Hormone Therapy Decoded: Black Box Warning Removal Transcript

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Show Introduction and Guest Background

Welcome to Energize and Revitalize with Dr. Amy. I'm Dr Amy Cooper-Smith, a doctor prepared nurse practitioner. And this show is about empowering you to live a radiant, healthy, and balanced life.

Shauna is a nurse practitioner who obtained her nursing degree from the Denver School of Nursing in 2012 and followed by a Masters of Science from The University of Cincinnati in 2019. She began her career as a dedicated labor and delivery nurse and later transitioned into becoming a women's health nurse-practitioner.

Shauna is now the lead practitioner at Amethyst Wellness, where she brings extensive training in hormone replacement therapy, PDO threads, and injectables.

So welcome and thanks for being here. Hi, thank you for having me. So I wanted you to be on this episode because for a while now I've wanted to do another episode about hormones and why they're still so controversial.

And then in the news, suddenly we've had a black box removal warning. So, I couldn't think of a better person in this area, in Palm Coast area who is more of an expert on hormones than you.

I think we should talk about this and explain to people what this really means. I agree. It's exciting news that it was removed and it's publicly been released.

Yes. So let's start with what is a black box warning? A blackbox warning is something that the FDA puts on a pharmaceutical that gives the highest risk warnings on the box.

Just some of the risks that could occur with that medication if you consume it or use it. So pretty scary stuff. And in this situation, hormones, and pretty much hormones were all linked together, but there was a warning on them that they could cause breast cancer and heart disease and even dementia.

Yes.

Black Box Warning and Hormone Controversy

So for a long time, we've been treating women with estrogen. But we had to learn how to do it safely. To put a black box warning hormones in general but estrogen has scared a lot of women away from using a hormone that can be so beneficial.

And not just the women but I've had women come in who maybe saw their primary care doctor And they said, oh, you're on hormones. Well, when Amy gives you breast cancer, or you can go have her treat it.

And, they come in and they say, Oh my gosh, am I going to get breast? And then we have to talk about what causes breast, cancer what increases risk of breast.

Cancer and what doesn't. Yes. Because they're. fearful now of hormones and it's actually beneficial. Right. And so just to backtrack, what happened about 20 years ago was they had the Women's Health Initiative, a huge study where they have thousands and thousands of patients and they looked at all this data, but unfortunately they I guess we could just say misinterpreted the data.

Yes. And gave women who hadn't had hormones in a long time, estrogen, no progesterone. The outcome was sad because it caused the black box warning on hormones for women and to advise them not to use it.

It was a poorly done study. And so for a woman going through menopause, and many of our listeners are in that

magic age. Menopausal, when your hormones, your natural production of estrogen declines, everything in your life is affected.

And to not have an appropriate treatment, earlier in my career, women were being given antidepressants for their hot flashes. Oh thanks, now I just won't mind so much.

It's just such substandard treatment. Yes, I agree. And then we stopped educating new physicians and nurse practitioners and people coming out into the medical world.

on hormone replacement therapy and it wasn't considered beneficial so they're not even talking about it with their patients and so women have just been ignored and their symptoms they just think they have to live through it or it's part of life and that's an injustice for women.

Absolutely. So what has happened recently is there was a committee and they all decided that it was okay to remove this warning. So basically the updates now, what are they saying?

So they're saying that estrogen prevents cardiovascular disease and they do have studies attached to support the removal of the black box warning. It prevents cardiovascular disease, helps extensively with bone density and helping, you know, prevent fractures in the bones.

And it's recommended that women, within 10 years of menopausal age, start a estrogen therapy if it is safe for them to do so. So it's basically removed and then that it does not cause breast cancer.

And so that was removed from the estrogen label. Yes. So interestingly enough, when I became a nurse, I was a cardiac care nurse. And every woman that came in who had a heart attack was put on hormone replacement.

And then a few years later, the study came out and they were all taken off of their hormones. It was so confusing for me as a young practitioner and I think for the whole medical community in general.

Yeah, because that's a huge change in treatment plans. So, and then I after that is when they started to see start to look at the increased cardiac events of women when they go through menopause and come off their estrogen.

And so it actually helps decrease cardiovascular events.

Why the Warning Was Removed

So the day after the news story came out, one of my colleagues said, Oh, What do you feel about this? What does this mean? I said, well, it's a great first step.

Finally, practitioners have been chastised for prescribing hormones for years now. So finally, its a start. And finally clients are saying, wait, are hormones free?

