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**POLITICS AND MEDICINE IN THE ESTROGEN REPLACEMENT CONTROVERSY:
A COMPARATIVE ANALYSIS OF THE UNITED STATES AND GREAT BRITAIN**

by

Frances B. McCrea

**..A Thesis
Submitted to the
Faculty of the Graduate College
in partial fulfillment of the
requirements for the
Degree of Master of Arts
Department of Sociology**

**Western Michigan University
Kalamazoo, Michigan
August, 1981**

POLITICS AND MEDICINE IN THE ESTROGEN REPLACEMENT CONTROVERSY:
A COMPARATIVE ANALYSIS OF THE UNITED STATES AND GREAT BRITAIN

Frances B. McCrea, M.A.

Western Michigan University, 1981

This thesis investigated social and medical aspects of the Estrogen Replacement Controversy (ERT) in the United States and Great Britain. American researchers claim that ERT, a treatment for menopausal and postmenopausal problems, substantially increases the risk of endometrial cancer; British researchers minimize the risk and instead emphasize benefits of the treatment. Whereas British medical practitioners are reluctant to prescribe ERT, their American counterparts widely prescribe the treatment. American feminists and consumer groups strongly oppose ERT; similar groups in Britain demand the treatment. Whereas the British government has not regulated the drug, in America, increasing restrictions have been placed on ERT. To shed light on the interaction between epistemological and ideological factors, the social forces which shape the controversy, varying independently cross-culturally, were explored and elucidated. This controversy is of interest since it demonstrates how two countries, reach contradictory conclusions to the same problem based on the same scientific data.

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Frances B. McCrea

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CHAPTER I INTRODUCTION

Estrogen Replacement Therapy (ERT), a treatment for menopausal and post-menopausal problems, is widely prescribed in the United States and Western Europe. By the mid 1970s, menopausal estrogens had become the fifth most frequently prescribed drug in the United States; in the early 1980s, menopausal estrogens were in the fastest growing segment of the British pharmaceutical industry.

In the past few years, however, a major controversy has developed around the risks and benefits of ERT. Controversies in Therapeutics, a book devoted to current medical disputes, designates estrogen therapy as one of "society's most pressing therapeutic questions" (Lasagna, 1980). Some scientists claim that ERT effectively treats and even prevents conditions ranging from hot flashes to osteoporosis (a bone disease which, in the United States, purportedly afflicts 15 million persons, and is a cause of death for nearly 20,000 persons per year). Some scientists make strong non-medical claims for the benefits of ERT, maintaining that the therapy will keep women "feminine forever".

Other scientists dispute these claims, and moreover argue that ERT significantly increases the risk of endometrial cancer, gall bladder and cardio-vascular disease, and may even increase the risk of breast cancer. Some researchers now warn that the estrogen-induced endometrial cancer risk exceeds the combined risk of breast, lung, ovary and colon cancer.

Whether ERT heightens femininity or whether it heightens the

risk of cancer is an important, perhaps even a life-shaping, question to the women facing the issue of ageing. On issues relating to health, most women are likely to seek, and follow, the advice of their physician. Others might read reports of, or indirectly learn about, medical research on ERT. Still others might turn to, or seek additional information from, various feminist and consumer groups which give advice on health-related issues. Finally some women will be influenced by government pronouncements and literature on the efficacy and safety of the drug. From these various sources a decision about ERT will be made. Yet depending on which side of the Atlantic Ocean women live on, that advice and the consequent ERT decision are likely to be quite different, even opposite, in nature.

Statement of Problem

This thesis is not a study of the safety and efficacy of ERT. Rather it is a study of the social forces shaping the ERT controversy. Our specific interest is in comparing and contrasting the ERT debate in the United States and Great Britain. In both countries ERT decisions are made from the same scientific data base. Yet preliminary analysis indicates that the medical and the non-medical aspects of the controversy vary independently, and in opposite direction, in the two countries.

To describe and analyze these anomalies, initial consideration is given to an historical analysis of the changing definitions of menopause. We investigate the origins of current medical views on

the menopause, and try to determine why the menopause is seen as a disease which needs routine treatment. We then examine the various loci of input into the ERT decision by focusing on cross-cultural differences in (1) the medical research community, (2) physician practices, (3) feminist/consumer groups, and (4) regulatory policy.

Cross-Cultural Design

Why study controversy? The answer, according to recent scholarship, is that controversy may offer a window through which the more general social relations of science can be viewed. Since controversies are usually played out within an adversarial framework, scholars may treat disputes as data to assess the strengths and weaknesses of opposing arguments (Mazur, 1981), or as a way to reveal "...The special interests, vital concerns, and hidden assumptions of the various actors" (Nelkin, 1979, p. 7). In a theoretical and methodological sense, controversies in science "seem to offer a research focus premitting concurrent exploration of cognitive and broad cultural factors" (Blume, 1977, p. 13). And from an historical view, the study of controversy may focus attention on the patterns of interaction between the cultural and positivistic aspects of science (Caplan, 1979).

These advantages notwithstanding, the study of controversy has generally suffered from the weakness inherent in case studies. Without comparative data there is no way of separating the ideosyncratic from the scientifically meaningful datum. A few comparative studies

of controversy now exist. Leahy and Mazur (1978) have contrasted the nuclear power, fluoridation and abortion disputes, while Petersen and Markle (1981) have examined the scientific and cultural dynamics of five cancer-related controversies. Yet even these studies are methodologically limited. (See Markle & Petersen, 1981, for a research strategy to ameliorate some weaknesses in the case study design.) By examining controversies within the same cultural setting, such designs must treat social structure and culture as constants, rather than as variables in the analysis. Thus is the richness and potential of cultural explanations limited.

What is needed, clearly, is cross-cultural analysis of controversy. When the scientific data are the same, and yet outcomes differ, then social structural and cultural factors as shapers of science cannot be ignored. Almost a century ago Emile Durkheim stressed the comparative method when he wrote: "Comparative sociology is not a particular branch of sociology; it is sociology itself insofar as it ceases to be purely descriptive [of a particular society] and aspires to account for the facts" (1938, p. 139).

The power of cross-cultural design is evident in a few recent studies. In an analysis of witchcraft in Renaissance Europe, Currie (1968) found that political and economic factors influenced the extent and form of persecution. Scott (1970) found that experts' conception of blindness in the U.S., Sweden, and Great Britain was influenced by different socio-cultural factors. In research similar to our own study, Gillespie et al. (1979) posed the question: "Why

were two pesticides, Aldrin and Dieldrin, judged to be carcinogenic in the U.S. but not in Great Britain when the same evidence was available to public authorities in both countries?" Four factors-- differentially developed environmental movements, differential economic well-being, democracy of expertise, and differential "styles of government"--seemed to account for some of the differences between the two countries.

Theoretical Issues

Similar to Durkheim's plea but more recent, Turner (1970) urged that if social "scientists are to generate a body of theory and concentrate their efforts on making theory more general and valid, comparative cross-cultural research is absolutely essential" (1970, p. 4). The ERT controversy is of considerable interest to the sociologist not only because it shows how two countries might reach contradictory conclusions based on the same scientific data, but also demonstrates how actors outside the scientific community might develop divergent definitions (and suggested solutions) to the same problem. Thus this thesis can shed light not only on theoretical debates in the sociology of science and knowledge, but also clarify debates in social problems, social movements and deviance studies.

The social problems and deviance literature can be dichotomized, based on Ritzer's (1975) distinction, into two divergent theoretical perspectives. Those following the "social factist" tradition, variously called "objectivist", "absolutist", or "positivist" (the

term used here), hold that social problems and deviance are objectively given, intrinsically real, and lend themselves to scientific analysis. This position is perhaps best explicated by Manis who defines social problems as "those conditions identified by scientific inquiry and values as detrimental to human well-being" (1976, p. 25). Thus the major focus of positivists is on the etiology and control of social problems and deviance.

The other position is derived from Ritzer's definitionist perspective, and variously termed "interactionist", "subjectivist", and "social constructionist" (the term used here). Social constructionists are less concerned with the etiology question, but instead focus on the social processes of defining and labelling putative conditions and behaviors as problematic or deviant. What makes a behavior or condition distinctive depends not on objective reality, but on the political process through which powerful interest groups and/or segments of the public are likely to impose their definitions of reality. Thus social problems and deviance are the result of enterprise, and the products of certain people or groups making claims based on their particular interests, values, and views of the world (Becker, 1963; Conrad and Schneider, 1980; Schur, 1979; Spector and Kitsuse, 1977). As Mauss has summarized:

No social condition, however deplorable or intolerable it may seem to social scientists or social critics, is inherently problematic. It is made a problem by the entrepreneurship of various interest groups, which succeed in winning over important segments of public opinion to the support of a social movement aimed at changing that condition (1975, p. xvi).

In the area of social movements, closely linked with social problems and deviance, a similar dispute has developed in recent years. The positivist model, often referred to as a "strain" or "discontent" perspective, holds that social movements arise because of deep and widespread discontent. Social conditions are such that a severe strain develops between different segments of a given society. The strain generates discontent, emotional anxiety and anomie, resulting in social disorder and conflict (Hoffer, 1951; Kornhauser, 1959; Smelser, 1963).

In the past few years the resource mobilization model has cast doubt on the traditional strain formulations. This newer perspective holds that conflict does not arise from disorganized anomic masses, but from organized groups able to advance and defend their interests. Discontent or strain is seen as relatively constant and is not sufficient to give rise to a social movement. What accounts for insurgency is the amount of social resources available to discontented groups and their ability to effectively mobilize these resources to upset the balance of power (Gamson, 1975; Oberschall, 1973; Tilly et al., 1975).

The internal-external debate in the sociology of knowledge and science has developed along lines similar to the positivist-social constructionist split. The internalist position views the substance of science as the result of rational, value-neutral activity, governed by the internal laws and logic of science, but isolated from external social forces. Because the empirical relationships of the

natural world are unchanging and universal, scientific knowledge develops unidirectionally and evolves through the gradual accumulation of permanently valid conclusions (Hall, 1963; Mannheim, 1952). As Gillispie (1962, p. 89) has summarized: "I think it is obvious that science, which is about nature, cannot be determined in its content by the social relations of scientists."

The externalist position, on the other hand, contends that scientific knowledge, as with all other knowledge, is socially constructed and mediated by social and economic forces. Mendelsohn has presented an eloquent argument for this stance:

Science is an activity of human beings acting and interacting, thus a social activity. Its knowledge, its statements, its techniques have been created by human beings. Scientific knowledge is therefore fundamentally social knowledge. As a social activity, science is clearly a product of a history and of processes which occurred in time and in place and involved human actors....The techniques for the proper study of science as a human activity will thus encompass the historical and the sociological and be comparative in mode (1977, pp. 3-4).

The content of science is thus not immune from external factors, but must be viewed within the social and political context of a given time. As MacLeod has written:

The shared values and normative goals of science of a given time can, with time, fade from view as explicit ideas which are part of the common culture, and become part of the received wisdom of the scientific field. In this event, external factors become internalized (1977, p. 176).

It follows then, concludes MacLeod, "that we cannot usefully dispute the causal influence of external factors on the content of science" nor is there any indication that the course of science has devel-

oped "in any simple, direct or uniform fashion" (1977, p. 176).

To summarize, then, our comparative, cross-cultural analysis of the ERT controversy ought to shed light on the foregoing theoretical debates. Since the same data base is used to make ERT decisions in the United States and Great Britain, it would appear that objective or internal factors are held constant. Any divergences between the two countries, such as the problematic nature of the menopause, or the differential evaluation of the risk-benefit equation for ERT, must be due to subjective or external factors. Views which are judged as "truth" might thus be shown to vary by time, place and social context. As Pfuhl has written:

Social reality is multiple rather than singular, and given multiple realities, it is often contradictory rather than consistent. The elements comprising social reality are in conflict rather than harmony. Consistent moral definitions of things may be said to exist only in the abstract. As they apply to concrete events, these definitions are highly variable, fluctuating from one setting or context to another (1980, p. 36). (Emphasis in original)

The remainder of this thesis, then, attempts to establish, describe and explain the nature of these subjective factors and how they have shaped the ERT controversy.

CHAPTER II HISTORICAL PERSPECTIVES:¹ CHANGING DEFINITIONS OF MENOPAUSE

Any attempt to understand the complexity of the current controversy over Estrogen Therapy will be deficient without an awareness of the historical development of the medical profession's perception and treatment of the menopause. Health care for women in general, and older women particularly, has been and still is a curious mixture of myth and reality, based on commonly held perceptions of women's changing roles, the changing roles of physicians and the interaction of these factors. Thus, a historical perspective of the treatment of menopause is presented to set the context for this research and to complement other components of this study.

Traditionally, historians of medicine have focused on the scientific and professional developments, or medicine as seen through the lives of its most renowned practitioners. The resulting picture has been linear and cumulative: medical history becomes a progression of advances in theory and practice as influenced by scientific breakthroughs, but insulated from social conditions (Verbrugge, 1976). Historical studies of women and health care challenge this narrow "internal" perspective of science, and reveal a much more complex and dynamic model. The dialectical relationship between society and medicine is forcefully demonstrated by women's health care. Medical views of women parallel societal ones and in turn legitimize them. The study of menopause demonstrates that historically physicians have served the interest of those in power, not only as healers but

also as arbiters of morality and staunch supporters of the status quo.²

Women's relationship to health care is distinctive: the provider for the most part is male, whereas the patient is female. Thus health care for women involves more than medical issues: the physician's attitude toward women becomes an important variable. This relationship becomes more complex when the patient is a middle aged woman. The physician must not only deal with his attitude toward women but also his personal and social attitude towards aging.

An historical analysis of medicine reveals that distinctive theories, treatment and institutions for women have existed since the beginning of scientific medicine. At least since the Enlightenment, philosophers have celebrated man as the "captain of his soul" and "master of his fate". Once again, as in Protagoras' golden age of Greece, "man" became "the measure of all things". Reason, rationality and free will were seen as inherent traits. For men it was "mind over matter", but not so for women. Medical literature from the eighteenth through twentieth century portrays woman's function, behavior and potential dependent on her reproductive organs. Biology, for woman, is destiny - whether it is determined by her uterus or her "raging hormones".

The medical definition of menopause has been heavily influenced by the social stigma applied to menopause. In a society where woman's social usefulness is largely defined by her reproductive capacity and sexual attractiveness, menopause, the loss of fertility

and youth, is generally perceived as a dire event, a symbol of decrepitude and decay. The aging woman is desexed and concomitantly stigmatized due to the loss of her primary social role. The medical literature on menopause reveals three consistent themes: (1) menopausal symptoms as sin and decay, (2) as a psychological problem, and (3) menopause as a deficiency disease. Although these definitions overlap and run throughout the entire time span, they vary in emphasis during any given time period. Before considering these stages, we briefly examine the sexual politics of women in Victorian medicine.

Women and Medicine in Victorian Society

During the later part of the eighteenth and the beginning of the nineteenth century, the Industrial Revolution and the concomitant development of capitalism brought about profound social changes in both Western Europe and America. With the triumph of the Market system, the old unity of work and home, production and family life, was irrevocably shattered. The household, no longer a self-contained unit, was reduced to a place of eating, sleeping, sex, and the care of small children. Life became experienced in two distinct spheres: the "public" sphere, dominated by men and ultimately governed by the market; and the "private" sphere of the household relegated to women (Ehrenreich & English, 1978). Under the impact of rapid social change and instability, the home came to be seen as an idyllic refuge from the competitive world of men. Sex roles, particularly the

expectation of women, changed accordingly. The perfect "lady" limited her role to marriage and procreation, for which her "natural" submission to authority and maternal instinct perfectly suited her. This drastic constriction of woman's role was reinforced by the romanticism of perfect womanhood. The prevailing ideology defined woman as naturally fragile, chaste, loving but not sexual, in need of protection, morally superior but intellectually inferior to men. By placing woman on a pedestal, she effectively lost the ability to stand on her own two feet. Sexual romanticism meshed ideally with the needs of the merging economy which increasingly depended on the nuclear household and individual domestic consumption.³

The need to restrict and codify women's proper sphere intensified as women began to question their narrow role. The "woman question" as it came to be called, stirred controversy throughout the nineteenth century (Stage, 1970). As some women challenged the ideas put forth by romanticism and demanded opportunities for education and birth control, science rose to the defense of the status quo. Science, the new faith of the century, provided the framework within which the "woman question" was examined. Men hopeful of preserving the existing social relationships put forth medical and biological arguments to rationalize traditional sex roles as rooted in anatomy and physiology (Smith-Rosenberg & Rosenberg, 1973). The Victorian physicians assumed the roles and duties previously reserved for the priest and minister, and held themselves responsible for the moral and spiritual, as well as the physical health of society. Medical

authority was brought against any elements which threatened the stability of society (Haller & Haller, 1974; Stage, 1979; Vicinus, 1972).

As Stage (1979, p. 18) noted:

...the constriction of woman's sphere apparent on the social level was paralleled in medical writing by a constriction in the field of vision which led doctors to focus, with obsessive concern, on woman's organs of reproduction.

