Midlife Clarity with Dr. Tracy Page

"Clarity Changes Everything"

Hosted by Dr. Tracy Page

Episode #18 — The Black Box Warning Removed from Estrogen

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Hi, welcome to Midlife Clarity. I am Dr. Tracy Page, and today's topic- let me just say it resonates with me in a thousand ways. I'm going to talk to you about the study that scared a generation, and why I believe the most repeated sentence in women's medicine was never actually true. So let's just talk about a 54-year-old woman. She hasn't slept through the night in two years. She has hot flashes, which are pretty much ambushing her meetings during the day. The brain fog has gotten bad enough that she started writing down words- common words, as she usually knows- and she wasn't sleeping, and she was feeling miserable, and she did the brave thing.

She went to her doctor, and she asked about hormones, and her doctor looked at her and kindly said, "Then I've heard this a zillion times. Oh, I would like to prescribe estrogen. It causes breast cancer. I can't tell you, begin to tell you how many women have come to my office and told me that their primary care or their physician taking care of them told them that estrogen causes breast cancer, or their friend, or their family member, or someone's sister, and they have a ton of patients, and they'll tell me, "Oh, my sister told me this, Dr. Page, help me understand why she thinks estrogen causes breast cancer." Right? And just like that, and I'm talking about the last decade, two decades, the conversation's over, because patients trust their doctor, right? So this patient went home, and she whined and white-knuckled it, like still many women have. She did that for years. I mean, I see patients when I practice that come in in their 60s, and they're like, "I've been struggling and suffering for 10 years, and all of that time I thought I couldn't have hormones."

So here's what nobody tells patients about the Women's Health Initiative. We're going to talk about it today. Okay? The idea that estrogen causes breast cancer is built on a single study from 2002. And that study did not say what the patient was told; it said, "In fact, for a huge number of women, it actually is almost the opposite, and I will point out right now that Black Box Warning has been taken off after then." This is the most misunderstood sentence in women's medicine today, and today I'm going to take it apart and explain to you why. I'm Dr. Tracy Page, and as I said, this is Midlife Clarity, and today we're talking about the study that scared an entire generation of women away from their own hormones. And what we now know in 2026 that changes the whole story.

Okay, let's go back. July 2002, a massive government study called the Women's Health Initiative, otherwise known as WHI, stops one of its arms, one of its arms. There are two arms, one of its arms early and holds a press conference. The headline, Ricochet, is throughout the world, and by morning, hormone therapy raises your risk for breast cancer. Okay, the reaction, is instant, as you can imagine; no one wants cancer. Within months, prescriptions collapsed. Before 2002, about 90% of women who had a hysterectomy were using estrogen, 90%. Okay, within a decade in women in their 50s, that year has fallen by nearly 80%. That means only 10% of patients were actually using estrogen after that. The class. Estrogen-related therapy in the United States for women between the ages of 50 and 59 fell roughly 79% between 2001 & 2011. An entire field of medicine reversed itself in a season. Doctors stopped offering it, women stopped asking for it because it wasn't prescribed. And the fear hardened into something that felt like common sense. Estrogen's dangerous. Estrogen causes breast cancer. I even hear it today, and in my practice still; it's ingrained in women, right?

But here's something about the study that almost nobody heard, nobody except medical professionals, because it didn't fit in the headline. But the Women's Health Initiative wasn't one study. It was actually two, and most of you don't know that. Two completely different groups of women, taking two completely different things, and the results with those two groups were not the same. They were actually opposite. The Women's Health Initiative had two arms. The headline only had room for one, and that's why you don't know about it. Okay? Let's talk about the two groups. Group one. Women who still had their uterus. They took estrogen, so they were in the menopausal state. They took estrogen, plus a synthetic progestin, specifically a drug called Medroxyprogesterone. Group two, women who had a hysterectomy, no uterus, and they took estrogen just alone by itself. Same trial, but just a different recipe. Okay? And when researchers followed these women out for nearly two decades, 20 years, more than 27,000 women, the gold standard of medical evidence.

Okay? The two groups split apart completely. And what did we find? Over 19 years, estrogen alone produced a 23% reduction in breast cancer, and estrogen plus a synthetic progestin produced a 29% increase. So let me repeat that. Estrogen alone provided a 23% reduction in breast cancer. So those were women who did not have a uterus. They were only given estrogen; no breast cancer. Women who had a uterus received estrogen and a fake progesterone called progestin; 29% increase in breast cancer. Two different groups. So the women on estrogen alone got less breast cancer,

not more. And they had fewer deaths from breast cancer too. The increase, the thing that scared everyone, only showed up in the group taking estrogen combined with one synthetic progestin. So basically two recipes that were blamed for one bad meal. So they put everything in one bucket. No one ever told women the other side of the recipe, the other, the other arm.

