SEX DIFFERENCES IN CLINICAL TRIALS: ANOTHER EXAMPLE OF INEQUALITY

INTRODUCTION

Ambien, the sleeping pill, which was prescribed 40 million times last year and approved 20 years ago, has been prescribed for women in a dose that is twice as high as they need, putting them at risk for drowsiness while driving and other problems. Indeed, it appears that women respond differently from men to a broad array of treatments, from aspirin to anesthesia, and often do not derive the same benefits from them as men. The extent of these effects, however, is unknown and unresearched. Ambien is the only drug that has been examined. There is no research on drug metabolism with the exception of Ambien. We do not know extent that other drugs are being prescribed to women at incorrect dosages.

The Food and Drug Administration (FDA) has long known of the gender effects of Ambien. In its original 1992 FDA review, a reviewer noted that two key measures of how much drug is in the bloodstream "were approximately 45 percent higher in females than in males."

It was not until 2014, that National Institutes of Health (NIH) announced that it would change its policies to ensure that female animals and cells are included, and sex differences analyzed at all stages of the scientific process. Until that announcement, differences between the sexes had been totally ignored in clinical studies. Scientists have routinely studied only male animals.

Our reproductive organs have been the concern of men from time immemorial. Hormones and surgery have been essential interventions by mainly male scientists-

doctors. Interventions effecting male functions are regarded as very serious and are seldom undertaken except to treat pathology. On the other hand, interventions effecting perfectly normal female functions such as the menstrual cycle, menopause, contraception, birth, and surgery are rampant. It is men who determined that we were the weaker sex, who didn't allow us to vote, who didn't allow us to own property, who decreed that our place was in the home and our product should be children.

According to the Western medical model, pre-menstrual syndrome is a disease, menstruation is a disease, pregnancy is a disease, childbirth is a disease, and menopause is a disease. From this model, I have reached the conclusion that being a woman is a disease. We are poisoned by prescriptions for normal functions or hysterectomized, as 685,000 women are every year at the hands of the medical profession.

Women make an average of 4.6 doctor visits per year. Per capita health care spending averaged $5,246 for women compared to $4,125 for men. Their normal bodily stages and functions not only are medicalized but are patholigized. In every era of history and in every phase of women's lives doctors have sought to control or intervene in women's reproductive functions. Functions have become symptoms, and symptoms have become diseases. Changes in hormone levels have become deficiencies. In 2002, NIH concluded that the terms "deficiency" and "replacement therapy" were not supported by the data. Despite this conclusion, both terms continue to be used by the medical profession today.

The notion that women need treatment from menstruation to death must be rejected. I believe that being a woman is perfectly normal for half of the population. Contrary to the women's model, men don't usually enter the health care system until they

reach middle age. They do not go for regular check-ups until a friend drops dead playing tennis or jogging.

Women are the victims of so much unnecessary medical and surgical intervention that it makes them sick. There is no greater illustration of this point than that of the pharmaceutical industry. Women are prescribed almost 70% of all medications. Not only do we usually take responsibility for contraception, we also visit doctors four times more than men do, making us the key market for doctors and pharmaceutical companies to target throughout our lives.

Medicine "discovered" early on that female functions were inherently pathological. Doctors from the late nineteenth century to the early twentieth century espoused that "many a young life is battered and forever crippled on the breakers of puberty" and, additionally, that women be "dashed to pieces" by childbirth, eventually arriving "upon the final bar of the menopause where protection is found in the unruffled waters of the harbor beyond reach of sexual storms." As late as 1916, doctors advised women to omit all heavy exercise for the entire "menstrual week" and that girls should stay out of school for one to three days, so as to "rest the mind" and get more sleep.

Today, we find that fertility, menstruation, pregnancy, births, menopause, and the broader process of aging are all medicalized. (See below for examples)

I. Gender Bias In Clinical Trials

The National Institutes of Health (NIH) has long acknowledged the problem of women's exclusion from clinical research, establishing a policy in 1986 for the inclusion of women. Congress reaffirmed this need through a section in the NIH Revitalization Act of 1993 (PL 103-43), entitled Women and Minorities as Subjects in Clinical Research.

Despite the establishment of the policy women were not represented in clinical trials and gender bias has persisted in the decades since.

