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WOMEN'S HEALTH RESEARCH IN CANADA: FEMINIST CHANGE IN A MURKY ZONE OF LAW, MEDICINE AND POLITICS

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ABSTRACT

The general aim of this paper is to explore the relationship between law and the potential for social change in the context of women's health. More specifically, I will critically examine the arguments made by Canadian feminists about the need for change in the ways that health research is structured and carried out in this country, particularly with respect to the generation of knowledge about women's health.

Part one of this analysis examines the nature and extent of the problem of gender-biased research. It is followed by an overview of the regulatory framework within which health research is currently conducted in Canada. The third part of this discussion provides a feminist analysis of the major arguments raised by those who seek to maintain the exclusionary status quo. Part four reflects upon the impact of political action for change taken by women's health activists. Recognizing that Canadian feminists have, to date, been more successful in influencing change through public activism in the political arena than through efforts to work within the dominant research institutions, the paper concludes with a brief assessment of the prospects for legislative intervention.

I. INTRODUCTION

Striking parallels exist between the histories of the Western institutions of law and medicine in terms of dominant underlying values and styles of discourse. Linear rationality and repeatability of results are key doctrines in the methodologies of both. Other shared features include an

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unquestioned commitment to positivism, a belief in objectivity and the ability to locate absolute truth through reasoned inquiry, the centrality of the rational individual, and views of civilized society as opposite to a violent state of nature. Similarly, one particular set of interests has been overwhelmingly represented throughout the rise of both institutions: the privileged social class of wealthy and highly educated white men.

Many feminists contend that liberalism, which forms much of the ideological basis upon which both law and medicine are founded, has played a critical role in the construction of patriarchy in Western societies. Feminists have pointed to writings by influential liberal thinkers which espouse a fundamental belief that the female body is inherently pathological, such that "...women's bodies, women's minds, and women's natures are essentially and dangerously inferior to those of men."¹ Women's unique reproductive capacity was central to this notion.

The concept of women as other – distinct from and less natural than men – has been a powerful and enduring concept. For example, as recently as 1979 the Supreme Court of Canada ruled that a federal law distinguishing pregnant persons from non-pregnant persons did not constitute unequal treatment of women and men. *Bliss v. Attorney-General of Canada*² illustrates the extent to which social inequality and scientific notions of biological difference are inter-related in traditional, androcentric legal thinking:

...[T]he Supreme Court used maleness as the standard against which pregnant women were compared. The absence of an analogous physical condition or equivalent life experience to pregnancy for men meant that there were not two similarly situated groups that could be compared to determine whether there was equal or unequal treatment. In doing so, they used the male body as the inarticulate major premise and differential treatment and special burdens could be imposed on women without there being any formalistic 'inequality.'³

¹ K. Pauly Morgan, "Contested Bodies, Contested Knowledges: Women, Health, and the Politics of Medicalization" in *The Politics of Women's Health; Exploring Agency and Autonomy* (Philadelphia: Temple University Press, 1998) 83 at 102 [hereinafter *Exploring Agency and Autonomy*].

² [1979] 1 S.C.R. 183. This approach to equality was overturned by the Supreme Court of Canada in *Law Society of British Columbia et al. v. Andrews et al.*, [1989] 1 S.C.R. 143 [hereinafter *Law Society*].

³ S. Martin, "The Control of Women through Gender-Biased Laws on Human Reproduction" in R. Devlin, ed., *Canadian Perspectives on Legal Theory* (Toronto: Emond-Montgomery, 1991) 291 at 297.

This formalistic approach to equality rights is central to the classic liberal vision of a fair society in which, as the *Bliss* case suggests, male experience is held to be the norm.

Fortunately, Canadian courts have now rejected formal equality as incompatible with social values in the *Charter* era and a more substantive concept of equality has emerged.⁴ Nonetheless, the idea that all individuals should be treated similarly, regardless of differing social realities, remains an appealing, deeply-rooted principle in this society where a liberal-democratic ethos is the dominant paradigm. Subsequently, and to a certain degree inescapably, liberalism tempers gender relations in all Canadian social contexts. The health care arena is no exception.

The general theory advanced by many feminists is that sexist presumptions are an inherent feature of traditional medical scientific discourse and continue to exert significant influence upon decision-making in health research. Many of the questions and problems historically identified as medically important (with the critical exception of female reproductive capacity), as well as the investigational approaches used to study those questions and problems, have tended to focus exclusively on the male half of the human species. A large knowledge gap exists as a result of this approach: comparatively less is known about women's health, beyond the limited scope of reproduction, than is known about men's experiences with health and disease. Consequently, women are frequently exposed to inappropriate, ineffective, and potentially dangerous medical interventions and information.

My own analysis of the situation is that the feminist position on this apparent inequity has gained a large measure of public credence, which has been reflected in a variety of political successes. The prospect for meaningful systemic change towards more equitable research practices is heavily constrained, however, by structural features of the medico-legal framework within which research is regulated in Canada. More particularly, the lack of a cohesive regulatory regime means that accountability for how public research monies are invested is highly diffuse; individual researchers, funding councils, and the pharmaceutical industry essentially hold the reins in determining the extent to which

⁴ *Law Society*, *supra* note 2.

women's health concerns are reflected in the research agenda. At present, research regulation is a murky zone of law, medicine, and politics and the diffusion of accountability makes it exceedingly difficult to dispel widespread, deeply-rooted "scientific" myths about the concept of women's health and its social value in contributing to social equality. I propose that this state of affairs is highly incompatible with Canada's commitments to advancing women's equality and that legislative intervention is essential to overcoming the structural barriers to change.

II. NATURE AND EXTENT OF THE PROBLEM OF EXCLUSIONARY RESEARCH PRACTICES

'Women aren't just asking for pink walls, a warm speculum and kinder doctors.' In fact, we're not asking, at all. We are engaged in a political fight for shared knowledge, for collective power, for health, for bodily integrity – for ourselves, our communities, and our world.⁵

Calling attention to male-biased research norms is part of the broader women's health movement through which feminists seek to challenge the legitimacy and paternalism of institutionalized medical science. The dominant medical paradigm understands health to be simply the absence of disease. Feminists like Margaret Lock⁶ and Ruth Macklin⁷ are critical of this model and its view of human bodies as narrow entities whose health status is determined by nature-given physiological and genetic features. Rooted in 19th century reductionist theories of biology, the disease-based construct ignores the potential impact of social dynamics upon an individual's experiences with illness and health. Consequently, reproductive capacity is seen to be the only substantive difference leading to varying health experiences between men and women. This focus on disease fosters a competitive, highly

⁵ Pauly Morgan, *supra* note 1 at 115 (citing P. Williams, "Sick of Dying: Neglect, Misinformation, and Gender Bias have Festered Unchecked in Women's Health Care" *Homemaker's Magazine* (November/December 1996) 46 at 49.)