French historian Jules Michelet declared that each century had its own great malady--leprosy in the thirteenth century, plague in the fourteenth, and syphilis in the sixteenth. Writing in 1868, Michelet characterized the nineteenth century as "the age of the womb" (Stage, 1972, p. 64). "The Uterus, it must be remembered", wrote Dr. F. Hollick in 1848, "is the controlling organ in the female body, being the most excitable of all, and so intimately connected, by the ramifications of its numerous nerves, with every other part" (quoted in Ehrenreich & English, 1978, p. 108). Professor Hubbard, addressing a medical society in 1870, observed that it seemed "as if the Almighty, in creating the female sex, had taken the uterus and built up a woman around it" (quoted in Wood, 1973, p. 3).

For other medical theorists, it was the ovaries which determined woman's physical, emotional and mental states. The following statement written by Dr. W. Bliss in 1870 typifies this opinion:

Accepting, then, these views of the gigantic power and influence of the ovaries over the whole animal economy of woman,--that they are the most powerful agents in all the commotions of her system; that on them rest her intellectual standing in society, her physical perfection, and all that lends beauty to

those fine and delicate contours which are constant objects of admiration, all that is great, noble and beautiful, all that is voluptuous, tender, and endearing; that her fidelity, her devotedness, her perpetual vigilance, forecast, and all those qualities of mind and disposition which inspire respect and love and fit her as the safest counselor and friend of man, spring from the ovaries,--what must be their influence and power over the great vocation of woman and the august purposes of her existence when these organs have become compromised through disease! (W. W. Bliss, 1870, p. 96). (Emphasis in original)

Thus, it is not surprising that any female disorder from headaches, to hysteria and insanity were blamed on uterine or ovarian disease.

Dr. M. E. Dirix wrote in 1869:

Thus, women are treated for diseases of the stomach, liver, kidneys, heart, lungs etc.; yet in most instances, these diseases will be found on due investigation, to be, in reality, no diseases at all, but merely the sympathetic reactions or the symptoms of one disease, namely, a disease of the womb (quoted in Ehrenreich & English, 1978, p. 110).

Victorian medicine furnishes a remarkable example of how scientific knowledge reflects, rather than determines the moral biases of an era. Since woman's reproductive organs supposedly governed every sphere of her life, they came to be seen as a sacred trust, one that she must constantly guard in the interest of the race (Stage, 1979, p. 69). The threat of disease was used as a sanction to enforce traditional behavioral norms. Physicians warned women if they transgressed God's or nature's law, by attempting to enlarge their sphere of action, they would pay a heavy price--their sexual organs would rise up against them in retaliation. This sentiment is captured in the following quote written by a physician in 1873:

Woman, in the interest of the race, is endowed with a set of organs peculiar to herself, whose complexity, delicacy, sympathies, and force are among the marvels of creation. If properly nurtured and cared for, they are a source of strength and power to her. If neglected and mismanaged, they retaliate upon their possessor with weakness and disease, as well of mind and body (quoted in Stage, 1979, p. 69).

Menopause as Sin and Decay

Medical theories served to warn women to limit their activities to the home, otherwise disease, insanity, and even death would surely follow. The day of reckoning came with the onset of the menopause. Victorian physicians advised endlessly on the dangers of menopause and saw menopausal problems as the punishment for earlier sins. Physicians invariably characterized it as the "Rubicon" in a woman's life, and measured the extent of discomfort and disease by the degree of "abuse" she had inflicted on her constitution (Haller & Haller, 1974, p. 35). Medical manuals blamed the frequency and seriousness of disease during this period upon "indiscretions" of earlier life. Gynecologist John Kellogg wrote in 1883 that the woman who transgressed nature's law "will find this period a veritable Pandora's box of ills, and may well look forward to it with apprehension and forboding" (quoted in Haller & Haller, 1974, p. 135). A woman "transgressed nature's law" when she ventured outside her narrowly prescribed role. Although physicians postulated a number of explanations for the heightened disease incidence of the older female, "the most significant cause of woman's menopausal disease", according to historian Smith-Rosenberg, was that:

virtually every doctor believed, lay in violation of the physiological and social laws dictated by her ovarian system. Education, attempts at birth control or abortion, undue sexual indulgence, a too fashionable life style, failure to devote herself fully to the needs of husband and children--even the advocacy of woman's suffrage--all might guarantee a disease-ridden menopause (1974, p. 30).

Even if a woman did not "transgress" in earlier life, a momentary lack of judgment in old age--e.g., engaging in sexual intercourse during or after menopause--could lead to hemorrhaging, ovarian tumor, or insanity. British physician John Tilt, in his widely read text concerning the menopause, wrote in 1871:

My experience teaches me that a marked increase in sexual impulse at the change of life is a morbid impulse. Whenever sexual impulse is first felt at the change of life, some morbid ovario-uterine condition will be found to explain it (quoted in Smith-Rosenberg, 1974, p. 31).

And in 1897, Dr. Andrew Currier warned that "irregular and unwomanly occupations, alcohol, poverty, opium, typhoid and excessive sexual indulgence" could all bring on a premature and difficult menopause.

According to historian Peter Stearns, European physicians in the 18th and 19th century believed that women decayed at menopause and that it marked the beginning of old age; men were not seen as old for another 15 to 20 years. Women were viewed as being sick from menopause until death, and physicians found their appearance as "disgraceful". Deprived of function, stated a French physician, "an old woman is for nature only a degraded being, because she is useless to it. Women could survive only if they abandoned the frivolous pleasures dominating their younger years" (quoted in Stearns, 1979, p.

45). American physicians gave similar advice. "We insist", wrote Dr. Taylor in 1872,

that every woman who hopes for a healthy old age ought to commence her prudent cares as early as the 40th year or sooner.... She should cease to endeavor to appear young when she no longer is so, and withdraw from the excitements and fatigues of the gay world (quoted in Smith Rosenberg, 1974, p. 31).

Therefore, sex as the definer of women, marked off an early old age by its presumed disappearance. Once sexual function was lost, care should be taken not to revive it. One physician emphasized the dangers of sleeping upon a feather bed for menopausal women. Feather beds might

...excite the generative organs, which should henceforth be left, as far as possible, in a state of inaction A woman at this time should avoid all such circumstances as might tend to awaken any erotic thoughts in the mind, and reanimate a sentiment that ought rather to become extinct, such as the spectacle of lascivious figures, the reading of passionate novels, and, in fine, every thing calculated to cause regret for charms lost that lost, and enjoyments that are ended for ever (quoted in Page, 1977, p. 67).

Historian Smith-Rosenberg also commented on the Victorian physician's revealing attitude toward aging women:

Male physicians displayed a revealing disquietude and even hostility when discussing their menopausal patients. In the medical literature, the menopausal woman often appeared as ludicrous or physically repulsive. Edward Tilt for instance, claimed that she characteristically has a "dull spudid look", was "pale or sallow" and tended to grow a beard on her chin and upper lip. Doctors scoffed at women who, long sterile or just married at menopause, believed themselves pregnant. These women, doctors commented heartily, suffered from a little flatulence, somewhat more hysteria, and most of all

obesity. Their fantasied fetus, another doctor joked, was just their belly's double chin (1974, p. 31).

Somewhat less hostile, Dr. Meings mourned a woman's lost charm and "feminine grace" at the "turn of life":

There is something melancholy in the conviction, that must attend the final cessation of the menses, of a decadence of the constitution. The subject of such a conviction is compelled to admit that she is now become - what? an old woman! ... The pearls of the mouth are become tarnished -- the haylike odor of the breath is gone, the rose has vanished from the cheek, and the lily is no longer the vain rival of the forehead and neck. The dance is preposterous, and the throat no longer emulates the voice of a nightingale (quoted in Page, 1977, p. 64).

Even if the Victorian woman had led an exemplary life, she was not exempt from a host of ills at the menopause. Female problems also developed because of the retention of humors which could no longer escape through menstruation. It was such a "plethora" or suffusion of the body with fluids which also was believed to cause a host of diseases. Following the notion of this ancient plethora theory, one physician labeled the uterus "the sewer of all the excrements existing in the body" (quoted in Stage, 1979, p. 70). The host of diseases that might develop as a result of the final cessation of the menses included, proclaimed Dr. Tilt,

...almost all the ills the flesh is heir to: flushes, dyspepsia, diarrhea, vaginitis, vaginal inflammation, prolapsed uterus, rheumatic pain, paralysis, apoplexy, ersipilas, uterine hemorrhage, tumors, uterine and breast cancer, tuberculosis, scrofula, diabetes. Also irritability, depression, hysteria, melancholy, emotional withdrawal, and insanity (quoted in DeLorey, 1981, pp. 10-11).

Victorian physicians practiced a variety of treatments for the problems of the menopause, but the most common one was "local treatment"--remedies specifically directed at the womb. Since almost all disorders were traced back to the reproductive organs, women displaying such a variety of symptoms as a simple headache or irritability, hot flashes, to prolapsed uterus and even cancer, were subjected to local treatment. Therapy consisted of four stages, although not every case went through all four: manual manipulation, "leeching", "injections", and "cauterization". Historian Woods recounts these four stages:

Dewees and Bennet, famous English gynecologists widely read in America, both advocated placing leeches right on the vulva or the neck of the uterus, although Bennet cautioned the doctor to count them as they dropped off when satiated, lest he "lose" some. Bennet had known adventurous leeches to advance into the cervical cavity of the uterus itself, and noted: "I think I have scarcely ever seen more acute pain than that experienced by several of my patients under these circumstances". Less distressing to the twentieth century mind, but perhaps even more senseless, were the "injections" into the uterus advocated by these doctors. The uterus became a kind of catch-all, or what one exasperated doctor referred to as a "Chinese toy shop": Water, milk and water, linseed teas, and "decoction of marshmellow ... tepid or cold" found their way inside nervous women patients. The final step, performed at this time, one must remember, with no anesthetic but a little opium or alcohol, was cauterization, either through the application of nitrate of silver, or in cases of more severe infection, through the use of the much stronger hydrate of potassa, or even the "actual cautery", a "white-hot iron" instrument (Wood, 1974, p. 4).

One must remember that this last treatment was used even if there was no uterine infection, and thus subject to great abuse. Alice Stock-

ham, one of a handful of women physicians at that time, severely criticized local treatment:

The severe caustic treatment that has been so universal in these affections is greatly to be deprecated. There are fashions in medicine as in other things, and the one fashion the last twenty-five years has been local treatment for diseases in women. In no department of medical practice has the physician's prerogative been more abused. For the slightest ailments the severest applications are often employed (Stockham, 1893, pp. 269-270).

Stockham urged women to "protest positively and persistently against the burning, probing and scarifying of the womb". This woman physician condemned local treatment, bleeding and blistering as a "relic of the past" and "contrary to science and common sense" (Stockham, 1893, p. 272). She also had sympathy for the plight of her contemporary sisters,

... is is easy for a sensitive woman to persuade herself that her afflictions from the toothache downward, are due to diseases of the womb. Here comes in the charlatan, to exaggerate her diseases, if any, and to beguile the patient with promises of cure. The speculum, the caustic and the knife look like work, and she thinks something is being done for her (Stockham, 1893, p. 291). (Emphasis in original)

Anticipating the charges of current American feminists, Stockham states that the menopause is a natural event that for the healthy woman should be attended by no unpleasant symptoms.

The change of life is one of the scape-goats of physicians ... If any lady from thirty-five to fifty-five years of age is afflicted with dyspepsia, neuralgia, rheumatism, consumption or any other ailment, the doctor, not being able to cure her, pronounces it the meno-pause, or "change of life" (Stockham, 1893, p. 276).

Catherine Ester Beecher also crusaded against local treatment, and in her Letters to the People on Health and Happiness (1855) saw the treatment roughly equivalent to rape. This "evil" is performed, she explained "with bolted doors and curtained windows, and with no one present but the patient and operator" (1855, p. 136).

American gynecologist Andrew Currier, writing in the 1890's also attacked his male colleagues for their negative attitude towards menopause and called them "bleeders, pukers, and purgers". Even though he still advocated leeching as an effective remedy for sexual arousal caused by congested genitals, in his book The Menopause (1897), he otherwise condemns local treatment as obsolete. Riding on the wave of progress evoked by English physician Robert Battey's invention of "female castration"⁴ in 1872, Currier advocated surgical menopause: the removal of any organs that directly affect the menstrual process (Currier, 1897, pp. 230-283). He advised his colleagues to be thorough, "for if you remove the fallopian tubes, then you might as well remove the ovaries, because without the tubes the ovarian function is gone, and remove the whole ovary instead of just part of one". But much of the success depends on the "judicious selection of cases ... some patients would be incurable by any operation, and this would include some who had long been subject to vicious habits, to the use of alcohol, chloral, opium, etc." (Currier, 1897, p. 249).

Entrenched as the medical attitudes toward women were, at the turn of the century, a young Viennese physician--himself a product of

the Victorian era--revolutionized the theories of the etiology of female complaints. Sigmund Freud's ideas led to the reinterpretation of the menopause.

Menopause as a Psychological Problem

Although physicians of the nineteenth century saw insanity and hysteria as frequently associated with the menopause, the immediate cause was believed to be a diseased uterus or ovary. In the early twentieth century the emphasis shifted from organic causes to psychogenic ones. The advent of Freudian theory, the subsequent mental health movement, and the synthesis of psychotropic drugs all set the stage for recasting virtually all "female complaints" into the psychological arena.

By the end of the 19th century, wrote Stern and Prados (1945, p. 358), the notion that personality disorders were "menopausal" had grown to the point that some psychologists referred to personality change as the first sign of approaching menopause. Although Freud himself did not extensively write on the menopause, it was a stage of potential crisis in his theory. He believed that previously undisturbed women could become neurotic, since the end of menstruation allowed for a re-emergence of the castration complex. Often, Freud noted, menopausal women "become quarrelsome and obstinate, petty and stingy, show typical sadistic and anal-erotic features which they did not show before" (quoted in Silberman, 1950).

Freud's perception of menopause were fully developed by Deutsch (1945) and Benedek (1950), whose theories had great influence on

subsequent writings. In Psychology of Women, Deutsch viewed menopause as the third of the infantile stages (the second being puberty). During both of these traumatic stages, women act out certain unconscious fantasies. Deutsch insisted that during menstruation women experience fears of castration and lost children and during menopause fantasies of rape and prostitution. Puberty, according to Deutsch, signifies the moment a woman becomes the "servant of the species," whereas at menopause woman's service to the species ends. The woman becomes socially useless with the loss of her reproductive function. Menopause becomes a critical period, since "mastering the psychological reactions to organic decline is one of the most difficult tasks of woman's life" (1945, p. 436). Homosexual panic is also frequently experienced and the yearning for a son becomes obsessive as the increased need for him is frustrated.

Almost every woman in the climacterium goes through a shorter or longer phase of depression. While the active women deny the biologic state of affairs, the depressive ones overemphasize it...hypochondric ideas appear which in an overwhelming majority of cases relate to the genital organs (1945, p. 437).

These depressive moods may disappear or turn into serious melancholia. Deutsch wrote that "feminine-loving" women have an easier time during menopause than "masculine-aggressive" ones. Engaging in a meaningful career might serve as a protection against the biological trauma of the climacterium, but not without running a risk. "If their social and professional interest have taken excessive hold of them, these women are threatened in the climacterium by the danger I call 'pseudomascularity'" (1945, p. 476). Pseudomasculine women are not

truly masculine, according to Deutsch, but are women whose feminine eroticism or maternal love has not fully developed.

Deutsch's influence can be seen in the writings of the well known psychoanalyst Eric Erickson. For example, Erickson wrote that when a woman's womb is "empty" she experiences pain. Her grief for lost children is experienced at each menstruation and becomes a "permanent scar" at menopause (1968, p. 278).

In a similar Freudian tradition, Benedek (1950a) interpreted menopausal symptoms as resulting from a threat to the ego. The life situation at the time of the menopause becomes complex and demanding: children leave, sons marry, and sexual needs between husband and wife change. When a woman no longer can respond to difficulties the way she did in the past, "her ego alien emotional responses threaten her." Not all women, Benedek believed, experienced menopause with the same degree of difficulty. For example women who have never borne children will have more intense reactions. The severity of psychological symptoms, Benedek asserted, are "motivated by the psychosexual history of the individual," and are the result of earlier deviations. In women who experience problems with menopause:

1. The bisexual disposition played a disturbing role in the development and
2. The psychic economy was dominated--much like that of men--by strivings of the ego rather than by the primary emotional gratifications of motherliness (1950b, pp. 239-240).

The message sounds familiar: women who reject their "feminine role" will find retribution waiting for them at the menopause.

Another psychologist described the symptoms of the menopause as a

...[P]rofound sense of internal inadequacy...reflected in the symptoms of intermittent depression or blues which appear characteristic of the menopause. The patient will complain of sudden, involuntary, easily precipitated crying spell, or a sensitivity to rejection, and an intolerance of loneliness. She reacts with bitterness and resentment to this inadequacy she experiences within herself and often projects this self-incriminating anger and hostility onto her husband, blaming the casualness of the familiar husband for her feelings of self-deprecation (Kerr, 1968).

Not only husbands but also children are frequently depicted as the victims of menopausal neurosis. The menacing mother-in-law is a major social stereotype for the menopausal woman. Unless they have the right outlet, wrote one physician, menopausal women are apt to become "mischief makers," developing a neurotic interest in their married sons and daughters and often becoming a great menace as meddling mothers-in-law (Sadler and Sadler, 1938, p. 296).