Women are also underrepresented in clinical trials carried out by pharmaceutical companies and medical device manufacturers. As a result, they may experience more severe side effects or be prescribed an incorrect dosage of a medication. Additionally, we know that science has not focused on the way certain diseases manifest themselves in women. Doctors are likely to misdiagnose life-threatening conditions. For example, heart disease presents itself differently in men (chest pain, radiating pain down the left arm) and women (nausea, fatigue, shortness of breath), yet the public has been taught to look for signs typical of males.

The bias against women in clinical testing extends to animal trials on rats and mice. Even drugs tested on laboratory mice have been tested predominantly on males, due to a belief among scientists that the hormones and menstrual cycles of females might skew the data. Such bias extends to studies on diseases that predominantly affect women (such as anxiety, depression, thyroid disease and multiple sclerosis). According to Dr. Janine Austin Clayton, associate director for women's health research at NIH, as a result of the over-reliance on male animals and male cell lines, "We literally know less about every aspect of female biology compared to male biology."

Only after the CBS Sixty Minutes segment aired did NIH decide to take action in 2014 by acknowledging that gender bias is unfounded, dangerous, and should be terminated and there is no scientific reason to avoid testing female animals, tissues and cells in their trials.

NIH also announced that it would distribute $10.1 million in grants to more than 80 scientists studying a diverse array of health problems with the objective of including more women in clinical trials and ensuring that their laboratory animals, even cell lines, are representative of both genders. The money also will be used to analyze gender differences in the resulting data.

II. Mental Health

One in four women takes medication for a mental health condition compared to just 15 percent of men. Antidepressant use is especially high among women, up 29 percent since 2001. Women use anti-anxiety medications at almost twice the rate seen among men. Eleven percent of middle-aged women are on an anti-anxiety medication compared with 5.7 percent of men that age.

Women's mental states are so often pathologized and treated with medication that we must wonder both the reasons why we rush to medicate women so much more often than men and the effects of such treatments. Even when researchers study anxiety and depression they rely mainly on male animals although the diseases are much more prevalent in women. We are left to wonder not only "why women are being medicated for more illnesses far more often than men", but also whether the treatment they are receiving takes their biology into account.

III. Contraceptives

Contraception itself is part of a long history of a culture willing to sacrifice women's bodies for profit.

At the First International Conference of Intra-Uterine Contraception, Dr. J. Robert Wilson said: "[P]erhaps the individual patient is expendable in the general scheme of things, particularly if the infection she acquires is sterilizing and not lethal."

The birth control pill was tested on 132 Puerto Rican women before marketing. Depo Provera—the shot heard round the world—was tested on so-called women 'volunteers' in Bangladesh in exchange for a chicken. Norplant, a five-year contraceptive, was used for social engineering in several developing countries.

Countless women have lost their fertility, their reproductive organs, and their lives because pharmaceutical companies have put unsafe, untested contraceptive drugs and devices on the market in pursuit of profit—and women trusting their doctors take them without question.

Contraceptive developments have been almost completely focused on women who, while the only sex who can get pregnant, are only half the duo required. The possibility that the manipulation of male hormones might interfere with men's masculinity, virility, or potency is so unacceptable that there is barely a whisper of interest in hormonal contraception for men. Vasectomy is a simple outpatient procedure while female sterilization a more intrusive and complex one, the surgical sterilization of women is still much more common. Men do not allow their genitals to be tampered with and do not want to be "fixed."

In 1970, A.H. Robins entered the contraceptive business with the Dalkon Shield, an inexpensive intrauterine device said to be tested by a doctor at a prestigious institution. Nine months after marketing the device, the company first began a two-year baboon

safety study. One in every eight baboons died, and 30 percent suffered uterine perforation. The results were never made public.

The Shield was promoted as preventing pregnancy without adverse effects, even though it was an untested product. FDA pressure led to suspension of marketing efforts in June of 1974, but not until 1984, 10 years later, did Robins recommend that women wearing a Shield have it removed. Through the 1980s, Dalkon Shields remained in the bodies of women in 80 countries. If our Toyota brakes fail, we return the car to the manufacturer. But if there's a defective device in women's bodies, we do nothing.

Judge Miles Lord admonished the corporate officials, saying:

> "It is not enough to say, 'I did not know,' 'It was not me,' 'Look elsewhere.'…If one poor young man were by some act of his—without authority or consent—to inflict such damage upon one woman, he would be jailed for a good portion of the rest of his life. And yet your company, without warning to women, invaded their bodies by the millions and caused them injuries by the thousands…You planted in the bodies of these women instruments of death, of mutilation, of disease."