⁶ "Situating Women in the Politics of Health" in *Exploring Agency and Autonomy*, *supra* note 1, 48.

⁷ "Women's Health: an Ethical Perspective" (1993) 21:1 J. Law, Med. & Ethics. 23.

technologized race to locate, within the body, ultimate sources of disease causation in order to develop successful treatment interventions. There are enormous financial stakes in the race to provide cures and halt disease progression. Thus, any attempt to uproot the disease model or cross-pollinate it with alternative models will face considerable resistance.

Feminists are not alone in pointing to the errors inherent in the biomedical disease-based model of health. In 1981 the World Health Organization (WHO) enunciated a broader alternative concept known as the determinants model. Health was accordingly redefined as “a complete state of physical, mental and social well-being, not simply the absence of disease or infirmity.”⁸ Recognition of a political dimension to the relative health of individuals and social groups is a key aspect of the feminist divergence from the disease model of health.

The gendered lines of oppression in societies are reflected in patterns of how women are treated by the health care system both as patients and as active participants, and the determinants approach is expanded to include gender as a determinant of health. In much the same way, the marginalization that occurs through racism in Canadian society is an important health determinant. From the determinants perspective, the experience of multiple discrimination in society will often be reflected in reduced health status among women of colour. In a significant departure from the traditional reproduction-centred view, feminism reconceptualizes women’s health as involving “...women’s emotional, social, cultural, spiritual and physical well-being, and it is determined by the social, political and economic context of women’s lives as well as by biology.”⁹ Women-specific health information, generated through research, is seen as critical to improving both the well-being and relative social equality of women. In addition to reconstructing the definition of health and calling for more information to reflect women’s health interests, feminists contend that traditional research methods themselves are fundamentally biased.

⁸ *Ibid.* at 24.

⁹ National Forum on Health, “An Overview of Women’s Health” in *Canada Health Action: Building on the Legacy* Vol. II (Ottawa: National Forum on Health) 3 (citing S. Phillips, “The Social Context of Women’s Health: Goals and Objectives for Medical Education” (February 1995) 154:4 *Canadian Medical Association J.* at 507) [hereinafter National Forum on Health].

1. Manifestation of Gender Bias in Research

According to feminist sociologist Margrit Eichler, bias against women as subjects in the research process manifests in four main ways: androcentrism; overgeneralization; gender insensitivity; and the use of double standards.¹⁰ A review of international articles published in 1989 by the *New England Journal of Medicine* found, using Eichler's framework, that 80% of original research articles published in that year contained at least one form of gender bias.¹¹

Androcentricity involves a presumptive reliance on the male paradigm or male-centered world view, which most often means that women are consciously excluded from subject populations. This has the effect (intended or otherwise) of pre-emptively eliminating any potential findings of difference in results between men and women. In so doing, women's different biological and social realities that impact on health status are rendered invisible.

Overgeneralization of findings often follows from androcentric research designs. In such instances, study results are presented in a universally applicable manner, while in fact it is unknown whether such is true because the study was conducted entirely on one gender (usually male). The double standard bias involves "...evaluation, treatment, or measurement of identical behaviours, traits, and situations by different means."¹² One of the best known examples of this biased approach was seen in early findings from the Framingham Heart Study (a long-term continuous study started in 1948).¹³ Initially, researchers simply dismissed complaints of chest pain among female subjects as essentially harmless, in contrast to similar complaints by male subjects, which were deemed highly significant. The different treatment stemmed from the presumption that the male subjects were more likely than the female subjects to experience heart attacks and sudden death as a result of their

¹⁰ L. Wallis, "Why a Curriculum on Women's Health?" in A. Dan, ed., *Reframing Women's Health: Multidisciplinary Research and Practice* (Thousand Oaks, Calif.: Sage, 1994) [hereinafter *Reframing Women's Health*]; also cited by Y. Lefebvre, *Women's Health Research in Canada* (Ottawa: Health Canada, 1996) (paper prepared for the Canada-USA Forum on Women's Health).

¹¹ K. Williams & E. Borins, "Gender Bias in a Peer-Reviewed Medical Journal" (1993) 48 J. American Med. Women's Assoc. 160 (cited by Lefebvre, *ibid.* at 6).

¹² *Reframing Women's Health*, *supra* note 11 at 19

¹³ B. Healy, *A New Prescription for Health; Getting the Best Medical Care in a Man's World* (New York: Penguin, 1995) at 332-333.

chest pain. This was consistent with prevailing opinions that heart disease was a man's disease and that women were hypochondriacs. Subsequent research concluded, however, that women's chest pains are indeed indicative of very real, potentially dangerous heart conditions that are not typically seen in men. By applying a double standard to the early reports from research subjects, the Framingham researchers had essentially validated the existing myths by applying a "scientific proof" label.

2. Pervasiveness of Bias in Canada

As the *New England Journal of Medicine* study indicates, the extent to which gender bias pervades medical research is significant. While no parallel study has analyzed the contents of Canadian medical journals, gender biased research appears to be the norm in this country. In 1994, the Advisory Committee on Women's Health to the Medical Research Council of Canada (MRC, the largest source of federal research funding) attempted to assess the extent to which it historically funded women's health research. Problems associated with data availability, definition of research designs, interpretation of findings, and unrecorded research activities made it clear that the MRC lacked the capacity to accurately review the gender dynamics of the research it had itself funded.¹⁴ Interestingly, the MRC study determined that roughly 5% of its funding was invested into women's health issues while a similar study of research funding led to the estimate that 7% of funding was directed towards men's health issues. As Lefebvre notes, "[t]hese figures of course imply that the remainder of the research funded is general neutral, which is probably inaccurate."¹⁵ Such findings suggest that gender insensitivity and other forms of bias exist in 88% of MRC funded research.

An important overall trend, moreover, is the fact that the vast majority of funded research with an explicitly gendered approach focuses exclusively on reproductive matters. This reflects the pre-eminence of a reproduction-centered view of women's health. Analysis of research funded in 1994-95 by the National Health Research Development Program (NHRDP) revealed that 70% of its total investment in women's

¹⁴ Lefebvre, *supra* note 11 at 4-5.