Rogers (1956) in a comprehensive review of the medical literature on menopause published in the New England Journal of Medicine, concluded that the menopause was a critical time since a woman is "forced to retire from her primary role" and since few women were prepared to deal with this role loss, psychotherapy was advocated to help women adjust to this crisis. Osofsky and Seidenberg (1970), in a more critical analysis of the psychological literature on menopause, charged that psychoanalysts (in the Freud and Deutsch tradition) frequently viewed menopause as a time of "mortification and uselessness" since the woman's "service to the species" is over. The authors noted that:

In contradiction to the male, female psychology is seen as being dependent on biology. Youth, attrac-

tiveness, sex and motherhood are viewed as the important roles for women...This thinking has influenced the therapy offered menopausal symptoms. Physical symptoms have been treated psychologically and psychogenic symptoms, physiologically (1970, p. 611).

As in the 19th century, biology is still destiny. Given the survival of this belief, it is not surprising that there is a double standard for mental health--one for men and one for women. Broverman et al. (1970) empirically validated this double standard. In a survey of 79 therapists, respondents were asked to list traits felt to be characteristic of healthy males, healthy females, and healthy adults (sex unspecified). Traits for healthy males and adults were found to be congruent, but healthy females were seen as less independent, more submissive, more easily influenced, less aggressive, less competitive, more emotional, more vain, and less objective. These same traits were judged pathological in males and adults. The conclusion is clear: a "healthy" woman equals a sick adult. The woman who rejects her "feminine role" becomes subject to medical control.⁵

A watered-down version of psychoanalytic theory is evidenced in the writings of many endocrinologists and gynecologists. In the December, 1944, Journal of Clinical Endocrinology, a special issue devoted to the menopause, various physicians discussed the implications of hormone therapy. "In almost every case," wrote Engle in the introduction to the issue, "the physician who gives advice or recommends therapy to a woman of menopausal years must deal first and primarily with a disturbed patient and only secondarily with an in-

dividual having lowered estrogen reserves" (Engle, 1944, p. 569).

(emphasis added) Another physician, critical of estrogen treatment, emphasized the psychological problems:

[I]s it any wonder that a third to half of them [menopausal women] suffer from "nervous instability"? The actual cessation of menstruation brings realistically to a woman the undeniable fact that she is aging, that her reproductive potentialities are leaving her and that she has therefore fulfilled her physiologic usefulness in life....It is therefore apparent that the climacteric is a condition of many facets--only one of which is estrogen depletion. As Ross says, it cannot be called a disease, unless the process of aging is called a disease; yet the insecurity, instability, depression and introspection which frequently accompany this period of life must be treated (Buxton, 1944, pp. 591-592). (Emphasis added)

Here the treatment of choice was primarily barbiturates, especially phenobarbital, followed by estrogen replacements if necessary.

Another contributor to the issue counselled the clinician:

"Every physician who attempts to treat a woman in the menopause syndrome should be prepared to undertake a species of psychotherapy"

(Sevringhaus, 1944). And in the final article of the series, a Harvard endocrinologist noted:

The essential psychosomatic nature of clinical endocrinology comes out with particular clarity in case of the climacteric disorders.... Even in case of the most effective specific hormone therapy, it is often an open question to what extent the benefit is determined by so-called psychological reactions rather than by direct corrective influences upon the organic processes.... Even when the physician regards himself as an uncompromising organicist, the feeling of security that his ministrations confer upon the patient is often the most potent factor in his therapy (Hoskins, 1944, p. 605).

This physician viewed anxiety as the central feature of the menopause,

caused by a threat to the ego which in turn is the result of castration fears. The recommended treatment for severe cases was psychotherapy; milder cases could be managed by "drug sedation" and sympathetic counseling. If the woman suffers from a loss of self-worth because of decreasing opportunities for accomplishments, then,

In such cases ways should be pointed out in which she can extend her sphere of productive activity. But more, she may need to have instilled into her enough enthusiasm to overcome a considerable degree of initial apathy. What form the activity takes is largely immaterial...It may be tray-painting, gardening, sitting with a neighbor's baby, bridge, bandage-rolling or what-not.

....Another approach to the "threatened ego" is actually to expand and fortify it by the various resources of sociability, ie, of "identification." Direct the patient into the way of life in which she has increasing use for the pronoun "we" and less for "I" (Hoskins, 1944, p. 609).

Psychoanalyst Benedek urged gynecologists to join in the search for signs of "rejection of femininity":

...women incorporating the value-system of a modern society may develop personalities with rigid ego-defenses against their biological needs. The conflicts which arise from this can be observed clinically not only in the office of the psychiatrist, but also in the office of the gynecologist and even the endocrinologist (1952, p. 527).

That gynecologists took this challenge seriously is evidenced in the introduction to a 1962 monograph, The Gynecological Patient: A Psycho-Endocrine Study:

We feel the discipline [gynecology] should embrace those disturbances in function or structure of any part of the female organism that influence or are affected by the performance of the reproductive system. We are impressed in particular with the dictum that much of the physical and mental health of the

individual woman can be properly understood only in the light of her conscious or unconscious acceptance of her feminine role (Sturgis and Menzer-Benaron, 1962, p. xiv).

That they serve as agents of social control is well understood by these two gynecologists. In the past, they argued, the general practitioner had been "friend, guardian and teacher" of his patient:

With the priest or pastor, he stood as a bulwark against illegitimacy, abortions and divorce... Today, in the medical profession, obstetricians and gynecologists are perhaps best able to fill this position (Sturgis and Menzer-Benaron, 1962, p. 238).

The belief that menopausal problems are largely neurotic responses to lost fertility and lost attractiveness or the result of rejected femininity has been incorporated into gynecological training. Posner (1979), in a content analysis of 29 gynecological texts, found that the prevailing view was that menopausal symptoms are "all in the head." Such labels as "menopausal syndrome" and "empty-nest syndrome" receive disproportionate attention, and physicians are repeatedly urged to look for "rejection of femininity."⁶

In addition to biased medical training, the role of the pharmaceutical industry cannot be overlooked. Psychological explanations for menopausal problems were reinforced by what Silverman and Lee (1974) called the "Pharmaceutical Revolution": the synthesis and manufacture of a large number of psychoactive drugs. Since the 1930s the prolific synthesis of these drugs has virtually revolutionized drug-making and drug-taking in the United States. The American Medical Association's change in policy in accepting more pharmaceu-

tical advertising in the late fifties (Conrad, 1975) was conducive to an explosion of advertisements promoting these drugs.

These advertisements in medical journals portray women as frustrated, anxious, neurotic, depressed and even suggest to doctors that they can "help" women adjust through drugs to an uncomfortable sex-typed role or get rid of elderly women patients who are becoming a "fixture" in their waiting rooms (Seidenberg, 1976). Physicians, like everyone else, appear to be influenced by advertisements which reflect prevailing social norms, and spend very little time investigating the therapeutic merits of a drug.

In a study by Linn and Davis (1972) the large majority of physicians reported the importance of drug ads and company detailmen in selecting drugs for their patients. With medical school training emphasizing the psychosomatic nature of female complaints (Howell, 1974; Posner, 1979; Scully and Bart, 1973) and pharmaceutical advertisements reinforcing those beliefs, it is not surprising that the "menopausal syndrome" became the dominant diagnosis to be treated with tranquilizers.

Menopause as a Deficiency Disease

During the eighteenth and nineteenth century conceptions of health and illness included viewing the body as a closed system of vital energy. Health was defined in terms of a dynamic equilibrium and balance which, in turn, was thought to be a product of the individuals' integration (or conformity) to the larger moral and social environment. Activities which made unusual, excessive (immoral)

demands on the body would lead to depletion, debility and disease. Thus immorality was believed to be a cause of sickness and disease (Conrad & Schneider, 1980).

With the advent of the germ theory, disease came to be viewed as a discrete entity, with specific causes which called for specific treatments. This reductionist view of disease was widely accepted in the twentieth century. With increased knowledge and new perceptions of disease, the physician was able to diagnose and treat a host of "new" diseases. As Freidson pointed out, in these activities the physician can be seen as a moral entrepreneur:

[Medicine] is active in seeking out illness. The profession does treat the illnesses laymen take to it, but it also seeks to discover illness of which laymen may not even be aware. One of the greatest ambition of the physician is to discover and describe a "new" disease or syndrome and to be immortalized by having his name used to identify the disease. Medicine, then, is oriented to seeking out and finding illness, which is to say that it seeks to create social meanings of illness where that meaning or interpretation was lacking before. And insofar as illness is defined as something bad--to be eradicated or contained--medicine plays the role of what Becker called the "moral entrepreneur" (1970, p. 252).

Although menopause in the Victorian period had been defined as a cause of, or being caused by disease, menopause itself had not been defined as a disease. During the 1920's and 1930's, however, a potential treatment became available with the isolation and synthesis of estrogen, a general name for three female hormones (estradiol, estrone and estriol). If estrogens were to become the cure, what was to be the disease? As estrogen therapy became widespread, it followed that

menopause had to be seen as a disease.

The earliest interest in hormone replacement grew out of efforts to find a cure for male impotency (Page, 1977). In 1889 a French physiologist reported to the Societe de Biologie in Paris that he had injected himself with extracts from animal testicals and had experienced renewed vigor and rejuvenation. Four years later another French scientist used an ovarian extract injection to treat a female patient for menopausal "insanity." And in 1896 a German doctor desiccated ovaries for treatment of menopausal symptoms at the Landau Clinic in Berlin (Buxton, 1944). In the later 1920s Allen and Doisey isolated and crystallized theeline (later known as estrone) from the urine of pregnant women (Page, 1977). In 1932 Drs. Samuel Geist and Frank Spielman described in the American Journal of Obstetrics and Gynecology their efforts to treat menopausal women with theeline (estrone). Such treatments, however, were expensive and the supplies limited since the drug was derived from human sources.

These problems were solved in 1936 when Marker and Oakwood developed a synthetic form of estrogen, known as diethylstilbesterol (DES). This cheap and potent hormone substance could be made readily available to a large number of women and paved the way for the development of the contraceptive pill. The last step in the development of hormone therapy occurred in 1943 when James Goodall developed an estrogen extract from the urine of pregnant mares. Termed conjugated equine estrogen and manufactured under the brand name of Premarin, it was only about half as potent as synthetic estrogen, but it created fewer unpleasant side effects (Page, 1977).

With a readily available treatment, the stage was set for the "discovery" of a disease. All that was lacking was a moral entrepreneur to lead the crusade for the redefinition of menopause. This role was filled by the Brooklyn gynecologist Robert A. Wilson. As head of the Wilson Research Foundation, his writings were crucial to the acceptance of menopause as a "deficiency disease" and the large-scale routine administration of Estrogen Replacement Therapy" (ERT). Wilson claimed that through his extensive research he discovered that the menopause was a hormone deficiency disease similar to diabetes and thyroid dysfunction. In a 1962 article published in the Journal of the American Medical Association, he claimed that estrogen prevented breast and genital cancer and other problems of aging. Even though the methodology was weak,⁷ it launched a campaign to promote estrogens for the prevention of menopause and age-related diseases.

By 1963, in the Journal of the American Geriatrics Society, Wilson was advocating that women be given estrogens from "puberty to grave." Crucial to the popular acceptance of the disease model of menopause was his widely read book Feminine Forever (1966). Here Wilson claimed that the menopause is a malfunction which threatens the "feminine essence." He described menopausal women as "living decay" but menopausal women need not despair: ERT could save them from being "condemned to witness the death of their womanhood." He further proclaimed that the menopause and aging could be allayed with ERT and listed 26 physiological and psychological symptoms--including hot flashes, osteoporosis (thinning of bone mass), vaginal atrophy (thinning of vaginal walls), sagging and shrinking breasts, wrinkles,

absent mindedness, irritability, frigidity, depression, alcoholism and even suicide--that the "youth pill" could avert.

Wilson also was aware of the physician's potential and even mandate for social control. In his chapter titled "Menopause--The Loss of Womanhood and Good Health" the first paragraph states:

...I would like to launch into the subject of menopause by discussing its effect on men. Menopause covers such a wide range of physical and emotional symptoms that the implications are by no means confined to the woman. Her husband, her family, and her entire relationship to the outside world are affected almost as strongly as her own body. Only in this broader context can the problem of the menopause--as well as the benefits of hormonal cure--be properly appreciated (1966, p. 92). (Emphasis added)

Wilson gives an example of how he helped a distressed husband who came to him for help with the following complaint:

She is driving me nuts. She won't fix meals. She lets me get no sleep. She picks on me all the time. She makes up lies about me. She hits the bottle all day. And we used to be happily married (1966, p. 93).

Wilson tells how the wife responded well to "intensive" estrogen treatment and in no time resumed her wifely duties. In another chapter Wilson conjures up visions of "Steppford Wives":

In a family situation, estrogen makes women adaptable, even-tempered, and generally easy to live with. Consequently, a woman's estrogen carries significance beyond her own well-being. It also contributes toward the happiness of her family and all those with whom she is in daily contact.

Even frigidity in women has been shown to be related to estrogen deficiency. The estrogen-rich woman, as a rule, is capable of far more generous and satisfying sexual response than women whose femininity suffers from inadequate chemical support (1966, p. 64).

A number of other prominent gynecologists supported Wilson's claims. For example, Shirwin Kaufman in The Ageless Woman described menopausal symptoms as the result of hormone deficiency and lamented:

Many women are obviously in need of estrogen replacements but are so afraid of "hormones" that it requires a good deal of explanation to persuade them that estrogen does not cause cancer and may, on the contrary, make them feel much better (1967, p. 61).

Kaufman regretted that some of his colleagues also share this unwarranted fear of cancer:

Some doctors prescribe estrogens reluctantly.... Historically, and too often hysterically, estrogens have been endowed with malignant potentialities. Paradoxically, it has been pointed out that even conservative physicians may not hesitate to give sedatives or tranquilizers, yet they stop at the suggestion of estrogen replacement therapy. This is baffling to a good many doctors (1967, p. 67).

Kaufman confessed that "Years ago, I used to discontinue such treatment (ERT) after a few months," but "today I am in no rush to stop" (1967, p. 64).

Best-selling author David Reuben proclaimed in Everything You Wanted to Know About Sex:

As estrogen is shut off, a woman comes as close as she can to being a man. Increased facial hair, deepened voice, obesity, and decline of breasts and female genitalia all contribute to a masculine appearance. Not really a man but no longer a functional woman, these individuals live in a world of intersex. Having outlived their ovaries, they have outlived their usefulness as human beings (1969, pp. 287-288).

But women need not despair: with estrogen replacements they can "turn back the clock" and adequate amounts of estrogens throughout

their life will protect them against breast and uterine cancer (1969, p. 290).

Another crusader for ERT, Helen Jern, a gynecologist at the New York Infirmary, published a book of case studies proclaiming the miraculous recoveries made by elderly women placed on ERT:

I know the remarkably beneficial effect of estrogen as energizer, tranquilizer and anti-depressant. I know that it stimulates and maintains mental capacity, memory, and concentration, restores zest for living, and gives a youthful appearance...Hormone therapy once begun, should be continued throughout a woman's lifetime. It is my firm belief that many female inmates of nursing homes and mental institutions could be restored to full physical and mental health through adequate hormone therapy (1973, p. 156).

Robert Greenblatt (1974), former President of the American Geriatrics Society, has claimed that about seventy-five percent of menopausal women are acutely estrogen deficient and advocates ERT for them, even if they are without symptoms. Echoing these sentiments, a San Francisco gynecologist stated:

I think of the menopause as a deficiency disease like diabetes. Most women develop some symptoms whether they are aware of them or not, so I prescribe estrogens for virtually all menopausal women for an indefinite period (quoted in Brody, 1975).

Meanwhile throughout the late 1960s and early 1970s Wilson's book was excerpted widely in traditional women's journals and over 300 articles promoting estrogens have appeared in popular magazines (Johnson, 1977). During the same period, ERT products were widely advertised in medical literature and promotional material as amelioratives for a variety of psychological, as well as somatic, problems.

For example one ad depicted a seated women clutching an airline ticket, with her impatient husband standing behind her glancing at his watch. The copy reads:

Bon Voyage? Suddenly she'd rather not go. She's waited thirty years for this trip. Now she just doesn't have the "bounce." She has headaches, hot flashes, and she feels tired and nervous all the time. And for no reason she cries.

Another ad promoted ERT "for the menopausal problems that bother him the most." And an ad for Premarin stated: "Any tranquilizer might calm her down...but at her age, estrogen may be what she really needs" (cited in Seaman & Seaman, 1977, pp. 281-282). Such advertisements paid off: between 1962 and 1973 dollar sales for estrogen replacements quadrupled; in 1975 alone 25 million prescriptions were written for ERT products, amounting to some \$80 million in sales (Wolfe, 1979).

The year 1975 was a watershed for ERT: sales were at an all-time high and physicians routinely used ERT to treat a wide variety of menopausal symptoms. In short, ERT had become one of the mainstays of medical practice. Yet within a few short years this was to change. The prevailing definition of menopause and ERT were to be challenged, not only from within, but from a variety of sources outside, the medical community. A description and analysis of the challenge follows in the next chapter.

