

52 - Off-label Use of Medicines as it Relates to Testosterone

BioBalance Podcast — Dr. Kathy Maupin and [Brett Newcomb](#)

Recorded on October 4, 2011

Podcast published to the internet on October 19, 2011

Published on [drkathymaupin.com](#) and [biobalancehealth.com](#) on October 20, 2011.

Dr. Kathy Maupin: Hi, welcome to episode 52 of the BioBalance Healthcast. I'm Dr. Kathy Maupin.

Brett Newcomb: And I'm Brett Newcomb. Today we are continuing our conversation about the FDA. Kathy and I are writing a book about testosterone for women in terms of hormone replacement for women. And as we have been writing this book we've been getting a lot of questions from a lot of people about is that legal? Is that something you can really do? What are the ramifications of that? Is this something slightly insidious? And so we did a podcast on the FDA and the regulation and the approval process. Today we are continuing that conversation as we talk about off-label use of medicines, because that's the area where testosterone for women comes into play. The FDA does approve testosterone usage for men with a specific diagnosis. But doctors can choose legally, appropriately, ethically, to use that medicine for women. And today we're going to talk about the process where by that occurs. We're going to start our conversation about a couple of other relatively famous and commonly known off-label uses of different drugs before we talk about testosterone.

KM: Most of the women in the audience will remember a drug called Tributaline. Now Tributaline is approved for asthma, that's it. Or it was approved for asthma.

BN: FDA approved, going through the whole regulatory process that we explained before for the treatment of asthma.

KM: And that was the diagnosis it was approved for. However back in the 70's when I was finishing up med school we used it and it was a new drug then and we used it off-label and we used it to stop labor. And it stopped labor very well.

BN: So someone that wasn't really ready to deliver but for some reason went into the labor process and you wanted to stop that process to buy you time.

KM: Preterm labor, to save the baby.

BN: So that was the drug that you used, even though it was an asthma drug. And did you know in med school that it was an asthma drug or did they just say this is what we use in this case.

KM: Well we knew it was an asthma drug but we also thought it was a preterm labor halting drug to stop preterm labor. So we had no idea that it wasn't approved for preterm labor. It's one of those things that we were trained with this. Here, use this it's better than IV alcohol and it was. IV alcohol was what we used before which was

horrible for babies and Tributiline had fewer side effects and was more effective. So we used it all the way through my residency into private practice. And then they came out with another drug that's very similar to Tributiline which is FDA approved for labor. So everybody, most people stopped using Tributiline. But, Tributiline is a generic so it's cheap. So it was just as effective as the new drug but the new drug had all the FDA approval for labor and it was expensive.

BN: So some smart pharmaceutical company went back through the administrative process to get a slightly modified version approved for use in labor.

KM: Change a couple side chains and you've got a similar drug. And it does the same thing.

BN: When you say side drugs you mean amino acids, protein?

KM: Yea, carbons, hydrogens, you just kind of change a few things on the molecule and it does the same thing as Tributiline but it looks different so we can name it something different.

BN: And then we can patent that and get a 5 or 7 year window to recoup and then go back to the generic we were using anyways.

KM: Right, but interestingly enough this is one of those things that we talk about testosterone all the time and we use testosterone like we use Tribulitine. It is an old drug. It's been used since the 1930's. It's a drug that's really similar, exactly similar in the bioidentical case as our own testosterone. So we've been using this for all these years.

BN: When you say exactly similar you're talking about the side chains, the carbons, all the organic chemistry components are exactly the same.

KM: Bioidentical testosterone. Exactly the same, that's what makes it bioidentical.

BN: So there is bioidentical testosterone and then there's non-bioidentical testosterone?

KM: And then they're synthetic testosterone. Like methyl-testosterone which has a little extra side chain on the side of it. There are different types of testosterone. And those are approved for use in men, not women. They're approved for hypogonadism which is what they call low testosterone or a lack of production of testosterone as we age. So for men, they're approved for that.

BN: I always get hyper and hypo confused.

