



EXCERPTS FROM 1991 PUBLIC CITIZEN'S HEALTH RESEARCH GROUP BOOK
WOMEN'S HEALTH ALERT
HORMONE REPLACEMENT THERAPY

Since the 1940s when estrogens were first manufactured cheaply and available by mouth, the story of their widespread use in treating women's "problems" is one of false promises, disregard for scientific evidence and the wishful thinking of women and their doctors that all female health problems can vanish with the magic of pills. It is a story of well-meaning doctors eager to please, and of women too easily sold the wonders of pharmaceutical cures. Unfortunately, years after women have been routinely consuming hormones, many of these otherwise healthy people have slowly been getting sick from estrogens.

In 1989 more than 4 million women were given estrogens for the symptoms of menopause--hot flashes, heavy sweating and vaginal discomfort. For the short term problems associated with menopause--these women *began* hormone replacement therapy. However, while the symptoms of menopause usually subside in less than two years, a large proportion of these women will take estrogens, and probably progestins (a synthetic form of the naturally occurring sex hormone progesterone) indefinitely.

By today's questionable medical reasoning, these potent drugs should be given to perfectly healthy women, not to treat any disease, but to decrease the potential of disease--specifically osteoporosis and heart disease.

Replacement hormones were the "feminine forever" drugs of the 1960s and 1970s, guaranteed to keep wrinkles away, hair glossy and depression to a minimum. In the 1980s, these drugs were advertised as the cure for osteoporosis, the long sought-after answer to brittle bones. Now in the 1990s, estrogens are being touted as the solution to female heart disease. Whatever their mission, these recycled wonder drugs have securely found a permanent spot in the medicine cabinets of millions of healthy women over 45. But the dangers of hormone replacement therapy have been tragically underplayed by American doctors, the press, and of course the drug companies, who make hundreds of millions more dollars every time a new use for these drugs is found. Throughout the history of their application in American medicine, estrogens have proven to be as dangerous as they are helpful. As with so many medical products sold to American consumers, taking them has become a risk-benefit game; the difference here is that women are not making choices based on all the facts.

Ovarian hormones, especially estrogens, have been linked to breast cancer in animal studies since the 1930s. But if you ask your doctor if they cause human breast cancer, you will probably be told the evidence is still "inconclusive" and "inconsistent," or that women are not the same as rats or mice.

You may have heard or read that if you take menopausal hormones you increase your risk of endometrial (uterine) cancer, heart disease, stroke, gallbladder disease, uterine fibroids, liver disease, and migraine headaches. If you combine estrogens with progestins, you will reduce your risk of uterine cancer, but may simultaneously be increasing your risk of heart disease and breast cancer. Progestins may also cause abdominal bloating, headaches, depression, or acne. You may also begin to menstruate again.



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Many women do not realize that menopausal hormones are grossly overprescribed for extraordinary lengths of time--now longer than ever before--longer than anyone can scientifically justify. Unless you are considered at high risk for potential problems with the treatment, physicians today are more likely to downplay any harm and persuade you that without them you will prematurely expire or snap under the weight of old age.

Prescription practices for these potent drugs have subtly but dramatically shifted over time. Today, it is not up to women to prove they need hormone replacement after menopause. The burden is on women to prove they don't. So widespread is the use that many women may not be completely sure why they are still taking estrogens at age 60.

These two grandmothers are examples:

I have been taking estrogens since I can remember. I don't know whether I'd still get hot flashes, but I don't want to find out.

and

I started taking estrogens 12 years ago when my surgeon prescribed them following my hysterectomy. I was having terrible hot flashes then, and Premarin (the most widely prescribed estrogen) completely got rid of them. I'm still taking it, because somewhere along the line, I don't remember when, my doctor told me they would protect me against osteoporosis. I feel great and don't see a reason in the world I should stop taking that pill along with my vitamin every day.'