Despite these frightening lessons of the past, the new generation of contraceptive choices such as Mirena, NuvaRing, and Yaz are advertised as safe and effective, though there is not enough data to support such claims. Indeed, safety and efficacy data show that they are actually dangerous.

Mirena, an intra-uterine contraceptive device carries serious risks such as ectopic pregnancy, sepsis, pelvic inflammatory disease, punctured uterine wall, and irreversible infertility. The NuvaRing is a once-monthly, vaginally-inserted device that secretes contraceptive hormones directly into the cervix, but such exposure to estrogren and progestin causes increased risk of blood clots and other side effects. YAZ was the best-

selling oral contraceptive in the United States, with recorded yearly sales of approximately $616 million. Bayer recently settled 6,700 lawsuits related to YAZ, in which women suffered deep vein thrombosis, pulmonary embolisms, or other blood clot injuries, and there are still over 5,400 lawsuits alleging similar injuries that have yet to be settled. Since the first quarter of 2004, hundreds of reports of injuries due to YAZ and YAZ-related products had been filed with the FDA. Yet YAZ is still an incredibly profitable oral contraceptive, generating $1.47 billion in sales in 2010 for Bayer, or 3.3 percent of the company's revenue.

IV. Medicalization of Childbirth

In our highly medicalized and technologically oriented culture, childbirth has not escaped medical intrusion into women's bodies. Of course, modern obstetrical practices can save the lives of mothers and babies but 99% of C-sections – the most performed operation in the United States – are unnecessary. After a brief interest in natural childbirth practices which reached only a small number of women, we have reverted to surgery that makes women the passive object of medical care. In fact, most husbands and doctors think the baby is theirs. They say, "We're pregnant, we're having a test, we're going into labor, we gave birth to a boy."

How do pregnant women fare in the United States? Our medical system has made us patients. Recent news tells of world-wide efforts to reduce maternal deaths—which occur every minute and a half. In the United States, 650 women die every year during childbirth. This should be a wake-up call to the United States to reverse the appalling upward trend in maternal deaths.

American women are more likely to die in childbirth than they were two decades ago, making the United States one of the few countries where the risks from childbirth have risen in the past generation, according to recent data from the World Health Organization. In the US, the maternal death rate is 136 percent higher than in 1990, while in China, the rate has dropped by two-thirds since 1990. Even though the United States spends more on health care than any other country, a woman's risk of dying in childbirth is higher here than in 40 other countries. Two to three women die every day, and African-American women are nearly four times more likely to die than white women. It is also a three million dollar industry.

C-sections are now the most commonly performed surgery in America. Planned pregnancies are in, natural childbirth is out. According to the CDC, C-sections account for a third of all birth in the United States, a 60% increase since 1996. The World Health Organization recommends that the rate should not be higher than 10 to 15 percent.

C-sections are more expensive and produce worse outcomes. Having a C-section puts a woman at increased risk for hysterectomy, hemorrhage, infection and deep vein thrombosis, and the risk rises with each subsequent C-section.

The rising C-section rate is not due to aging mothers or assisted reproduction which make up a small fraction of births. Nor is it due to rising obesity. In fact, the biggest increase in C-section rates is among women under twenty-five and the increase is in low-risk births. In lower-risk pregnancies, in which more limited variation might be expected, hospital cesarean rates may vary 15-fold, from 2 percent to 37 percent.

Why are so many women undergoing dangerous and major surgery that is not medically warranted? Commercial insurers pay 60 percent more for a C-section than a

vaginal delivery. From 2004 to 2015, the average total price charged for pregnancy and newborn care was about $30,000 for a vaginal delivery and $50,000 for a C-section, with commercial insurers paying out an average of $18,329 and $27,866, respectively.

What we have now is better décor but the same medical interference in childbirth. The New York Times featured a tale of two hospitals, one with the highest rate of C-sections in the city – the other with the fourth lowest. They represent the city's obstetric extremes, yet they sit just five miles apart in Staten Island serving similar populations. What accounts for the difference?

