



Where We Are and Where We're Headed

*The Importance of
Over-the-Counter
Hearing Aids to the
Future of Hearing
Health Care*

By Frank R. Lin, M.D., Ph.D.

The number of adults with hearing loss is staggering. Nearly two out of every three individuals older than 70 years have a significant hearing loss that can affect daily communication. As a result, hearing loss has often been perceived as an inevitable, and hence, relatively inconsequential part of aging. In other words, if hearing loss is so common, how could it be important?

This perception is reflected in the statistics. Among adults with hearing loss, fewer than 20 percent report using hearing aids, and this low rate hasn't changed in more than 40 years despite substantive improvements in the sophistication and performance of hearing aids and other hearing assistive technologies. While many people have long been aware of the importance of hearing loss (think HLAA members!) and lamented about these low usage rates, there have never been any national initiatives or momentum to confront hearing loss as a public health priority, until recently.

Over the past seven years, epidemiologic research from Johns Hopkins University, as well as from other institutions around the world, has demonstrated that hearing loss, while being a usual aspect of aging, is not without consequence. For example, these studies have shown that individuals with hearing loss are at a greater risk of developing dementia, falling, and being hospitalized.

These links are not purely by correlation or chance, but likely the result of mechanisms through which hearing loss increases the risk of these adverse outcomes. These mechanisms include the “load” that hearing loss puts on the brain, reduced auditory stimulation contributing to faster brain aging over time, and the loss of social connectedness that comes with not being able to easily communicate.

These research findings have served as a wake-up call to policymakers given that addressing hearing loss could potentially lead to real and tangible benefits that would help reduce the risk of dementia and other important costly health outcomes.

Recent Initiatives to Address Hearing Loss

A cascade of national initiatives to confront the barriers that limit broader uptake of hearing care has followed in the wake of this research. An initial exploratory workshop on hearing loss and healthy aging was convened by the National Academies of Sciences, Engineering, and Medicine (NAS) in January 2014. This was followed by a report on hearing loss from the President's Council of Advisors on Science and Technology (PCAST) in October 2015.

Most recently, a committee consisting of hearing health care professionals, physicians, public health researchers, and other experts was convened by the NAS

in 2015 to study hearing health care for adults. In June 2016, the committee produced a definitive report, *Hearing Health Care for Adults: Priorities for Improving Access and Affordability*, which provided 12 recommendations to increase the accessibility and affordability of hearing care for adults.

A key recommendation of both the PCAST and NAS reports was for the Food and Drug Administration (FDA) to create a new regulatory class for hearing aids intended for individuals with mild to moderate hearing loss and that could be sold over the counter (OTC). These over-the-counter hearing aids would need to meet certain FDA specifications to ensure they were both safe and effective.

One of the most important aspects about an FDA-regulated OTC hearing aid category is that it would establish evidence-based performance standards for these devices to ensure they are both safe and effective.

The importance and urgency of this recommendation has come to the attention of senior members of Congress. On March 21, 2017, bipartisan legislation (S. 670), led by Senators Chuck Grassley (R-Iowa) and Elizabeth Warren (D-Mass.), was introduced mandating the FDA to create a new class of OTC hearing aids. A companion bill, led by Representatives Joe Kennedy III (D-Mass.) and Marsha Blackburn (R-Tenn.), was also introduced in the House (H.R. 1652).

The Over-the-Counter Hearing Aid Act of 2017 requires the FDA to create a new class of OTC devices within three years (in contrast to other NAS report recommendations that have no set timeframe and no binding legal mandate). ***It is imperative that HLAA leads the way as the voice of the consumer to ensure passage of this bill!***

This legislation and the resultant FDA classification would trigger a sea change in the uptake of hearing health care by consumers. It would have far-reaching implications that would have greater impact than other initiatives and forms of legislation being considered, such as hearing aid tax credits, public information campaigns, or even insurance coverage for hearing aids.

In order to understand why this legislation would have such a profound impact, there are two background pieces that need to be explained—first, past federal policy that has shaped the current model of hearing health care delivery; and second, an understanding of the key barriers

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(not just cost) that presently limit broader adoption of hearing health care.

Why Medicare Doesn't Cover Hearing Aids

When Medicare was enacted by Congress in 1965, hearing aids were statutorily excluded from coverage, and reimbursement for rehabilitative audiological services for the programming and fitting of hearing aids was similarly excluded. Audiologists could be reimbursed only for performing diagnostic tests (e.g., audiograms), and that continues to this day.