Summary and Conclusion

The foregoing literature shows that the medical definitions of menopause fall into three broad categories: (1) menopause as sin and

decay; (2) as a psychological problem; and (3) as a deficiency disease. Although these three themes permeate the whole time period examined, differential emphasis has been specific to historical periods.

In the eighteenth and nineteenth century, physicians depicted the menopause as disease-ridden and attributed the severity and frequency of symptoms to indiscretions of earlier life. In the early twentieth century, psychogenic explanations began to vie for dominance. Freudian theory laid the groundwork for viewing menopausal symptoms as neurotic responses to lost fertility or rejection of femininity. After the synthesis of a cheap estrogenic substance, the deficiency disease model gained prominence and was widely accepted by the early 1970's.

Despite the changing perception of the etiology of menopausal symptoms and the treatment of choice varying from leeches to estrogen, there are several underlying, persistent themes: women's potential and function are biologically destined;⁸ rejection of the feminine role will bring physical and emotional havoc; women's worth is determined by fecundity and sexual attractiveness; and aging women are repulsive and useless.

These medical definitions can be seen as collective and political achievements, rather than inevitable products of the evolution and progress of science. Powerful social groups can construct and define reality and impose their collective definitions on less powerful groups. Throughout the time-span examined, the medical profession had defined menopause as a pathological and stigmatizing

event.

Yet there is evidence that the subjective experience of women has not always been congruent with the physicians' constructed reality. Carroll Smith-Rosenberg, in an analysis of Victorian women's letters, diaries, and unpublished manuscripts, found that some women viewed menopause as a release from the bondage of menstruation and pregnancy. She quotes social reformer and suffragist Eliza Farnham, writing in the 1860s, that for many women menopause was a time of "secret joy", of spiritual unfolding, and of "super-exaltation". The stigma attached to menopause, she attributed to "masculine error" (Smith-Rosenberg, 1974, p. 33). Historian Stearn (1976) found that despite the widely held medical belief that women decayed at menopause, they were healthier and lived longer than men. Surveys conducted in the 1960s have shown that menopausal and post-menopausal women have a more positive attitude toward this period than do younger women, and do not consider it a significant event (Kraines, 1963; Levit, 1963; Neugarten, et al., 1968). Contrary to psychoanalytic theory, Bart (1970) found that traditional, "feminine" women experienced greater depression at menopause than did more "liberated" women. Cross-cultural studies strongly suggest that depression occurring at the menopause is related to cultural and structural factors rather than psychological changes (Bart, 1969; Dowty, 1972). Dowty, et al., (1971) in a study of five sub-cultures in Israel, found that although menopausal problems were related to status changes, the women in the sample did not regret lost fertility.

All these studies suggest that women's subjective experience has been ignored or at least de-emphasized. As McKinlay and McKinlay state in their review of menopausal literature, "the power of physicians ... has served to shield the knowledge and practices of the medical profession, including the quality of research" and "clinical experience has assumed unparalleled legitimacy as a basis of knowledge and practice, regardless of its lack of objectivity and substantiation" (1933).

Several historians have suggested that Victorian physicians feared and envied women's sexuality and expressed their hostility by inflicting painful and ineffective therapy. Wood (1974) argues that male physicians, acting in fear, were engaged in "psychological warfare" and that medical practice was based on "veiled but aggressively hostile male sexuality and superiority". Barker-Benfield (1976) also focused on the psychological make-up of doctors. According to his thesis, drastic gynecological surgery and sadistic treatment were the result of a tacit conspiracy between insecure husbands and anxious gynecologists, as a way of controlling women.

Yet to portray women as passive victims at the hands of sadistic doctors, as recent historical and feminist writers have done, is to present an incomplete if not distorted picture. Women and physicians are the products of the same cultural milieu, and share some of the same assumptions and beliefs. Psychological explanations might be tempting, but ignore larger structural factors. Motives are generally inaccessible to the social scientist, but placing whole segments of past societies on the couch poses even more serious

methodological problems. As Verbrugge (1976) notes:

Sexual oppression has been a powerful factor in medicine and society. But to see it as the primary force oversimplifies history. Sexism and social control are not intrinsic to medicine, but relate to the socio-economic system at a particular time.

In that spirit, the remainder of this thesis is an attempt to understand one controversial aspect of the menopause, Estrogen Replacement Therapy, within a broad social context. The chapter that follows will examine how scientific, professional, political and social movement factors have, and continue to, shape an important medical practice.

CHAPTER 3 THE ERT CONTROVERSY IN THE UNITED STATES AND GREAT BRITAIN

In this chapter we demonstrate that the ERT controversy has developed quite differently in the United States and Great Britain. We focus on four cross-cultural differences: (1) the medical research community, (2) physician practices, (3) feminist/consumer groups, and (4) regulatory policy. Before examining these differences we present a brief overview of the medical controversy concerning ERT.

Medical Controversy

When did the controversy over estrogens begin? While such an assignation is arbitrary, it seems clear that the dispute is not a new one. A general association between estrogens and cancer has been suspected since the 1890s (see Johnson, 1977). Experimental animal studies, conducted in the 1930s and 1940s, claimed that estrogenic and progestinic substances were carcinogenic (Cook & Dodds, 1933; Gardner, 1944; Perry & Ginzton, 1937). In an article published in the American Journal of Obstetrics and Gynecology, Novak and Yui (1936) warned that estrogen therapy might cause a pathological build-up of endometrial tissue.

Most investigators trace the roots of the contemporary ERT controversy back to 1947. In that year Dr. Saul Gusberg, then a young cancer researcher at the Sloane Hospital and Columbia University in New York, made the histologic link between hyperplasia (proliferation of the cells lining the uterus) and adenocarcinoma in the human endo-

metrium. After finding a significant increase of endometrial cancer among estrogen users, Gusberg wrote in 1947:

Another human experiment has been set up in recent years by the widespread administration of estrogens to postmenopausal women. The relatively low cost of stilbestrol and the ease of administration have made its general use promiscuous.

Why was more attention not paid to these early warnings? In addition to the low cost and ease of administration of estrogens mentioned by Gusberg, these early studies were judged to be scientifically inadequate: those based on animal studies were dismissed as not applicable to humans. Perhaps most importantly, though, estrogens were seen as effective in treating vasomotor disturbances and vaginal dryness and irritation, providing dramatic and immediate symptomatic relief of even the most severe hot flashes. This latter sentiment was expressed in 1941 by Geist et al.:

...it is suggested that extreme caution be used before attributing carcinogenic properties to estrogen in human beings, lest an extremely valuable therapeutic agent be condemned unjustly.

The current ERT controversy erupted in 1975 with the publication of two independent epidemiological studies. These and subsequent studies concluded that women on ERT had a four to twenty times greater risk of developing endometrial cancer than non-users. Moreover the risk of cancer increased with the duration and dose of estrogens (for a review of eight such studies published between 1975 and 1979, see Gusberg, 1980). Indeed according to Gusberg, endometrial cancer has apparently "superseded cervical cancer as the most common malignant tumor of the female reproductive tract" (1980, p. 729).

The current medical controversy over ERT focuses on three questions: (1) is ERT a risk to health? Strong claims have been made that ERT significantly increases the risk of endometrial cancer. Weaker but significant claims are also made that ERT, once thought to protect against cardiovascular disease and breast cancer, actually might increase the risk of those conditions. Each and all of these claims are disputed on a variety of clinical and methodological grounds. (2) What are the benefits of ERT? Many researchers claim that estrogens can prevent osteoporosis, the thinning and weakening of bones associated with postmenopausal estrogen decline. The extent of these claims is questioned: some assert dramatic, others only marginal, value of ERT in treating vasomotor instability (hot flashes or flushes) and various vaginal and urinary tract problems associated with the menopause. ERT is also purported to alleviate mental problems and act as a prophylactic against age related changes in skin, hair and breasts; most current American research dismisses these claims. (3) Are the purported benefits of ERT worth the purported risks? Here, in a matter of urgent medical and public policy, a judgment is necessary. We will show that, based on the same scientific evidence, that judgment had developed quite differently in the United States and Great Britain.

U.S. and British Differences

The different actors and their positions are schematically presented in Table 1. Any classification scheme necessarily is sim-

plistic and obscures individual case differences. We do not imply that groups are homogeneous in their endorsement or opposition to ERT, only that the majority of literature examined points to pro or con positions.

Table 1
ERT Positions Taken by Different
Groups in Each Country

Group	United States	Great Britain
Researchers	Con	Pro
Practitioners ^a	Pro	Con
Feminists/Consumers ^b	Con	Pro
Regulatory agencies	Con	Pro

^aPractitioner is the physician of first contact: a GP in Great Britain, usually a gynecologist in the U.S.

^bThe distinction between feminists and women consumers is not always clear.

The remainder of this chapter is organized to explicate Table 1. In turn we focus on each row of the Table. First we examine the American point of view; then we develop the British view by contrast.

The Researcher Community

In both countries researchers agree that risks as well as benefits are associated with ERT. However, Americans have conducted research on the risks, whereas the British have concentrated on the

benefits, of estrogen therapy.

American Researchers. In the U.S. the major focus of ERT research is now on the cancer linkage. Since 1975 eleven American studies have associated estrogen use with the development of endometrial cancer.¹⁰ In these retrospective studies, estrogen use of patients with endometrial cancer was compared with that of matched controls. The women were of menopausal age or older and the estrogens were of the type usually taken to relieve hot flashes and other symptoms that accompany the cessation of the menses. The results of these studies showed that significantly more of the cancer patients had been estrogen users than of the controls.

The frequency of endometrial cancer in all postmenopausal women is 1 per 1000 per year; these studies report that for estrogen users the frequency is about 4 to 20 per 1000 per year. The first two of these studies were published in the December 1975 issue of the prestigious New England Journal of Medicine. Smith et al. (1975) found that 152 of 317 patients with endometrial cancer had taken some kind of estrogen for at least 6 months. Of the 317 controls, only 54 had taken estrogens. The researchers concluded that estrogen users had a 4.5 greater risk of developing endometrial cancer as compared to nonusers.

At the Kaiser Permanente Medical Center in Los Angeles, Ziel and Finkle (1975) compared the hospital records of 94 endometrial cancer patients with 188 matched controls selected from the membership files of the Southern California Kaiser Foundation Health plan. The inves-

tigators found that 57 percent of the cancer patients had used estrogens, whereas only 15 percent of the controls had done so. For women who had used estrogens for one to five years, the risk of developing cancer was 5.5 times greater than for nonusers. Moreover it was found that the risk increased with the duration of the treatment: women who had used conjugated estrogens for seven years had a 15 times higher probability of developing the cancer.

Six months later the probability of a causal relationship between estrogen and uterine cancer was strengthened with two more reports published in the New England Journal of Medicine. The first, a demographic study, noted that between 1969 and 1973 the incidence of endometrial cancer had generally increased from 20 to 60 percent, dependent on the geographical area surveyed. The incidence was highest among white middle-aged women belonging to the upper socioeconomic strata (a 40 to 150 percent increase)--the usual target population for ERT. The magnitude of that increase, concluded these researchers, "has rarely been paralleled in the history of cancer reporting in this country" (Weiss et al., 1976, p. 1259). This increase of endometrial cancer was found to be strongly correlated with the temporal estrogen consumption among older women in the United States.

The second study, conducted by Mack et al. (1976) on women at an affluent retirement community, found that the odds of developing endometrial cancer increased by a factor of eight among estrogen users. Although the type of estrogen was not an important variable, higher doses were found to increase the risk. The authors concluded

that the risk of developing endometrial cancer among estrogen users is greater than the combined risk of breast, lung, ovary and colon cancer.¹¹

Recent studies have differed on whether the dose and duration of estrogens are an important factor in the risk-benefit equation. Even so the use of estrogens has been consistently related to increases in the likelihood of cancer. Indeed in a review article titled "The negative side of long-term postmenopausal estrogen therapy," Ziel stated:

These [cancer] studies have been attacked on every conceivable basis, but they have withstood the criticism and the test of time. The association of endometrial cancer with estrogen exposure is nearly as strong as the association of lung cancer with cigarette smoking. In fact the association is so well established that no further research grants are offered to study it (1980, p. 450).

Other American studies have also asserted that ERT increases the risk of breast cancer (Hoover et al., 1976; Ross et al., 1980), atherosclerosis (Coronary Drug Project Research Group, 1973; Stadel & Weiss, 1975), myocardial infarction, pulmonary emboli, and thrombophlebitis (Coronary Drug Project Research Group, 1970), hypertension (Pfeffer et al., 1976), gall bladder disease (Boston Collaborative Drug Surveillance Program, 1974), and diabetes (Hammon et al., 1979).

At a 1979 Consensus Development Conference on Estrogen Use and Postmenopausal Women--sponsored by the National Institute for Aging--researchers unanimously concluded that ERT substantially increases the risk of endometrial cancer. The final report of the conference recommended that ERT, if used at all, should be administered on a

cyclical basis (three weeks of estrogen, one week off), at the lowest dose for the shortest possible time. Any candidate for postmenopausal estrogen, it was recommended, "should be given as much information as possible about both the benefits and risks and then, with her physician, reach an individualized decision regarding whether to receive estrogens" (Gastel et al., 1979).

British Researchers. British research is skeptical of the cancer link, and instead has focused on the benefits of ERT. For example our analysis of the Consensus Development Conference bibliography showed that nine British research studies were cited; all nine emphasized the benefits of ERT. At the Twentieth British Congress of Obstetrics and Gynecology the consensus was to endorse the efficacy of ERT and Cooper (1975) stated, "providing oestrogens are administered on a cyclical basis, most gynecologists today dismiss the cancer link completely."

At a 1976 Menopausal Conference sponsored by the Royal Society of Health, the efficacy of ERT was reaffirmed (this coming after several American cancer studies), even for emotional problems. "It is well known," stated British endocrinologist Stuart Mason,

...that hot flushes can be relieved by oestrogen...
It is equally well known that the genital tract atrophy which may be so troublesome a feature of oestrogen deficiency is relieved by oestrogen. Less well recognized are the aches and pains due to connective tissue changes induced by oestrogen lack and the varied emotional disturbances that may be related to oestrogen deficiency (Mason, 1976, p. 71) (Emphasis added).

In a similar vein, a recognized authority in endocrinology claimed

that ERT was indicated for such problems as "depression, irritability, anxiety, loss of energy, headaches, palpitations and absent mindedness" and should be used "before resorting to expensive and addictive tranquilizers" (Dalton, 1976, p. 75). Another researcher (Senior, 1976, p. 75) applauded the fact that British physicians were finally recognizing the menopause for what it was--a deficiency disease.

The participants at this conference also advocated the expansion of NHS menopausal clinics (to be discussed in the "regulatory" section of this chapter)--specifically designed to promote estrogen treatment. But women should not wait for the universal establishment of such clinics, for

...under the National Health Act it is the duty of the general practitioner to give "reasonable and necessary care" to those on his list. Who can deny that hormone replacement therapy for those with signs of oestrogen deficiency symptoms is "reasonable and necessary"? (Dalton, 1976, p. 77).

Perhaps the best way to summarize research opinion is to examine the editorial positions of prestigious medical journals. Here an opinion or judgment, though written by an individual, carries the imprimatur of the entire journal. The editorial position of Lancet, a prestigious British medical journal, has changed from a rather cautious position in 1975 to a pro ERT one by 1977. The first editorial in 1975 acknowledged the efficacy of ERT to counteract the most "insidious" hormone deficiency states such as osteoporosis and "most importantly, the loss of femininity associated with progressive atrophy of the secondary sexual characteristics", but

warned of the unknown side-effects of long-term treatment. It was feared that "popular demand" for ERT would "overtake proper medical caution" for

[i]n the van of the defence is a small but highly vocal group of doctors and patients who claim that long-term steroid replacement is a woman's right, and represent any contrary views as male chauvinism (Lancet, 1975, p. 182).

Five months later, another Lancet editorial referring to the American cancer studies stated:

Of the advantages [of ERT] there can be little doubt--and some say that this therapy is a woman's right. In contrast the disadvantages are nebulous ...(Lancet, 1975, p. 1135).

Finally a 1977 editorial criticized the methodology of the five American cancer studies and judged the epidemiological evidence as "fragile":

The main objections to the five studies are: that they were not double-blind and allocation to case control groups was not randomized; that they were not prospective; and that the groups were unrepresentative of the female population. Other variables may have contributed to the association --use of oestrogens for perimenopausal bleeding caused by an unsuspected but pre-existing malign or pre-malign lesion; greater frequency of diagnostic examinations amongst hormone treated women; and possible misinterpretation of oestrogen induced hyperplasia as neoplasia (Lancet, 1977, p. 577).¹²

The British Medical Journal found the American studies somewhat more disquieting. A 1976 editorial noted that since physicians have been under considerable pressure to prescribe estrogens, many menopausal clinics have been established. Therefore, a "possible causal link" between estrogens and cancer "warrant careful examination."

But the dilemma was resolved:

What should we do now? Smoking 20 cigarettes a day increases the risk of death from lung cancer 17-fold. The risk of oestrogens is less than that. In view of the positive benefits of oestrogen therapy for postmenopausal women we are justified in continuing to expose them to this risk (British Medical Journal, 1976, p. 792).

