FDA Rolls Back HRT Black Box Warnings

especially you know even anecdotally look at it when do women start getting breast cancer usually it's when their hormones start to decline yeah in their 40s and above right now there's the genetic variations where you have the BRCA gene and that you're to predispose all your life to breast cancer but we know that we can test for that we could look for that yeah um but in general you'll see that now one of the biggest misjustices we're doing to women is is birth control pills Yeah, because of the progestins in birth control pill, we're increasing the risk for breast cancer over time for these women.

Men need to start manning up and start doing birth control as well, because we're killing our women. Progestins will increase the risk for heart attacks too.

That's the negatives of those drugs. So ultimately, we got to come back to a nation, which I think this is awesome, but it's It's frustrating. It's 20 years.

We've had women sit for 20 years and suffer because we can't get our heads out and you know what, because we can't get our own out our own way and just understand there's a difference between synthetic hormones and biodynamic.

Welcome to Proactive Healthcare with XL Medical, the podcast where we redefine what it means to age well. I'm Leif Womwell, your host and co-founder of XL Medical, where we are rewriting the rules of aging.

Join me and expert guests as we explore topics like hormone optimization, boosting energy, losing stubborn weight and achieving mental clarity. Because ageing better isn't just about adding years to your life, it's about adding life to your years.

Let's dive in. Welcome to another episode of Proactive Healthcare. And I'm very pleased to have Dr. Fatinos here, my business partner and guest. And it's been a very, very interesting couple of weeks in our world.

And it's twice in less than 12 months, the FDA has rolled back. black box warnings from male HRT and female HRT. So for men, they've just removed the heart attack risk, saying it is no longer a heart risk.

For women, that it's a cardiovascular, dementia and breast cancer risk, which you've been saying for 20 years straight, the FDA is finally catching up Couple of things to ask you about this.

Firstly, before I get to the obvious of why on earth did it take 20 years, what is a black box warning? What does that mean?

Why the Old Hormone Studies Were Flawed

So a black box warning, I think back, it was initiated early on in probably in the eighties and our seventies or something of that nature, maybe even before then, but it was basically to warn patients of an imminent potential risk that could be harmful to either a fetus or a baby or a person in the form of maybe a death or something like that.

Okay. Uh, most of that comes from studies that show significant, um, a sign of significance based on statistical analysis. So for example, you know. So do you know where these came from then?

Well, they're crap. So it's kind of funny that the one for, okay, so there used to be, so for testosterone, there used to

be a black box warning for blood clots.

And in my book, I talk about this, it came from two, from very bad studies done by Dr. Glueck, where he basically gave testosterone to people who already have clotting disorders and saw whether they clotted.

Didn't have a control group. And for some reason, the FDA adopted it and said it was, but that was since been disproven from a lot of studies. In fact, if you look at several of the studies where people have no blood clotting and they were given testosterone or blood clotting disorder and given testosterone, they saw no increased risk in blood clots.

So the other one is the heart attack one that came from three studies that were really, really, really bad. The vegan study, which was done on VA patients.

It was basically what we call that insurance database study. You great studies by letter. So an A study is phenomenal. The B is decent. C average D knows crappy.

And then F is you don't want to even look at it. Yep. And the insurance database studies, basically what they do is they, they go back and look in an insurance database.

specifically for this study and see whether somebody was prescribed testosterone and what happened to that person. Okay. Didn't check levels. Didn't check to see if the patient was taking it.

No real follow up. They just, and also the people that are looking at this data, you can have one guy who's using a different criteria from the other.

They're trying to keep the same criteria, but there may be, this might be considered a criteria for one and not the other. And the other guy may be doing the exact opposite.

So a lot of the data was really bad in that study. In fact, if you look at the analysis, They use the wrong statistical analysis tool. When you do studies, you have either perspective studies, meaning you're going forward, or retrospective studies where you go back, a retrospective study.

Well, they use a prospective study type of statistical analysis for that retrospective study, which essentially flip the numbers. When you look at the raw data, there was a reduction in mortality and heart attacks in that study.

In the title of the study, testosterone increases the risk of heart attacks in men. Well, that was a big mistake because 25% of the people in the study were women.

So this is what we held our hand on. So there's not, this is a lot of the black box warnings does come from good studies, but a lot of them come from sensationalism.

The year before that, there was a study in the same group of population that showed a decrease in mortality and nobody heard about it. So it's being extra cautious to cover their asses.