Twelve years later, in 1977, the FDA developed specific regulations for hearing aids that mandated special controls such as a medical exam requirement or waiver before purchasing a hearing aid. As a result, every state audiological board stipulates that hearing aids cannot be sold over the counter and can be obtained only through a state-licensed provider such as an audiologist, hearing instrument specialist, or in many states, a physician.

For some Americans, the purchase of hearing aids represents the third largest purchase in life after a house and a car.

These policies that date back more than 40 years have resulted in audiologists not being able to bill Medicare (or most private insurers) for hearing aid fitting services. However, audiologists and other hearing care professionals still serve as gatekeepers to consumers in obtaining hearing aids. As a result, the vast majority of hearing care professionals sell hearing aids using a “bundled” pricing model, wherein the cost of the hearing aid is combined with the costs of all the professional services needed to program and adjust the hearing aid. In contrast, an “unbundled” model would list the cost of the device and the required audiological services as separate line items.

Generally, the wholesale cost of the hearing aid to the audiologist is about one-third to one-half of the total price the consumer pays. For example, for a pair of hearing aids costing a consumer \$6,000, the audiologist pays roughly \$2,000-\$3,000 for the hearing aids themselves with the remainder covering the audiological services such as fitting, programming and follow-up visits.

Bundling raises two issues—first, not all consumers need the same amount of services, particularly with differing communication needs and advances in technology that now allow consumers to self-adjust hearing aids; and

second, even wholesale hearing aid costs to audiologists are still too high. For instance, the U.S. Department of Veterans Affairs (VA) purchases hearing aids in bulk at a cost of about \$300 each.

Barriers to Seeking Hearing Care

There are several barriers that prevent the broader adoption of hearing care for adults in the U.S.—affordability, access to services and hearing technologies, awareness and understanding, and technology design and utility. Reducing or eliminating only one barrier (e.g., providing insurance coverage to reduce cost to consumers) will have little impact if other barriers aren't simultaneously addressed. For example, in the U.K. and many parts of Scandinavia, hearing aids are fully covered by insurance and government programs, but hearing aid adoption rates among those with a mild to moderate hearing loss are only marginally higher than in the U.S.

Affordability—The high wholesale cost of hearing aids to audiologists is passed on to consumers. For some Americans, the purchase of hearing aids represents the *third largest purchase in life* after a house and a car. Further, there is seldom transparency in either the services being provided in a bundled pricing model or stipulations that might be attached to the purchase. For instance, some hearing aids can be serviced only by the original dispenser, which raises an issue if the patient moves or wants to change to a different provider.

Accessibility—Hearing aid provision and other related services remain clinic-based, and consumers must often make repeated trips simply to obtain a hearing aid. For individuals requiring communication assistance but who might not necessarily need a hearing aid, such as someone who needs assistance with an amplified telephone or TV listening device, finding a hearing professional who is willing to provide such services outside of the clinic is even more difficult.

Awareness and Understanding—There is little awareness among consumers or health providers about the manifestations or consequences of hearing loss. Both groups are often poorly informed about such things as how to access hearing care, the differences between over-the-counter amplifiers sold as “miracle listening devices” versus a hearing aid, and the training that distinguishes a hearing instrument specialist from an audiologist.

Hearing Aid Technology Design and Utility—Ninety-eight percent of the world's hearing aid market is controlled

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by six companies (only one of which, Starkey, is based in the U.S.), and arguably these devices are created more with the audiologist in mind than the end user. Features such as connectivity with smartphones, rechargeable batteries and proprietary wireless streamers are all still considered options that are added to the price, despite the fact many of these features were introduced long ago. In contrast, in any analogous field involving technological advances, innovative new features are often sold at a premium initially but then quickly become standard as even more advanced features are developed and introduced.

While other barriers such as stigma or ineffectiveness of hearing aids in crowded rooms could also be considered, they are likely secondary to the root causes detailed above. For example, the stigma might be lessened or eliminated if other barriers to hearing aid acceptance and use were reduced, and hearing aids would be more effective in a crowded room if routinely and easily coupled with wireless microphones that directly stream to the hearing aid.

Why Is Passing a Bill for Over-the-Counter Hearing Aids So Important?