Okay, we're going to talk about the scary numbers. Even in the group where the risks did go up, I want you to understand what a 29% increase actually means because relative numbers are designed to fool you. Think about the lottery. If your odds of winning double, that sounds enormous, a 100% increase. But if you start at one and a hundred million, you're now at two and a hundred million. Okay, the relative change is huge. The absolute change is almost nothing. So think about the lottery again. If your odds of winning double, that sounds enormous, right? Your odds of winning double is a hundred percent increase. But if you started at one and a hundred million, so your odds are one hundred million, and now you're two and a hundred million, the relative change is huge, right? The absolute change, so being a hundred percent more, a hundred percent increase, is really nothing. The 29% increase in the combined group translated to fewer than one additional case of breast cancer per a thousand women per year. So even though the women who had the progestin, the increase would be one additional case of breast cancer per a thousand women per year. For context, breast cancer is in the same neighborhood as breast cancer risk from drinking a couple glasses of wine a night or carrying extra weight through the middle. This is real, and it's worth knowing, but not the monster it was made out to be. The combined therapy increase amounted to less than one extra breast cancer case per thousand women per year. Comparable to the risk we really tend to worry about, like having a couple glasses of wine or carrying a little extra weight, right?

I tell this to my patients every day: my concern for you and breast cancer goes far beyond the hormones that I give you. It's about the weight that you're carrying; the hormones are actually going to help you lose. It's about the alcohol that you're drinking to help you fall asleep at night because you don't have your hormones, but that's really is the problem area.

So what did the cost of this fear cost us? Okay. And the 2005 reversal. So in the reversal of all this information. So, as you're aware, it was actually protective what happened to all those women who were scared off of it? Researchers at Yale asked exactly that question, and the answer is hard to hear, but I'm going to share it with you. They estimated that

in just one decade, women in their 50s who had had a hysterectomy and avoided estrogen out of fear died prematurely, somewhere between about 19,000 and 91,000 women died prematurely. Their best estimate was around 50,000. So 50,000 women from avoiding a hormone that for them was protective. The Yale analysis estimated up to 50,000 excess deaths, ranging from 18,601 to 91,610 among hysterectomized US women, ages 50 to 59, who avoided estrogen through 2002 and 2011. I just want to sit with that for a minute because those women died prematurely because they didn't have a hormone that they needed because they thought that it was going to cause cancer.

For 20 years, the strictest warning the FDA can issue, the Black Box Warning, was set on every estrogen product telling women it raised their risk of breast cancer, heart disease, and dementia. And here is the news that makes this episode matter right now more than anything. In November of 2025, after reviewing the full body of evidence, the FDA removed the Black Box Warning from all estrogen products for breast cancer, for cardiovascular disease, and for the risk of dementia. The change took effect early in 2026, and there's a great podcast with Dr. Rachel Rubin that talks about this.

The FDA commissioner said in plain language that millions of women had been denied the benefits of hormone therapy because of the distortion of the risk. And I'm afraid that makes you mad; that really makes it bad. In November of 2025, the FDA removed the Black Box warnings for breast cancer, cardiovascular disease, and dementia from estrogen products, and it became effective in February of 2026. Now you know why we have a sort of estrogen tantrum. We are experiencing that because now women are like, give it to me, right?

Let me be very clear about what this does and doesn't mean because I never want this show to swing from one oversimplification to another, so I want to make sure I point out all the nuances. It does not mean every woman should run out and start estrogen. I want to say that clearly. It is still a prescription medication. It still has real considerations, and there are women for whom it is generally not the right choice. So it's not every woman. The FDA also kept one warning in place about uterine lining cancer for women using estrogen alone, which is exactly why progesterone matters, and that's the entire next episode that we're going to talk about. What it means is that the fear is no one is allowed to make the decision for you. The conversation is open again, and you should be talking to your doctor about estrogen replacement. So the one really, an FDA left down there was the endometrial lining.

So if you give estrogen to a woman who has a uterus who's in menopause, if you give her too much systemic estrogen, it can grow the endometrial lining, and if the lining grows too much, it can have changes in the cell structure, and it can cause endometrial cancer. That is why we always give our patients who have a uterus and are menopausal estrogen and progesterone, which is called Prometrium which is not progestin, which is actually progesterone. Prometrium is a bioidentical progesterone that your body makes, and I'll talk more about that in the next episode.

