



The newsletter of the Hearing Loss Association of America, Albuquerque Chapter

WIRED FOR SOUND

OTC Hearing Aids—what's the buzz about?

Mary Clark, HLAA Albuquerque

OTC stands for “over-the-counter”, but most of us have never seen or bought hearing aids this way. So what's new about this new way of buying hearing aids?

The recent announcements were about the FDA releasing proposed regulations to cover OTC hearing aids. Please understand that hearing aids as we've known them have always been regulated by the FDA as medical devices, which requires submission of data to show safety and effectiveness before the FDA will clear them for sale.

The advent of online hearing aid sales, and studies that have shown that only about 1 in 5 people who could benefit from using a hearing aid actually have them, prompted the government to pass a law mandating the FDA to add regulations to their current hearing aid regulations that will cover OTC hearing aids, too.

Because the existing regulations were a bit hodge-podge (my word, not the government's), this was the opportunity to streamline the regulations and the guidance documents regarding hearing aids. Much of the proposed regulation refers to accompanying updates to regulations on “labeling”, which includes not just claims made in the brochures or the user manuals, but also any advertising for the hearing aids. All of these have been updated now in this new proposal.

OTC hearing aids are specifically restricted for mild to moderate hearing loss. In addition, no referral from a doctor or audiologist is required to buy OTC hearing aids by consumers over the age of 18. The idea was to encourage those who had



been reluctant or unable to afford hearing aids, so they could begin to get some amplification for their hearing loss and improve their lives accordingly.

The safety of OTC hearing aids is specified to avoid amplification that could harm a user's hearing, and includes warranties. For their effectiveness, emphasis is placed on the user manuals for “labeling” or claims of what the device can do.

So, what if you have a hearing loss that progresses beyond “moderate” loss? Now you enter the category of “prescription” hearing aids. I was confused about what the regulations meant by “prescription” hearing aids. Essentially, any time you get a full evaluation of your hearing with an audiologist or hearing healthcare professional, this becomes your “prescription”. A real prescription should include not just a screening with a simple graph, but also other testing, such as speech recognition, listening in background noise, pain threshold.

The brand names we know—that many of us have had or wear now, like Oticon, Starkey, Widex, Phonak, etc.—will now be classified as “prescription” hearing aids. The presumption from those who mandated that the FDA update their regulations was that prescription hearing aids come with the overhead of follow-up visits, ongoing maintenance and upgrades with professional guidance. Therefore, the services of the professionals who have the training to do all of this increases the cost.

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Providing support and advocacy for
people with hearing loss

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20 Nov Meeting 10:00 AM - Noon On **Zoom**

As long as COVID high case rates remain, so do restrictions. We will continue meeting only on Zoom the rest of 2021. Our Web Page (HearingLossAbq.org) will have updates and the link to join the Zoom meeting.

What the pandemic taught me about inclusion

Our speaker for the month of November is Dr. Carolyn Adamski. Carolyn is a research scientist at Baylor College of Medicine in Houston, Texas. She studies how small molecular changes in the brain lead to symptoms in patients with neurological disease.



Carolyn progressively lost her hearing over the course of her scientific training. In 2019, she received bilateral cochlear implants and rediscovered the world of sound. She finds fulfillment in using her experiences to create a more inclusive scientific research enterprise. Carolyn's talk will be an extension of her article written for science.org entitled "I'm a scientist with hearing loss. The pandemic taught me we can prioritize inclusion". She will discuss her hearing loss journey pre-pandemic and post-pandemic and how she has navigated to returning to in-person meetings. She serves as a patient liaison at the Center for Hearing and Balance at Baylor College of Medicine, where she supports others through their hearing loss journeys and the cochlear implant process.

Upcoming programs:

Scheduling programs and speakers has become more difficult during COVID. Last-minute changes may happen after Wired For Sound is published. Check our Home Page, HearingLossAbq.com, for the latest information.

The HLAA ABQ Chapter is always looking for volunteers. You can man a special project. You can help us out for a few months, or consider a longer-term commitment. "Try us out" for a month or two. We will provide orientation for working on a nonprofit board, share our chapter's mission and goals, and discuss topics we can use your help with. If interested, contact any board member (contact info at left), or use the chapter email hlaabq@gmail.com.

