

“Can you say that again?”

It's a frustrating lament for millions of Americans, having to ask people to repeat themselves because they can't clearly hear what's being said.

However, for many that could be changing due to federal legislation that likely will go into effect sometime this year. The Food and Drug Administration Reauthorization Act of 2017 directed the FDA to develop rules for an OTC class of hearing aids that could be marketed to patients 18 and older with self-realized mild to moderate hearing loss. Previously OTC hearing devices were defined as personal sound amplifiers and could not be marketed for hearing loss.

What this means is that community pharmacies will have new devices to offer in their front end, creating not only a potentially new revenue stream, but more importantly providing relief to many of their patients experiencing hearing loss. According to the National Institute on Deafness and Other Communication Disorders, nearly 30 million U.S. adults could benefit from hearing aids, in particular elderly people, as it's among the most common chronic condition in older adults.

AN INCREASINGLY NOTICEABLE CONDITION

Lucas A. Berenbrok, PharmD, associate professor of pharmacy and therapeutics at the University of Pittsburgh, says that he teaches his students to visit community centers for medication reviews, and it

the students on hearing loss and medication management.' And I'd love to see our students go out to senior centers, so that's what we did," Elaine says.

Luke says that when Elaine told him about the new law that would make hearing aids available OTC, he knew they needed to act.

"I thought to myself, 'Wow, nobody in pharmacy is talking about this,'" he says. "We've got to get pharmacists ready. Elaine and I said we needed to put some things in place so pharmacists feel ready for this, because when the devices are sold over the counter, people are going to find them at the pharmacy, and they are going to ask the pharmacist questions."

You heard that right!

OTC hearing aids in community pharmacies could bring hassle-free relief to patients with hearing loss

by Chris Linville

became apparent that hearing loss was becoming more noticeable.

"When we were there, I wondered what else older people need other than somebody to look at their medications," he says. "It turned out that older adults need help with their hearing."

In 2017 Luke says he cold-called Elaine Mormer, an audiologist and professor of audiology at the University of Pittsburgh, asking if she wanted to bring her students along in a joint effort to review people's medications and do hearing screenings.

"When he called, I thought, 'This is a perfect thing. We'll co-educate

Elaine says, "As we talked about it, we thought we could be uniquely positioned to educate pharmacists since I have a background in audiology, I spent many years fitting hearing aids and working directly with patients, and he has the pharmacy background, and we're both educators. I thought we could put something together to educate both our students here in the Pitt pharmacy program and for continuing education."

BUILDING AN EDUCATION FOUNDATION

To help create a CE program, Luke and Elaine applied for and received internal funding for an Innovation in Education grant from the University of Pittsburgh. They then assembled



Photos by Tom Altany/University of Pittsburgh



“The OTC hearing aid law was passed because hearing aids were considered to be inaccessible and unaffordable to so many Americans.”

a panel of stakeholders to reach agreement on what it was that pharmacists should know. They reached out to the American Speech-Language-Hearing Association, the American Academy of Audiology, the American Pharmacists Association, American Association of Colleges of Pharmacy, and National Association of Chain Drug Stores. They also contacted a couple of different manufacturers of hearing devices and consumers with hearing loss and included a representative from the Hearing Loss Association of America, which is a consumer organization for people with hearing loss.

“We brought them all together and we used a research method called the Delphi Technique, a systematic way for bringing together a diverse group of people to reach a consensus on something,” Elaine says. “What we didn’t want to do was provoke a turf war, so we thought, let’s bring these parties together, follow a methodology, and get some consensus.”

The entire process took about a year, from May 2019 to May 2020. Several hundred students took the course and tweaks were made based on their feedback. The CE program is called Championing Hearing using Accessible Medication Experts at the Community Pharmacy, or CHAMP for short. The course was launched for professionals in 2021. CHAMP was created by Elaine and Luke and is owned by the University of Pittsburgh.

(Check out pittprofessional.catalog.instructure.com/courses/champ to learn more.)