¹⁵ Lefebvre, *supra* note 11 at 6.

health issues went to reproductive studies, a broad category which included investigations into the health of newborn infants (a group which hardly fits into the category of 'women' at all).

3. Implications for Women

Generally, the impact of systemic marginalization of women in health research results in skewed treatment of some health problems and non-treatment of other concerns peculiar to women that have not been taken seriously by the health care establishment.

Specific examples abound. In 1977-78, for instance, Canadian feminists Leah Cohen (a social scientist) and Constance Backhouse (a lawyer) identified the following disturbing patterns:¹⁶

- overmedication of women, particularly with mood-altering drugs,
- high rates of unnecessary surgeries on the women, in particular hysterectomies, breast surgery, and cesarean section births,
- estrogen replacement therapy targeted to women pathologized simply by virtue of going through menopause,
- the frequency of crisis-oriented, technology-managed hospital births along with the absence of 'legitimate' alternatives such as home births,
- suppressed information about the legality of abortion, hospital-introduced delays and quotas, and restricted access to abortion services, and
- negligence, avoidance, and trivialization of female rape victims by many physicians and health care professionals in emergency rooms.

In 1998, Morgan contended that all of these patterns remain relevant concerns for Canadian women.¹⁷

Particular attention has been directed towards the situation of women as consumers of pharmaceutical products that have been tested only on male subjects in clinical trials. Despite the reasons suggesting

¹⁶ "Women and Health: the Growing Controversy" 1:4 Can. Women's Studies 4-10 (cited by Morgan in *Exploring Agency and Autonomy*, *supra* note 1 at 83.)

¹⁷ *Exploring Agency and Autonomy*, *supra* note 1.

that the conventional approach of testing drugs on men and generalizing the results to women may not be effective or appropriate, this has long been a widespread norm in Canada,¹⁸ as elsewhere. As will be discussed below, some recent change has been seen at the federal level through introduction of the *Guidelines on Inclusion of Women in Clinical Trials*¹⁹ under the auspices of the *Food and Drugs Act*.²⁰

III. REGULATION OF HUMAN EXPERIMENTATION IN CANADA

In Canada, research involving human subjects is a quasi self-regulating industry that operates within a broad legal framework but under few specifically directed legislative provisions. Legal problems that arise in relation to questionable research practices can be addressed through a wide variety of mechanisms including courts of law (in cases where criminal charges are laid or civil actions for damages are pursued), public administrative bodies (research funding organizations, for instance), or professional associations' internal disciplinary proceedings.²¹ In practice, administrative bodies make most decisions stemming from potential legal quandaries and courts of law are used only in rare circumstances. The true locus of accountability for research involving human subjects in Canada is the individual research ethics boards (REBs) which are located in virtually every institution where research takes place. These committees do not look to laws but rather to codes of ethics, guidelines, and policy statements for guidance when dealing with quandaries in human research.

1. Federal Statutory Provisions

In an extremely general sense, the provisions of the *Criminal Code*²² can be presumed to apply to researchers in the same general sense that

¹⁸ National Forum on Health, *supra* note 10 at 4.

¹⁹ *Inclusion of Women in Clinical Trials, Therapeutic Products Programme Guidelines* (Ottawa: Health Canada, April 1997).

²⁰ R.S.C. 1985, c. F-27.

²¹ Law Reform Commission of Canada, *Biomedical Experimentation Involving Human Subjects* (Working Paper 61) (Ottawa: LRCC, 1989) at 7.

²² R.S.C. 1985, c. C-46.

the criminal law applies to all Canadians.²³ Verdun-Jones and Weisstub contend that researchers generally overlook the potential impact of criminal law in the research context and focus instead on avoiding civil litigation.²⁴ No record has been found of criminal charges being laid under Canadian law against any researcher engaging in human experimentation. The criminal law plays a minute and peripheral role in ensuring acceptable standards of research involving humans.

The Law Reform Commission of Canada (LRCC) has recommended a series of general amendments to the *Criminal Code* to make it more relevant to research activities. Among the numerous reasons cited as evidence of a need to amend the criminal law, the LRCC contends that there should "...be consistency of thought and action..." among provinces with respect to research standards of conduct.²⁵ As this reasoning indicates, the lack of a national legal framework and corresponding diffusion of authority for decision-making in human research has led to substantial variance in ethical norms across the country.

The federal *Food and Drugs Act*²⁶ and accompanying regulations govern the introduction of new pharmaceutical products to the Canadian consumer market. The legislative scheme specifies the conditions that manufacturers must meet prior to distributing new pharmaceutical products to researchers for clinical testing, which is a prerequisite to obtaining government consideration for approval of a new drug.²⁷ "These conditions provide a basic level of protection for experimental subjects who agree to have new chemical substances tested on them. The regulations also stipulate that researchers must strictly monitor the use of medications, indicate any serious incidents resulting from their administration, and submit a detailed report."²⁸

²³ While generally applicable, the *Criminal Code* makes no express or implicit reference to medical research in any of its provisions. Among other recommendations, the LRCC has said that "The *Criminal Code* should be amended by the addition of a provision which excludes from offences against bodily integrity those cases of non-therapeutic biomedical experimentation in which free and informed consent is properly obtained and the risks incurred are not disproportionate to expected benefits.": LRCC, *supra* note 22 at 35.

²⁴ "The Regulation of Biomedical Research Experimentation in Canada: Developing an Effective Apparatus for the Implementation of Ethical Principles in a Scientific Milieu" (1996-97) 28:2 Ottawa L.R. 297 at 305.

²⁵ LRCC, *supra*, note 22 at 59.

²⁶ *Supra* note 21.

²⁷ LRCC, *supra* note 22 at 12.

²⁸ LRCC, *supra* note 22.

Canada's only formal regulatory statement mandating the inclusion of women in any research context operates under the authority of the *Food and Drugs Act and Regulations*.²⁹ In April of 1997 Health Canada's Therapeutic Products Programme (TPP - also known as the Drugs Directorate), which administers and evaluates new drug submissions from industry, established *Guidelines on Inclusion of Women in Clinical Trials*. The *Guidelines* establish that sponsors of clinical drug trials must enroll both men and women "...in the same trials in numbers adequate to allow detection of clinically significant sex-related differences in drug response."³⁰ Where significant differences are found to exist, researchers will be required to develop gender-specific prescribing information and warnings before the drug can be approved for marketing. While there are no formal penalties for failure to adhere to the *Guidelines*, certain administrative incentives within the TPP encourage compliance among drug trial sponsors: "It's in their best interest as the review can take much longer if we ask them for information they don't have on file or better yet, in their submission."³¹

The creation and implementation of these *Guidelines* within the *Food and Drugs Act* regulatory scheme is a significant development and is largely attributable to the advocacy work of women's health activists.³² It is important to appreciate, however, that it operates exclusively in relation to government approval of new pharmaceutical products – which is only one feature of the much larger research landscape.