No, actually, it's basically whatever media kind of picks up on, right? Got it. So what happened with the Women's Health Initiative was the same thing.

You'll listen to a lot of the authors of that study. They were never given a chance to really look at the data and to dissect it. When they saw that quote unquote statistical significance of an increased heart attack, or breast cancer or whatever you want to call it.

The main author who released it without even getting it with the other doctors and the authors in the study. So that's a big no-no. You have to vet the data and do all that.

The biggest problem with that study, and this is why now they know it's not a significant increase in breast cancer

and heart attack, was that the control group Women in that step part were never supposed to be on hormones.

Well, they found out a lot of those women were on hormones prior to starting the program. So what that happens is that control group, they were being actually protected.

We now know estradiol will decrease the risk of breast cancer by 23%. Wow. We know your mortality risk from dying from breast cancer reduces about 40% if you're on estrogen.

And so think about it. We were treating the control group with estrogen beforehand.

Estrogen, Progestins, and Breast Cancer Risk

So those women were actually protected. Well, the control group is supposed to be a standard of the population, right? Well, the population, not all women were taking estrogen, right?

And so that actually treated those women. So the gap, the significance got higher versus the women who were in the control group versus the women who were in the treatment group.

So it falsely looked like there was a significant difference between the two groups. What I find so ironic is the cardiovascular health. heart health for men and women is one of the primary benefits of HRT, which is exactly what these two black box warnings were.

Which is hilarious. But the problem is we fell into the trap too, because we thought, and even myself, we thought it was the synthetic hormones versus the biogenic hormones.

But if you look at the research, Premarin, because the only difference between Premarin and estradiol is Premarin increases the risk for clots, because it causes the increase in vascular reactivity and stuff.

That's the only real difference. When you see premen, premen does decrease the risk for heart attacks too. But the problem is why use premen when you can use estradiol where you're not going to get clots?

Totally. Of course. And you get the same benefit. Yeah. So both help. One just helps. Yeah. One causes a harm of potential clots, you know? So when you look at the study, like for the Women's Health Initiative, estrogen was not the culprit.

And when I say estrogen, I mean premarin. When I say estradiol, I mean the bioidentical estrogen. It wasn't the culprit. The culprit in that whole study was the progestin.

This 10 year window crap, that's based on premarin. It's not based on estradiol. If you look at the research, the finished study and the Danish osteoporosis prevention study, Even women who were above 10 years out of menopause saw a benefit and didn't see an increase in heart attacks.

They saw a decrease in heart attacks and strokes. So yes, there is a 10 year window with Premarin, but I would not put that same window on estradiol. What about the breast cancer risk that they've removed?

What's the relationship between that? It was the progestins that increased the risk for cancer. Got it. And it was a 2.86 relative risk ratio or heart cancer ratio of an increase.

Does the current program that we have in Femex cell, would that influence someone's risk of breast cancer? It would reduce it because we use progesterone, which has been shown either a neutral effect or a benefit against breast cancer.

So, I mean, we know this because it up regulates the P53 gene. P53 gene is a very important gene for anti-cancer. They also prevent proto-ochogean. Proto-ochogeans actually increase the risk for cancer.

So you're getting progesterone's benefit by not only up-regulating p53 gene, but also down-regulating proto-ochogeans. That makes sense. Which is very beneficial for the breast tissue.

You know, it's crazy. Especially, you know, even anecdotally look at it, when do women start getting breast cancer? Usually it's- When their hormones start declining.

Yeah. in their 40s and above, right? Now there's the genetic variations where you have the BRCA gene and that you're to predispose all your life to breast cancer.

But we know that we can test for that. We can look for that. But in general, you'll see that. Now, one of the biggest injustices we're doing to women is birth control pills.

Because of the progestins in birth control pills, we're increasing the risk for breast cancer over time for these women. Men need to start manning up and start doing birth control as well because we're killing our women.

A progestin will increase the risk for heart attacks too. That's the negatives of those drugs. So ultimately we got to come back to a nation, which I think this is awesome, but it's It's frustrating.

It's 20 years. We have women sit for 20 years and suffer because we can't get our heads out and you know what, because we can't get our own out our own way and just understand there's a difference between synthetic hormones and biodynamic hormones.

I think of the physical and emotional cost of this 20 years. And the deaths, the amount of women that are dying from this, you know, that's the problem.

And we always sit here and make our women our second-class citizens. Good example, most studies are done on men on when we do pharmaceutical drugs, unless we're going to market towards women, which is kind of interesting because the GLP-1s, most, there was a lot of women in it because I think a lot of the way they make these studies are based on who you're going to market to.