Cesarean births are primarily more prone to complications than natural births. And while hospitals give lip service to reducing them, very few have managed to do it. Dr. Mitchell A. Maiman, the Chairman of Obstetrics and Gynecology at the Staten Island hospital with the lower C-section rate and his colleagues do not allow inductions for first-time pregnancies since that is the main cause of C-sections. He also did not allow C-sections simply because the mother wanted one. Dr. Maiman says if you went to your doctor and said, "I want my gall bladder taken out" electively, your doctor would refuse that. Dr. Maiman favors the same noninterventionist policy for pregnancy, as long as it is safe. Maybe you believe a mother's choice should extend to controlling the hour of her delivery and how much it will hurt, and therefore do not like Dr. Maiman's policy. But you have to give him credit for creating protocols to support women's health and enforcing them. There is not a lot of incentive for hospitals to let conviction trump convenience. If this can be done in one hospital, it can be done in every hospital and it can be done for every unnecessary C-section and every unnecessary hysterectomy.

Cesarean sections are dangerous and expensive operations, but save the doctor time. Perhaps we are saving some babies but we are losing more mothers.

Medicalization of pregnancy, starting in the 1940's, was through the use of another hormone – a synthetic powerful estrogen known as DES. Its inventor, Sir Charles Dodds, never patented it and was against the automatic prescribing of estrogen for any reason. The men in his laboratory were growing breasts and he thought that DES might cause breast cancer. Dodds sent samples to the National Cancer Institute just being established in the United States to Dr. Morris Shimkin. Dr. Dodds asked Dr. Shimkin to investigate the carcinogenicity of Stilbestrol in male rodents. Shimkin and Grady reported in the Journal of the National Cancer Institute in 1950 that Stilbestrol produced breast cancers in both male and female mice, which were normally resistant.

Six million American women were given this unsafe, untested, and ineffective drug during their pregnancies. By 1939, more than 40 articles documenting carcinogenic effects of synthetic estrogens, including DES, had been published in medical journals. DES did not save a single baby.

In 1959, the Secretary of Health, Education and Welfare announced the potential cancer hazard to the public "occasioned by the use of Stilbestrol-treated poultry." He ordered a blanket ban on the use of diethylstilbestrol die as a poultry additive.

On December 15, 1961, Deputy Food and Drug Commissioner Harvey also ordered a blanket ban on the use of DES as a poultry additive, saying: "There is a substantial evidence that this drug may be expected to produce, incite, or stimulate cancer growth in human beings."

However, DES was not banned for pregnancy – yes for chickens, no for childbirth – until 1975. How much cancer, infertility, miscarriages – expense and worry – could have been prevented? Eli Lilly's expert stated at the first trial, Bichler v. Eli Lilly, that the human (woman) was the best test animal and Lilly's lawyer said succinctly: "Eli Lilly is like any other company … I would be a dummy to stand up here and say it is not in business to make money … of course it is." While we no longer use DES in the United States, DES is still part of the food supply in China, Kenya, and India.

There are still many modern obstetrical interventions that increase the incidence of obstetrical complications and emergencies. It is questionable whether our society understands that childbirth is a process in which a woman's body extrudes a baby rather than a process by which a medical professional removes a baby from a woman's body.

V. Menopause and Hormones

We know the road for menopausal treatment is more like a street lined with gold leading up to the door of the pharmaceutical companies. The term *menopause* was first used in 1872. By that date, Western medicine viewed menopause as a medical crisis that had the potential of causing a variety of diseases, from diarrhea to diabetes. The crisis was deemed greatest for women who had acted indiscreetly in the past. Such indiscretions included getting too much education, having too much sex, attempting to use birth control, or even being insufficiently devoted to husband and children. As a prescription for menopause, doctors recommended a quiet lifestyle centered on the family.

By the middle of the twentieth century, the medical profession switched from looking upon menopause as the cause of disease and began to think of it as a disease itself – a

deficiency disease, like diabetes. This gave doctors the exclusive right to diagnose menopause and to treat its symptoms with estrogen, the hormone women were said to be lacking.

Estrogen was first prescribed for menopausal symptoms in the 1930s. It could be taken as a pill, administered via injection, applied directly to the vagina as a cream, or even taken as a "pleasant-tasting cordial" – 14% alcohol! But in 1947, an alarming report revealed that estrogen therapy could seriously disturb the endometria, thickening the uterine tissue and ultimately causing cancer.

In 1966, in *Forever Feminine*, gynecologist Dr. Robert Wilson trumpeted estrogen therapy as an "elixir of youth" to protect women from the "living decay" of menopause. He declared that estrogen could cure nervousness, crying spells, memory loss, chronic indigestion, aching joints, neuroses, and even suicidal thoughts. In addition to making his book a best-seller, these claims also fueled skyrocketing sales of estrogen, from $20 million before 1966 to $83 million in 1975. Not surprisingly, Wilson had received money from the drug companies for conducting his so-called "research."