With the advent of apps on smart phones that can control your hearing aids, the line starts to get blurry between “consumer electronics” and “FDA regulated medical devices” such as hearing aids. Now we hear about terms like “hearables” and see ads for earbuds that “function like a hearing aid”. It will be a bit like the “Wild West” for a while as all these regulations change, companies want to sell cheaper hearing aids without intervention of an audiologist, and opportunities for charlatans and deceiving advertising will be wide open. Some hearing aids bought online for cheaper prices may be adequate for some people, but without the help of hearing healthcare professionals, the risk of dissatisfaction increases. The mantra will have to become “buyer beware”.

What should you be aware of with OTC hearing aids?

The whole definition of “mild to moderate” hearing loss is as the users perceive or describe their hearing loss when selecting OTC hearing aids. So, the use of online hearing tests may increase. With online hearing tests, the variability of sound levels and speakers on phones and computers risks an inaccurate classification of hearing loss. In truth, I have tried to do a few of these, and have never been able to get one to work for me. Even AARP has one.

Since the protections for the consumer who buys an OTC hearing aid is limited to things like warranties and printed instructions (which constitutes “labeling”) and return policies, these will need to be carefully understood to ensure that the buyer can make a good choice.

Where will you be able to buy these? In the lead-up to release of the proposed FDA regulation, the typical discussion has been to make OTC hearing aids available at pharmacies, consumer electronics stores (think Best Buy) and dedicated sales offices. Online hearing aid sales will start to blur the boundaries between the “mild to moderate” degree of hearing loss covered by OTC regulations and more powerful hearing aids for more severe

Yearly dues are \$15 per household. They are due in January, but you may pay yours early and get it out of the way in 2021.

hearing loss. There will be no screening of who can buy these based on level of hearing loss, so it will be up to the user to make that decision. The only restriction for OTC hearing aids will be based on age—no one under 18 will be able to buy one.

One of the other documents that was updated for release of this proposed regulation was the “guidance document” identified as “Regulatory Requirements for Hearing Aid Devices and Personal Sound Amplification Products – Draft Guidance for Industry and Food and Drug Administration Staff.

Okay, now we’ve got another term – Personal Sound Amplification Product or PSAP. All of the publications from the FDA, old as well as the newer guidance document are very clear that PSAPs are not hearing aids and are **not** OTC hearing aids. Their intended use is to assist people with normal hearing to amplify sounds they would like to hear better, such as bird watchers or hunters, but very specifically not those who have a hearing loss. In fact, there are penalties for advertising or even implying that these products could help if you have a hearing loss.

This gets muddy, since if you enter “PSAP” into Google, you will get some of the online hearing aids in your results, making it confusing. If a family member or friend comes to you asking about

Do you have a personal experience relating to hearing loss that would benefit your fellow HoH readers? It could be something practical or a warning of something to avoid or even something humorous. If you don’t mind sharing a short note, send it by email to:

EditorHLAAbq@gmail.com

hearing aids, there are some checklists you can refer them to. (This will be the subject of another article for this newsletter: the various checklists that are out there, what they cover, how to use them, and when they can help protect you from making a mistake when buying a hearing aid). Once OTC hearing aids are legal, the door will be open to increasing innovation, and hopefully as the sales volume increases, the costs can come down on hearing aids. Unfortunately, the door will also be opened to opportunistic venturers who are less interested in quality and developing a good reputation and more interested in the easy money if they hire slick salespeople.

So who do you contact if you suspect a product has been mislabeled, like stating expectations that are not in line with the ability of the product to deliver on those promises? The FDA has a complaint process, and if you go to the FDA.gov website, and search on “complaints”, you will be directed to the section for consumer complaints.

Of course, some expectations of buying hearing aids have already been set with so many online sales, and some of those companies are already out

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of the picture after running afoul of the FDA. Whether you are investing in an OTC hearing aid, or a “do-it-yourself” hearing aid online, it pays to do your homework. Working with an ethical professional hearing healthcare professional should minimize the risk you face when buying a hearing aid, so that would be the safest approach, since most of them still offer hearing devices that work for mild and moderate loss as well as those for more severe hearing loss.