This editorial was criticized by a prominent British researcher for drawing "alarmist conclusions based upon so many suspect data". He continued that the "positive benefits of hormone replacement therapy are now beyond dispute" and that:

It can be safely stated that there is no clinical or epidemiological evidence that oestrogen in the doses used to treat the climacteric syndrome are in any way incriminated in the causation of endometrial carcinoma (Studd, 1976, p. 1145).

A 1977 British Medical Journal editorial criticized ERT as a "fashionable" treatment and that short-duration treatment had been abandoned in Britain because "long-term oestrogens have come into vogue" (1977, p. 209). The editorial then called attention to the increasing number of American cancer studies. This editorial drew an angry response from the numerous British researchers who called the editorial "misleading" and stated that ERT is "fashionable" only because it is "effective" and that present evidence does not prove a cause-and-effect relationship between estrogens and cancer (Whitehead et al., 1977, p. 453). Another researcher stated that numerous studies have failed to establish any association and it therefore was unfortunate that an editorial would only state one side of the controversy:

It is an unfortunate feature of the news media in general that bad news seems to carry more weight than good news, but this selective attention to sensational positive reports at the expense of less exciting negative results should not be allowed to penetrate the scientific field (Nordin, 1977, p. 454).

As several more American studies strengthened the purported cancer link, British opposition shifted from methodological criticism to criticism of the mode of therapy as practiced in the U.S. It was acknowledged that "unopposed" estrogens probably increased the cancer risk, but that the addition of a sequential progestagen--the last five to 13 days of a twenty to thirty-day course of estrogen--would act as an anti-estrogenic agent and protect against endometrial hyperstimulation.¹³ Thom has summarized these British claims:

The symptomatic and long term metabolic advantages of oestrogen treatment should now be beyond dispute....There is no published evidence that low-dose cyclical oestrogen with progestagen is in any way associated with an increased risk of endometrial hyperplasia or carcinoma (1979, p. 457).

John Studd, an insistent and vocal ERT proponent, stated that the increase in endometrial cancer in the U.S. is a measure of "bizarre therapy" rather than of dangers inherent in hormones, "a mistake that would not be made by any final year medical student" (1979, p. 922). In a 1980 interview Studd stated that the American experience was the "result of inappropriate practice" and that the current belief of American physicians that estrogens cause cancer is to be regretted since many women have severe menopausal problems, such as "hot flushes and sweats" and have "terrible sexual problems, depression, irritability, shouting at the kids in the family and can't

cope with feeling." All these problems, according to Studd, can be alleviated safely with combined estrogen-progestin therapy. Another researcher, drawing attention to British studies, stated:

If we are to avoid the incidence of endometrial carcinoma currently reported in the United States, we must surely adopt the conclusions of our own studies and encourage the wider usage of progestagen - containing regimes of therapy for menopausal women (Sturdee, 1979, p. 1399).

The British argument has not been confined to the cancer issue. Three recently published medical books are devoted to the benefits of ERT (Beard, 1976; Campbell, 1977; Studd, 1977). British research has shown the efficacy of ERT for non-life threatening symptoms such as flushes and sleeplessness, but has concentrated mainly on osteoporosis.¹⁴ These studies claim that ERT significantly retards bone loss and may even prevent osteoporosis. But once bone loss is started, there is no evidence that estrogens can reverse the process. Also if therapy is stopped, bone loss accelerates and returns to base line in a short span of time. The implications from these studies are that for greatest effectiveness, ERT should be started early, and once begun, continued to the end of the woman's life. British researchers are advocating just that, but a 1980 British Medical Journal editorial is somewhat more cautious:

The present evidence is still insufficient for a final decision whether treatment with oestrogen should be offered to all women from the time of the menopause for the rest of their lives in order to protect against osteoporosis. (Emphasis added)

American Response to British Claims. Does combined therapy mini-

mize the cancer risk? According to American researchers progestin might reverse endometrial hyperplasia, but it is not yet well established that hyperplasia is a precursor of endometrial cancer (Stolley & Davis, 1979). Furthermore, as was concluded at the Consensus Development Conference (Gastel et al., 1979), the dangers associated with progestin have not yet been fully evaluated, and the FDA has not approved the combined treatment for menopausal use. There is indication that estrogen-progestin therapy is associated with hypertension, heart disease, and diabetes (Hammond et al., 1979; Kase, 1980). Some American research also indicates that this combined sequential treatment did not prevent endometrial carcinoma:

The monthly addition of a progestin to a course of estrogen did not prevent all endometrial cancers in young women taking the sequential contraceptives. Postmenopausal women, who are at greater risk for endometrial neoplasia, would have even less protection (Ziel, 1980, p. 451).

Less serious, but a bother that older women often find unacceptable, is that combined therapy causes monthly bleeding, mimicking the menstrual cycle.

American researchers seem undecided about whether long-term therapy can prevent or ameliorate osteoporosis. The Consensus Development Conference and the FDA state that estrogens are "probably" effective if combined with calcium supplements and exercise but claim that the cancer risk does not warrant long-term therapy. Summarizing the American position Ziel states:

The only potentially valid long-term use of estrogen is for combating the development of osteoporosis...Becker et al. have shown that as

little as four 10 grain calcium carbonate tablets daily stabilize bone density nearly as well as 0.625 mg of conjugated estrogen and 5 mg of methyltestosterone taken daily. Perhaps, with the addition of an exercise program or with protein, fluoride, or Vitamin D supplements, bone density would be equal or even exceed the density achieved with estrogen (1980, p. 450).

Physician Practices¹⁵

After weighing the research evidence, the patient's symptoms and preferences, the physician decides whether or not to prescribe ERT. Thus the physician of first contact becomes the crucial mediator between the research community and the consumer. In both countries, the prevailing physician practice is in contradiction to the research findings and to the demand of consumers.

American Physician Practices. In the United States the physician of first contact is most often a gynecologist,¹⁶ particularly for white, middle-class women, and appears to be quite willing to prescribe ERT. That American physicians endorse ERT is shown by the widespread use of the treatment. Between 1963 and 1973 dollar sales for estrogen replacements quadrupled (U.S. Bureau of the Census, 1975). Indeed, as one Harvard researcher stated, "few medical interventions have had as widespread application as exogenous estrogen treatment in postmenopausal women" (Weinstein, 1980). By 1975, with prescriptions at an all-time high of 26.7 million (Wolfe, 1979), estrogens had become the fifth most frequently prescribed drug in the country (Hoover et al., 1976).

According to population surveys in the 1970s, approximately one-

third of the 30 million postmenopausal women were receiving estrogens (Barrett-Connor, 1979). The drug use varied by social class and geographic area, with the highest use reported among middle-class women living on the West Coast. For example, a 1975 survey conducted in the Seattle/Tacoma area revealed that 51 percent of postmenopausal women had used estrogens for at least three months, with a median duration of over 10 years (Weiss, et al. 1976). Pfeffer (1977) found that estrogen use continued into the seventh, eighth and even ninth decades of life, and Barrett-Connor (1979) reports that 24 percent of women aged 70-74 were on ERT--this is in direct opposition to FDA and research recommendations of "shortest possible use".

Even after the publication of the first three cancer studies in 1975, a spot check of gynecologists revealed that the new reports had little effect on physician practices (Brody, 1975). Each of the doctors interviewed pointed out that the studies did not conclusively prove that estrogens cause cancer, and therefore no drastic change in practice was warranted. Brody quoted a San Francisco gynecologist:

I think of the menopause as a deficiency disease like diabetes. Most women develop symptoms whether they are aware of them or not, so I prescribe estrogens for virtually all women for an indefinite period.¹⁷

Even though prescriptions for ERT have steadily declined since 1975, some 16 million were still written in 1978 (Wolfe, 1979). Indeed a recent survey showed that two-thirds of all women who saw their physicians about menopausal complaints received estrogens and 50 percent received tranquilizers (Dosey & Dosey, 1980). In fact a 1978 FDA drug analysis study concluded that menopausal estrogens, even

after a major decline, were still "grossly overused" (Burke et al., 1978). Again in contradiction to FDA labeling, an analysis of 1979 estrogen replacement prescriptions revealed that a substantial portion (31 percent) were still written for such vague diagnostic categories as "symptoms of senility", "special conditions without sickness", and "mental problems" (IMS, 1981).^{18,19}

Other measures of physicians' endorsement of ERT are authoritative references which describe menopause as a morbid condition for which estrogen therapy is indicated. For example, The Merck Manual (Berkow, 1977; Holvey, 1972), a book of diagnosis and therapy widely used by physicians, lists menopause under "Ovarian Dysfunction" and Drugs of Choice (1980) lists it under "Diseases of the Endocrine System". Both sources advocate estrogens for treatment, and Drugs of Choice states in the 1980 edition that "objective studies" evaluating the risks and benefits are "not currently available" (Modell, 1980, p. 540). Likewise, Current Medical Diagnosis and Treatment (Krupp, 1980) lists menopause under "Endocrine Disorders" and notes that "estrogen therapy has been recommended for life" but "the advisability of this practice remains unsettled" (1980, p. 731).

In its 1980 edition, Current Therapy claimed that the many symptoms of the menopause "constitute the syndrome of estrogen deficiency":

The philosophy underlying treatment should follow the guidelines proposed for the other deficiency diseases. There are parallels with hypoenestrogenism, hypothyroidism, and hypoinsulinism (Kantor, 1980, p. 839).

Under the risks and benefits of estrogen therapy, eight benefits are listed including "improvement of disposition and unreasonable outburst of temper" and "avoidance of the shrinking and sagging of breasts." Attention is called to recent cancer claims but "when doses are small and administration is in interrupted courses, any potential risk is indeed small and perhaps theoretic." But a patient who has been frightened by "magazine articles" or "Food and Drug Administration bulletins" may "psychologically block the benefits" of ERT (Kantor, 1980, p. 389).

Finally we note that physicians' professional associations have taken pro ERT positions. The American Medical Association, the American College of Obstetricians and Gynecologists, and the American Society for Internal Medicine joined in a lawsuit (described later in this chapter) to stop the FDA from warning consumers about the risks of ERT. Their affidavit claimed:

...that it interferes with the practice of medicine by physicians according to their best professional judgment and by dictating the way in which they may practice their profession...The regulation will discourage patients from accepting estrogen therapy when prescribed by doctors which will impair the reputation of estrogens and reduce the sale of the drug (quoted in Epstein, 1978, p. 236).

In another affidavit a Detroit gynecologist stated "The best [it] will accomplish is a massive scare which the medical evidence indicates is wholly unwarranted" and the patient could experience such an erosion of confidence

...that she would not bother contacting her doctor at all, but simply discontinue consultation with the physician in the mistaken belief that he

lacks competence or adequate concern for her
(quoted in Grossman & Bart, 1979, p. 167).

Speaking for the AMA, William Barclay feared that patients, upon reading the warning, "will develop symptoms through suggestibility and will blame the physician and the medication for problems that are really caused by the [warning]" (1980, pp. 95-96).

The official journal of the American Medical Association, in contrast to the research oriented New England Journal of Medicine,²⁰ has as recently as 1979 and 1980 endorsed long-term estrogen therapy and severely criticized the FDA for regulating ERT products. In a "special communication" the Journal noted that the benefits of ERT outweigh the risks and reprimanded the FDA Commissioner for mandating a "biased" warning: "In doing so he has officially expressed his distrust of the medical profession. He has also committed himself to a slanted, if not dishonest, presentation of the facts" (Landau, 1979, p. 47). In the 1980 American Medical Association Journal editorial the FDA was again criticized for creating unnecessary "public anxiety" since "Estrogens already rank among the safest of all pharmaceuticals" (Meier et al., 1980, p. 1658).

The tenacity of American gynecologists in maintaining the use of estrogen therapy is evidenced by the publication of a new popular book titled A Woman Talks with Her Doctor: A Comprehensive Guide to Womens' Health Care (Flowers, 1981). The author, a "practicing gynecologist for nearly thirty years" states

My personal position is that long-term estrogen replacement may be appropriate and beneficial for many patients and it certainly can be safe when used under a doctor's care It is dis-

trussing to me to think of a number of women in our country, who are developing painful intercourse or having unnecessary bone fractures from osteoporosis because they have been frightened away from estrogen therapy by the exaggerated dangers described in package inserts (Flowers, 1981, pp. 246-247).

British Physician Practices. The National Health Service (NHS), instituted in Great Britain in 1948, took great care to preserve the general practitioner (GP) as the physician to provide first contact and also long-term care. Indeed, it has been estimated that the GP is the only point of contact for 90 percent of all persons seeking medical help (Sidel & Sidel, 1977). Only patients with major or complex illnesses are referred to a specialist (known as a consultant) at a clinic or hospital.²¹

Numerous secondary sources indicate the GP's reluctance to prescribe ERT. The best known is British feminist and journalist Wendy Cooper who stated that she has received over 5000 letters from women complaining that their GPs refused to prescribe hormone treatment. Though "more and more top British gynecologists are coming out in open support," she lamented that "...at the family-doctor level there is still considerable resistance based on either apathy or ignorance" (1975, p. 20). It is one thing to prove that ERT works, noted Cooper, but quite another to get the traditional minded GP to "accept the revolutionary idea of the menopause as a deficiency condition that needed treatment":

After all, over the centuries the "change" had been considered a natural and inevitable part of aging, a normal state for a woman at a certain time of

life (Cooper, 1975, p. 18)

Similarly Evans, a physician herself, stated:

British doctors have undeniably been, and many still are, slow to accept the wider use of hormone treatment at the climacteric. If they thought about it at all, the last generation of doctors was likely to regard the menopause as something women had to get on with (1979, p. 99).

Evans feels that general practitioners are not well informed about the climacteric and many do not feel "equipped for the routine management of menopausal problems, and have neither the time or inclination to become closely involved" (1978, p. 100).

To circumvent the GP's reluctance to prescribe ERT, NHS menopausal clinics, usually attached to research hospitals, were established beginning in 1973. Additionally, an organization called Women's Health Care, Ltd.²² was established with the sole purpose of providing information on menopause and to make available lists of gynecologists and menopausal clinics specializing in ERT (Gillie, 1975).

It appears that the continued demand for ERT (this demand is documented in the next section) has had an effect on physician practices. An analysis of British prescription data (in contrast to American ERT prescriptions which have declined 40 percent since 1975) revealed that between 1971 and 1977 the number of ERT prescriptions increased roughly threefold to about 1.2 million (Bungay et al., 1980). Since this figure includes both new and refill prescriptions, it is difficult to establish the actual number of women on ERT. The pharmaceutical industry estimated that in 1973 some 50,000 UK women

were receiving ERT whereas by 1978 that figure was nearer to 200,000 (Bye, 1978; Evans, 1979). A 1979 London Times (Edmunds, 1979) article claimed that about 500,000 women were receiving ERT; and a survey of 40,000 people in a general practice population found that 3 percent of women aged 40 to 79 had received at least one ERT prescription during the year (Doll, 1976).

In Great Britain there are some 10 million women aged 45 and older (United Nations, 1978). Whether the actual number of women on ERT is 200,000 or 500,000--from 2 percent to 5 percent of the population at risk--it is still considerably less than the 20 percent (6 to 7 million) of American women in that age bracket who are currently receiving estrogens. Even with a more than three-fold increase in estrogen prescriptions--an increase which "place them in the fastest growing section of the pharmaceutical industry"--British women, according to Evans, are still under-treated since only about "a fifth of those who need treatment receive it" (1979, p. 132).

A final discrepancy between research recommendations and physician practice can be noted in the prevailing mode of ERT therapy. British researchers have been highly vocal in their criticism of "cyclical" therapy (three weeks of estrogens, one week off) as practiced in the United States and have advocated "sequential" therapy with an added progestagen to avoid the endometrial cancer risk. Ironically, an analysis of British prescriptions revealed that only about 6 to 10 percent of ERT prescriptions contained the added progestagen (Bye, 1978; Thom, et al., 1979).

Feminist and Consumer Groups

In both countries feminist and consumer groups (the two relevant types of voluntary associations) view the menopause differently and take a different stance toward ERT.

American Feminists and Consumer Groups. In the late 1960s and early 1970s feminists began to challenge medical authority by questioning the legitimacy of the disease model of menopause. They have argued that menopause is not a disease or sickness but a natural process of aging, through which most women pass with minimum difficulty. The medical problems that do arise can be effectively treated or even prevented by adequate nutrition and exercise combined with vitamin supplements. According to feminists, the menstrual and menopausal myths serve as a form of social control. If women are perceived as physically and emotionally handicapped by menstruation and menopause, they cannot and may not compete with men. The medical health care system is seen as legitimating, under the guise of science, societal sexism through its depiction of women's physical and mental capabilities dependent on their reproductive organs.

On these ideological grounds, feminists have opposed the routine use of ERT. For example, a 1972 Ms. article, written before strong medical evidence against ERT was uncovered, maintained that menopause was not a traumatic experience for most women, but rather a sexually liberating one. ERT as an attempt to keep women "feminine forever", was thus viewed as a male exploitation of female sexuality (Solomon, 1972). In a feminist interpretation of the menstrual and menopausal

taboo, Delaney, et al. (1976, p. 184) state that "the main fault of Feminine Forever lies not in the medicine but in the moralizing".