2. Provincial Provisions

Interestingly, despite an apparently high level of anxiety within the research community about the potential for private action,³³ Canadian casebooks have reported very few civil actions for damages incurred in

²⁹ LRCC, *supra* note 22.

³⁰ *Supra*, note 20 at 2. Note, however, the subsequent proviso: "In some cases, however, it may be appropriate to conduct studies in a single sex (e.g., to evaluate the effects of phases of the menstrual cycle on drug response).

³¹ A. Goldstein, Health Canada (Therapeutic Products Programme) personal communication, October 26, 1999 (on file with author).

³² F. Baylis, J. Downie & S. Sherwin, "Reframing Research Involving Humans" in *Exploring Agency and Autonomy*, *supra* note 1 at 238.

³³ Verdun-Jones & Weisstub, *supra* note 25; V. Merton, "The Exclusion of Pregnant, Pregnable, and Once-Pregnable People (a.k.a. Women) from Biomedical Research" (1993) XIX:4 Am. J. Law & Med. 369 at 400.

the course of research. Of the small number that are reported, only two arose in the direct context of formal research projects;³⁴ several other cases relate to damages arising where practitioners have administered innovative or novel treatments that the professional mainstream viewed as untested and unsound.³⁵ In all instances, the primary issues related to the information provided by the researcher prior to the participant's decision to consent.

From the caselaw, it is clear that the relevant standard of disclosure increases sharply when a medical intervention is deemed to have a strongly experimental component. In cases where the intervention has no intended potential direct to the participant (i.e. the intervention is "non-therapeutic"), the participant's consent will not be held as valid unless it was granted after all risks, no matter how remote, were disclosed.³⁶ This is, however, virtually all the information provided by Canadian caselaw regarding the legal duties owed by medical researchers in respect to prospective research subjects.

The province of Quebec is the only jurisdiction in Canada to have enacted specific legislative provisions regulating activities relating to human experimentation. In response to quandaries arising in conjunction with early heart transplantation procedures, sections 18 to 25 were added to the chapter on "Enjoyment of Civil Rights" in the *Civil Code* (CCQ). Like the common law elsewhere in Canada, these provisions held that the major legal requirements for research on humans were that the subjects provide free and informed consent and that the risks of harm must not outweigh the anticipated benefits of participation.³⁷ Unlike the common law, however, the CCQ goes further and establishes specific requirements for research involving children and adults who lack capacity to consent.³⁸ These provisions further provide a statutory basis of authority for institutional research ethics boards to judge the ethical soundness of research activities in the province of Quebec.

³⁴ *Halushka v. University of Saskatchewan et al.* (1965), 53 D.L.R. (2d) 436 (Sask. C.A.) [hereinafter *Halushka*]; *Weiss v. Solomon* (1989), 48 C.C.L.T. 280 (Que. S.C.) [hereinafter *Weiss*].

³⁵ *Cryderman v. Ringrose* (1978), 89 D.L.R. (3d) 32 (Alta S.C.); *Zimmer v. Ringrose* (1981), 28 A.R. 69 (C.A.); *Coughlin v. Kuntz* (1987), 17 B.C.L.R. (2d) 365 (S.C.)

³⁶ *Halushka*, *supra* note 35; *Weiss*, *supra* note 34.

³⁷ LRCC, *supra* note 22 at 13.

³⁸ Art. 21 C.C.Q.

³⁹ Verdun-Jones & Weisstub, *supra*, note 25 at 317.

3. Research Ethics Boards and the Ethics Review Process

Outside of Quebec, REBs do not operate under any enabling legislation but rather under the by-laws and policies of the hospitals, universities and other organizations in which REBs are housed. REBs "...have no independent power to require that research protocols involving human subjects be submitted to them for prior approval."³⁹ Public funding agency rules provide the most compelling practical source of authority for the REB role in research review in Canada. The Canadian Institutes for Health Research (CIHR, formerly the Medical Research Council of Canada), the Social Sciences and Humanities Research Council (SSHRC), and the Natural Sciences and Engineering Research Council of Canada (NSERC) are the country's largest sources of public funding for research in those respective fields. They stipulate that they will only fund research initiatives that are approved by an REB in an institution that has certified compliance with the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans*.⁴⁰

The general procedure for ethical review is similar in public institution-based REBs throughout Canada.⁴¹ Before a researcher commences research activities on human subjects, he or she first submits a research protocol describing the project's proposed purpose, methodology, and safety precautions to the REB of the institution or facility where the research will take place. After an ethical and scientific review is completed, the REB typically approves the protocol, approves it with specified modifications, or disallows it altogether.⁴² A 1995 study found that among the one hundred REBs associated with medical schools in Canada, all approve most protocols submitted for review and request only minor modifications.⁴³ While the terms of reference of many REBs indicate a responsibility for on-going monitoring, the reality is that due to intense resource constraints, the monitoring function has traditionally

⁴⁰ Medical Research Council of Canada, Natural Sciences and Engineering Research Council of Canada, Social Sciences and Humanities Research Council of Canada, (Ottawa: Agency, 1998) at i-1 [hereinafter *Tri-Council Policy Statement*].

⁴¹ F. Baylis et al. eds., *Health Care Ethics in Canada* (Toronto: Harcourt Brace, 1995) at 322.

⁴² *Ibid.*

⁴³ The NCBHR study found that 22% of submitted protocols were approved as first presented, 75% were approved with minor modifications, and 3% were rejected outright (in Verdun-Jones & Weisstub, *supra* note 25 at 322).

been often minimal or non-existent.⁴⁴ This pattern should change, however, as the Tri-Council Policy Statement now expressly requires continuing review processes for research projects that are over one-year in duration and those that are seen to pose significant risks.⁴⁵

Numerous critics have questioned the ability of this model of monitoring to ensure that socially acceptable standards of conduct are upheld in research involving human subjects. A 1995 report by the National Council on Bioethics in Human Research (NCBHR) found that Canadian REBs exercised review powers over almost all of the research initiatives being undertaken within their host institutions. The NCBHR report further found that the existing review model is under-inclusive, however, in that it provides no assurance that research outside the scope of an REB's institutional authority will be reviewed for consistency with acceptable standards of conduct.⁴⁶ There is no formal requirement that privately-funded research conducted outside of hospitals and universities be subject to ethics review or, moreover, be required to conform with accepted ethical norms.