KM: Yea well not on that one. Hyper is too much, hypo is too little. So hypogonadism means you're not making enough testosterone. So they've approved that for men, they've approved testosterone use even in the bioidentical form for men, which is

interesting because it kind of was grandfathered in. It's been around forever. And it's more of a generic drug. But they've said you know testosterone pellets are okay for men. Unfortunately they have not approved testosterone pellets or any form of testosterone for women. And women have more testosterone, prior to andropause or their 40's, they have more testosterone than they do estrogen. And we need it as well.

BN: That's innately, naturally, biologically, they produce testosterone. And then when they're in their 40's and they start to go through what you're calling andropause in men and something new in this book for women.

KM: Right, testosterone deprivation syndrome.

BN: Right and part of the book is to argue the case for having a label for this condition which occurs in women naturally as part of the aging process, but has not yet been defined by the medical establishment as a definite set of syndromes or diagnosis for women, and because that has not been done, testosterone for women.

KM: And that's true. We don't have a drug for it. If you don't have a name of syndrome or a name of a disease they can't possibly approve a drug for a particular condition because that condition hasn't been named. So they've named it in men but not in women.

BN: Sort of the corollary to Murphy's Law. If it ain't broke, don't fix it.

KM: Not exactly, except that it is broken.

BN: Except that it is broken, yes, exactly. So now it's a matter of coming up with a label that people agree upon as a set of symptoms and coming up with a treatment for that, which you have done in your practice. So that brings us back to the whole conversation about the regulation of testosterone by the FDA. It is a legal drug it is a regulated drug, it is approved for use in men. But physicians can choose to use it in treating women if they're willing to do that.

KM: And many of us are across the United States but it's very quiet. And it's very quiet partially because there's no money to really test it because it's individual physicians. The pharmaceutical companies really aren't all that crazy about doing anything with it because they're not going to make money, they can't patent it.

BN: So that testing process through the FDA is generally funded by large pharmaceutical companies or major universities because they have the financial backing. Rarely does it start with a hand full of doctors getting together and saying let's combine our patient base and accumulate the statistical data and make an application for this.

KM: In general doctors don't have that kind of financial backing. Neither do pharmacists. Compounding pharmacists are the pharmacists who make bioidentical

testosterone; they make it in their pharmacies. There are not enough of them to fund it.

BN: Let's talk about that for a minute too.

KM: Okay

BN: Because I know we've covered it in a couple other podcasts but I think it's relevant to come back and review the terminology. A compounding pharmacist or a compounding pharmacy is kind of like the old fashion idea of the pharmacy with the mortar and pestal and the guys in the back that are putting these ingredients together.

KM: It's really much more sophisticated than that.

BN: I would hope that it would be.

KM: They have air filters and it looks like a high tech sterile lab.

BN: It's a high tech lab.

KM: And they are very careful about exactly what the dosage is because they have to be just as careful as a drug company making pills on a machine. They have to be just as accurate, there can't be a variance in the amount of milligrams, it has to have the exact substance, I mean that's a process of regulation.

BN: So it's not like buying an e-mail drug from china.

KM: Right that would be bad or eastern Europe. The reason testosterone has such a bad rap is that is because it has been used improperly. And not necessarily by doctors giving a prescription to people in this country, like athletes which gives them an uneven advantage. But most of the time it is [weight] lifters and people like that getting their steroids or testosterone type drugs from eastern Europe and you're not even sure what's really in them. I don't know how they get it. I interviewed a couple of guys at several gyms and they get it on the internet they didn't tell me exactly where. And they inject themselves with this stuff and I have no idea what's really in it. And neither do they. And they have tons of side effects it's not pure testosterone. But worse yet, it's such a high dose they use too much, don't have a doctor managing it. They use such a high does that they shut down their adrenal glands. And they shut down their testicles. So that when they come to me, or they used to come to me for infertility they didn't make sperm anymore, they were infertile. Tthat's a real problem. Especially in younger men who don't need testosterone who use it to buff up. It's not true testosterone, it's a testosterone kind of drug.

BN: So you're not making yourself more of man, you're making yourself more of a eunuch?

KM: Eventually. You're making yourself feel like superman but it makes you feel good to use those drugs. That's why those drugs are controlled pretty carefully but the internet we haven't come to that yet. But we don't use those drugs in the United States.