“Our philosophy is that we wanted to build something that could be delivered both to students and to practicing pharmacists,” Luke says. “The idea is that we were teaching our students how to practice in the future knowing that they weren’t out yet, but they would be soon. We wanted to prepare the people already in practice so they would be ready right away, and we wanted to prepare the students so they would be ready once they graduate.”

SPREADING THE WORD

Luke and Elaine appeared together at APhA’s annual meeting and then shortly after that at the American Academy of Audiology conference to give an overview of their ideas to two different audiences.

Elaine admits that some audiologists might view pharmacists as a threat to their profession. She says during a question-and-answer session somebody asked Luke how a pharmacist is going to know how to change the wax guard in a hearing aid. At that point Elaine stepped up and said the answer was simple.

“They aren’t going to replace you,” she says. “They aren’t going to do what you do with your patients, and OTC hearing aids are probably not going to have a changeable wax guard.”

Luke thinks his answer was “What’s a wax guard?” he says with a laugh.

Despite that minor bit of skepticism, Luke and Elaine say the feedback was extremely positive. “The attitude seemed to be, let’s work with pharmacists, let’s do this,” Elaine says.

When Elaine spoke at the APhA annual meeting, she received comments from pharmacists who had hearing loss themselves, and who explained the complexities (not to mention cost) of acquiring hearing aids for themselves and their patients.

“The OTC hearing aid law was passed because hearing aids were considered to be inaccessible and unaffordable to so many Americans,” she says. “One gentleman spoke to us after the session talking about all the hassles. It confirmed that it is as complicated as it seems to get hearing aids.”

Elaine also mentioned some simple tips that could help when interacting with patients. She described a phone app that can transcribe words into text, in real time. Another app allows you to use your phone as a remote microphone.

“I think overall the questions were more focused on the issue of how challenging hearing loss is,” Elaine says.

Luke adds, “I think it was clear that pharmacists know and can recognize when they are speaking

to someone with hearing loss. But we're not always so great at understanding what that means and helping someone figure out how they can better hear us or better understand the message, so that's probably why we started with some simple tools that can help."

HOW WILL OTC HEARING AIDS BE SOLD?

When OTC hearing aids become available at community pharmacies, how and where will they be displayed and sold? What about merchandising and marketing? Will pharmacists purchase a few boxes of OTC hearing aids, put them on the shelf next to the toothpaste, and wait for someone to purchase a set? Probably not.

"Would they be behind the counter, can anyone grab one off the shelf, or would it be behind a glass panel where a sales associate would have to come help you retrieve them?" asks Luke.

His thought is that they will likely be secured in some way on the shelf, because of the cost.

"They aren't going to be grab-and-go, but they will be visible so they can be sold," he says. "There's not necessarily going to be a conversation with the pharmacist to gain access to the device. How many people are actually going to go up to the pharmacist and ask questions, and how can the pharmacist and pharmacy team, including technicians, be proactive and help people make good choices about what device to buy?"

This is where Luke believes the CE program can be useful.

"It teaches the pharmacist to ask those questions," Luke says. "Before I sell this to you, who is this product for? If it's for you, and you are at

WHAT ARE AUDIOLOGISTS AND WHAT DO THEY TREAT?

Audiologists are the primary health care professionals who evaluate, diagnose, treat, and manage hearing loss and balance disorders in individuals of all ages from infants and teens to adults and the elderly. Most audiologists earn a doctor of audiology (AuD) degree. Some audiologists earn a doctor of philosophy (PhD) or doctor of science (ScD) degree in the hearing and balance science.

Audiologists treat and help individuals manage many hearing and balance conditions including:

- Sensorineural hearing loss
- Hidden hearing loss
- Non-syndromic genetic hearing loss
- Syndromic genetic hearing loss
- Congenital cytomegalovirus infection
- Noise-induced hearing loss
- Auditory process disorders
- Ototoxicity
- Symptoms such as tinnitus (ringing in the ear), vertigo, and dizziness

least 18, great. In what scenarios do you have trouble hearing? If you have mild to moderate hearing loss, are there any red flags or exclusions where it's unsafe to use this device or there's something bigger going on that can't be solved by this device?"

In the latter scenario, pharmacists would recognize that the patient should see an audiologist, physician, or even a specialist.