Further questions about the effectiveness of this model relate to the sanctions that can be imposed for non-compliance with REB recommendations. Given the lack of statutory authority, the primary sanctions available are withholding of grant monies and denial of opportunity to publish in some international medical journals.⁴⁷ The Law Reform Commission has spoken on this point as well, positing that in addition to amending the *Criminal Code*,⁴⁸ the Parliament of Canada should enact general legislation on human research that prescribes state-sanctioned penalties for non-compliance.⁴⁹ Furthermore, the Tri-Council Policy Statement requires institutions to vest their REBs with authority to withdraw initial approval and effectively halt research projects when it is determined that unethical practices are occurring.⁵⁰

⁴⁴ Verdun-Jones & Weisstub, *supra* note 25 at 325.

⁴⁵ *Tri-Council Policy Statement*, *supra* note 41 at 1.10.

⁴⁶ Verdun-Jones & Weisstub, *supra* note 25 at 320.

⁴⁷ M. Fox, "Research Bodies: Feminist Perspectives on Clinical Research" in S. Sheldon & M. Thomson, eds., *Feminist Perspectives on Health Care Law* (London: Cavendish, 1998) 115 at 120-121 [hereinafter: *Feminist Perspectives on Health Care Law*]; Verdun-Jones & Weisstub, *supra* note 25 at 327.

⁴⁸ *Supra* note 23.

⁴⁹ LRCC, *supra* note 22 at 59.

⁵⁰ *Tri-Council Policy Statement*, *supra* note 41 at Art. 1.2.

Another set of concerns surround the dual function most REBs serve in reviewing and assessing the soundness of both the scientific and ethical dimensions of proposed research projects. The main problem is that REBs have generally been “dominated by scientists and researchers, even though the fundamental ethical issues facing the REBs cannot be resolved by applying an exclusively scientific or technological expertise.”⁵¹ The Tri-Council Policy Statement now mandates that REBs must have a broad membership, including both men and women. The minimum requirement is that each REB must have two members with research expertise, one who is “knowledgeable in ethics”, one who is “knowledgeable in the relevant law”, and one who is not affiliated with the REB’s institution but represents the community that is served by the institution.⁵² While this is an important development in theory, it is hard to ascertain its practical implications. In the past, where lay members have been encouraged to participate in ethics review, they have tended to be disempowered. Lacking research expertise, they have often been “...dependent of researchers for information regarding research practices.”⁵³

4. Codes of Ethical Conduct in Human Research

When ethical questions emerge in the course of a protocol evaluation, REB members consult codified statements of ethically acceptable conduct. While some universities and research institutes have developed their own internal Codes or Guidelines, the most influential statements in Canada have emanated from the Medical Research Council (now CIHR). Unfortunately, with respect to the issues surrounding inclusion of women in research, the *Tri-Council Policy Statement* does more to create uncertainty than provide guidance.

Research ethics codes reflect formal repudiation of medical science’s tradition of exploiting oppressed peoples for research purposes. For example, enslaved black women and poor white women were subjected to experimental gynaecological surgery in the United States in the nineteenth century, with one woman known to have survived thirty

⁵¹ Verdun-Jones & Weisstub, *supra* note 25 at 323.

⁵² *Tri-Council Policy Statement*, *supra* note 41 at 1.3.

⁵³ Fox, *supra*, note 48 at 121

separate invasive procedures.⁵⁴ While it was long customary for researchers to use people in disadvantaged social classes for experimental purposes, international moral opprobrium was voiced for the first time during the post-war Nuremberg trials.

Codifying the major principles of consensus has not, however, put an end to exploitative research practices. Subsequent transgressions gaining international notoriety since the Nuremberg Trials have included: the Tuskegee Study where standard antibiotic treatment for syphilis was withheld, for a forty year period, from four hundred infected black men and⁵⁵ the Jewish Chronic Disease Hospital in Brooklyn where patients suffering from chronic debilitating conditions were involuntarily injected with live cancer cells as part of a cell rejection-rate study.⁵⁶ The dominant approach to research ethics, which is reflected in the *Tri-Council Policy Statement* and the earlier MRC Guidelines, primarily aims to curb abuses like these where people are deliberately misled or involuntarily recruited to serve as research subjects. To this end, mainstream research ethics emphasizes the fundamental value of individual rights to autonomy, dignity, and bodily integrity.

Feminist bioethicists concur that all individuals must be free to refuse to participate as research subjects and that the potential harms should not outweigh the potential benefits of agreeing to participate. However, feminists diverge from traditional bioethics literature, when they draw attention to the gender dynamics inherent in both the underlying theory and the patterns that emerge through practical adherence to the mainstream principles. The principle of autonomy, for instance, is generally thought of in a highly individualistic manner, focussing mainly on the potential research subject's relative freedom to refuse to participate as a research subject. This approach effectively removes from consideration the social context which influences how potential participants exercise their power to choose. "Rather than just asking whether research subjects truly understand all relevant details about their involvement (a question we still consider important), we argue that questions must also be asked about who is invited to participate and who

⁵⁴ S. Harding, *Whose Science? Whose Knowledge?* (Ithaca, N.Y.: Cornell University, 1991) at 204.

⁵⁵ S. Sherwin, *No Longer Patient: Feminist Ethics and Health Care* (Philadelphia: Temple University, 1992) at 162-163 [hereinafter *No Longer Patient*].

⁵⁶ *Ibid.*

is not and how the specific research questions were selected.”⁵⁷ True to the form of its predecessors, the *Tri-Council Policy Statement* ignores these kinds of questions and retains the traditional emphasis on individual liberty rights.

The *Tri-Council Policy Statement* indicates in commentary passages that “[w]hether intentional or inadvertent, the exclusion of some from the benefits of research violates the commitment to societal justice.”⁵⁸ It continues to state that “distributive justice imposes on researchers and REBs a duty not to act in a discriminating fashion.”⁵⁹ Unfortunately, neither of these important principles is reflected in the formal Articles that follow.

Under the heading “Research Involving Women”, the *Tri-Council Policy Statement* provides one simple Article: “Women shall not automatically be excluded from research solely on the basis of sex or reproductive capacity.”⁶⁰ The accompanying narrative states some important principles but gives little in the way of concrete direction to REB members who may be struggling with the exclusion criteria in a particular research protocol.