BN: But that's part of why the questions that we've been getting arise, which is people know that there's a market out there for those drugs that people use them individually without going through medical supervision for gain mostly in athletics to get an unfair advantage to buff up or bulk up or something like that and so the common wisdom is that that stuff is out there and there's something wrong with it.

KM: That's right. Everybody thinks that it's a bad thing and that it's illegal. It's certainly not illegal. It's like any other drug. It is actually managed by a doctor.

BN: Let's be clear. When you're talking about it not being illegal, you're talking about for what you're using it for and where you're getting it. That is all legal and regulated.

KM: And the type of testosterone. It's pure testosterone and not some kind of byproduct.

BN: So the production systems are standardized. They're monitored. They're regulated. They're legal. Their usage is legal.

KM: And a doctor is prescribing it.

BN: So this isn't the same thing. And that's part of what we're trying to prove.

KM: We're also not using it in young men. We only use it in people who have lost the ability to produce testosterone. And when we do that in older men, older women it brings back a lot of our health. We don't need all of those other drugs we've been taking for cholesterol and sometimes high blood pressure, diabetes. Many of those drugs fall by the way side. And for women all of the drugs for bone thickness go away because testosterone is a great bone builder.

BN: So that whole osteoporosis issue.

KM: Right there's like 5 drugs for that now and that is something that competes with testosterone because really after 2 years your bone density comes back and so it's one of those things with testosterone.

BN: Yes with the treatment of testosterone in women the bone density for them returns. So now is there that same 10 year window for starting it after menopause?

KM: No matter when you start it if you take calcium and vitamin D, you're going to start growing bone. But if you think about it we start losing bone when our testosterone drops. And then when our estrogen drops we lose even more. So you're going to start at a much lower level of bone to try to recover from. So you can't recover

really in 2 years that way but you'll recover at least better bone. You'll make better bone if you take testosterone.

BN: And that's a conversation for another day. To stay on target and on focus for what we're discussing today. We're talking about the legal, regulated, consistent, medically supervised use of testosterone for women which is a legitimate thing, especially the use of bioidentical pellets which are manufactured by a compounding pharmacy that is also consistent dosage regulated and legal.

KM: By the FDA. And they come in and inspect them just like they do any other pharmaceutical companies. But these are still, there are not enough compounding pharmacies to get together and try to fund a study that's going to prove this. And then when they did anybody can make it of course. So once it's proven, we've already proven it in many studies, but once it's proven for the FDA then anyone can make it or formulate it so they would lose their investment because there's no patent.

BN: So you go back to the economic mechanics of the system and the fact that there's not a large body of capital out there to come into the production of bioidentical testosterone for women.

KM: But I want to make perfectly clear that doctors are here to prescribe for problems and illnesses and even things that go along with aging to replace hormones. We have the knowledge to do it. We have usually 8 years of training and we have pharmacology behind us. We understand how these work and how a safe way of giving them helps a patient but doesn't hurt them. So it's very important that a drug be given by a physician. So that what is the limiting factor in making a drug a productive drug or a safe drug versus a drug that can be abused, because almost any drug can be abused.

BN: And you know what most physicians are really ethical, really highly trained, really legitimate. There are some that float around the edges for whatever reasons, and those you have to be careful about. But this is an ethical, legal, standardized use of a legitimate drug for a legitimate purpose under the supervision of a licensed physician. So that's what you need to know when you go to consider this treatment and when you go to talk to your own physician about obtaining this treatment. So when the book comes out and you get a chance to look at it, that's what we're going to be emphasizing. This is for consumer education, for you to become knowledgeable about your own body and its treatment so that you can talk to your physician about it if your physician is not current on the data.

KM: That's right, I just want to add there's other forms of testosterone that can be written that they're pure testosterone but it can be given through the skin, or it can be given sublingually, vaginally, there are lots of different ways to take testosterone, it's not just pellets.

BN: It's different delivery mechanisms but we're still talking about the same drug and the legitimate use and the consistent methodological production of those drugs.

KM: So if you'd like to know more about bioidentical hormones please go to our website at BioBalanceHealth.com or you can call my office at 314-993-0963.

BN: Or you can reach us through my blog at brettnewcomb.com.

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