So how to think about this, okay. So if you're sitting there with the symptoms, hot flashes, night sweats, weight gain, belly fat, drive vagina, dry skin, hair loss, and you have fear and the doctor who has shut the door on you until you can't estrogen, I want you to think it through in this order for yourself. Know which study actually applies to you. Do you have a uterus or not? The single fact determines which arm of the WHI study is relevant to you, and they had opposite results. Demand absolute numbers, not relative ones; that's what's important. If anyone tells you estrogen raises your risk by x percent, ask: common actual woman out of a thousand.

Thus, the answer is usually reassuring and the right side one. Okay. Separate the estrogen from the progestin. The breast signal came from a specific synthetic progestin, not estrogen itself. That type of signal matters enormously. More on that next time I talk about estrogen and progesterone. And then a factor in time when you start relative to menopause changes the whole risk-benefit ratio, and we're going to talk about that in the third one on estrogen and individualize your family history and your personal risk, your symptoms, your goals. This is all a conversation that has to occur. This is not just a formula. You really have to have this conversation with your provider, and you deserve to have it. You deserve to have a conversation about hormone replacement.

Okay. So what are your action steps? I'm going to give you a few. Six things you can do before you talk to anyone.

Write down your symptoms and how they actually are affecting your life. So know what you're feeling. Right. So that's the first step. Okay. Sleep, work, mood, intimacy- that's all: dryness, skin, hair. It's not like I'm fine. Like really think about these areas.

Find out whether you still have your uterus on record, and I don't think you have to find that, you know, have you had a hysterectomy, right? It sounds obvious, but the evidence does apply whether or not you need progesterone. And I'm going to say I do

give progesterone to my patients who don't have a uterus because progesterone is a very calming hormone. It balances out estrogen. So I don't say that just because you don't have a uterus, you don't need progesterone. And I'll talk more about that later.

At your visit with your doctor or provider, ask the question directly. Does the breast cancer concern come from estrogen or from the progestin? Because the progestin is what was shown in the study, and I would say ask about your absolute risk. So many cases per thousand, right? That we're talking about. So what is your absolute risk?

Now, if you had breast cancer before, it was estrogen positive, then of course you are not eligible for hormone replacement. But I don't tell you that you didn't have some patients who are so miserable that, for quality of life, they still consider it. And that's a personal choice. Okay?

No, how many years has it been since your last period? Bring that number with you when you talk to your provider. And don't let a 2002 headline make a 2026 decision. If your provider is still working from the old script, the old information, it may be time to find a new one because you need more information.

So if you hear nothing else from me on this podcast, please hear that estrogen decreases the risk of breast cancer in greater than 23% of patients. Okay? Estrogen hasn't changed. The myth that scared everyone in 2002 is the exact same one we have today; what changed was the story we were told about it. How long we let in this red headline outlive the evidence. And it is mentioned too in the Women's Health Initiative. It was oral estrogen, which does increase the risk of clotting factors, which can increase the risk of stroke or heart attack. Remember in functional and integrative medicine, we don't use oral estrogen. We use transdermal, a cream or a patch. The woman I told you about at the beginning, she lost years to a sentence that was never true, right? Estrogen causes breast cancer. You don't have to have that. You're allowed to ask the question again with the real numbers in your hand.

Next week, I'm going to go deeper into the part that had lines got wrong. It was never really about estrogen. It was about progestin, and the difference between this synthetic one and the one your body actually recognizes is one of the most important things a woman in their life can understand and understand why we prescribe it. This is Dr. Page. If you have questions, please reach out to info@wisconsinfunctionalmed.com. But

please know that hormone replacement is available to you, and then what you're scared about. Remember, it is not what the Women's Health Initiative leads it to be.

I'm going to review with some statistics. Okay, 27,347 women in two women's health conditions hormone trials randomized, placebo-controlled. That's the study that I looked at. Estrogen alone 23% reduction in breast cancer over 19-plus years. Estrogen and synthetic progestin 29% increase, right? Over 19.2 years. Estrogen only used in women 50 to 59 fell by 79%. Between 2001 and 2011, just because of that statement. And about 50,000 estimated excess deaths occurred from not using estrogen. And the FDA removed the estrogen black box warning for breast cancer, cardiovascular disease, and dementia in November 2025. And it became effective in February of 26.

So ask yourself, what did you personally believe about estrogen and breast cancer before today? Why did it take the new more than 20 years to reach the public, which I find very interesting? And what would you want your own daughter to know walking into this decision? And what should you know? So really think about those, and I'll continue this series in the next episode. We have clarity. It changes everything. Talk to you soon.