Clearly, the *Tri-Council Policy Statement* is ill-equipped to assist REB members who make the ultimate decisions on issues relating to the inclusion of women in research. Given that this statement is the major source of rules for researchers operating with grants from CIHR, SSHRC, and NSERC, Canada’s largest public research funding agencies, its inadequacy is staggering. One cannot avoid concluding that the *Tri-Council Policy Statement* is complicit with the medical establishment’s traditional bias towards men’s interests over women’s interests in health and broader social equality.

⁵⁷ S. Sherwin, “A Relational Approach to Autonomy in Health Care” in *Exploring Agency and Autonomy*, *supra* note 1 at 39-40.

⁵⁸ *Tri-Council Policy Statement*, *supra* note 41 at 5.2.

⁵⁹ *Tri-Council Policy Statement*, *supra* note 41.

⁶⁰ *Tri-Council Policy Statement*, *supra* note 41 at 5.3.

IV. FEMINIST ANALYSIS OF JUSTIFICATIONS FOR THE EXCLUSIONARY NORM

Proponents of the traditional status quo in research generally raise four justifications when forced to defend practices that marginalize women. These are the need for scientific rigour and gender uniform data, prohibitive monetary expense, fetal protection and avoidance of potential liability. However these arguments favouring maintenance of the exclusionary status quo reveal the persistence of deeply and dangerously traditional views of women. None of these justifications for exclusionary research practices is tenable from a feminist perspective. These excuses do not reflect an interest in the promotion of women's health but rather in protecting the particular interests of the medical research establishment.

1. Locating the Roots of the Exclusionary Phenomenon

One explanation for the persistence of the liability-avoidance excuse is gender-biased misunderstanding of the informed consent doctrine within the research community. Justice Ellen Picard has observed that in the 1980s and 1990s, examples could still be found in Canada where doctors and hospitals refused to accept the consent of a woman to medical treatment, clinging to the belief that women and girls could not provide valid consent and that husbands and fathers were the more legitimate decision-makers.⁶¹ The underlying issue is general equivocation around women's autonomy rights and capacity to make reasoned healthcare decisions. This has been particularly evident in abortion debates.

In the 1989 case *Tremblay v. Daigle*,⁶² the Supreme Court of Canada overturned a lower court's injunction which prohibited a woman from obtaining an abortion on the grounds that her former common law partner objected. The Quebec Court of Appeal trivialized Ms. Daigle's reasons for seeking to terminate the pregnancy and devalued the harms she believed would result to her if the pregnancy were carried to term.⁶³

⁶¹ E. Picard & G. Robertson, *Legal Liability of Doctors and Hospitals in Canada*, 3^d ed. (Scarborough, Ont.: Carswell, 1996) 60.

⁶² [1989] 2 S.C.R. 530.

⁶³ Martin, *supra* note 3 at 305.

On appeal, the Supreme Court rejected this reasoning and held that a potential father does not hold a legal right to veto a woman's decision to terminate pregnancy. As this judgement clearly indicates, there is no legal requirement for medical professionals to seek consent from a woman's spouse or any other person prior to commencing any medical intervention. Uncertainty about the validity of autonomous consent by women to participate as medical research subjects may nonetheless continue to linger, particularly where researchers have a strongly paternalistic orientation towards potential fetuses.

The distrust shown by both legal and medical institutions in Canada in the ability of women to make autonomous decisions about their reproductive capacity, and their health more broadly, suggests outdated views of women as essentially non-rational beings who should be divested of power to control their bodies.

Exclusionary research practices may also reflect the idea that researchers and research funders attach priority to the health issues that they personally fear.⁶⁴ Given that researchers and those who make funding decisions have historically been men, the lack of attention directed to women's health (with the exception of women's reproductive capacities) makes sense. This is reinforced by the system of research funding. "Researchers do not pursue whatever projects come into their heads but those for which they can receive funding. Needing to attract grant money and produce results, they shape their research interests to serve the orientations of funding sources."⁶⁵ From this perspective, where key decision-makers are predominantly white, upper to middle class men, the research agenda can be expected to reflect the interests of that social group.⁶⁶

It is worth noting that while the number of women in the medical profession has grown considerably in Canada, women continue to hold fewer leadership positions than men do. Institutional priorities can subsequently still be seen as structured around gendered concepts despite the influx of women.

⁶⁴ Merton, *supra* note 34 at 373 cites US Congressional Representative Patricia Schroeder as saying, "[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."

⁶⁵ Sherwin, *No Longer Patient*, *supra*, note 56 at 17.

⁶⁶ Fox, *supra*, note 48 at 126; S. Rosser, "Gender Bias in Clinical Research: the Difference it Makes" in *Reframing Women's Health*, *supra* note 11.

Probably of more fundamental importance than the sheer number of women in medicine and research, however, is the dominance of scientific research methods that pose as gender-neutral while contributing to highly gendered health implications. One group of feminists writes:

Science is not a value-neutral activity in practice, nor should it aspire to be. The demands of disinterestedness do promote, not better science, but rather science that preferentially serves some interests and neglects others by blocking efforts to expose that fact by denying and thereby hiding the interests that are operative. When the determinate interests are those of the dominant group(s) in society, they seem to be both natural and general since they blend seamlessly with the cultural dominance of those groups in all spheres of activity. It is only when the particular interests of marginalized groups (i.e., those who are subject to oppression) that appear to be 'special interests' that threaten to contaminate otherwise 'pure' scientific methods.⁶⁷

This line of argument is a strong departure from the long-held view of scientific researchers as objective, value-neutral investigators.⁶⁸ Feminist standpoint theorists contend that knowledge, which represents the sum of a society's opinions and best beliefs, is unequivocally a socially-grounded phenomenon. Accordingly, knowledge-generators are seen as heavily influenced by the dominant social constructs of the milieu in which they function.⁶⁹ While this view of the role of the researcher is generally accepted in the social science disciplines, it is met with significant resistance from quarters of the research community that associate themselves with the so-called 'hard' or 'pure' positivistic fields. Thus, researchers identifying with the classic biomedical disease model of health are usually highly skeptical of feminist epistemological theory and extremely critical of the notion of a researcher as an active participant who influences the results of the research process.

In a revealing parallel, similar lines of debate are often heard within Canada's legal community regarding the adjudicative function. Since the 1970s, feminists have been instrumental in challenging the long-held view of the judge as a truly neutral arbiter.⁷⁰ While the standpoint approach to knowledge-as-truth and the use of knowledge in decision-

⁶⁷ Baylis, Downie & Sherwin, *supra* note 33 at 237.