Makes total sense. You know, and that's not good. You know, we need to know whether these drugs. When it's across. Yeah. Yeah, we didn't know how to fix men too, or vice versa.

How does this drug, for example, a statin affect women? They do increase the risk for breast cancer in women. That's been shown. Yet nobody tells you that.

What about the other aspect they brought up was dementia, that it no longer increases that. What's the effect of that? So, remember the blood clotting part I was telling you about.

When they looked at these women in the Women's Health Initiative, They saw an uptick in what they thought was Alzheimer's disease. Yep. When you look back at it, it actually was micro thrombotic events or microembolic events that were globally hitting every part of the brain.

Dementia, Clots, and the Real HRT Benefits

So think of this, you have a clot that small little clots that go everywhere in the brain and cause little infarctions. So little mini strokes everywhere.

Not enough to where you go to have a drooping face or anything, but enough to affect your mental capacity. So they misconstrued that for Alzheimer's disease, which actually what it is truly is a vascular dementia.

You see a reduction because you see improvement in cholesterol numbers. You see in industry, estrogen is phenomenal for reducing the risk for Alzheimer's disease.

You'll see it. So what do you do if you're, you're someone out there, you're listening and you've been, you've been,

you've been 20 years of black box.

This is going to increase your chances of cancer, of dementia, of all of the cardiovascular now, oops, we're, we're wrong. What, what do you do? What, what's the, what's the, what's the patients?

What I fear. So. You can go right to your regular doctor. I fear 50 to 75% of them are still going to say the same thing. Yeah. Because they don't believe either the administration or what the research says, you know, um, and they're specialists and they're not specially, but that's the other part that you're going to have to have them go to these doctors and they're going to start putting them on stuff.

They're not used to doing, or don't understand how to do it. Yeah. And they may end up harming people. Like let's say you put them on a synthetic progesterone because they think it's the same thing as a progesterone.

That's a big no-no. You don't do that. Or they put them on Premarin and increase the risk for clot when you can easily put them on estradiol, right? But again, a lot of them are not going to believe this.

They're going to continue to say estrogen causes breast cancer. They're going to say, you're going to see it. I can guarantee you because ever since I've been showing study after study that it doesn't, they still believe this.

Maybe they won't. We don't know. But they'll go to somebody who's inexperienced that doesn't have almost 20 years of experience in hormone replacement.

who has studied and looked at the research and actually digested it and made it a protocol from it. And they're going to get treated, but they're going to either be treated inadequately or treated with the wrong drugs and have other issues kind of occur.

Little sense. To me, this is almost like this is a justification of what you've been saying. Oh, it's phenomenal. It's 20 years late. Too late. Too late.

Agree. And it should have been mainstream all those times ago based off… Because the problem was what they were back and even do it now is they were trying to sell journals.

They're trying to cessation lies, whatever gets them into the freaking… It's crazy that we're… Self-perpetual, self-realizing phenomena. But we're dealing with people's lives here.

We don't, we don't, we sit there and make these snap judgments and snap things, but we don't realize, hey, what is a clinical, what's this going to do for people down the road?

I think the other major shift then is, is taking the female protocol. It's, it's been out there as this will help you with hot flashes. But it hasn't been out there as this is your long-term way to grow old gracefully, to grow old with dignity.

That has not been what this is all about. And I think that the black box change will, you know, well, I can take it while I'm having hot flashes, but I'm at risk.

It's not true at all. This is how you end up feeling better, feeling better, feeling better and reducing the risk for diseases. You know, this mantra.

of a traditional medicine where they sit there and say shortest period of time at the lowest dose is not correct. Correct for synthetics, but even synthetics, like I said, Premarin was the only difference was it causes blood clots versus estradiol didn't.

So why the hell would I want to take Premarin, not take estradiol? But you're correct. You know, we're seeing that not only as hot flashes and night sweats and all that stuff, which is important for women, because you want to be able to sleep because sleep is very important.

Yeah, of course. Getting rid of the risk for diabetes, high blood pressure, cholesterol, heart disease, strokes, osteoporosis, Alzheimer's, all these things, reducing that risk is very important too.

And like I said, I'm vindicated, but my thoughts are out to all the women that have suffered. the women have died, the women who have contracted breast cancer, when we could have prevented a lot of this stuff because we're not using our brains.

I get that. I get that brings me to another question is the relationship between science and policy. Yeah. Because they're not the same thing by any strips you imagine.