In brief, the ramifications of passing the Over-the-Counter Hearing Aid Act of 2017 are that *OTC devices would address and reduce all four of these barriers simultaneously*. Their availability would leverage market forces and innovations that are happening at lightning speed in the consumer technology industry and fundamentally shift how hearing health care is perceived, accessed, and delivered.

The feasibility of developing high-quality over-the-counter hearing aids has only emerged in the last decade, since the introduction of the iPhone ushered in the era of the smartphone. For the previous 20-30 years, the FDA and state restrictions made sense in a way—namely, safe and effective hearing aids would not necessarily have been possible without the involvement of a hearing professional.

However, a phenomenal amount of technological progress in the last 10 years means that OTC hearing aids are now possible, and recent research indicates that select devices which are already sold over the counter (but cannot be labeled as hearing aids due to current FDA regulations)

can perform on par with some hearing aids that are available only through a professional. Without proper regulatory guidance, however, it's impossible for consumers to distinguish which devices that are currently available are safe and effective and which are not.

An FDA-regulated classification for OTC devices would lead to several cascading effects that would directly eliminate or reduce the current barriers to hearing health care:

Affordability—As mentioned previously, the wholesale cost of hearing aids to audiologists remains high compared to the price paid by such organizations as the VA or even the National Health Service in the U.K. Much of this inflated cost comes down to the low-volume, high-margin business model employed by most audiologists. In contrast, the world of consumer electronics functions on a high-volume, low-margin model. Creating an OTC device classification would allow both traditional hearing aid manufacturers and established consumer technology companies such as Apple, Samsung, and others that benefit from economies of scale in manufacturing, to enter the marketplace and sell devices directly to consumers, which will come at a lower cost as many more are sold.

Accessibility—The predominant hearing health care model that exists globally involves multiple visits to a hearing professional to obtain a hearing aid. This model is not sustainable and cannot meet the needs and requirements of everyone who has a hearing loss. Availability of OTC hearing aids that meet performance criteria set by the FDA would ensure that adults have access to a basic level of hearing technology simply by going to a local store.

An OTC option does not in any way preclude the invaluable services in counseling, education, fitting and programming that an audiologist provides. One would expect that many adults would in fact seek the services of an audiologist to learn how to use these devices and customize them to their hearing needs, while others might learn to use them on their own much like any other consumer electronics.

The important point is that access to OTC hearing aids by consumers would bring hearing technologies out from under the explicit control of a relatively small group of individuals who serve as the intermediaries to hearing care. This new model would further lead to far greater transparency in hearing health care costs, as professionals will need to unbundle the services they provide from the cost of the actual device.

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Both consumers and hearing care professionals alike often forget that the role of an audiologist or other hearing care professional is not to just sell a hearing aid. Instead, their role is to ensure people with hearing loss can communicate effectively, and whether this is done with a custom hearing aid, an OTC hearing aid, a smartphone-based app, or even just with simple education and counseling does not matter. The availability of OTC hearing aids will trigger this important paradigm shift in the transparency of hearing care and allow consumers to distinguish the value between audiological services and hearing devices.

Awareness and Understanding—Drugstores and magazines are often cluttered with devices purporting to be a “miracle hearing device” or “super hearing amplifier” and all at a “fraction of the cost of an expensive hearing aid.” Unfortunately, while the vast majority of these devices will not offer any benefit to consumers with hearing loss, some devices already available over the counter (but not labeled as hearing aids) can perform as well as some hearing aids obtained through an audiologist.

At present, however, consumers have no way of knowing what’s good, what’s bad, and what could even be downright dangerous because of unsafe amplification levels. An FDA-regulated class of OTC hearing aids would provide much needed clarity by stipulating the performance standards that would need to be met—standards that would ensure the amplification would be both safe and effective.

As acceptance and use of these devices proliferates, broader awareness about hearing loss will naturally follow as consumers will ask questions, research these products on the internet, and seek out professionals for more answers.

Technology Design and Utility—Creating this new class of hearing aids will have *profound* implications on the pace of innovation in hearing technologies. It would allow both established technology companies as well as smaller startup companies to enter the market. These companies currently do not develop innovative devices for hearing loss because federal and state regulations preclude them from marketing or selling their products directly to consumers.

Over the past decade, product cycles for consumer electronics such as smartphones have been on the order of months as the newest and most advanced features (touch screens, digital cameras, GPS) quickly become standard

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features on successive models. The same cannot be said of the hearing industry where features such as advanced noise suppression algorithms are still somehow considered premium features sold at a premium price many years after they were first introduced.