⁶⁸ *Supra* note 33 at 236.

⁶⁹ Harding, *supra* note 55 at 302-303.

⁷⁰ N. Wikler, "Identifying and Correcting Judicial Gender Bias" in S. Martin & K. Mahoney, eds., *Equality and Judicial Neutrality* (Calgary: Carswell, 1987) at 254.

making has gained a certain level of credence on a theoretical level, there is marked discord over the practical implications of taking this jurisprudential approach.

The Supreme Court of Canada's four-way split decision in the 1997 case *R. v. R.D.S.*⁷¹ reflects the enormous degree of controversy surrounding the issue of socially contextualized decision-making on the bench. Accepting that judges must often incorporate untested presumptions about human and societal nature when making decisions, the contested issue today seems to be the extent to which (if any) these presumptions should be recognized and enunciated in a judge's formal reasons. Proponents of the traditional approach suggest that sphinx-like posturing is necessary and appropriate in many circumstances in order to avoid needless controversy which may bring the administration of justice into disrepute.⁷² This suggestion completely side-steps the argument that it is the status quo approach itself which has brought the administration of justice into disrepute and led to views of the system as catering mainly to the political and economic interests of dominant social groups. According to critical race theorist Carol Aylward, judicial silence about social context presumptions permits an unacceptable lack of accountability. Silence disallows opportunity to guard against reliance on myths and prejudicial beliefs infecting the decision-making process.⁷³

While Canadian legal commentators agree that unproven social context assumptions play a meaningful role in decision-making, there appears to be no agreement on the question of whether the administration of justice will be improved or compromised if judges are more explicit in sharing their untested views of social truth in the course of rendering decisions. In contrast, decision-makers in biomedical research seem less inclined to accept, even on a theoretical level, standpoint-based epistemological arguments about the relationship between social context and choices exercised in the course of research. While certain progress has been made in this area, particularly by women in the research field,⁷⁴ mainstream medical researchers and institutions have

⁷¹ [1997] 3 S.C.R. 484.

⁷² B. Archibald, "The Lessons of the Sphinx: Avoiding Apprehensions of Bias in a Multi-racial, Multi-cultural Society" 10 C.R. (5th) 54.

⁷³ "Take the Long Way Home": *R.D.S.* and Critical Race Theory" 41 U.N.B.L.J. 61.

⁷⁴ Harding, *supra* note 55 at 296-312.

not yet opened enough to enable feminist reframing of the knowledge-generating enterprise.

The purpose of this discussion has been to show that general notions of what constitutes 'good' decision-making in both the judicial realm and the realm of biomedical research place significant emphasis upon the role filled by individuals in key positions of authority. Feminists and other critical theorists have demonstrated that the long-prevailing view of decision-makers in both realms as purely objective and politically neutral is itself an inherently ideological position. By exposing this central fallacy, the notion of 'good' decision-making becomes contestable and the results of supposedly 'good' decisions can be more critically assessed.

V. ACTION FOR CHANGE

The women's health movement and its calls for more inclusive research practices have made an unmistakable impact upon federal health policy in Canada. As this section will show, however, it is uncertain whether the successes won through political channels will result in meaningful change at the substantive level, where basic decisions about funding and research protocol design are made.

The international women's health movement has grassroots origins, stemming from radical feminists' efforts in the 1970s to encourage women to reclaim the knowledge and ownership of their bodies. Part of the broader women's equality movement, the women's health agenda has moved from its initial fringe position to a central, highly visible one and has gained wide public support over the past two decades. Bernadine Healy, a former Director of the U.S. National Institutes for Health, reflects this transition when she states "[i]t is not 'politically correct,' nor is it radically feminist, to suggest that disease prevention is critical to the public health of all Americans; it is common sense."⁷⁵ Nonetheless, the reality that mainstream medicine has not fully embraced the feminist agenda is reflected in the title of Healy's book: *A*

⁷⁵ *Supra* note 14 at 15.

*New Prescription for Women's Health; Getting the Best Medical Care in a Man's World.*⁷⁶

The starting point for Canadian government recognition of women's health and research as distinctly important public policy issues was the 1985 Third World Conference on Women in Nairobi.⁷⁷ In 1988 the Department of Health and Status of Women Canada sponsored a national symposium on women's health which led to the creation of a permanent Federal/Provincial/Territorial Working Group on Women's Health to advise the Conference of Deputy Ministers of Health. Publication of the Working Group's first report in 1990 coincided with a period of intense lobbying of Canadian and American governments by women with breast cancer.⁷⁸ A House of Commons Standing Committee on Breast Cancer was established in response and increased government funding for breast cancer research followed shortly thereafter. In 1993 the National Forum on Breast Cancer research brought together an unconventional mix of researchers, women with breast cancer, cancer agency volunteers, physicians, and government policy workers and demonstrated a high-level commitment to promoting forms of researching women's health that extend well beyond the biomedical sphere.

Contributing to improved knowledge about women's health was a component of the Liberal Party's 1992 election platform and the government has followed through with many of its promises in this regard. A Women's Health Bureau was established at Health Canada in 1993, and in 1996 Ottawa provided funding to establish five national Centres of Excellence for Women's Health (CEWH). The CEWH Program has a six-year lifespan and will provide \$2 million annually to each of the five Centres during this period. The ultimate objective of the Program "...is to improve the health status of Canadian women by enhancing the health system's understanding of, and responsiveness to, women's health issues. The work conducted by the funded Centres will be policy-oriented and aimed, ultimately, at making necessary changes to the health system."⁷⁹ Narrowing the knowledge gap between gender and the other

⁷⁶ *Supra* note 14.

⁷⁷ *Supra* note 11 at 2.

⁷⁸ *Supra* note 11 at 2.

⁷⁹ Health Canada, *Centres of Excellence for Women's Health Program* (January 1997) fact sheet prepared for the Canada-U.S.A. Women's Health Forum.

determinants of health is seen as critical to accomplishing these general aims.