Hormones: Not Harmless Little Tablets

Little pills that deliver hormones to your body are not simple vitamins or candy-coated aspirin. They are manufactured duplicates of substances that play amazingly diverse roles in females. Besides their role in maintaining reproductive cycles, estrogens alter lipid (fat) levels, metabolize carbohydrates, affect how blood coagulates, adjust blood pressure, and assist in calcium absorption, all of which are complex biologic events.

When the natural supply of estrogen slowly diminishes after menopause, can its job all be "replaced" in a pill?

Obviously not. The enormous and complicated functions of hormones are not completely understood by science. Experts are still exploring the effects--both good and bad--of replacement hormones. There is still a lot to know about their long term risks, since long term use is relatively new. In fact, identifying which women will ultimately benefit from these drugs is still impossible, which is why their use is so general and widespread. There is an excellent probability that the vast majority of women receiving hormone replacement therapy will obtain no benefit at all while subjecting themselves to all the potential risks and side effects.



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Since ovarian hormones have been known to promote cancer, the trend toward grossly overprescribing them can't be taken lightly. As Allan S. Brett a researcher from the New England Deaconess Medical Center wrote in a 1989 editorial in the New England Journal of Medicine, "pharmacologic interventions are powerful symbols of the triumph of medical technology. Patients are likely to believe implicitly that the benefits of drugs clearly outweigh the risks." This can be a very dangerous assumption.

Cancer and Hormone Replacement Therapy

In the United States in 1989, an estimated 142,000 new cases of breast cancer were diagnosed in women and 43,000 women died of the disease. Because women of the "baby boom generation" are now reaching age 40, the number of breast cancer cases and deaths will increase substantially over the next 40 years. For this reason, even a small increase in the risk of breast cancer caused by menopausal estrogens will translate into a lot of lost lives.

As women in menopause by the hundreds of thousands are being given replacement hormones, that increased breast cancer risk is being further investigated now. But accumulated evidence over the past decade shows that if you use menopausal estrogens for a long time, you roughly double your chance of getting breast cancer by the time you are 75.

What's a long time? Let's briefly look at the scientific studies. While they go back earlier than this, the first reliable studies of women taking menopausal estrogens for longer than five years were published between 1977 and 1983. These were strikingly consistent in their findings, and overall, showed that women using the most commonly prescribed dose of estrogen (1.25 mg tablets at the time) for five or more years double their chance of developing breast cancer.

Four of the five studies found that the risk of breast cancer was highest in women who used higher doses of the drug, women who used the drug for a long period of time or both. In the first of these studies, researchers found that women using doses higher than .625 mg per day (the dose most commonly prescribed today) were 2.7 times as likely to develop breast cancer 10 years after starting drug treatment as women who did not use the drug.

In the second study, researchers found that women who received any dose of menopausal estrogens for at least seven years had an 80 percent increase in breast cancer.

The 1981 study found that women who had surgical removal of the ovaries and estrogen replacement therapy increased their risk of breast cancer; dramatically the longer they were on estrogens. The risk worked out like this: In less than five years of estrogen replacement therapy these women had a 38 percent increased risk of breast cancer; at nine years, their risk had increased to 55 percent; and after 10 years it reached 70 percent.



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In 1986, an expanded study of menopausal estrogen use showed that 20 years after first using estrogens, women had increased their risk by 50 percent.

But all these findings have been called "inconclusive" because other studies have shown little or no connection between breast cancer and menopausal hormones. Proponents of menopausal hormones are reluctant to implicate this wonder drug as a contributor to breast cancer, an admittedly complicated disease caused by many factors.

In 1989 at a meeting of the Food and Drug Administration Fertility and Maternal Health Drugs Advisory Committee in Washington D.C. leading researchers met to decide if the evidence over the last decade did indeed point to an increased risk of breast cancer in postmenopausal women.

Janet Daling from the Fred Hutchinson Cancer Research Center in Seattle called the question of risk "very tricky" to answer: " My conclusion would be that estrogen replacement therapy may have a modest effect on breast cancer risk, something in the range of 1.5 to 2.0 [times increased risk] in women who have used estrogens for long periods of time."