In more recent years, with ideological arguments strengthened by medical ones, feminist criticism has become widespread. In Women and the Crisis in Sex Hormones (Seaman & Seaman, 1977) the ERT controversy receives a 70-page analysis titled "Promise Her Anything But Give Her ... Cancer". These authors object to what they see as the increasing medicalization of normal female functions:

Pregnancy or non-pregnancy are hardly diseases; and neither is menopause. The latter is a normal developmental state wherein reproductive capacity is winding down; the temporary hot flashes some women experience may be compared to the high-to-low voice register changes adolescent boys evidence when their reproductive capacity is gearing up.

We no longer castrate young boys, nor should we treat hot flashes with a cancer-and-cholesterol pill (1977, p. xi).

In a collection of feminist critiques (Hubbard et al., 1979), two social scientists make a similar claim in a chapter entitled "Taking Men Out Of Menopause":

...[the] actions of the medical and pharmaceutical groups dramatize the sexism and general inhumanity of the male dominated, profit oriented U.S. medical system. A "deficiency disease" was invented to serve a drug that could "cure" it, despite the suspicion that the drug caused cancer in women. That the suspicion has been voiced for so many years before anyone would investigate it is yet another example of how unimportant the well-being of women is to men who control research and drug companies who fund much of it (Grossman & Bart, 1979, p. 167).

The 1981 edition of The Ms Guide to a Woman's Health warns women that "Estrogen replacement therapy (ERT) is a dangerously overused

treatment. Avoid it if at all possible" (Cooke & Dworkin, 1981, p. 310). The chapter on menopause repeatedly states that the change of life is not a disease but a normal process. Similarly, The New Woman's Guide to Health and Medicine states "The truth is that menopause is a positive or at least neutral experience for many women" (Derbyshire, 1980, p. 269). Several other publications, such as Majority Report and Off Our Backs, have taken strong stances against ERT. And the leftist publication, Mother Jones, condemned ERT in an article entitled "Feminine Straight to the Grave" (Wolf, 1978).

Though most of the criticism has been voiced by younger feminists, some older women have also begun to join the opposition. In Menopause: A Positive Approach, Rosetta Reitz refers to ERT as "The No. 1 Middle Age Con":

I accept that I'm a healthy woman whose body is changing. No matter how many articles and books I read that tell me I'm suffering from a deficiency disease, I say I don't believe it. I have never felt more in control of my life than I do now and I feel neither deficient nor diseased. I think that people who are promoting this idea--that something is wrong with me because I am 50--have something to gain or are irresponsible or stupid (1977, p. 181).

Marjorie Collins in an article in Prime Time, a publication devoted to ageist issues, stated:

Even today the literature...defines menopause as a deficiency disease. Of course that may sell estrogen, and we'll stay out of the controversy over whether that's a good thing or not. But it certainly echoes once more the male prejudice against menopausal and post-menopausal women (1977, p. 3).

Health related associations and consumer groups have also joined feminists in their opposition to ERT. Consumer Report (1976), the

official publication of Consumers Union, published a lengthy article warning women of the risks; and Citizens Health, the Nader organization, opposes (and regularly testifies against) ERT. Smaller groups such as WHISTLE (Women's Hormone Information Service), Coalition For the Medical Rights of Women, and National Action Forum for Older Women, have all warned women of the risks of ERT and advocated alternative menopausal treatments. Menopause workshops and self-help groups have sprung up across the country. On the national level, the National Women's Health Network has actively opposed ERT and in their 1980 Menopause Resource Guide, they urge women to stay away from ERT and flatly state that estrogens do not protect against osteoporosis (National Women's Health Network, 1980, p. 17).

After the 1975 cancer studies, these organized feminist health and consumer groups began to put pressure on the government to legitimize their claims. These activities will be discussed in more detail in the last section of this chapter when we examine regulatory policy.

British Feminists and Consumer Groups. British feminists and consumer groups have strongly endorsed ERT. They argue that estrogens are a woman's right and that male chauvanism makes physicians insensitive to women's health and pain. Whereas the U.S. crusade for ERT took place in the 1960s, the message did not arrive in Britain until the 1970s. Also in contrast to the American experience, where the ERT movement was led by prominent gynecologists, in Britain the treatment was demanded by women consumers.

Wendy Cooper, a feminist journalist and medical writer, is generally credited for the popular acceptance of ERT in Great Britain.

As one British physician stated:

Thanks to the enthusiasm of crusading journalists like Wendy Cooper, many doctors in Britain and their patients began to realize for the first time the benefits of [hormone] treatment (Evans, 1979, p. 13).

Cooper documented the struggle to overcome physician resistance to ERT in her widely cited book Don't Change (1975). She admonishes women to be firm with uncooperative doctors since "We are having the menopause" therefore "we shall have hormone replacement":

Indeed, the real problem facing women today in connection with ERT reflects the basic problem facing them in every sphere of life--the problem of how to enforce their equal rights, including the right to make their own vital decisions, particularly decisions concerning their own bodies (1975, p. 131).

With the availability of estrogens, women now were seen to have a choice: they no longer needed to be "fobbed off during the menopause with palliatives such as aspirin, Librium or Valium, or worse still, be dismissed with the words: It's just your age" (1975, pp. 12-13).

Although Cooper appears to be heavily influenced by the works of Robert Wilson (whom she personally interviewed), she is critical of his emphasis on femininity:

Writing as a women for other women and also writing almost a decade later in the age of Women's Liberation, I have put less emphasis on femininity and more on feminism and on the right of women to have more say in decisions, medical and social, which affect their own bodies and their own lives (1975, p. 20).

To spread her message, Cooper has appeared on numerous radio and television programs, and has written extensively in both the medical and lay press. That a segment of the medical community has taken her seriously is evidenced by her numerous articles appearing in the medical literature. For example, she has published in Current Medical Research and Opinion (1975), World Medicine (1976), the Royal Society of Health Journal (1976) and has original chapters in two recent medical books on menopause (Beard, 1976; Campbell, 1976).

Cooper was soon joined by other feminists and consumers. An analysis of the London Times and British medical journals reveals that the feminist demand for the therapy is widely acknowledged. For example, one physician credits feminists for the "medical profession's belated interest" in ERT but cautiously continues "It is hoped that the proper clinical interest does not lead us into the trap of creating a fashionable specialty if that trend is motivated merely by feminist politics (Tunnadine, 1977).

Barbara Evans, a well known woman physician and author of the recent pro ERT book Life Change, acknowledged Wendy Cooper and her feminist sisters:

We owe a great debt to the women who have written and canvassed so energetically to bring the needs of women and the help that is available not only into public but also into medical consciousness (1979, p. 95).

Evans continues that male physicians are often ignorant of female sexuality and physiology and therefore the "more enthusiastic advocates of hormone therapy have often been women doctors, especially those who have personal experience with the climacteric" (1979, p. 98).

Ironically, "as British women are demanding oestrogen therapy their American sisters are becoming reluctant to take the implied risk" (Evans, 1979, p. 10). In direct opposition to American feminists' claims, British feminists insist that the menopause is not a natural process but a hormone deficiency disease. Writing in 1979 Evans noted that a large number of British women are still denied ERT. She found this particularly regrettable, since, as noted in the foreword to her book:

The years after the menopause should be regarded as a hormone-deficient state, in the same way as diabetes. The hormone insulin is usually required for the treatment of diabetes and the fact that insulin has side effects and such therapy may not correct all the hazards of the disease in no way alters the truth of this definition (1979, p. 10).

Cooper called the "natural process" model an excuse for "benign neglect" and carried to its logical conclusion would imply that other "natural" aging processes such as failing eyesight, impaired hearing, decaying teeth and arthritis should not be treated either (1976, p. 81). Cooper has eloquently summarized the British feminist argument:

With the short-term advantages so clearly obvious and the long-term protective role so strongly indicated, women are entitled to ask why medicine has been so reluctant to accept HRT?....If it were men who faced menopause with atrophy of their sex organs, the male dominated medical profession would long since have done something about it. There would certainly be far less talk about its being natural and needing no treatment (1975, pp. 51, 62).

In contrast to the U.S., most pro ERT feminists have been middle aged women. A young radical feminist group, the Brighton Women and Science Group, has shown considerable ambiguity toward ERT and the menopause.²⁴ In Alice Through the Microscope, a book devoted to

women's health issues, they indict the medical profession for perpetuating the menstrual and menopausal taboo. At the same time they view menopause as a difficult time for most women. They also acknowledge the benefit of ERT but note "too much enthusiasm about the wonders of ERT is premature. Quite simply, there has not been enough research to indicate whether taking drugs for long periods of time might be hazardous to health" (Birke & Best, 1980). They conclude their brief, three-page section on menopause with considerable ambivalence:

As we write this, we are still young, still menstruating. One day, we will go through the menopause just as our mothers are doing now. We hope that we cope with it as well as they do (Birke & Best, 1980).

Health groups in Great Britain also appear to endorse ERT. In the February 1980 issue of Patient Voice, a publication of the Patients' Association (devoted to promoting patients' rights), the therapy is strongly endorsed, the cancer link is disclaimed and it is maintained that estrogen replacements effectively treat such symptoms as absent-mindedness, forgetfulness and depression as well as hot flashes and osteoporosis. In this same issue, the question is posed why doctors still dismiss symptoms of the menopause as being "all in the mind" and prescribe anti-depressant drugs when "oestrogen supplements can produce complete remission". Readers are also made aware of a newly organized "Steroid Self-Help Group" and urged to write for details.

Regulatory Policy²⁵

As in other public realms, regulatory policies in the United States and Great Britain have differed sharply in response to the estrogen replacement controversy.

American Regulatory Policy. In the U.S. the Food and Drug Administration (FDA) has placed increasingly stringent regulations on menopausal estrogens. In January, 1976, at the conclusion of a highly publicized Senate Subcommittee hearing, the FDA released a public statement citing evidence of a strong positive association between estrogen use and endometrial cancer (Burke et al., 1977).²⁶ The March, 1976 issue of the FDA Bulletin, a bi-monthly publication sent to all health professionals, emphasized the limited utility and short-term low dose indications of ERT. It recommended that the risks be carefully considered by both physicians and patients. In the fall of 1976 the FDA revised and strengthened the physician package insert which accompanies all bulk packages of estrogens distributed to pharmacies and physicians.

After the 1975 cancer studies several consumer and feminist groups, including the National Women's Health Network and Consumers Union, began to exert pressure on the FDA to warn the consumer of the dangers of ERT. In 1977, after two years of public hearings, the FDA mandated that a "patient package insert" (PPI), warning consumers of the cancer risk and other possible dangers, be included with every estrogen and progestin prescription (New York Times, 1977).

In an effort to block this regulation, the Pharmaceutical Manufacturing Association--joined by the American College of Obstetricians

and Gynecologists, the National Association of Chain Drug Stores, the American Society of Internal Medicine, and various state and county medical societies--responded by filing a law suit against the FDA. To represent the interests of women patients, the National Women's Health Network, Consumers Union, Consumers Federation of America, and Women's Equity Action League, intervened in the law suit on behalf of the FDA.

On 5 October 1977 a Federal District Court judge denied the plaintiffs' motion for a preliminary injunction; and on 11 February 1980, after a lengthy legal challenge, this judge ruled that the FDA did have the legal authority to mandate a PPI for estrogen replacements (Stapleton, 1980).

The ruling gave estrogen replacements the distinction of being one of only four classes of drugs which require such patient package inserts.²⁷ The judge outlined several categories of information which must be included in the PPI. In addition to an increased risk of uterine cancer, increased risks of breast and liver cancer and increased risks of cardio-vascular and thrombo-embolic diseases were also required to be mentioned. This information was to be provided to the patient every time the drug was dispensed or administered (i.e., injected).²⁸ Thus physicians and hospital personnel as well as pharmacists were required to provide the labeling when they act as dispensers of the medication (Stapleton, 1980).

Regulation, however, does not mean compliance and the victory for ERT opponents appears to be more symbolic than instrumental. A recent FDA survey of 271 drug stores in 20 cities showed that only 39

percent of all estrogen replacement prescriptions were accompanied by a PPI (Morris et al, 1980).²⁹ In an interview with us, an FDA official stated that the agency did not have the means to enforce these regulations (Morris, 1980).

British Regulatory Policy. From the British point of view, drug regulation in the U.S. leads to "inflexibility", "rigidity", "polarization", and "irrationality", (Breckon, 1972; Dunlop, 1973; Gillespie, 1980). An "informal" and "friendly" approach is seen as more palatable to the "British character". Indeed no government agency overseeing drug safety even existed until 1964, when the Committee on the Safety of Medicines (CSM) was formed.³⁰ This Committee acted solely as a voluntary advisory body with no legislative powers. Although the 1968 Medicines Act, implemented in 1971,³¹ gave the Committee statutory power, it still operates on a relatively informal basis.

The CSM does no official drug testing, but relies on the pharmaceutical manufacturers to carry out their own drug safety tests. The Committee reviews and comments on the industry findings, but the commercial concerns themselves are responsible for, and trusted to make, judgments on safety standards (Breckon, 1972).³² "The Committee is always ready to listen to manufacturers or trade associations," stated one member, "and tries hard to be fair." The Committee is also

concerned with maintaining and improving standards,but is emphatically not concerned with restricting doctors' freedom or otherwise control their use of drugs (Binn, 1980, p. 1615).

Operating in that spirit, it is not surprising that the CSM has issued a statement exonerating both estrogens and progestins from any causal relationship with cancer (Cooper, 1975, 1976).³³

British regulatory efforts, by American standards, have been quite timid. However the British National Health Service (NHS) has adopted an innovative program on menopausal treatment. In response to the researchers' endorsement of ERT and a burgeoning public demand for the treatment, the NHS, in 1973, began operating menopausal clinics. These clinics, designed to circumvent the GP's reluctance to prescribe ERT, also serve as centers for research and evaluation of the treatment.

The first clinics were deemed highly successful and "filled with strikingly happy patients (Evans, 1979, p. 101). But demand quickly exceeded available service and clinics soon had to contend with long waiting lists. At a 1976 Royal Society of Health menopausal conference, the participating researchers reaffirmed the value of ERT and advocated the expansion of NHS menopausal clinics.

Gradually more menopausal clinics are being established and regular examinations are instituted, and hormone replacement is undertaken. The optimistic hope that as more financial help becomes available within the National Health Services, more clinics will be established (Dalton, 1976, p. 77).

By 1979 about forty NHS and an additional 17 private menopausal clinics had been established across the Kingdom. The NHS clinics are attached to major research and teaching hospitals and provide "service-oriented research" (Evans, 1979). Since only an estimated one-fifth of menopausal women who are seen to need treatment actually

receive it, the expansion of clinics appears likely (Evans, 1979).

Summary

Though medical objections to estrogen treatment for menopausal problems have been voiced for several decades, the current controversy arose in 1975 with the publication of three epidemiological studies linking ERT to cancer. The controversy, however, has developed quite differently in the United States and Great Britain. Most U.S. researchers accept the endometrial cancer link and are cautious in recommending estrogen therapy; their British counterparts, on the other hand, are skeptical of the cancer link and recommend long-term treatment for the prevention of osteoporosis. Despite U.S. research findings, American physicians, still commonly prescribe ERT; British physicians, in opposition to their research community, are reluctant to prescribe the treatment. Whereas American feminists and consumer activists have opposed the use of ERT, these same groups in Britain have demanded estrogen therapy. Finally regulatory policy has differed in the two countries: the FDA has imposed increasingly stringent regulations on ERT, whereas the CSM has not moved to restrict the treatment.

CHAPTER IV DISCUSSION

In the previous chapter we delineated differences in the estrogen replacement controversy in the United States and Great Britain. For each row of Table 1--researchers, physicians, feminists/consumers, and regulatory policy--we found, and documented, variance between the two countries. For each column in Table 1 we noted that feminist and consumer groups are in opposition to prevailing physician practices; clinical practice, in turn, is in opposition to research conclusions in each country. Thus the U.S. and Great Britain appear in mirror image with regard to ERT: group alignment is identical; direction is opposite.

The purpose of this chapter is twofold. First we attempt to explain some of the cross-cultural differences and similarities by focusing on scientific, ideological, political and economic factors. Second we relate our findings to some current theoretical debates in sociology in a speculative way that is intended to raise, rather than answer, questions.

Cross-Cultural Similarities and Differences

That scientific experts disagree and oppose each other's view is hardly a novel finding. Considerable discussion has been devoted to this topic in the sociology of knowledge literature. In an analysis of scientific and technical controversies, Mazur (1981) found that ambiguity of data was always an underlying condition of controversy. Ambiguities lead to different interpretations, and consequently

experts talk past one another. Using similar rhetorical devices, each expert tends to reject the other's data as discrepant. Differences in underlying definitions and in basic premises thus become obscured or ignored as both sides present their findings as "definite facts."