And I had other friends who judged me. Oh, should I be on hormones? Like, maybe. Let's talk about it. It's good. People are talking. I like that. I agree and since it is so publicized, women hopefully will be able to bring it up to their providers and not be nervous about talking about their symptoms and hopefully getting some help besides antidepressants.

So while I feel like this is a very positive thing that's happened, I did want us to talk about the black box removal doesn't address the difference between synthetic hormones and bioidentical hormones, and in our clinic we use bio identical, but I wanted to about why that is important.

So bioidentical hormones are plant-based, still created in a lab, but they look very similar to your natural molecular makeup of your naturally estrogen testosterone.

So your body tends to absorb it better, you have less side effects, and so people tend to respond. better with those

plant-based hormones. Whereas synthetic is man-made also, but it is not a plant based.

It does not look anywhere near what your natural molecular makeup is. So people tend to have a little bit more side effects, also some different risks with them.

And I think the method of delivery is also very important. A lot of, or I thinks all of the synthetic or most of them, hormones are delivered orally. So when we take something through the mouth, it has to go through digestive system and pass through liver and then a lot times metabolites occur from that and that's where a side effects occur.

Whereas some of methods we use that are topical or implanted do not go through the liver. And that's another reason why they're healthier. Yes, and cut back on the risk of blood clots, because you have women who are smokers, still have hot flashes, need estrogen, but you're not going to give a smoker a pill, she at least has the opportunity to get a pellet or a cream and skip the livers and still get relief of her symptoms.

So another really important thing that I don't think has been in the news is progestins. Because the Women's Health Initiative did find a correlation between progestins in blood clots and heart disease.

Yes, and those are your synthetic, again. So your plant-based, your projesterone that we use from a compound pharmacy is yams with a peanut oil or an olive oil.

And there was no clarification between Progestin, projesterone, where it comes from and so they haven't removed any black box warning from the progestins.

It's still recommended, obviously, if you have a uterus that you take a projesterone to prevent endometrial cancer when you are on estrogen. So we still prescribe projesterone.

Bioidentical vs Synthetic Hormones

So why do people need progesterone in addition to their estrogen? So estrogen builds lining in the uterus and pro gesterones keeps it thin. So when you're post-menopausal and you are not having periods every month, you aren't shedding that lining.

And so it's important to have a pro-gesteron on board so that you can keep that linings thin, healthy, prevent endometrial cancer, endo-metrial hyperplasia.

We actually use pro testosterone to prevent hyper-plasia or a woman who has hyper plasia gets a progesterone inserted in an IUD form, so it's still an important hormone.

Absolutely. And so, again, just to reiterate, progesterone is good. Yes. Micronized progeterones is great. Progestins actually do have side effects. But any woman who has not had a hysterectomy and is in menopause cannot receive estradiol without that progesterone.

That's why there's still a black box warning because, yes, people can get endometrial cancer from estrogen if it's not managed properly. And it still sometimes is not managed properly.

Right. So even if everything's done right, some people do get endometrial hyperplasia, but it's important to have a provider who's hormone trained so that if that does happen, they know what to do with it.

And a lot of times there are warning signs before it becomes cancer. Things that we can treat. Yes. If you have signs, then hopefully your provider knows, like you said, how to manage it send you to your OBGYN after proper testing has started.

And so, yes. Absolutely. Okay. So who benefits most from hormone therapy? Well, women and men benefit from hormone replacement therapy, but if we go back to black box learning was mostly estrogen, then obviously women

would benefit most.

We don't give men estrogen. But women benefit greatly from Hormone Replacement Therapy in general. Testosterone, estrogen progesterone to help symptoms of perimenopause and Menopaus.

Absolutely. And I wanted to circle back to the recommendation that hormones are started before the age of 60 or, you know, even there is some suggestion that after 60 they don't need them anymore.

So I am more cautious in my women who have not had a menstrual cycle in greater than 10 years or they've been postmenopausal for 10 you can still gain benefit in bone and cardiovascular health and prevention of urinary tract infections because that starts to become very prevalent in the older age, you know, 70s, 80s in women and so estrogen becomes very important for prevention UTIs and then the fractures and the bones and even though the woman they recommend starting within that 10 year window or before the age of 60, women over 60 can still receive hormone replacement therapy safely and benefit from it.

Absolutely. And we have clients who are over age 60 and they're very active and protecting their bones is so imperative to them living a healthy lifestyle.

Um, and that was the black box morning, um, did talk about the bone health, which is very important for men and women, but women especially the older they get for longevity and health.

Progesterone, Uterine Protection, and Safety

You don't want to be breaking bones and becoming immobile. And it's so important. For many older people, a broken bone is the beginning of the end, you know, within six months there, they're not with us anymore because that once somebody cannot do their normal functions of daily living, A lot of people that that's it.