In 1975 an article in the New England Journal of Medicine firmly announced what the 1947 study had suspected – women who took estrogen were about 5 to 14 times more likely to develop cancer of the endometrial lining than women who never used the drug. Further, the longer a woman remained on estrogen therapy, the greater her cancer risk. Finally, in the early 1970's, after lobbying by the women's health movement, the FDA passed a regulation that any estrogen drug had to have a patient package insert describing its health risks. The medical and pharmaceutical lobby opposed this regulation vigorously, arguing interference with the physician-patient relationship. One

doctor went so far as to say that seeing such a package insert might be too emotionally upsetting for women seeking estrogen treatment. However, women seemed to heed the warnings about the dangers of estrogen. Between 1975 and 1978, sales of estrogen decreased by 40%, and the incidence of endometrial cancer fell by about 27% nationwide.

Revenues from the Premarin family of products, including Prempro, have declined by 25 percent. But the newest member of the Premarin family, Duavee, is expected to generate over $200 million per year, according to market analysts.

In 2002, the W.H.I. hormones-versus-placebo trial was ended three years earlier than planned. W.H.I. officials 'were persuaded that the trial was too dangerous to the hormone-taking participants to let them continue.' Women on hormones were having more heart trouble than placebo taking counterparts, the risk for stroke went up, the risk for blood clots went up, and the risk for breast cancer increased by 24%.

Companies are developing new products that deliver estrogen therapy to menopausal women. Ascend Therapeutics' "EstroGel", a form of estradiol applied to the arm once per day, purports to "manage" menopause symptoms such as hot flashes, night sweats, and vaginal dryness. Upsher-Smith Laboratories produces Divigel, a similar drug. Estrodial gels are also marketed to improve bone mineral density. The warnings associated with these estrogen gels include cancer, heart attack, stroke, and dementia.

It has therefore become evident that despite the contra-indications and side effects resulting from hormones given for a non-disease, the pharmaceutical industry will not stop promoting them because it is a $3 billion industry.

VI. Hysterectomy

Perhaps the most over-medicalized aspect of our biology involves removal of the reproductive organs, female castration—otherwise known as hysterectomy, which is a $17 billion industry.

A comedy sketch on British television some years ago illustrated the perceived expendability of women's genitals as compared with men's. A male patient sat on an examining table, in gynecological stirrups, with a female physician examining his pelvic region. Appearing embarrassed and uncomfortable, the patient answered questions from the doctor about how many children he had, their health, and whether he was satisfied with the number. The doctor concluded that the patient had "finished his family," and casually suggested that he "just have them [his testicles] off" in order to relieve certain unspecified "symptoms" and forestall possible negative developments, such as cancer. This is funny (to men, anyway) because no doctor would ever seriously suggest this course of action as a preventative measure. However, women are routinely submitted to unnecessary hysterectomies and ovariectomies by doctors who insist that such surgery is needed to prevent disease. Indeed, doctors at an Ob/Gyn conference once agreed that "no ovary is good enough to leave in and no testicle is bad enough to take out."

Apparently, the safety of the hysterectomy in modern times has served as an invitation to doctors to perform the procedure even when it is medically unnecessary, as it is 99% of the time. As late as the 1970s, the physician overseeing a Cesarean birth by a minority or indigent woman would ask how many children the patient had. If the number seemed excessive, the operating resident would be invited to perform a hysterectomy to increase his experience with this procedure. The patient, under general anesthesia, obviously could not give her consent, so the operative report would note excessive

bleeding or some other excuse for the hysterectomy. In the 1970s, Diana Scully observed Ob/Gyn residency programs and found that doctors were taught to "think of the uterus as a cradle. After you've had all your babies there's no reason to keep the cradle. And removing your uterus will save you from the risk of developing cancer in later life."

More than 40 years later, this cradle analogy is still being used. The New York State Department of Health produces a pamphlet about the dangers of hysterectomy and alternative treatment options. The pamphlet continues to assert that the only function of the uterus is to "cradle and nourish a fetus from conception to birth, and aid in the delivery of the baby. It also produces the monthly menstrual flow, or period." No other function of the uterus is mentioned, nor is any further information about this important part of our body described. It vaguely asserts that after a hysterectomy, ovaries still produce hormones but "may have reduced activity." It fails to explain that removal of the uterus and ovaries constitutes castration. It also does not explain that sex will never be the same, or describe other consequences such as personality change, difficulty with social interaction, memory loss, pain, loss of energy, and even suicidal thoughts.