There is no conclusive evidence that ERT causes cancer, as most American researchers contend, or that it prevents osteoporosis, as most of their British counterparts claim. Mazur (1981) also noted that group alignment in scientific disputes is often based on situational rather than objective factors. Alignment often comes first, and only then does the new partisan construct a rationale for the alignment. In many cases alignment serves as an anchor point around which the various findings are interpreted. As Mulkey stated:

We have seen that scientific fact depends on prior commitments of various kinds, that these commitments are often made in accordance with participants' position in a special social setting, and they influence the informal acts of interpretation which are essential to give meaning to observations (1979, p. 114)

For whatever reasons, British researchers first conducted research on the role of estrogens in osteoporosis, whereas American researchers conducted the cancer studies. Both sides have clung to their initial findings and are skeptical of the other country's findings.³⁴ Researchers on both sides of the ERT controversy have accused the other side of this bias as the following letter to the editor in Lancet demonstrates:

For a scientist to pretend that his observations are unprejudiced is a fiction that underlies what Medawar called the fraudulent form of the tradi-

tional scientific paper. He said "Every act of observation we make is biased. What we see or otherwise sense is a function of what we have seen or sensed in the past." Your editorial is... guilty of that observation (Greenblatt and Gambrell, 1979).

It is also evident that British and American researchers have different assumptions about what constitutes carcinogenicity. Marvin Schneiderman, former Associate Director of the National Cancer Institute, noted in a letter to us:

Recent British work on carcinogenesis seems much more conservative than ours in that they seem to be much more reluctant than American researchers to assert cause-effect relationships (1980).

Similarly Gillespie et al. (1979) have shown that the British demand evidence of causality before a substance is judged carcinogenic; in the U.S. a demonstrated risk, as determined by scientific consensus, is sufficient. A persistent British criticism has been that retrospective epidemiological studies, using historical controls, cannot prove a cause and effect relationship between estrogens and cancer. Only double-blind, randomly assigned prospective studies, conducted over a span of several decades, can establish the carcinogenicity of estrogens. To summarize the British position:

Until specific answers are forthcoming we can keep an open mind on the subject. In the interim it is not justifiable to withhold such therapy from the informed patient requesting it (Utian, 1977).

American researchers argue that causality can be deemed likely if the risks uncovered are high, replicable, consistent, show relationship between dose and duration of exposure and are biologically plausible. The American cancer studies seem to meet these criteria.

Thus it is argued that randomized controlled trials are no longer ethically feasible.³⁵ It is often pointed out that the smoking-lung cancer debate was settled (at least in the U.S.) without randomized trials:

There has never been a randomized controlled trial (similar to that which they [the British] demanded for estrogens) to determine if cigarette smoking causes lung cancer in human beings; do these physicians withhold judgment forever while awaiting the impossible study, or do they advise patients to stop smoking? (Stolley & Davies, 1980).

One reason for the British scientists' more rigorous (or conservative) standards in deciding carcinogenicity of a substance might be that fear of cancer is heightened in America as compared with Great Britain. Gillespie et al. (1980) noted that fear of cancer does not carry the same political weight in Great Britain, especially in policy circles. That Americans are "cancerophobic" has been shown by repeated public opinion polls, in which the killing potential of cancer is vastly over-rated (Gallup, 1977). Susan Sontag (1978) also contended that cancer is highly stigmatized in American society.³⁶

In both countries current policy is consistent with research findings and consumer demand, but inherent political factors might also be important in determining cross-cultural differences. Despite a greater socialistic tradition the British medical and scientific communities appear to be more elitist and resist government interference to a greater degree.³⁷ According to the first chairperson of the CSM, a formal and compulsory system like the FDA would never work in Britain. Such a system would be unacceptable, he said, to the medical profession which prefers decisions to be taken by scientists

and physicians who are not dependent for their income and reputation on government bureaucracies (quoted in Breckon, 1972).³⁸

Some scholars posit an economic explanation for the stricter American regulation. They argue that since the U.S. has a much wealthier economy than Great Britain, its pharmaceutical industry is sufficiently robust to absorb the costs of closer scrutiny (see Breckon, 1972, Gillespie et al., 1979).

In both countries, the feminist-physician dispute--seen as a consumer challenge to professional authority--is largely ideological. In his seminal work on professionals, Hughes (1958) pointed out that professional authority is inherently problematic and open to challenge. Clients do not automatically grant authority and autonomy to professionals. Rather authority is the result of professional enterprise. Professionals who serve clients can maintain their authority when it becomes institutionalized in ways that minimize reliance on explanation or persuasion (Freidson, 1968). In recent years clients--particularly from subordinate or subjugated groups such as women, minorities, homosexuals, etc.--have begun to challenge professional authority. It has even been suggested that conflicts between clients and professionals represent the new dialectic. For as labor shifts from industrial production to services, control over this segment of the economy becomes increasingly important (Bell, 1978; Freidson, 1973; Gartner & Riessman, 1974).

In the United States as well as in Great Britain, feminists are becoming more militant in demanding control over their own bodies and a voice in medical decisions which affect their own lives. As

one British feminist declared:

...for the last couple of thousand years, it has been men of the ruling class...doctors mainly concerned with their own power and prestige, who have created laws, laying down to women what they may or may not do with their bodies (Wandor, 1972).

In both countries the male dominated medical profession is coming under increasing criticism for defining women's psychological, as well as their physiological reality. The authority and competence of the medical profession is being challenged as women attempt to redefine the prevailing medical definitions of menopause. In Britain women contend that the menopause is a hormone deficiency disease, and do not want to be told that it is "all in their heads" or be put on anti-depressant drugs. ERT is seen as a woman's right and should be given on demand. But as one British feminist decried:

Unfortunately, many women still stand in such awe of their doctor....that if he refuses to prescribe HRT, they give up the fight, accepting this one verdict as law. Indeed, although the trend is definitely toward wider usage of HRT as the indicated treatment for the menopause, the divergence of views is confusing to women nourishing the naive belief that modern medicine is a science (Cooper, 1975, p. 83).

In the U.S., feminists are trying to counter the prevailing medical definition of menopause as a disease by claiming that it is a natural occurrence in the process of aging; proper nutrition and exercise, it is claimed, will alleviate most transitory symptoms. As these self-declared radical feminists contend:

This redefinition of a natural event such as menopause into a disease is an example of the increasing medicalization of normal events in our lives.... This process is both a cause and effect of the enormous power American physicians have to define and

manipulate our reality (Grossman & Bart, 1979, p. 165).

It would be simplistic to characterize the British claim of menopause as a disease, and the American feminists' claim of a natural stage of aging, solely as an arbitrary challenge to professional authority and a wish to control their own bodies. The data also indicate a demographic variable: American opposition to ERT has been mainly by feminists who are still young and menstruating;³⁹ the pro ERT British crusade has been led by older feminists. The actual experience of menopause and the reality of aging might be conducive to viewing ERT as a viable treatment. It has also been suggested that psychoactive drugs (the most common treatment for menopausal problems available from British GPs) are particularly repugnant to British women. With the British tradition of "keeping a stiff upper lip", the reliance on tranquilizers might carry a greater cultural stigma than would a drug for a somatic problem.⁴⁰

The American and British women's movements have also developed along different ideological and political lines which might explain some of the variance in ERT positions. The American movement is best described as "free floating", not aligned with any particular political or class movement.⁴¹ Although the movement is comprised of many different factions, neither the liberal (as typified by NOW) nor the more radical groups have seriously challenged the political-economic system. Whereas the older NOW members have advocated liberal reformism and have lobbied for their equal place in the economic sphere, the younger radical groups have concentrated on conscious-

ness raising, self-help and alternative life styles.

For most American feminists the locus of women's oppression is seen as rooted in biological inferiority arguments. Feminists have tried to settle the nature-nurture debate by showing that differential socialization accounts for women's inferior status and not biological differences. In their attempt to overthrow the dictum "Biology is destiny", feminists have argued that menstrual cramps, problems during pregnancy and childbirth, and menopausal symptoms are largely culturally induced and do not warrant medical intervention. American feminists often revert to micro-psychological explanations such as that male supremists are afraid and envious of women's reproductive and greater sexual capacity and thus invented the menstrual and menopausal myths as forms of social control to keep women in their subordinate role.

The feminist movement in Britain, as in most European countries, is closely aligned with the socialist movement (Adam, 1977; Boxer & Quetaert, Currell, 1974). Marxist feminists contend that sexism and women's oppression is an inherent function of capitalism, and thus advocate a radical restructuring of society along socialist lines (Fee, 1975). Since the locus of women's oppression is seen as structurally located, it appears that the biological debate as a feminist issue has a lower priority for British women.

In both countries, clinical practice is largely discrepant with research findings. In the U.S. large numbers of women are still receiving ERT for indefinite periods. In Britain the relatively small number of women who are on ERT are receiving it in a mode contradicto-

ry to research recommendations. McKinley and McKinley (1973, p. 535) attribute practitioners' dismissal of research findings, particularly in regard to menopause, to their over-reliance on "clinical practice" and subjective experience, regardless of its lack of objectivity and substantiation.

Medical sociologists also call attention to the conflict created between the different segments of the medical community, as each group tries to further its special interests (Freidson, 1971; Zola & Miller, 1971).⁴² As Pfohl so aptly stated:

Although the medical profession often appears to outsiders as a separate and unified community, and although medical professionals generally favor the maintenance of this image, it is nonetheless more adequately described as an organization of internally competing segments, each striving to advance its own historically derived mission and future importance (1977, p. 317).

Organizational and economic factors inherent in the different health care systems probably explain much of the divergence in physician practice between the two countries. British medicine is nationalized, whereas U.S. health care is in private hands. In Britain the GP is paid by the National Health Service on an annual capitation fee, which is fixed for each patient on his list, a rate not affected by the frequency of patient visits. The relatively low pay and prestige associated with general practice has resulted in a severe shortage of GPs (Barnard & Lee, 1977; Forsyth, 1966).

The average British GP is overworked, which encourages work patterns that minimize patient contact. Women on ERT need to be kept under close diagnostic surveillance and it is recommended that an endo-

metrial biopsy be performed every six months. Since frequency of visit does not increase the GP's income, he might be more willing to treat menopausal complaints with tranquilizers (as has frequently been charged) to minimize contact. In the U.S., on the other hand, the situation is different. Since the American physician operates on a fee-for-service basis, frequent patient contact is economically rewarding and encourages what Freidson (1971) calls "medical imperialism."⁴³

The doctor-patient interaction is also subtly influenced by the structure of the health care system. Freidson's (1975) comparison of prepaid group practice to private entrepreneurial practice provides a useful insight to the effect of structure on physician and patient roles. Though his analysis is confined to the U.S., the structure of prepaid-service-contract practice is analogous to Britain's National Health Service and is thus relevant to our analysis. According to Freidson, private practice is conducive to a "merchant-customer" relationship. Like merchants, physicians are concerned with maintaining or increasing their income and must "sell" the customer to buy their service. The pre-paid group service eliminates the fee and discourages the profit motive, while it sets up the physician as official "gatekeeper" to service. The patient is put in a "bureaucratic client" role--their rights and obligations specified in a formal contract. In private practice the "customer" can shop around for desired service; but the "client" must get his or her service from the pre-paid practice. The contractual arrangement is conducive to the emergence of an aggressive client demanding his or her right to ser-

vice or medication.

The British GP, in his role as gatekeeper, constrained by a tightly controlled budget, must prioritize the available resources. Blomqvist (1979) has attributed the relatively low cost of health services in the UK (relative to Canada and the U.S.) to the GP's gatekeeper role. He maintained that the GP is a powerful barrier to any unnecessary service or medication.⁴⁴ Were the use of ERT to become widespread in Great Britain, physicians maintain that the cost would tax the already tight NHS budget prohibitively (Evans, 1979). British women, on the other hand, demand ERT:

...for under the National Health Act it is the duty of the general practitioner to give "reasonable and necessary care" to those on his list. Who can deny that hormone replacement therapy for those with signs of oestrogen deficiency symptoms is "reasonable and necessary"? (Dalton, 1976, p. 77).

A somewhat different but complementary explanation is offered by medical sociologist and historian Rosemary Stevens (1977, pp. 27-28). In an historical analysis of the British and American health care systems, she concluded that American medical care is linked with selling technology, whereas British care has an "almost antitechnological bias." Stevens also stated that British and American practitioners have different conceptions of health and illness. British family practice focuses on maintaining health and on the individual's ability to cope with everyday working situations, whereas American medicine is relatively more focused on diagnosing and treating illness. A result of this difference is that American physicians find more illness and disease, while the British doctor tends to under-

diagnose (in American terms) and perhaps finds less disease. The British GP also spends relatively more time on depression and anxiety states. In a private communication, Stevens (1980) also hypothesized that the more conservative British GP is more concerned with "feeling well" and the American practitioner, influenced by the American youth culture, with "looking well".

It has often been charged that America is an overmedicated society (for example Illich, 1976; Lee, 1980). The widespread use of ERT might be an indication of this general trend.⁴⁵ Conrad and Schneider (1980) also state that American society provides a fertile ground for medicalization. A variety of factors--such as the American medical profession's unparalleled power, the profit motive of a private system, a strong heritage of experimentation and extraordinary faith in scientific and technological solutions, a fetish for the latest and the best, and a strong penchant for pragmatic and individual rather than structural solutions--contribute to excessive medicalization.

Finally the pharmaceutical industry has also played a role in shaping the ERT controversy in both countries. In the U.S. the locus of this influence was on physician practice. The work of Robert Wilson was financed by drug companies and in the late 1960s the drug industry launched a major promotional campaign for ERT in the medical literature and lay press. Immediately after the 1975 cancer studies, Ayerst Laboratory hired the public relations firm of Hill and Knowlton to counteract the negative publicity.⁴⁶ In Great Britain there has been significant interaction between the pharmaceutical industry and the research community. Though the behavioral implications

are not clear-cut, we should note that virtually all the osteoporosis and sequential therapy research in Britain was partially or fully funded by drug companies. The one American study refuting the cancer studies (Horwitz & Feinstein, 1979) was also funded by the pharmaceutical industry.

Theoretical Implications

If a sociological theory or perspective is to go beyond mere philosophizing, it must help us gain a greater understanding of specific social phenomena. Thus we examine and assess the utility of the positivist and social constructionist perspectives in helping us understand the origins, dynamics and possible resolution of the ERT controversy.

Positivist Explanation

Positivists define social problems as objective conditions which are detrimental to human well-being (Manis, 1976). Thus ERT became a social problem in the U.S. because scientific inquiry found it to be harmful to women's health. New knowledge about ERT and cancer produced social strain--defined as a disharmony between objective conditions and normative standards (Smelser, 1962, p. 287)--which in turn caused widespread discontent and social protest. Strain, in short, turned a latent problem into a manifest one.

Yet in Great Britain ERT is not defined as a social problem, not at least in the same way as it is in the U.S. What accounts for the British differences? ERT has not become a social problem in Great

Britain, positivists would say, because the English have not experienced the same rise in endometrial cancer rates; moreover, osteoporosis, for which ERT might be an effective treatment, constitutes a serious health problem for British women.

The positivistic view of science holds that disputes are settled according to the scientific merits of arguments, and that adjudication proceeds according to a logical, rigorous method. Then why do American and British researchers still disagree? Obviously one side must simply be in error, led temporarily astray by social and contextual factors.

There are several problems with these positivistic explanations. First, health risk is not a consistent factor in determining what conditions become social problems. Scientific inquiry has determined that alcohol and cigarettes⁴⁷ represent a serious health risk, yet they are both legal, freely available drugs. Environmental pollutants and many industrial working conditions constitute a great threat to the health and safety of millions of Americans, yet the current trend is for deregulation. On the other hand, scientific inquiry has been unable to determine a convincing health risk associated with marijuana use, yet it is defined as a social problem.

Second, that strain, in the form of cancer, gave rise to social protest is also an inadequate explanation. Feminists have historically opposed medicine's definition and treatment of menopause. Feminist opposition to ERT developed before the 1975 cancer studies. Also: why were early cancer warnings, such as Gusberg's 1947 study, ignored by the medical community and feminists alike? Positivists

must explain a 28-year lag between a scientific finding and its emergence as strain.

Third, that osteoporosis constitutes a health problem of greater dimensions than endometrial cancer for British women is probably true. However, osteoporosis is also a major health problem in the U.S. It is estimated that each year 195,000 hip fractures occur due to thinning bones, resulting in 19,500 deaths and a total cost of over one billion dollars (Gastel & Brody, 1979). In contrast annual deaths attributed to endometrial cancer, because of its high cure rate, number only about 3300 (American Cancer Society, 1977).

Regarding differences among researchers, the absolutist position--that one side must be in error--is not particularly useful. Accepted practice often seems in error when examined historically. Since American and British researchers share a common data base, and science is seen as universalistic, an error explanation does little to help us understand the origins, dynamics and possible resolution of the ERT controversy.

Social Constructionist Explanation

The social constructionist perspective is based on the assumption that there is no such thing as a single "objective" definition of reality; there are various (often competing) realities, which are defined by different interest groups, publics, or cultures. As Mauss stated:

We are dealing here with various definitions not only of social reality, but even of physical reality. The same empirical data, whether about society

or about the universe, can be used to support a variety of conceptions of reality; indeed, we might say that a certain socially defined design, organization, or meaning is simply imposed on data or "facts" which otherwise have no meaning in and of themselves....So it is that even physical or "scientific" reality can be socially constructed and thus relative to a particular people and particular time (1975, p. 4).

Objective conditions may have little or nothing to do with consensual reality. Standards of health and illness are not fixed scientific ones, but rather they entail judgments that vary along sociocultural lines (Schur, 1980). Our historical analysis of the changing definitions of menopause (see Chapter 2) shows that medical explanations of the menopause have always been profoundly influenced by cultural views of women and aging. Such historically located events as the Industrial Revolution, the rise of Freudian ideas and the mental health movement, and the pharmaceutical revolution all have had an impact on the medical profession's perception of menopause.