Yeah, so we need to protect those bones. Yes, we do All right. I'm gonna have you hold that thought we're gonna pause for a break from our sponsor You're listening to energize and revitalize with dr.

Amy. Don't go anywhere. We'll be right back Welcome back to Energize And Revitalize With Dr. Aimee, I am dr Amy Cooper-Smith and my guest today is Shauna Sanford and Before the break, we were talking about hormones, the new recommendations, that black box warning removal about traditional hormone therapy.

And we've had a really great conversation so far. I agree. It's exciting news. Absolutely. So one of the biggest fears women have is that they will develop breast cancer.

And the statistics, unfortunately, we have way too much breast in our country. People, when they want to start hormones, one the first questions they ask is, is this going to give me breast Yes, I get asked that all the time, and the response is, first off, there's different types of estrogens.

Estrone, estriole, estradiol. We use estridiol in our practice for hormone replacement therapy, typically. And what I always tell women is if you were destined to get an estrogen-dominant breast cancer, because there are many different types of breast cancers, and I give you estrogen, then I'm fueling the fire.

You're going to see that breast-cancer appear sooner than if were on no hormones. But we are, you know, good at making sure they do their breast imaging, keeping up on their own self-breast exams, It's easily curable, treatable these days, and it's important to catch it early.

And so estrogen will not just cause that breast cancer. It would have to be an estrogen-dominant breast. Even some women who have had breast caner get cleared to use estrogen because it was a triple negative or something that estrogen didn't impact.

The black box label coming off of estrogen stating that it does not cause breast cancer is beneficial for women and hopefully will ease some of that, but also being able to explain to them the root causes and staying up on imaging,

making sure we catch it if you are going to have something.

Absolutely. And so I always say it's not going cause it. It's going not to increase your risk. But if you had a hormone-positive tumor and I gave you hormones, yes, it could grow and get worse.

So with anything, its not completely risk-free, but when we learn the facts, we can make informed decisions. Yes, and you've got to be in the hands of good providers.

Absolutely. One of my thoughts and concerns, I'm so happy that we're talking about hormones and more providers will be open to them. But I do want people to make sure that whoever is giving them their hormones has done proper training and research.

Because they are safe when administered appropriately. I agree. Back to what we had talked about earlier. They just haven't been educating providers in school.

And so then they don't, they're not even knowledgeable in the hormone replacement therapy, how to dose it, where to start, what route to go, risks and who's the right candidate for hormone-replacement therapy.

Who Benefits from Hormone Therapy

Hopefully now we'll have better trained and educated providers out there. That starts with an open mind and willingness to learn. Yes. So let's go back to one of the recommendations talks about lowest effective dose.

What's going on with that? So lowest effective dose is starting your patient at a low dose of estrogen or testosterone, whatever you're giving, and managing their symptoms at the lowest dose, because you'll have less side effects.

But there was always, you know, patches and pills are given an exact dose like a 0.25 and you always start at that. And then, sometimes you get leery the higher dose you go to treat the patient's symptoms.

It should be at the discretion of the provider. that they're hopefully educated on that and they can, you know, treat that patient effectively. But you should start low on anything.

We can always give more. So if we're giving a blood pressure medication, we started a low dose and monitor for effect because everyone is different. It's that individual response.

Yes. Um, so, similar with hormones. Yeah. And everybody is. Different. That's the best part of being able to treat with, um, well, our plant-based hormones, you can really adjust dose and fine tune each patient because they're not made like a textbook.

Exactly. So do you think now that the warning has been removed, do think more providers will be open to exploring hormone therapy for their clients? I think some providers we'll be more open.

Like you said, we have to be an open-minded providers that, physicians or PAs or NPs during those studies, it can be ingrained in them that, you know, those were the results and hormones are bad for you.

But I do hope, with this being removed, people will be open-minded or just the education will out there so that we can help our patients. Absolutely. And we can start talking and our clients can started talking about it.

Yes, that will make such a difference if they're not scared to share how they are feeling or feel like they just going to be closed off and not listen to.

Because we get patients all the time who are like, oh my primary care said I am fine. Everything looks fine, my labs are fine but I don't feel fine and they feeling like nobody is listening.

Absolutely. I think for women especially, we treat men as well. But when our labs look normal, but we don't feel normal and the process of perimenopause and menopausal, it takes years.

So it can be a little subtle when it starts and it could be little tricky to treat.