The uterus and ovaries have been a favorite target for surgeons – only the reasons for their removal seem to change. During the last 200 years gynecologists have proceeded from their first tentative attempts to perform hysterectomies to where it is the second-most performed operation in the United States – at the rate of about 1,643 a day. That is more than one every minute. Clearly this qualifies as fad proportions. In total, American doctors perform 685,000 hysterectomies each year. Compare this to another industrialized Western nation, England, where only 40,000 such procedures are

performed per year. The United States has four times the hysterectomy rate of any industrialized nation.

In Saudi Arabia a gynecologist may perform only one hysterectomy a year, usually due to a life-threatening event such as an obstetric hemorrhage. In Somalia, uterus removal is viewed as so rare and abhorrent that the family of a hysterectomy patient dispatched gunmen to threaten her doctor. They argued that she was as good as dead without a womb, and demanded 50 camels – the usual Somali compensation offered upon a woman's death. The doctor, who was fined $2,000, promised that in the future he would consult patients' families before performing such operations.

In the U.S., 45.1% or more of women ages 65 and under in the U.S. report having undergone a hysterectomy. Rates vary by state; in New York the rate is 13.3% with 3.2% in the 44 and under group. Mississippi has the highest rate at 57.1%. No wonder hysterectomies are often called "Mississippi appendectomies." In California, only about half of the female population will die with their uteruses intact. (Another joke – What do you call a woman in San Diego who still has a uterus? A tourist.) Regionally, the South continues to have the highest rate of hysterectomies at 60.2 out of 1,000 women, while the Northeast has the lowest rate at 3.7 out of 1,000. But do women's reproductive organs differ by geography?

Approximately 1 in 2 American women will have a hysterectomy by the time she is 70. 400,000 are performed for uterine fibroids, which is a benign condition. Even by conservative estimates, 9 out of 10 American hysterectomies are elective procedures. That means that there is no medical imperative that a hysterectomy is done and that if it is *not* done, nothing dire will happen. In many cases, if the hysterectomy is not done, the

women would be much better off and only the doctors' wallets would suffer. In addition, surgical removal of the ovaries is done in about 75% of women who have hysterectomies, without medical justification.

Removal of the uterus and ovaries may increase risk of heart attack, and (even when ovaries are not removed) chances of experiencing an earlier menopause. Hysterectomy has also been associated with urinary problems, such as increased frequency of urination, incontinence, fistula, and urinary tract infections; sexual function problems, such as decrease in sexual sensations and lack of lubrication; depression or psychological stress (stemming from feelings associated with losing reproductive organs); hormone deficiencies, which may be caused by removal of the ovaries, or a decrease in blood supply to the ovaries.

Hysterectomies have often been referred to as 'hip pocket surgeries' because in most cases they serve only to line the pockets of the surgeons and hospitals that do the surgery. In this country, hysterectomies and oopherectomies have boomed into an industry worth $17 billion per year. The long-term cost of treatment and corrective surgeries for the problems cause by hysterectomy and ovary removal could easily exceed this amount. Further, Medicare and Medicaid statistics reveal that the more body parts a doctor removes, the more money he and the hospital receive.

This provides zero incentive to doctors to change their ways. Meanwhile, the increasing number of women physicians has been ineffectual in curtailing the contrast in attitudes towards women's and men's reproductive organs. Women doctors may relate better to women patients, but their training is the same as their male counterparts. Perhaps because men still control the overall medical establishment, the terms for these

procedures remain misleading. The plain meaning of "total hysterectomy" seems to entail removal of the uterus in its entirety; instead, it refers to removal of the uterus, ovaries, and fallopian tubes. And only a male-dominated profession could use the term "simple hysterectomy" to refer to removal of the uterus – which is decidedly not simple!

VII. Osteoporosis

Osteoporosis is another condition that inspires fear in the hearts of millions of elderly women. But when we ask what osteoporosis is, it becomes clear that the definition of osteoporosis has gone through many permutations over the years. For most doctors, an osteoporotic woman is identified through a series of bone mineral density (BMD) tests. The National Osteoporosis Foundation recommends BMD tests for all women 65 and older, as well as for all post-menopausal women and women who have been taking hormones for a prolonged period of time. The more deviation from the bone density score of a normal young adult of the same sex, the more negative the number and the greater the risk of fracture. A score higher than -2.5 marks the point at which doctors diagnose a woman as suffering from osteoporosis.

