Promising Drug to Treat Fibromyalgia May Never Be Approved by FDA

Over 6 million Americans suffer from fibromyalgia, a disorder that causes chronic pain, muscle soreness, moodiness and fatigue. Fibromyalgia is difficult to treat and there is no known cure.

Researchers at Stanford University’s School of Medicine have conducted two small studies showing that low doses of naltrexone, a generic drug currently used to treat drug addiction, can reduce fibromyalgia symptoms by as much as 50 percent. However, the FDA has not approved the use of naltrexone to treat fibromyalgia, so it is only available through “off label” use.

American News Report spoke exclusively with Stanford researcher Jarred Younger, PhD, who presented his latest findings about naltrexone at the annual meeting of the American Academy of Pain Medicine.

You’ve been working on naltrexone for awhile and it shows a lot of promise. A layman would ask, if naltrexone shows a lot of promise why can’t it be prescribed for fibromyalgia?

I think what physicians are waiting for is the gold standard through clinical trials. With one study, which is all that’s been published so far, we can’t really recommend, especially with the low sample size, that people change prescribing habits. With two studies, that’s more interesting, but really you need the large study, hundreds of people to try it, before you can be really confident that this is going to work for people. I know some physicians who have tried it but you won’t expect the majority to touch it until it has larger trials.

When you get into off label use, what does that mean?

It’s very commonly done. The off label just means that no one has gone through the FDA process of getting approval for that particular application. And the reason why that’s never going to happen for naltrexone is that it’s already generic, so there’s no financial incentive for any pharmaceutical company to go through that multi-million dollar process to get FDA approval. So this will always be generic, it will never have FDA approval unless someone comes up with a new way of administering it. This will always be off label. That doesn’t mean anything’s wrong. Many drugs are given off label. It just means it won’t have that ultimate stamp of approval for that reason.

Nobody can make money from it, so it’ll never be widely used for fibromyalgia?

It’s an expensive process to get that approval. The FDA has a lot of criteria you have to go through and there’s no incentive to do it. So it’s up to the academic centers to do the trials and the National Institutes of Health to fund it.

What is naltrexone’s history? And what is it most commonly prescribed for now?

It’s been used clinically for over 40 years and it’s typically used for opiod addiction. So when you give it at 50 milligrams to 100 milligrams, which is the typical dosage, it blocks your opiod systems. And if someone is addicted to heroin and they have naltrexone in their system, the heroin won’t do anything. It blocks those effects. So it helps people wean themselves off of their opioids.

So it’s kind of like methadone?

Yes. Methadone has some positive opiod actions as well. You can get a little bit of a euphoric effect from methadone. Naltrexone will stop that in its tracks. In fact, if you were on a high level of an opiod and you took naltrexone, you would feel pretty crappy because it takes opioids out of your system.

Can you describe in layman’s terms how naltrexone works on the nervous system?

I’ve used the metaphor that naltrexone may be aspirin for the brain. Aspirin reduces inflammation in the body, so this may be the equivalent. It may be something that reduces low level inflammation in the brain and the spinal cord. Now, we can’t know that for sure, because we haven’t done the studies, but that’s what I think is happening. It’s basically quieting things down, quieting the immune system that’s hyperactive, reducing a lot of the symptoms of fibromyalgia.

You’re clearly excited about your research. Do you feel frustrated that you’re onto something and it’s time naltrexone was widely used for fibromyalgia?

I am fine with people waiting for that big trial. We’ve got one trial with 10 people. We’ve got a second one with 30 people. This next one, if we can get funding for it, will have hundreds of people. So I totally understand why physicians are wanting to wait. And I think the fact that they’ve had me here to talk about it shows that they’re interested in it. They want to hear more. So I think the response so far has been actually pretty good. I get emails everyday from physicians who’ve tried this. Pretty good, considering how small the studies have been.

And what about people with fibromyalgia? When they read about this, do they go to their physicians and say I want naltrexone?
Any physician is legally able to prescribe this. Anyone can do it. It's just a matter of whether they want to or not. Some physicians will say let's give it a shot, let me monitor you. Some physicians will say absolutely not.

Your 50 percent success rate is pretty good.

It's pretty good, yes.

Do you see naltrexone as something that will cure fibromyalgia or something people would have to take the rest of their lives?

I don't think it addresses whatever originally caused the problem. I think it's quieting it down, but I don't have any evidence that it's fixing the problem. This is a maintenance thing. It's something they would probably take everyday for the rest of their life. But it does allow a lot of people to reduce their other medications. Instead of taking ten, they can get it down to one or two. Overall, that's pretty good for them.

Thank you, Dr. Younger.

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