Breast Cancer Concerns and Provider Training

Oh yeah, because if you're in your later 30s and you have a new onset of anxiety, you're thinking it's situational or maybe I'm just an anxious person and then you are getting prescribed, you know, anti-anxiety or anti depression medication when really it can be the start of menopause and it is called peri and can go on eight to ten years before you ever actually stop having periods and go through menopsause.

And so that can can tricky for people to look at, finding a root cause but then realizing it could be hormones. Absolutely. So how does somebody know if it's their hormones?

So everyone's favorite question is, can you check my hormones. Yes. And we can check your hormones, but often it symptoms. We rule out things that can cause, you know, the symptoms, whether it is thyroid related or vitamin related, or you know, kidney function is something we look at and liver function.

And there's a lot of things that we're looking at in ruling out, but we will check your hormones. They will often tell us you're a menstruating female when you are perimenopausal.

So again, they look normal, then you have to look the symptoms and rule everything else out that it could be. Then we try hormones at a low dose and see if it improves the symptom.

I think that's the biggest thing. How do you feel? I love having labs and it gives us objective data. Sometimes that symptomatic improvement is overlooked.

I agree. People get very hyper focused on lab work. It's a guide for us as providers. Also, we have to look at your symptoms. I always address the symptoms first, coming back to what are my labs?

Well, my lab's could be better or, but it really is symptoms and how you feel and treating you at the low doses. And then even if your labs don't look in a range where it's expected, they're lower than that, um, you, feel great, then we're not going to give you more.

We'll keep it there and manage your. Symptoms. So when somebody gets their labs done, and they also have a comprehensive health history with one of our providers, what is the next step?

So we look over the blood work. And then we've already done a counseling session on different forms of hormones, how you receive them, side effects, risks, benefits.

Then once you decide, you and your patient, the best route to receive, we'll bring you in the office. and get you started on your hormone replacement therapy.

So pellet therapy is my preferred route. It's convenient for a lot of patients because women typically only need to come in every three to four months.

Testing, Pellet Therapy, and Testosterone Benefits

Men only needs to coming every four to six months, you get more of a sustained constant release of hormone versus a peak and a fall every day that you'll get with your daily dosing of your creams drops and trochies.

Plus, as we discussed earlier, skipping the liver gives you benefits of not activating clotting mechanisms or genetic components. And so people usually do really well on pellets and it's not something you have to consider, you know, am I taking this every day?

Did I forget it? What's the difference in my mood? Oh, I forgot my testosterone cream today. It's just that consistent release and we can really dial that in for a lot of patients and help them with their symptoms.

It's a busy society, so anything we can do to make things a little easier for people I think is… Awesome. Yes, eliminating a daily pill. Great modality.

So what is in the pellets? So pellet are testosterone or estrogen. We obviously don't give men estrogen, so when we treat our men, we're giving them testosterone pelletes.

And then when our women come in, if they need estrogen they're postmenopausal or they are symptomatic, then we can give them estrogen pellete. but we also give them testosterone pellets.

So they are separate pellet but they're testosterone and there are estrogen pelletes. We really haven't talked about testosterone during this episode.

Why does a woman need testosterone? Testosterone is so beneficial for women. Yes, we spoke a lot on estrogen but testosterone is good for a man and a women for sleep.

Helping with libido, helping with energy, help with inflammation in the body. Testosterone is a very potent anti-inflammatory and so it helps with the inflammation of the joints, it will help lubricate eyes, nose, mouth, joints.

Um, really good for bladder. People start to get irritability and urgency in the bladder and testosterone is very beneficial since it's a, your bladder is a massive muscle.

Um. And so testosterone's actually very calming on the mood. Despite that everybody thinks that causes aggression and proper doses. It's really for anxiety, depression, and irritable.

Absolutely. People just feel really good when we get their hormones optimized. Absolutely, they do. Life changing is what we hear a lot.

Closing Thoughts and Listener Call to Action

So if you can encourage our listeners to do one thing or study one, what would it be? I would encourage them to talk about getting their hormones tested.

That's a start. Even with your primary care, test your hormones and see where they're at and just consult. You can come in and do a consult with us, even if you've had labs drawn somewhere else.

It's great way to start and become a little more educated. Absolutely. Well, thank you so much for being here and talking about this exciting news with our with me and our listeners.

Yes. Thank you for having me. I will always love to come talk about hormones. Our favorite. And I do want to mention that this was an educational program for our clients.

This is not medical advice. But if you do need medical advise from us, please come see us at Amethyst Wellness. We would love Thanks to our listeners for tuning in to Energize and Revitalize with Dr.

Amy. If there are topics you would like to hear more about, please send an email to radiantpodcasts2025 at gmail.com. Check out past episodes on Amethyst Wellness YouTube.

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