It is estimated that more than 20% of most menopausal women have osteoporosis and that estimate has reached as high as 50%. Scaring women about their bone strength is a burgeoning industry which urges us to "talk to our doctors before it's too late." Free bone mineral density tests are offered to see "how much we lost."

During the 1990s, the immediate response to a diagnosis of osteoporosis was to put a woman on a hormone therapy regimen. Estrogen was recommended as a preventive treatment for post-menopausal osteoporosis as early as 1941, and by 1975 the annual number of estrogen prescriptions written was nearly double the number written in 1966.

Premarin, the country's leading estrogen product, became one of the top five prescription drugs in the country. Although it was marketed for the psychological discomforts of menopause, keeping bones strong was an important part of its purported youth-giving properties – feminine forever equaled estrogen forever.

After 5 years of cancer warnings, the number of annual prescriptions for Premarin fell by 50%. The advertising claims were altered to include only menopausal symptoms and vaginal dryness. The company found salvation later by aggressively promoting hormone therapy as the preferred treatment for osteoporosis. A risk factor had been turned into a disease and there was a situation in which the people profiting from osteoporosis as a disease were the ones defining it.

Young women should also be aware of the side effects before deciding to go on Depo-Provera, a progesterone contraceptive given by injection that has been shown to cause bone loss in some users. In her book *The Menopause Industry*, Sandra Coney writes that "after measuring the bones of young women who had been using Depo-Provera for over five years, it was found that they had 7.5% less bone in the spine and 6.5% less bone in the hip than women who had never used the drug." The bone loss seems to result from the drug's blocking of estrogen and causing amenorrhea (the absence of menstruation).

The FDA has now placed black boxes not only on estrogen, but on some of the newer osteoporosis treatments that are coming to market warning that serious side effects may occur. Instead of science by press release, living a healthy lifestyle, including nutrition and exercise, will be a lot better for your health than Wyeth Ayerst products.

VIII. Insurance

With women being pushed to medicate and butcher their bodies in so many ways, the financial burden on women has become enormous. More than 90 percent of individual insurance plans charge women higher premiums than men for the same coverage, a practice known as gender rating. Overall, women spend $1 billion more each year on their health insurance premiums than men do. This practice is banned starting in 2014, but it is not yet clear whether change will really occur. More than a quarter of women—26 percent—delayed care in the past year because of cost, compared to just 20 percent of men, according to a Kaiser Family Foundation study.

CONCLUSION

As the year 2014 comes to a close, the trend of medicalizing women's biology shows no signs of abating. According to the American College of Obstetricians and Gynecologists, about two-thirds of American women rely on their gynecologists for primary care. Unsafe and questionable methods of contraception are still used. The Mirena intrauterine device promises effective birth control for up to 5 years. During pregnancy, upwards of 20 tests are performed on both mother and unborn child, some of which are more perilous than the conditions they purport to detect. Pharmacies offer menopausal women so-called "bio-identical hormones," which are supposedly "natural" because they are derived from plant materials. In addition, pharmacies have begun what is known as "compounding" – the mixing of drugs as tailored to the needs of a particular patient. These products, including hormone replacements, are dispensed in quantities and combinations not approved by the FDA. Surgically, women undergo numerous unnecessary C-sections, hysterectomies, oopherectomies, and other procedures.

Women's reactions to medications are assumed to be identical to men's, and doctors and the medical pharmaceutical complex treat them as such.

The current situation can be summarized as follows:

> "Many of the procedures performed on women's reproductive organs, and medications administered to control them, have been unsupported by empirical evidence. Reproductive technologies penetrate the female genitalia, whether medically or surgically…. Finally, women's doctors decreed that menopausal women are deficient, that women must maintain childbearing levels of hormones rather than progress through the normal stages of life. Each of these interventions has been justified by 'science'… [but] seldom have we examined the reasons we ask the 'scientific' questions." [1]

Despite the social progress made by women in recent decades, we have not advanced far enough when it comes to our biology. In the face of overwhelming medical literature, reports, and advice, we must assert our rights and regain control over our own bodies.

[1] Nada L. Stotland, "Women's Bodies, Doctor's Dynamics"