

Over-the-Counter Hearing Aids: While We're Waiting...

BY LISE HAMLIN

The Over-the-Counter Hearing Aid Act of 2017 was signed into law in August 2017. We are now in the first quarter of 2019. What's up with access to these over-the-counter (OTC) hearing devices?

Since the passage of the OTC Hearing Aid Act, the Food and Drug Administration (FDA) has been working to create regulations regarding this new category of hearing device. Because the rules have not yet been written, OTC devices are not yet on the market. When they do arrive, according to the law, they are specifically intended for people with mild to moderate hearing loss.

If you have a mild to moderate hearing loss and are considering purchasing a device that claims to be in this new category now, we have a couple words of caution: buyer beware.

Case in point: I found an article on the Hearing Tracker website, "Over-the-Counter Hearing Aids—What Are They, and When Will They Be Available?" The article provides information about the law itself, a timeline, and also includes this statement:

"Technically, Over-The-Counter hearing aids don't exist yet. The FDA is expected to publish proposed regulations for the new category of hearing aids by August 18, 2020. Following the publication of the proposed regulations there will be a public comment period, and this will be followed by the publication of finalized regulations."
(hearingtracker.com/over-the-counter-hearing-aids)

So far, we're good. But right next to that text I found an advertisement for "New OTC Hearing Aids" with a link to a website where you can buy them. The website claims that these devices will work for people with "noticeable to severe hearing loss." But wait, it gets better—the ad states you can get a pair of these hearing aids for under \$500! Then if you scroll down, you see 3,036 customer reviews, all either 4 or 5 stars.

So, what to do when faced with what looks like a really good deal on the internet? There is a lot to unpack here. But this is one offer I'd be very skeptical about.

The claim that it's an "OTC Hearing Aid" raises the first red flag. The FDA tells us, "At this time, there are

no products that can claim to address hearing loss that are, or can claim to be OTC hearing aids. Currently, hearing aids continue to be restricted devices, for which sales must follow applicable federal and state requirements. FDA has published a letter to clarify the status of these products." **Strike one.**

When a company claims to provide a product that is not yet available, I worry. But perhaps they are simply trying to get my attention. Okay, I get that. But then their next claim that the product is "for noticeable to severe hearing loss" is also not allowable under the OTC Hearing Aid Act. The FDA will write regulations for devices that are intended for people with hearing losses from **mild to moderate**. **Strike two.**

Now, I'm looking at the "customer reviews." There are pages and pages of reviews. But there is not one negative review. Not one. Somehow it seems highly unlikely that there would not be one disgruntled customer. **Strike three.**

In short, what a consumer must do is be very skeptical when it comes to taking advantage of some of these online "offers." Do your homework and ask a lot of questions. Not only that, you can get help. The Federal Trade Commission (FTC) provides a great set of tips for shopping online (consumer.ftc.gov/articles/0020-shopping-online#details). There is good information about any type of online shopping, along with steps on how to complain if things go sour.

In the end, if you are eager to try OTC hearing devices, the best advice is to wait for the rules to come out. But if you need hearing aids now, don't wait until 2020. Go see an audiologist and get them. It may cost more, but that's got to be better than getting scammed. **HL**



Lise Hamlin is director of public policy at HLAA and can be reached at lhamlin@hearingloss.org.