Since there are still many questions, and confusion will be likely, your goal should be to proceed carefully when purchasing an OTC hearing aid if that is what would suit your hearing loss or that of a loved one.

Times are changing, and there will be more confusion about hearing aids, but our goal is to provide you some insight as it starts to become more clear over time. Good luck!

Amazon Smile You can donate to the Albuquerque Chapter of the Hearing Loss Association of America every time you make a purchase of most of the products from Amazon.

Go to <http://www.hlaabq.com/amazonsmile.html> for more information and detailed instructions on how to designate HLAA-ABQ Chapter as your charity of choice when you make amazon.com purchases.

Once you have set it up, always log into smile.amazon.com to purchase from amazon. 0.5% of the purchase price is automatically donated to HLAA Albuquerque Chapter—at no cost to you.

Loop People, Loop Places

Ginevra Ralph

Family & Friend Supports

Our Loop Committee chair has a particularly empathetic and engaged family supporting her hearing loss. But I don’t think they should be considered “unusual” in this regard. Rather, she has done an especially good job of involving the family to understand the problem and help brainstorm solutions for keeping her supremely active in the

community, in their social life, and in family relations.

First, her husband is a powerful community advocate on her behalf. As an active, amateur musician, he wanted to be sure to keep her engaged in music-making and concert-going as her hearing worsened. He helped articulate to “hearing” friends why looping concert venues and houses of worship was so important. He serves on our Loop Committee with a critically important perspective of what

other sites in our area need to be more auditorially accessible.

When she acquired a personal/portable loop and various microphone extensions, she experimented with it in all sorts of settings – from socially distanced wine socials in their gorgeous backyard and book clubs, to family dinners and instant computer audio for all the Zooming. Her teenaged grandson, who has a challenging deep voice, was fascinated with the loop and let her know he and his girlfriend wanted to do everything possible to be sure she could hear them. Her son purchased a loop for his

own house so that when she visits they can loop her in immediately. And with a secondary mic on a cord, she can listen to the new great-grandbaby sleeping in the next room or grandkids in the back seat of the car.

Friends and family truly WANT to communicate! Letting them know what works or not – and it can take some reminding – means that when they see you or encounter others with hearing loss, they will know better what to do. My motto: If you can't beat them, make them join you!

Follow-Up on Tinnitus

A. E. "Rod" Rodríguez, Editor, WFS

Last month, Dr. Julie Prutsman spoke to us about tinnitus. One of her slides (below) suggested ways to get involved, and the first item is "join ATA" (American Tinnitus Association).



How Can We Partner?

- ▣ Consider Joining ATA!
- ▣ Donate to ATA
- ▣ Provide articles for Tinnitus Today Magazine
- ▣ Direct people you know with tinnitus to ATA website. www.ata.org
- ▣ Questions for ATA: email at tinnitus@ata.org, or phone 1-800-634-8978

I was recently diagnosed with tinnitus. My HoH wife has had it for years, so she joined the ATA.

I perused their latest Tinnitus Today Magazine, and found that there is no support group in New



Mexico. However, there are in neighboring Arizona, Colorado and Texas. I emailed the contacts, and got a prompt response from John Ogrizovich dfwtsg@yahoo.com in Dallas. He said anyone interested is welcome to join their Zoom meeting every 6 or so Saturdays at 10:00 AM Central (9:00 Mountain).

Meeting Id: 401 937 6416

Passcode: Tinnitus

Meeting Id: 401 937 6416

Passcode: 47536477

He invites anyone interested to email him. You can ask for the next meeting date and find out the next speaker and topic.

An older man had serious hearing problems for many years. He went to the doctor and the doctor was able to have him fitted for a set of hearing aids that allowed the man to hear 100%.

The old man went back in a month to the doctor and the doctor said, "Your hearing is perfect. Your family must be really pleased that you can hear again."

The man replied, "Oh, I haven't told my family yet. I just sit around and listen to their conversations. I've changed my will three times!"