What policy allow, what do you think, what was the policy that caused this rethink? Do you have any idea? I think, you know, for all the people that whatever they think about this administration.

Yeah. Well, I think the administration is part of it again. Yeah, agree with that. I'm not trying to be one way or another politically, but I think this administration is starting to wake up and say, hey, you know, what have we been doing?

However, however, I do have a negative towards the administration and relates to thyroid, this idea that You know, these desiccated thyroid, these animal derived thyroid, they put out that letter, which said they're going to try to get rid of it.

And they haven't looked at the research. A, the letter was completely off base with whatever their assumptions were. A, one of the main assumptions was that desiccated thyroid, armor thyroid, MP thyroid, those kinds of thyroid.

What Patients and Doctors Should Do Now

are not standardized. Sorry, back in 1985, the USP standardized those drugs. They're actually on formularies. So that was wrong. And in addition, there's the fear that somebody is going to get a viral or bacterial disease from taking up the pig thyroid.

Armour, no studies ever shown this, by the way. In addition, Armour even has it in their insert that nobody's ever derived a disease from taking thyroid.

And they're sitting there with a bacon sandwich when they make the roll. I think the administration is doing the right thing. That perplexes me that they came up with this thing also because it falls in the same wheelhouse as hormone replacement.

Thyroid is probably the most important hormone on this and yet you're trying to get away from true what thyroid should be in the human body versus you know, the synthetic centroid.

So another thing with this change, I'm wondering if through the years is also the empowerment of more and more female clinicians, female people doing the studies.

You think that has anything to do with it? Were they more aware of that? Some of the best clinicians and some of the best researchers I've met are female.

So I think they, they understand the human, the women, the, especially the, the woman, women's, you know, struggle, what they've gone through. Um, And they've, they're, they're, they're tired, tired of it being controlled male dominated.

And like, I even give this an example in my book, you know, when, when Viagra came out, it was fast tracked to get, you know, of course we're trying to find a testosterone for women that they can take.

And it's still not been there. It's kind of funny. And we are in a. patriarchal society. I mean, we're still in that. We're

coming a long way, but we've done a lot of injustice to our women, you know, and it's kind of sad.

But I see the horizon. You know, Dr. Broody is phenomenal. Yes, she is. You know, we have also, you know, Nikki, I've met, you know, Dr. Lubbett, and all these people that I've, you know, met, they're phenomenal.

And they see it. They see how this has changed women, and they want to get it to women. So let's talk about the male change. The core finding here, it's a label change on testosterone product.

They had a black box warning for heart attacks, which is the amount of people who I've spoken to, oh, you're an HRT, you're involved in that, you have a TRT company.

First thing they talk about heart attack and cancer for men. You're going to get yourself a heart attack. So now, is that black box when you've talked about the false?

Where are we now with that? Now they've removed that. They removed it because of the Traverse study, which is still not the greatest study because it looked at low-dose testosterone, which is what we consider the product, androgel and stuff.

And what they did, it's a long-term study, it was a randomized control trial, a fair amount of patients in it, and they wanted to see if it was non-inferior to doing nothing.

Basically, they wanted to see if you gave testosterone, does it cause you to have a heart attack versus not giving you anything? And they found that both of them don't give you heart attacks.

Didn't prevent heart attacks, however, when you look at the research and you give enough testosterone, you can see there's benefits for cardiovascular disease.

But because they're using such a small percentage, 1.62 percentage androgel, they didn't cause a heart attack, but it didn't prevent a heart attack. Okay.

Okay. Is there anything to do with like the increase in people's blood production or in blood? Oh no, don't start with me with hematocrit and hematobin.

Has that got anything to do with where that came from? Well, it's part of it. It's the idea that it thickens your… By the way, there's no scientific evidence of it thickening your blood.

That's based on polycythemia vera, which is a completely different disease that is a genetic disorder that you would know you had that has an increase in clots.

And actually it's what they call a myelodic proliferative disorder, which is a form of cancer. And people with cancer tend to clot. Okay. Okay. So don't conflate the two.

Don't confuse. I hear that like with the high dose with a physiologic or secondary thruster cytosis. They're not the same thing. In fact, I can quote you a study in 2021 from Dr.

Strange. Yeah. His name is not the one on the marble, but this doctor was looking at, and this is probably an association. Because we know when your testosterone is low, you're more likely to die than if your testosterone is high.