In understanding the different positions taken by ERT partisans, socio-historical alignment may be more important than "objective facts." Indeed we claim that the feminist-physician and the researcher-physician disputes over ERT can be best understood in contextual terms.

In both countries, the physician-feminist variance can be interpreted as sexual politics. The substantive nature of the dispute is relatively unimportant (sociologically); what matters is the power relationship between male physicians and female patients. Women and physicians are engaged in a struggle over competing definitions of menopause. Schur (1980) calls these struggles over collective defi-

nitions "stigma contests". Various subordinate groups in a given society who have been labeled deviant, be they homosexuals, former mental patients, the handicapped, minorities or women, increasingly organize to counter such stigma. Although economic, legal, and narrow political power are often involved in stigma contests, "what is essentially at stake in such situations is the power of moral standing or acceptability" (Schur, 1980, p. 6). Thus stigma contests are always partly symbolic in nature, since prestige and status are important issues (see Gusfield, 1966, 1967). Stigmatized individuals must rectify a "spoiled identity" (Goffman, 1963) through collective efforts. As we have noted women in both countries try to counteract the stigma of menopause. In the U.S. feminists tried to neutralize the stigma by claiming that menopause is normal; in Britain women claim that menopausal problems are "real" and not just in their heads.

The researcher-physician dispute can also be understood in terms of cultural context. Researchers' professional prestige, whether American or British, is increased if they have found a cause of cancer or a cure for osteoporosis. At the level of the practitioner, judgmental criteria differ. For the American practitioner a disease label is economically rewarding; no such advantage exists for the British GP, indeed the label may be disadvantageous, in his gatekeeper role.

Social problems and deviance categories do not arise by themselves, according to social constructionists, but are the result of enterprise. Becker (1963) has sensitized us to the role of moral entrepreneur in the creation of collective definitions. Both Robert Wilson in the U.S. and Wendy Cooper in Great Britain filled this role

of moral crusader and were instrumental in the promotion of the disease label.

Similarly Mauss (1975) contends that social problems are the result of social movements. Conditions that become defined as social problems often have existed for a very long time before they acquired the label. It takes the concerted efforts of interest groups to define what constitutes a social problem. Most of the conditions that feminists decried have existed for a long time. It was through the collective actions of the women's health movement that gynecological care became defined as a social problem.

Resource mobilization theory holds that the success or failure of social protests depends largely on challengers' ability to organize and mobilize resources. In Britain the feminist opposition is still largely an individualized effort. The relatively greater success of American feminists can be attributed to greater organization. The menopause issue is one of several health related issues under the umbrella of the women's health movement. As a national movement with access to media and government, various women's health groups, in coalition with several national consumer groups, have lobbied (with some success) for policy changes about ERT.

In conclusion, the medical model, essentially a positivistic view of science, does not adequately explain why two countries reached contradictory conclusions to the same problem, when the same scientific data were available to both sides. The social constructionist model, attuned to cross-cultural richness and subtlety goes further in explaining the development and dynamics of the Estrogen Replacement Con-

troversy.

One can only speculate on the likely outcome of the controversy. The positivist position would hold that the controversy will eventually be resolved based on the scientific merits of the arguments. It is our contention that social forces will continue to play a central role. If the controversy is to be resolved at all, it will most likely be settled by external social factors rather than purely internal, scientific ones.

FOOTNOTES

¹Though history is the focus of this chapter, my approach has been as a sociologist, not an historian. My interest is in background and context rather than a compilation of detail. Thus I have made no systematic investigation of primary materials, particularly of the Victorian era. The best listing of primary sources for that period is found in The Surgeon General's Catalogue. I made no attempt to locate and read all materials listed under the heading of menopause. Indeed no historian has done so and a history of the menopause has not yet been written. We await the investigation of a feminist medical historian to shed light on this subject.

For the Victorian era I relied mostly on fragments of work and brief mentions of the menopause, mostly in the work of historians. Where primary works were often cited or seemed crucial, I obtained them from local collections or on loan. The later periods covered in this chapter presented fewer problems. I read all important primary sources, such as the work of Robert A. Wilson as well as a variety of gynecological texts and books and articles published in medical journals. My interpretation of these various sources was aided by a variety of sociologists, psychologists and feminists.

The availability of sources has two important implications for the scope of this chapter. First, we begin with the Victorian era, rather than some earlier time, because contemporary scholarship has so far ignored previous periods. Moreover, because of the interest of historians, this section emphasized European materials. Second, and in opposition to the previous point, for the 1960 to 1975 period, most primary and secondary sources come from the United States. Thus the chapter concludes by focusing on the American scene.

²Since the eighteenth century, medical science has increasingly assumed social control functions which previously have been the prerogative of religion or the state. For a discussion of physicians as agents of social control see Conrad and Schneider (1980), Ehrenreich and Ehrenreich (1975); Freidson (1975); Haller and Haller (1974); Ruzek (1978); Smith-Rosenberg and Rosenberg (1973); and Zola (1972).

³Thorsten Veblen in The Theory of the Leisure Class (1908) pointed to the burden placed on women to bring about order and stability to the confused and transient social structure during the rise of industrialization. A wife was expected to stay home as a symbol of her husband's earning power. Yet the middle-class woman, according to Veblen, acted only as "ceremonial consumer". Her transformation from producer of goods to consumer marked no advancement in her personal freedom. "She still quite unmistakably remains his chattel in theory.

For the habitual rendering of vicarious leisure and consumption is the abiding mark of the unfree servant" (1980, pp. 81-83).

⁴For an interesting discussion of gynecological surgery see Barker-Benfield (1976). According to this historian, "female castration" ("oophorectomy") was a widespread and frequently performed operation for mental disorders, practiced from the mid-nineteenth century to as late as 1946. "During the operation's heyday doctors boasted that they removed from 1,500 to 2,000 ovaries a piece" reports Barker-Benfield (1976, pp. 120-121). Another common sexual surgery performed on women for mental disorders and to check what was thought to be a growing incidence of masturbation was clitoridectomy, the surgical removal of the clitoris. This procedure was first performed in 1872 and continued until 1925.

⁵Women are more subject to institutionalization on specious grounds than men, are treated more extensively with shock therapy and mind controlling drugs, and receive the majority of lobotomies, according to a study done by Roth and Lerner (1974).

⁶In diagnosing menopausal symptoms as largely psychological, the gynecologist's function as the dominant labeler of female physiology was extended to define female psychology as well. Weideger defines the gynecologist's intrusion into a field where he has little training as taking on the role of shaman:

The gynecologist has taken upon himself the role of diviner. He assesses the quality of normal behavior - normal not only in the biological sense but in a social sense as well. By his own declaration he has specialized knowledge of a woman's body, her real spiritual potential, and the true nature of her unconscious as well (1976, p. 133).

In his role as witch doctor, the gynecologist uses a medical school training but combines it, in a peculiar mixture with a watered down version of psychoanalytic theory (1976, p. 134)

Of course, this intrusion into a woman's psychological sphere by gynecologists is not new, as the Victorian era has shown.

⁷For example, the author stated that 86 of the 304 women had undergone a total hysterectomy either before or during treatment without giving a reason for the hysterectomy.

⁸As late as the 1960s, a White House physician publicly stated that women were unsuited for high governmental office and could never be President because of their "raging hormones" (quoted in Frieze, et al., 1978).

⁹The data for this section are the various journal articles, editorials, and conference reports written by medical researchers, as well as various published interviews with key scientists. Our purpose is to treat these reports as indicators of medical opinion, and as measures of consensus or discensus. Thus we make no attempt to assess the medical validity of these researches. Rather we treat them naturalistically--as claims-making activities. This approach to data applies to all groups and claims discussed in this chapter.

One stylistic note: where American and British spelling or terminology differ, we use American notation except in direct quotation of British material. Thus the British "oestrogen" is rendered American style; "flushes" become "flashes", and Hormone Replacement Therapy is written as Estrogen Replacement Therapy.

¹⁰See Gray et al., 1977; Hoogerland et al., 1978; Horwitz et al., 1978; Mack et al., 1976; McDonald et al., 1977; Smith et al., 1975; Ziel et al., 1975; Ziel et al., 1976 as interpreted by Antunes et al., 1979; Hammond et al., 1979; Hutchinson et al., 1978; and Jick et al., 1979.

¹¹One study criticized the previous cancer research on methodological grounds. Among the criticisms were that women come under greater diagnostic surveillance from their physicians so that cancer is more likely to be found. Moreover most epidemiological studies use historical controls; that is, they compare current cases of cancer with controls matched on a post-hoc basis, leading to a possible over-estimation of the cancer risk. Misclassification of endometrial hyperplastic lesions as early endometrial carcinoma has also been charged (Horwitz & Feinstein, 1978). This work was partially funded by Ayerst Laboratories.

¹²A fourth editorial, written in May of 1979, acknowledged the cancer link. This editorial drew several angry responses from researchers.

¹³See Paterson et al., 1980; Sturdee et al., 1978; Thom et al., 1979; Whitehead et al., 1977. These studies were all partially or totally funded by the pharmaceutical industry.

¹⁴See Horsman et al., 1977; Lindsay et al., 1976; Lindsay et al., 1978; Nordin et al., 1980. Again, these studies were all partially or totally funded by the pharmaceutical industry.

¹⁵Since there are no data on physician-patient interaction concerning the ERT decision, all of our measures of physician behavior are necessarily indirect. In this section, therefore, we relied on various survey data, authoritative medical references, various

medical writings, statements made by physicians' professional organizations, and marketing data. Marketing data are published by International Medical Statistics (IMS), and consists of surveys of physician practices and prescription counts.

¹⁶ A 1975 article in JAMA estimated that 86 percent of all women use a gynecologist as their principal physician (Pearson, 1975) and the AMA recently proposed to have obstetrician/gynecologists formally recognized as women's primary health providers (cited in Ruzek, 1978).

¹⁷ This statement drew an angry response from feminists. Grossman and Bart (1978, p. 182) state: "A symptom is an outward sign of an underlying problem. That this physician chooses to give carcinogens to women to deal with problems they are not experiencing is the ultimate in medical arrogance and represents medicine's attempt to take over not only our bodies but even our sense of reality".

¹⁸ These statistics are taken from the IMS National Disease and Therapeutics Index. "Data are obtained from a representative panel of physicians who report case history information on private patients seen over a given period of time. Over fifteen hundred physicians report four times a year on a 48-hour period of their practice.... The basic information document for this study is the physician's case report of each patient contact, whether it occurred in the physician's office, in the hospital, in the patient's home, via telephone, etc." (IMS, 1981).

¹⁹ Sidney Wolfe testified at a FDA hearing that in 1978, 75,000 progestin and 5000 DES prescriptions were written for pregnant women (although physician inserts clearly state that estrogens and progestins should not be given to pregnant women since they may seriously injure the fetus) and 194,000 to suppress lactation--a practice for which there is no evidence of effectiveness (Wolfe, 1979).

²⁰ The New England Journal of Medicine has consistently warned of the cancer risks associated with estrogen use, and in 1978 editorially denounced the Horwitz and Feinstein (1978) study which questioned the validity of the previous cancer studies.

²¹ The consultants based at teaching and research hospitals hold highly prestigious salaried posts, and all other physicians are excluded from hospital practice. They also have the option of retaining a private practice outside the hospital (Sidel & Sidel, 1977).

²² A London Times article (Gillie, 1978) charged that Women's Health Care was financed by Ayerst Laboratory and served as a front for PR activities.

²³The data for this section are a wide variety of books, articles, organizational newsletters and brochures written and prepared by feminist, health and consumer groups. Additional material comes from court testimony and affidavits prepared for court cases and FDA hearings relating to ERT.

²⁴We thank Professor David Edge of Edinburgh University for bringing this group to our attention.

²⁵In addition to various secondary sources, data for this section come from government documents, correspondence and interviews, and from affidavits, court testimony and judge's opinions in Federal court cases.

²⁶At about the same time, Ayerst Laboratory (the manufacturer of the most widely used ERT product, Premarin) sent a reassuring "Dear Doctor" letter to all physicians. The letter did not refer to the recently published cancer studies but recommended "business as usual." Alexander Schmidt, then FDA Commissioner, called this act "irresponsible" (Lieberman, 1977).

²⁷The other three are oral contraceptives, progestational drug products, and isoproterenol inhalation preparations used by asthmatics.

²⁸Since the regulation was first promulgated, the FDA has proposed changes which relax the dispensing requirements for incompetents and eliminate them for men (Stapleton, 1980).

²⁹It is likely that this figure would even be lower if physician practices were surveyed.

³⁰Only after considerable public furor over the thalidomide disaster was this Committee formed. Originally it was known as the Committee on the Safety of Drugs (or informally as the Dunlop Committee, named after its first chair), but under the Medicines Act of 1968 was renamed as the CSM.

³¹Products already on the market in September of 1971 (about 36,000) were given product Licenses of Right, products which never had undergone independent evaluation. To review these drugs, the Committee on Review of Medicines (CRM) was created in 1975 and given a 1990 deadline to complete this task. This Committee operates very much like the CSM--its members are appointed by the health ministers and also represent physicians, scientists and drug manufacturers.

³²In contrast to the FDA, an agency which rules on both efficacy and safety, the CSM is mainly concerned with safety. In further contrast to the FDA, the CSM's decisions are not final. The Committee only advises the Licensing Authority, which is part of the Medicines Division of the Department of Health and Social Security (DHSS). Manufacturers may appeal an adverse decision of the Licensing Authority, taken on the advice of the CSM, to the Medicines Commission. This 14 member committee is again composed of scientists, physicians, pharmacists, veterinarians, and representatives of the pharmaceutical industry. These members are appointed by the Ministers after consulting with interested organizations, and serve in a part-time virtually honorary capacity (Binns, 1980; Dunlop, 1973).

³³We have not been able to get primary documentation of this CSM statement, and members of the CSM and the Medicines Division of the DHSS have denied our requests for interviews. Considering the informal structure of the CSM, it is possible that no such documentation exists. As Sir Derrick Dunlop, the first chair of the Committee stated, "much of the Committee's contact with the applicants took place in robust but usually good-humored encounters over the telephone or in informal meetings rather than in official communications duplicated for the record" (1973, p. 232).

The senior principal medical officer of the Medicines Division stated in a letter that the CSM has not issued any "public releases" on ERT but that the Committee was "concerned that literature related to unopposed oestrogen preparations [promotional literature to medical practitioners] should contain the warning that prolonged unopposed oestrogen therapy may increase the risk of development of endometrial carcinoma" (Griffin, 1980). (Emphasis added)

³⁴One explanation for this might be what a former NCI official facetiously called the NIH (Not Invested Here) Syndrome. With as much insight as humor, Schneiderman (1980) wrote us: "if we did not invent it here, how could it possibly be true?"

³⁵One purpose of the NHS menopausal clinics is to carry out such randomized controlled trials.

³⁶As evidence Sontag cites the use of cancer as a metaphor to depict various kinds of evil. Slums and pornography shops are depicted as "cancers" in our cities, communism as "cancer in our midst," and the Nixon administration as a cancer, rotten from within.

³⁷This anomolie has been puzzling to scholars (for example Kessel, 1973). Even Sir Derrick Dunlop, first chairperson of the CSM, stated: "it is...surprising that in the United States, the home of big business and enterprise, the control of medicines should be

more bureaucratically rigid than in the United Kingdom with its so-called socialized medicine" (1973, p. 237).

38 That the scientist and physician depend on the companies that manufacture the drug for their income did not seem to disturb Sir Derrick.

39 These feminists have recently been accused of a subtle ageism and of denying their own hormones (Posner, 1980).

40 We thank Rosamond Robbert for this insight. The same sort of thinking is also implicit in the writings of Cooper (1975) and Evans (1979).

41 Although most American feminists come from a middle-class background, they have not pursued any particular "class" interest in Marxist terms.

42 The conflict created by the status and income disparity between the British GP and the hospital based consultant has been amply documented (Barnard et al., 1977; Forsyth, 1966; Mechanic, 1972; Sidel & Sidel, 1973; Wallace, 1975).

43 Much has been written about the extent of unnecessary surgery performed by American physicians. For example the rate of hysterectomies in the U.S. is more than twice the rate in Britain (Bunker, 1970).

44 A comparison of drug consumption revealed that in the U.S. the rate per 1000 population for prescription drugs was 344, whereas in Great Britain it was only 247. This was the reverse for non-prescription, over-the-counter drugs with a rate of 9 for the U.S. and 14 for Great Britain (Lee, 1980).

45 A World Health Organization survey found that in a comparison of seven countries, the U.S. ranked first in the consumption of prescription drugs (Lee, 1980).

46 In December of 1976 a Hill and Knowlton vice president wrote a letter to Ayerst outlining a promotional campaign "to protect and enhance the identity of estrogen replacement therapy." This letter was intercepted by an employee and turned over to a feminist newspaper, Majority Report, which published the letter (Lieberman, 1977).

47 In recent years there has been a reemergence of interest group activities trying to define cigarette smoking as deviant behavior (Markle & Troyer, 1979).

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