competition. We can, therefore, aspire to recognize and incorporate, not ignore and exclude, the values, needs, and knowledge that resides there.

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[383]Joe Neel, "Protease Inhibitors, AIDS, and the Homeless," reported on All Things Considered, National Public Radio, November 1996.

CONCLUSION: THE EVOLUTION OF JUSTICE IN HUMAN SUBJECTS RESEARCH

Early efforts at normative reflection on the ethics of human subjects research reflect the social and historical period in which they arose. From within a post World War II industrial capitalist moral universe governed by protectionism and an economic growth imperative that emphasized the accumulation of wealth and the expansion of markets, emerged a policy structure aimed at preventing, or at least mitigating, the exploitation of subjects, and insulating industry from expense. While women have taken research institutions to task for their restricted commitment to justice, the resolutions generated from within the system they critique cannot capture the soul of justice. Lacking the conceptual resources necessary to identify, challenge, and, where appropriate, erode social and institutional structures that inhibit women's potential to flourish, to reflect upon, express, pursue, and accomplish their goals, they cannot successfully cultivate the conditions that might nurture its realization. The scope of justice, in sum, continues to be narrow in this contemporary context.

There is, however, a zeal among women and other oppressed groups to break free from the confines of distributive frameworks and the grander web of assumptions and lines of inquiry liberal capitalist values weave around thinking about justice. Although the realm of research is arguably a showcase for the accomplishments of a free society, as I have tried to demonstrate here, the structures, relations, and processes that give it form reflect and reinforce domination and

oppression, inhibiting the development and exercise of persons' capacities. We are therefore challenged to theorize anew, to envision, articulate, and act upon a conception of justice for research that reckons with socioeconomic and cultural injustices. There is potential for justice latent in research institutions, and aided by the insights of social justice as enablement we may yet see it realized.

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