What’s that sound?
Huh?

We were really excited! My wife and I were going on a much-needed vacation, just the two of us. We were headed to the Caribbean. A couple of weeks of too much food, fruity drinks with little umbrellas, and sand in places sand should never be.

We had arrived at the airport for the flight. A quick hop to Miami, board a plane for St. Lucia, and the rest of the time, no responsibilities. It was a busy day at the airport. Lots of people going lots of places. Everybody was in a hurry, the intercom was announcing flights, people everywhere were scurrying. It was a raucous scene! We dove right in. We pulled our luggage up to the airline check-in desk, handed the clerk our identification, and got our suitcases on the scale. My wife and I stood

OTC hearing aids may provide a clinical opportunity for pharmacies

by Richard Logan, Jr., PharmD
immediately in front of the airline’s desk attendant while she printed our tickets. As she handed me the tickets, the clerk proceeded to give us instructions for the international flight. She gave detailed instructions, from what our departure gate was, to what forms would need to be filled out to enter the country, and what was acceptable to take into the country.

As soon as she finished the instructions, I looked at my wife, standing directly on the other side of the attendant, and said, “What did she say?” You see, I didn’t get a word of what was said. I missed the instructions entirely. My wife rolled her eyes, huffed, looked me in the eye and said, “I got it, and you need to get your hearing checked!”

My wife was right. When we returned, it was a trip to the audiologist for an evaluation. I was diagnosed with mild to moderate hearing loss that was especially evident with a lot of background noise. I was told my mild hearing loss was more of an inconvenience than a handicap, but that I may benefit from hearing aids. Some $4,000 later and I’m the proud owner of a set of state-of-the-art hearing aids. Yes, they help. The world opens up when I wear them. I think myself very fortunate to have been able to afford my hearing aids.

HEARING LOSS NOT UNCOMMON
My story is not uncommon. Hearing loss affects some 23 percent of Americans over the age of 12. Most of that 23 percent experiences mild hearing loss, but the severity increases with age. There are more than 30 million Americans who could benefit from hearing aids. That’s 60 million ears! And based on actions at the federal level in recent years, that patient population could be served by community pharmacists.

Historically, hearing aids have been Class 1 or Class 2 medical devices. A trip to a hearing professional, a diagnostic exam, and a prescription have been required before hearing aids could be fitted. Congress, concerned about lack of access to hearing devices, saw these steps as potential barriers to care for the millions of Americans with mild to moderate self-diagnosed hearing loss. In 2017, with the consideration of the Food and Drug Administration Reauthorization Act, Congress set about to make hearing devices more accessible and more affordable to this population.

CREATING AN OTC HEARING AID CLASS
In August of 2017, the FDA Reauthorization Act was signed into law by President Trump. The law has come to be known as the OTC Hearing Aid Act. Previously OTC hearing devices were defined as personal sound amplifiers and could not be marketed for hearing loss. They were sold only as sound amplifiers for things like hunting and bird watching. This law has changed that. The FDA Reauthorization Act of 2017 directed the FDA to develop rules for an OTC class of hearing assist devices that could be marketed to patients with self-realized mild to moderate hearing loss. Those rules are to be
promulgated no later than August of 2020. Understanding the depth of need, the FDA has tried to fast-track these rules to release them before August 2020. Maybe they’ll make it, maybe not.

The rules promulgated by the FDA will follow the guidelines of the law, which defines an OTC hearing device as a device that uses the same fundamental scientific technology as air conduction hearing aids, and is intended for use by adults over 18 years of age for mild to moderate hearing impairment. The law allows the user to control the device and customize it to their hearing needs and is available over the counter without the supervision or involvement of a licensed hearing professional. As the FDA continues to work on the final rules, there will be, most certainly, more information to add to this definition but the end result will be a vastly increased patient base that will have quality hearing devices available to them over the counter.

This new regulation is set to open up a huge market of unmet need in this population. Pharmacy can fill this need. Think of your current patients. How many of them will fit the profile? How many of them could benefit from a high quality, low cost, non-prescription OTC hearing aid? If your practice is similar to mine, the answer is a lot! The question for community pharmacy becomes: how best do we serve this patient population?

**PROVIDING HEARING AIDS AS A CLINICAL SERVICE?**

While it’s true that community pharmacy is well placed to meet these needs, it takes some forethought and decision making before we enter this market. Community pharmacy is very good at providing clinical services to patients. Should the sale of hearing devices be anything less than a new clinical service? We could, as a profession, 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. Conversely, we could view the sale of an OTC hearing device as a clinical service, offer self-administered hearing screenings, suggest appropriate devices, and assist the patient with both the expectations and purchase of those devices.

We have opted for the latter in our practice. We are 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. That cannot be done without screening. In offering screenings and assistance with choosing an appropriate device, along with appropriate referral, this becomes a new clinical service of the pharmacy, 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. I liken this to the beginnings of pharmacy vaccinations.

**FAR REACHING HEALTH IMPLICATIONS**

As pharmacists began offering vaccinations, it became apparent that the public health implications of that clinical service would be far-reaching. The availability of vaccinations in the pharmacy has significantly improved vaccination rates in the U.S. I see the opening of the OTC hearing aid market to be no less meaningful. Pharmacists have unparalleled access to patients and trusted relationships with these patients. We are able to utilize these relationships in ways to improve their health and quality of life. Hearing loss can affect a patient’s earning potential, personal relationships, self-esteem, and can reduce their overall quality of life.

Congress, with the passage of the FDA Reauthorization Act of 2017, has afforded pharmacists an opportunity to step up and positively impact our patient’s quality of life even further. If we’re going to do this, we must do it right, we must do it with a patient-first attitude, and we must do it quickly. Those looking only for profits will be quickly to market, to the detriment of our patients.

It’s rare to have this type of opportunity just “pop-up.” The market is huge and the opportunity is huge, so let’s not blow it. Let’s serve our patients and our profession well.

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**Quote:**

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