The committee was also asked to review all the evidence and their conclusion was: "The committee's unanimous response is, while the evidence is not conclusive, some studies have reported an increased risk of breast cancer in long term use of estrogen replacement therapy."

Today, instead of getting only a prescription for estrogens, you will probably also get another little bottle, this one with progestins. You will take these for 7 to 10 days at the end of your cycle of estrogen pills.

In the mid-1970s, three striking studies found that taking estrogen by itself increases your risk of endometrial or uterine cancer from 5 to 14 fold. This news sent shock waves through the medical community, but in 1989 it was shown that by adding progestins, the problem of endometrial cancer was largely ameliorated.

Good news and bad news. It was somehow "hoped" by some doctors that progestin would also offer women some protection from breast cancer, despite the known differences between how each organ responds to hormones. However, not surprisingly, in the summer of 1989, a new study from Sweden suggested that progestins in combination with estrogen may cause more harm than good.

The study showed, once again, that women using estrogens alone for an extended period double their risk of breast cancer, but it also showed that when progestin was added there was no protection against breast cancer. Instead, the few women who used the two hormones together for more than six years had a higher risk of breast cancer than those taking estrogen alone.



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The study has been criticized because the Swedish women who participated in it were given differently manufactured hormones at different doses than women typically get in the U.S. But one of the study's authors, Dr. Robert Hoover, Chief of the Environmental Epidemiology Branch of the National Cancer Institute, says the results shouldn't make any hormone proponent feel vindicated. "It looks as though the cancer risk may be an estrogenic effect and not some nuance of the chemical structure of different estrogen compounds."

The results of the Swedish study, says Hoover, are not surprising.

'The fact that ovarian hormones might relate to increased risk of breast cancer is not on the bizarre fringe of biological reasoning. The biological plausibility was established 100 years ago, so new data which shows that women on replacement therapy have an increased risk is exactly what you would predict. You can argue about what level of risk there is, but the reasonableness of the observation is firmly steeped in biology.'

Arguing about the level of risk is what researchers are doing these days, which may be the reason that practicing physicians are told, and will tell you, that studies are inconsistent and inconclusive, so basically there is nothing to worry about. In fact, if you increase your risk of breast cancer, that is obviously something to worry about.

Getting Started on Replacement Therapy

Why have women adopted the notion that menopause is a cruel consequence of being female, "one of nature's mistakes," an illness that needed to be cured? Menopause is not a disease. No one has ever died from it. It is a natural event that results in some temporary and some permanent changes for all women. Physiologically it's the time when a woman's ovaries stop functioning, a process that can take several years. The cessation of periods and the thinning and drying of the vaginal tissues are among the two most obvious permanent changes associated with menopause. Hot flashes are temporary changes most women encounter. However, many other psychological conditions have been described as "symptoms" of menopause. Irritability, depression, anxiety, loss of sexual feelings, and an almost limitless list of other states are all attributed to it, but not proven to be caused by it.

Menopause is not the first time most women experience these symptoms, but they may be worsened at age 45 or 50 in a society that discriminates against aging women, promotes superficial notions of exclusively youth-related sex appeal and encourages everyone to answer all problems with a pill. Menopausal estrogens will not eliminate wrinkles, increase your libido, or ameliorate all the psychological conditions that come with growing older. Those hoped-for effects don't happen, plain and simple.

However disruptive and annoying, a small number of the symptoms of menopause may be alleviated by reintroducing estrogen as its own production is slowly reduced. Menopausal estrogens in low doses over short periods can eliminate hot flashes and night sweating associated with menopause. They can also reduce vaginal dryness. While useful for both problems, treatment seldom needs to continue for longer



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than several months. Most women are free of hot flashes in under two years and vaginal dryness can be can be treated with topical creams.

While some women do experience hot flashes that are incapacitating, more frequent is the experience of Dorothy, 50, a psychologist.

The first time I felt one I thought I had forgotten to turn on the air conditioner. Now I can feel one coming and I know its going to last a minute or so. Occasionally I have to take off a sweater, or wipe my brow but it never gets in my way. It's simply not a big problem.