Availability of these OTC devices would allow for innovation and competition and would lead to a convergence of hearing aids and consumer electronics. Apple AirPods, Samsung IconX, and the Bragi Dash are all examples of earbuds that can play music, accept voice commands, or serve as a phone earpiece. While they currently do not amplify sound, it would likely take no more than six months of research and development for any of these companies to convert the earbuds to a high-end hearing aid that could be sold for a few hundred, rather than a few thousand, dollars.

Such innovation would likely spill over into all segments of the hearing industry. Developments in technologies for wireless streaming of sound in a theater or lecture hall directly to hearing aids or controlling and obtaining voice feedback from a smartphone via the hearing aid would allow hearing aids, or “hearables,” to become as enmeshed in our daily lives as smartphones are today.

This integration and convergence will not happen until consumer technology companies can enter the market, and that cannot happen without FDA re-regulation of hearing aids. Passage of the Over-the-Counter Hearing Aid Act of 2017 will allow all this to happen.

What About Safety?

There are questions that come up regarding the issue of safety. Will the devices be safe for my ears? Is it safe to get a hearing aid without first seeing a hearing professional? The short and resounding answer to both questions is YES! These questions and many others were thoroughly considered by both the PCAST and NAS committees in their studies and resulting reports.

Device safety—One of the most important aspects about an FDA-regulated OTC hearing aid category is that it would establish evidence-based performance standards for these devices to ensure that they are both safe (e.g., limiting maximum sound output levels) and effective. At present,

and without this new classification, the consumer market is awash with devices from companies that make wild and unsubstantiated claims about performance, and many of which have unsafe sound output levels.

Consumer safety—Some clinicians will make the argument that obtaining a hearing aid without first having a medical exam is unsafe. While this is sound advice for children, it doesn't make sense for adults. Two out of every three adults older than 70 years has a hearing loss. In the absence of signs such as discharge from the ears or sudden hearing loss—both of which would be listed as warning signs to see a doctor in the labeling of an OTC device—the chances of missing important clinical diseases are extraordinarily miniscule (e.g., an acoustic neuroma (a hearing nerve tumor) is diagnosed in about .001 percent of people per year). This is far outweighed by the benefits of access to hearing technology for the millions of people who currently do not seek help for their hearing loss.

By the same extension, we have long accepted the risks and benefits of over-the-counter reading glasses, despite the fact that poor vision could be from glaucoma, which is prevalent in five percent of older adults, or aspirin for headaches, despite the fact that headaches might be masking neurologic conditions or that aspirin can, and does, occasionally lead to internal bleeding.

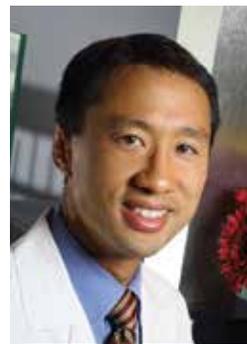
What Can I Do to Help?

The Over-the-Counter Hearing Aid Act of 2017 has bipartisan support in both the Senate and the House, but its passage is not assured. Industry groups and some professional associations are lobbying to weaken the

provisions of the bill, and they're doing so because it would be in their members' financial interest to preserve the status quo as much as possible (i.e., keeping hearing aids and hearing care expensive for consumers and retaining their role as gatekeepers).

Unfortunately, this would not be in the best interest of the 48 million Americans with hearing loss, and would run directly counter to the unbiased and expert recommendations made by the NAS and PCAST committees in their reports. Implementation of the recommendations in these reports would promote innovation, competition, accessibility, and affordability in hearing health care—all features which unfortunately do not currently characterize the market.

You can help ensure passage of the Over-the-Counter Hearing Aid Act of 2017 by directly contacting your congressional representatives to let them know that you support the bill. Actions such as sending emails, letters, and making phone calls all make a huge difference. You can find complete details of steps you can take at hearingloss.org/content/call-to-action-otc and freedomtohear.org. **HLM**



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What is Your Chapter's Success Story?

In our Spotlight on Chapters we want to share your story and let everyone know about the initiatives that have contributed to your chapter's success.

You can send your story (800 words or less, please) to Dave Hutcheson, publications editor, at dhutcheson@hearingloss.org. We all have a common mission, and this is a great way to share ideas and get some inspiration that will help all chapters grow!