<https://www.startas.com/deaf-jokes/>

Motorcycles and Hearing Health

Kevin H. Franck, Ph.D., Chair of the HLAA Board of Directors

I like to ride my motorcycle. I'm aware of its risks. In part, because the first thing people tell me when they hear I ride is that they know someone who knows someone who had something terrible happen. This is typically when I change the subject or start talking to someone else. But if we can get past this, sometimes I like to mix my interest in hearing with my interest in motorcycles and talk about another risk – hearing.

Wind is loud – loud enough to damage hearing. Especially on long rides at highway speeds. I take precautions by plugging my ears. I've tried all kinds of technology. I've used custom ear protection like the kind many people use for hearing aids. These work the best. They are made of a nice firm material that's easy to wash and tethered together with a cord so less likely to drop when taking them in and out with gloves. They fit me just right and can be worn for long periods of time. I've also tried noise-cancelling earbuds. They work pretty well, but the relatively poor, shallow fit makes it quite difficult to put the helmet on and keep them in place. And they always twist and contort when taking the helmet off. But truthfully, most of the time I just wear the cheap foam ear plugs that come in a box of 100. I keep multiple pairs in storage parts of the bikes for when I lose them, or they get too dirty.

When I use these buds, I risk getting a ticket because in some states, protecting your hearing is against the law! Occasionally on long rides I might daydream about going to court. Given my background as an audiologist, I think I could get the case thrown out. I'd make the case that it's easier to hear the sounds around me when they aren't masked out by the wind noise. And I'm less fatigued and concentrate better when my ears aren't under attack.

Protect your hearing! Have fun.

Understanding the Cost of Hearing Aids

Thomas Powers, Ph.D.

President Biden released an executive order on July 9 urging the FDA to issue the proposed rules for Over-the-Counter Hearing Aids. These devices will be for adults only with mild to moderate hearing loss. While we wait for these rules, people are confounded by the array of products available. Without rules in place, how do consumers know which products will work? Without rules, who will consumers turn to if some of these products are not safe or effective?

As Dr. Powers states in his blog post, “In recent months, 16 State Attorneys General have issued consumer alerts urging citizens to exercise caution when purchasing Direct-to-Consumer hearing products given the growing popularity, availability and confusion about the products. It is important to remember that hearing aids are medical devices that currently must meet FDA standards/regulations to be safe and effective for the wearer.”

Helpful Resources to Further Understand the Issue:

[Rules are Long Overdue](#) by Lise Hamlin
[Are There “FDA Registered” or “FDA Certified” Medical Devices? How Do I Know What is FDA Approved?](#) From the FDA website

[Hearing Aids: Over-the-Counter, Direct-to-Consumer and Connectivity](#), an HLAA Virtual Convention 2021 workshop with Thomas Powers, Ph.D.

[Over-the-Counter Hearing Devices](#) from the HLAA website

Hear well. Stay vital. 8 out of 10 say hearing aids improve quality of life. Stay engaged and do what you love. Check your hearing wellness every year. (Source: Johns Hopkins Medicine) Learn more at [HearWellStayVital.org](https://www.hearingwellstayvital.org).

These two blogs can be found at <https://www.hearingloss.org/news-media/hlaa-blog/>

Thanks to those listed below for their generous donations.

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The Hearing Loss Association of America is a volunteer association of Hard of Hearing people, their relatives and friends. It is a non-profit, non-sectarian educational organization devoted to the welfare and interest of those who cannot hear well. Membership in the national organization is by annual dues, which are separate from the annual Chapter fee paid to your local chapter. National membership includes a subscription to the bi-monthly publication Hearing Life.



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A map of Albuquerque, New Mexico, centered on the area around Indian School Rd NE and Haines Ave NE. A red location pin is placed at the intersection of Indian School Rd NE and Haines Ave NE, marking the location of Los Altos Christian Church. The map shows various streets, including Indian School Rd NE, Haines Ave NE, and Constitution Ave NE. Other landmarks like Big 5 Sporting Goods and Arby's are also visible.

Meeting
HLAA Albuquerque Chapter Meetings are held at Los Altos Christian Church,
11900 Haines Ave NE, on the 3rd Saturday of the month, Sep-Jun.
Socializing starts at 9:30 am; presentation at 10:00.
The public is cordially invited to attend.
on Zoom