Health Canada's *Women's Health Strategy* is the most recent federal government statement of its commitment to improving women's health and usage of the health determinants model in research and policy-making.⁸⁰ Among other things, the *Women's Health Strategy* directly addresses the need to promote more and better inquires into women's health across the research spectrum. Health Canada pledges to make the research programs and activities it supports "...more relevant to women's health concerns."⁸¹ The CEWH Program is featured prominently in the subsequent statements of intention. Whether or not the CEWH Program is capable of facilitating change of such magnitude in the research realm remains to be seen. Prospects do not appear good, however, given that the Program is designed to be short-lived, and that the allocated funding is minute relative to the total federal investment in health research (\$10 million annually versus the \$500 million the government has pledged to spend from 1999 to 2002). The *Women's Health Strategy* further states that additional federal monies will be made available to support high priority women's health issues. No figures are provided, however, so the extent of this support is unknown.⁸²

The *Strategy* document also makes reference to Health Canada's relatively new Guidelines on *Inclusion of Women in Clinical Trials*.⁸³ The *Strategy* promises that this policy "...will be monitored."⁸⁴ A medical doctor on staff at Health Canada's Therapeutic Products Programme (which is responsible for implementing the inclusion policy) provides the following insight: "To be frank and brutally honest, while we, the civil servants, are interested in ... finding out if there are differences between males and females [in responses to new drugs studied in clinical trials] ... we all wonder if push came to shove whether our government would stand up to the companies to require this."⁸⁵

⁸⁰ Health Canada (Women's Health Bureau), *Women's Health Strategy* (Ottawa: Health Canada, 1999).

⁸¹ *Ibid.* at 9.

⁸² *Supra* note 82. Priority areas noted include: the causes of breast cancer including environmental concerns; chronic illnesses; mental health, including self-esteem of the girl child; and barriers to the utilization of services such as diversity and socio-economic issues.

⁸³ See description of the *Women in Clinical Trials* Guidelines above.

⁸⁴ Health Canada, *supra* note 82 at 4.

⁸⁵ *Supra* note 32.

This indication of resistance to the policy by the private sector and the government's corresponding unwillingness to move from "guidelines" to more coercive measures is revealing. It suggests that, to a certain degree, the government's oft-avowed commitment to women's health and an equitable research agenda is mere posturing. The Canadian Women's Health Network (CWHN) is one activist group that has called on the federal government to intervene more directly to demonstrate that this pessimistic scenario does not reflect reality.

In its February 1999 budget the government announced plans to significantly increase research funding and to change the organizational structure of public funding for health research. Aiming to promote a more collaborative Canadian research sector, the government indicated its intention to merge health research funding into a single entity called the Canadian Institutes for Health Research (CIHR). The MRC was replaced by CIHR and health research funding is no longer distributed through SSHRC and NSERC. Enabling legislation was passed on November 4, 1999. The new organization was functional by April 1, 2000 and includes an Institute for Gender and Health (one of thirteen Institutes). Promotion of women's health does not appear to be an express theme within the CIHR structure.

A CWHN working group was active from the outset in pressing CIHR's government-appointed Interim Governing Council to ensure that women's health interests would be reflected in the new structure.⁸⁶ Among other specific measures, the working group recommended that the government create legislation mandating the inclusion of women, children, and minorities in CIHR-funded research activities.⁸⁷ The CWHN working group was seeking legislative intervention modeled on a U.S. federal statute, the 1993 *National Institutes of Health Revitalization Act*.⁸⁸ This Act directed the National Institutes of Health (NIH), a federal research funding body with structures similar to the new CIHR, to establish guidelines for the inclusion of women and minorities in

⁸⁶ The CWHN working group operates with coordination and secretariate support from the Women's Health Bureau at Health Canada. An interdisciplinary group, it includes academic and community-based researchers, health policy workers, medical researchers and practitioners. For further information see online: Canadian Women's Health Network <<http://www.cwhn.ca>> (date accessed: November 7, 1999).

⁸⁷ *Ibid.* See "Communiqué #2" October 1999.

⁸⁸ Pub. L. No. 103-43.

clinical research. Giving effect to the federal Act, the NIH released extensive guidelines in 1994 and established the clear policy that NIH research awards would hinge upon conformance with the *Guidelines*.⁸⁹

The NIH *Guidelines* and the companion piece, an 81-page *Outreach Notebook*, present a detailed and forceful contrast to the vague statement from Canada's Tri-Council that "women shall not automatically be excluded from research solely on the basis of sex or reproductive capacity."⁹⁰ Moreover, it is far more broadly applicable than Health Canada's *Guidelines on Inclusion of Women in Clinical Trials*.⁹¹

It is unlikely such legislative intervention will transpire in Canada in the near future given the federal government's 'hands-off' policy approach to the regulation of research involving humans. The Medical Research Council has consistently advocated against legislation, arguing, among other things that guidelines are more flexible than laws and thus more adaptable to shifting a social consensus of acceptable norms.⁹² The Tri-Council has taken a similar stance:

...legal and ethical approaches may lead to different conclusions. The law tends to compel obedience to behavioural norms. Ethics aim to promote high standards of behaviour through awareness of values, which may develop with practice and which may have to accommodate choice and liability to err. Further, though ethical approaches cannot preempt the application of law, they may well affect its future development or deal with situations beyond the scope of the law.⁹³

Given the inadequacy of the Tri-Council's statement with respect to inclusion of women in research, and the general criticisms about the effectiveness of the fragmented model of accountability at present, the research community does not seem poised to make the types of progressive changes called for by the feminist critique. In light of the deep roots of gender bias in the history of medical science, and the bias which continues to exist in society more generally, it does not seem reasonable to expect that the research community will voluntarily dispose of its

⁸⁹ *NIH Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research*, 59 FR 11146 at III.C.

⁹⁰ *Tri-Council Policy Statement*, *supra* note 41 at Art. 5.2.

⁹¹ *Supra* note 20.

⁹² Medical Research Council, *Guidelines on Research Involving Human Subjects* (Ottawa, Ont.: Agency, 1987) at 11.

⁹³ *Supra* note 20 at i.8.

traditional exclusionary practices. Subsequently, as the government has repeatedly expressed commitment to advancing women's health through research, it seems that more meaningful action is required than what has occurred thus far.

VI. CONCLUSION

The women's health movement has had some political success in Canada. This is reflected in the establishment of a Women's Health Bureau at Health Canada, funding for women-centred research programs, and the implementation of an inclusionary clinical trials policy in the area of new drug submissions. At the same time, however, the extent of conceivable social change within the existing regulatory framework of law and ethics is very limited. Federal legislative intervention, which would be consistent with the numerous international pledges made by the Canadian government to advance the women's health agenda, may prove to be the most viable route to facilitating substantive change at the level where the bulk of research decision-making occurs. Intensive public lobbying is needed to ensure Ottawa resists simply accepting the agenda of the entrenched, deep-pocketed research community.