"That's what our education teaches pharmacists to do and that's what we think should really be happening in a perfect world," Luke says. "That's kind of what Elaine and I have built our mission on, making sure that pharmacists know enough to help people make safe choices when these are available in the pharmacy."

PRODUCT RANGE AND CATEGORIES

Elaine says she's not sure at this point how many different OTC hearing aid products might be available when they are sold in pharmacies. She says that some of the legacy

hearing aid companies are developing OTC versions of their products. They will have much of the same technology and functionality, but the primary difference is they probably will be self-fitting as opposed to custom fittings done by audiologists, and they will be self-managed by the user.

"Also, calling something an OTC hearing aid is very specific," Elaine says. "Because there are other types of amplifiers that you can buy off the shelf that look exactly the same as what an OTC hearing aid will look like, but they can't be called an OTC hearing aid."

She's referencing personal sound amplification products, also known as PSAPs, which are not regulated by the FDA. They are not technically intended to treat hearing loss; they are designed to help people hear in very certain situations that they might not otherwise hear.

"The classic example is somebody who does birdwatching and wants to hear birds better. That person

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could buy a PSAP,” Elaine says. Some PSAPs look like hearing aids, and some look like headphones, she says, with price ranges between \$20-\$500 (or more). For OTC hearing aids she estimates a pair will cost anywhere from \$300-\$1,000.

WHAT PHARMACISTS WILL AND WON’T DO

Elaine says that one thing that tends to come up regarding OTC hearing aids in the pharmacy is the concept of pharmacists actually fitting the hearing aids.

“What we’ve really tried to emphasize is we don’t envision pharmacists will actually be fitting hearing aids,” she says. “They will be providing guidance on appropriate and effective use and choices of products, but I don’t think it’s the kind of thing where they are going to be doing anything kind of hands on – they’re not going to be creating a customized earmold like an audiologist would do. Audiologists have a set of tools that allows us to customize a hearing solution well beyond what an OTC product would do.”

Luke and Elaine say that community pharmacists should seek out local audiologists and invite them to come to the pharmacy and do some hearing screenings. At the very least the pharmacist should get to know the audiologist so patients can be referred if they have hearing issues that don’t allow them to use the OTC products.

“I think every pharmacy will have their own way of setting that up to make sure there is something in it for the audiologist,” Luke says. “I think what’s in it for the audiologist is the referrals when the pharmacist sees those exclusions. When the 80-year-old patient is coming in and says she has severe hearing loss, the pharmacist can say, ‘This is not for you, let’s get you connected with an audiologist. She’s two blocks down. She can take you tomorrow. Let’s get you an appointment with her.’ I think that’s where the collaboration is going to happen because there’s 38 million people out there with hearing loss, and not all 38 million are going to be able to use an OTC hearing device.”

Elaine says that hearing loss has been a vastly overlooked condition. She notes that it’s associated with several other ailments.

“People with hearing loss are at greater risk for developing dementia, a greater risk for falls, a greater risk for isolation and depression, cognitive decline – all of those things,” she says. “In any health care situation, if you aren’t able to engage in an important conversation (because of hearing loss) where a person is giving you information – this is how you take this medication or this is what you should do to be healthier – if you can’t hear that, it’s going to be a lot harder to follow those directions. Addressing somebody’s hearing is just fundamental in any provision of health service.”

WORKING TOGETHER

Luke says it bears repeating that collaboration is the key for successful patient outcomes.

“Elaine and I have found that this can only be successful when pharmacy as a profession and audiology as a profession want to work together, and we’re hearing very strongly and loudly that the two professions want to do this together,” he says. “So having the education available, getting pharmacists educated, and then educating the professions and bringing them together to look at this as a brand-new opportunity and probably make a difference for millions of lives with people having access to devices.” ■

Chris Linville is America’s Pharmacist® managing editor.

