Episode # 18 FDA okays eTNS device to treat ADHD

Hello. In this episode we will discuss the new device that the FDA has approved for treatment of ADHD. This is episode 18. Let's get started.

Smarter Parenting welcomes you to our podcast series, The parenting coach for ADHD. Here to heal and elevate lives, is your parenting coach, Siope Kinikini.

Well, hello everybody. I hope everybody's doing great. We are busy here doing a lot of different things at Smarter Parenting. Specifically, we found a very interesting release article about a new device that is available in the treatment of ADHD for children. It just happened a couple of weeks ago and there is a lot of dialogue actually happening within the community about this particular device because it is a device, there's no medicine involved.

I wanted to give it a brief kind of introduction to it based on some of the release, and then talk about what this means and what this can mean actually in helping to treat ADHD with children. The FDA has just approved the first non-drug medical device to treat ADHD in children. The way that it works is that it delivers a low level electrical pulse through a patch on the child's forehead, and it will be marketed as a treatment for children from the ages of 7 to 12 years old.

Here's the stipulation, they cannot be taking medication. Again, it's this patch, it will send this pulse, a low level electrical pulse on the child's forehead. Again, the child has to be between the ages of 7 and 12, officially diagnosed with ADHD, and they cannot be taking any medication for it. They've had some studies, obviously, they had to do some studies to get approval from the FDA. There are questions about the study though, and we're still going through some of the numbers.

Actually, I want to revisit this in a couple of weeks to get more information from the community, and also to take some time to really delve into the report and find out how they came to the conclusions that they did, that this is safe for children and for patients. There is some dialogue that the sample size that was used to approve this wasn't large enough, that they should actually test it more before actually allowing it to come to the use of the public. But we'll know more actually as time progresses.

That's the interesting thing about treatments. When new treatments come up, it's new and everybody is super excited, but again, we don't have the longevity of time to really evaluate what the repercussions are to the treatment. Anyways, studies have been done on this and the FDA felt that it was okay to release. Now this is an available treatment here in the United States

for children between the ages of 7 and 12 who do not take medication for ADHD, they have to be officially diagnosed with ADHD.

The device itself they say is as big as a cell phone and it has wires that attach to a patch, and you placed that on the child's forehead, and they are to keep it there overnight. What it says here is it emits a low level electrical pulse that essentially stimulates a cranial nerve called the trigeminal nerve. The idea is that the nerve then send signals to the brain, particularly to the areas that are important for attention, and for functioning and behavior. They did this study over four weeks, about 60 kids, and they were able to notice some reduction in the symptoms. Yes, pretty interesting.

There are other non-medical treatments for ADHD. Obviously, parents jump online and they look for all these other things. Behavioral interventions are one. That's what we do here at Smarter Parenting, is we actually help with behavior by using specific skills. They didn't find that there were any huge adverse effects to using this treatment other than headaches, drowsiness, increased appetite, fatigue, and sometimes the clenching of the teeth. Again, it was a small study over a short period of time. Why the FDA wanted to push this through, I have no idea. I think a larger study would have been more helpful for parents because we want to know that this has been tested at least to the maximum rather than just a few kids over a few weeks.

It's estimated that there are over 6.1 million children with ADHD or have been diagnosed with ADHD. This can have a huge impact if this is the wave of the future in treating ADHD. One thing I do want to state though is according to the information that I currently have, and again, this was released just a couple of weeks ago, is that it is not covered by medical insurance. The cost of the treatment is roughly around $1,000, it could be more, at least that's based on the information that we've been able to gather. About $1,000 for the device itself and for the treatment.

If you were to weigh the pros and cons of using that versus something else, it's estimated that parents with children with ADHD will spend a couple thousand dollars a year just on treatment. If you want to focus your attention on this, you're probably spending less over time than medication, but again with medication, there's been more amount of time that we've been able to access information and there's more study behind it. We know what the after effects are and what possible side effects there are.

Let's see, what else did I want to talk about? I'm just like flabbergasted in a way because for the FDA actually to allow something to be endorsed by the FDA, it's pretty stringent. Specifically with medication, and that's important, we need that for medication because there are side effects to it. Yet, there are side effects to this and it seems like it was kind of pushed through rather quickly. Somebody else may have more information on this, and actually I invite you to share that with us because I would love to talk to a parent who's actually used this with their child to evaluate how successful it was.

Did it reduce it completely? Did they find that their child was able to focus more appropriately? I'm just wondering what the electrical stimulants or the electrical pulse actually does in the brain. What does it do? Yes, what does it do that makes it so the symptoms of ADHD actually are less? These are questions that obviously we all want to know. The device, it's a non-drug option obviously for treatment of ADHD, but again, it's for pediatric patients so you want to go small.

I guess it comes from a company called Monarch eTNS system, and it's intended to be used at home under the supervision of a caregiver. This is great stuff for parents who are looking for additional resources to help out in dealing with symptoms that involve ADHD. I mean I have a lot of questions, let's be honest, I have a ton of questions about this device. I'm wondering why it only works with children between the ages of 7 and 12. Can you increase the electrical pulse for older children? Is there a reason why that's the only age that this can be tested on? I also want to know if they're planning to make a device for adults because there are many adults with ADHD symptoms and they struggle. Is this something else that they can try?

I would like to know how we can study this more. Is the FDA going to continue evaluating the effectiveness of this or not? We don't know, we don't know. The job of the FDA as an agency within the US Department of Health and Human Services is to protect and promote health, public health. They have to go through and evaluate the safety and the effectiveness of anything that comes on the market that is marketed to improve life, medications and things like drugs, vaccines and other biological products for human use. Medical devices are included in that.

I would love to talk to someone from the FDA. Does anybody know anybody from the FDA that has information on this specific device? Why it was pushed through, how they are gathering the data and evaluating why this is something that didn't take longer to test and to see if it works. I'm not knocking it because I haven't tried it and I don't know it, there's just not a ton of information that's available. I jumped on the FDA website to look for information and it was pretty vague.

I read a few other articles and news press releases as well just to gather as much information as I could about it, and it was pretty sparse. The news outlets just followed pretty much the press release about this new treatment. For parents, let's keep communicating, let's just keep talking to each other about these things so we can all keep each other informed, aware, and we can really find what is in the best interests of our children.

Again, the clinical trial was only over four weeks and it involves 62 children. What they say is they tested children with severe to moderate ADHD. What does that mean exactly? We need more information. Waiting for the FDA to do that. Anyways, if it is effective and if it's something that is useful, I would love to have more parents exposed to it and use it as a way to help their children. Your children are still going to need some behavioral skills, and that's important for you to remember. They're still going to need some of that behavioral intervention. Keep that in mind as we move forward.

I'm going to follow up on this actually further down the line. Probably in a couple of weeks I'll revisit this and I'm going to reach out to other people, and I'm going to reach out to other people who either have tried this or are communicating with the FDA. I'll try and get something with the FDA to find out more information about this item because I think it's great. I think it's great if it works.

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