But he looked at men who take testosterone and look at their hematocrit levels, which is another way of looking at their blood levels. He looked at people 49 and below and people above 49. Yep.

All of them were taking testosterone and he wanted to see what happens to them. People 49 and below tended to die more than the ones at 49 and above. So we need to keep your hematocrit high probably because we get more testosterone and more testosterone you give, the hermatocrit goes up and we know that when your testosterone is

low, you're more likely to die.

Now we're showing that maybe it's going to be beneficial if you get it high enough. Okay.

Testosterone Warnings and the Male HRT Update

So, and the only black box warning that's come from this stupid study, the Traverse study, although it did vindicate that testosterone does not cause, does not vindicate.

Basically, It gave us the thing that testosterone does not cause heart attack was the fact that they still couldn't get it out of their mind to put a black box warning.

They put a black box warning in that it increases your ambulatory blood pressure by 0.3. That's a black box warning. Are you serious? Yes, because it was significant.

point three of one so if you were at 120 that's sitting up and standing and you wouldn't go from 120 to point three that's what that would do wow sounds like a real signal so they had to put some kind of black i don't know why i do know why because they don't want abuse and well they want this and there's already a control substance so what i love here on my notes this is one of my favorites saying so little shout out back there to katie who helped me put this all together the swamp in safety warnings.

I think that's just the perfect headline. It is, it sounds like a complete swap. Like, and the things, the problem is that these are decade long fears that people have.

Decade long. Yeah, but you know how long we've been using testosterone? I mean, since our species started. Well, that's, we made it back then. But we've been using it in the 1900s.

Really? I did not know that. Every place has been used for forever. Wow. I don't believe it's been that long. Now we have these safety things? Yeah. A lot of that's born from the illegal use of synthetic hormones, synthetic testosterone.

A lot of those drugs, those drugs do harm you. And again, we do the same thing with Premarin and estradiol. We do the same thing with progestins and progesterone.

Synthetic testosterone, we say the same thing that happens with testosterone. You cannot do that. They're completely different molecules. Makes sense.

And that's the problem. Yes. I don't give synthetic hormones. especially synthetic testosterone orally or injectable into men because of the harm that it can occur.

But I do give testosterone that your body produces because I know the studies show it's beneficial. Real sense. I have one last question for you. This has been absolutely fascinating, by the way, Don, so thank you.

For both providers who are out there, and they've had this misconception, what should they do? And then how does this, what can people do to get this into the general population?

To this, like this, to me, this was kind of like a quiet removal. Like, yeah, we screwed this up. Let's just quickly erase that. There was no announcements.

It's not on TV. It is on TV, but it's not the significance that it should be. How, how do we get the word out there and how, how should people, how do we reeducate?

Well, you know, come to learn from me, you know, I could teach you about hormones, uh, world link, which is whatever our partners in teaching Dr. Rose, that group that is phenomenal teaching.

I, I, you know, if you work with me, I'll show you how to do this. I think a lot of doctors need to start waking up and go into these training programs and understanding this.

Reeducating Providers and Closing Remarks

Come to the website, MelXL. The world time has been phenomenal. I know I've been through that. It was, yep. FemExcel, MelXL, come to our websites, you know, talk to our staff.

I mean, anything you could do. I mean, like, I know I'm not trying, I'm trying to, I'm trying not to plug, but I am saying that there's a right way to do it.

You plug when you're right here. You were right the whole time. There's a right way and there's a wrong way to do this. There's multiple wrong ways to do it.

And a lot of these companies are out there doing it right now and they're doing it incorrectly. I'm telling you, we do it correctly and I've been doing it for a long time and I follow the research.

You know, it's just sad how people are just latching onto this because they see a profitability from it, but they're not really looking at how they, you know, it was amazing to me.

This is one thing I want to, it's amazing to me that some of these so-called specialists in TRT or HRT in the United States have their physicians, the medical directors, the chief medical officers have very little or no experience in hormone replacement.

In addition, the experience they have is called conventional traditional medicine experience, which guys, they just walked that all back right now. They just walked it all back in women, especially in even a man.

So I'm surprised at how these companies are able to function. And what they do, they follow these cookie cutter, you know, weightlifting protocols or whatever they may be, but they don't follow the science.

And that's sad, you know, that's really sad. Closing special statement would be to go with the specialists who were right the whole time. Well, thank you so much for listening.

I hope you guys enjoyed this as much as I did and until next time. Thank you. That's it for today's episode of Proactive Healthcare with Excel Medical.

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I'll see you in the next episode.