HEARING LOSS BY THE NUMBERS

- Approximately 15 percent of American adults (37.5 million) 18 and over report some trouble hearing.
- Age is the strongest predictor of hearing loss among adults 20-69, with the greatest amount of hearing loss in the 60-69 age group.
- About 28.8 million U.S. adults could benefit from using hearing aids.
- Among adults 70 and older with hearing loss who could benefit from hearing aids, fewer than one in three (30 percent) has ever used them. Even fewer adults 20-69 (approximately 16 percent) who could benefit from wearing hearing aids have ever used them.

Source: National Institute on Deafness and Other Communication Disorders

Hearing his calling

by Chris Linville

For Richard Logan, Jr., PharmD, a multi-pharmacy owner in southeast Missouri, his interest in serving patients with hearing loss is personal. Several years ago during a vacation he tried to listen to instructions from an airline desk attendant in a busy and noisy flight terminal, but realized he was having trouble understanding what was being said. His wife insisted he get his hearing checked, so after the trip Richard visited an audiologist for an evaluation.

"I was diagnosed with mild to moderate hearing loss that was especially evident with a lot of background noise," he says. "I was told my mild hearing loss was more of an inconvenience than a handicap, but that I may benefit from hearing aids."

Fortunately, Richard could afford a pair of \$4,000 state-of-the-art hearing aids, and they proved to make a significant difference. But he also knew many in his mostly rural community did not have the financial means to purchase such devices.

When Richard heard about the Food and Drug Administration Reauthorization Act of 2017 that directed the FDA to develop rules for an over-the-counter class of hearing aids that could be marketed to patients ages 18 and older with self-realized mild to moderate hearing loss, with prices in the range of \$300 to \$1,000, he saw an opportunity.

Richard viewed this as a new clinical initiative for community pharmacies.



Anticipating OTC hearing aids being available in the pharmacy, he began offering hearing screenings.

"Remembering that these devices are indicated for adults over 18 with self-realized mild to moderate hearing loss, we need to be able to refer patients whose screening indicates a more severe hearing loss to an audiologist for clinical assessment," Richard said in a 2020 article in *America's Pharmacist*[®]. (www.ncpa.co/issues/APMay20_WhatsThat-Sound.pdf) "That cannot be done without screening."

But just as the pharmacy's screening program was getting off the ground, COVID-19 hit, putting everything, including implementation of the OTC law, on hold.

"As with many things, COVID-19 brought drastic changes to our practice," Richard says. "We were forced to close our pharmacy to walk-in traffic and no longer able to offer in-person screenings. The entire premise of our patient hearing care service was predicated on individualized service and our OTC hearing aid business was put on hiatus for two years."

Other challenges included the subsequent supply chain issues, which made obtaining OTC hearing aids almost impossible. Richard is hopeful that those issues will be resolved, the OTC law will go into effect soon, and he can dust off his original business plan in anticipation of re-entering the consumer hearing aid market.

As with before, he intends to utilize hearing screenings and OTC aids as an additional patient care service in his pharmacy's toolbox.

"We daily see patients who could benefit from these services," he says.

"We practice in a very rural area with a poor and vulnerable population. We see OTC hearing aids as an alternative for folks with mild to moderate hearing loss who would benefit from a quality hearing device but cannot afford multi-thousand-dollar units. We intend to utilize our pharmacy community health workers (PCHWs) as in-pharmacy experts to advise and direct patients to appropriate units."

Obviously making sure staff is properly prepared and knowledgeable about products and services is especially important.

"Those PCHWs who will be assisting patients in the selection of OTC hearing aids will need training not only in the specifics of individual units, but in the patient care issues and quality of life costs surrounding hearing loss," Richard says. "Previously, our staff received training from the hearing assist device manufacturers and suppliers. Additionally, our pharmacy provided training surrounding the prevalence, severity, and personal costs of hearing loss."

What advice does Richard offer to others who might be interested in exploring this potential new market?

"Hearing assist devices, specifically affordable, quality hearing assist devices, have the potential to make vast positive influences on those with hearing loss," he says. "The sheer number of people in need of these services is staggering. This has the potential to bring new patients in the door, offers a source of non-dispensing revenue, and provides for a largely unmet need in our patient population. Pharmacists are accessible, capable health care professionals who can provide these services to those in need." ■

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