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Hear! Hear! Industry Responds To FDA Proposal On OTC Hearing Aids

Poll finds few Americans know about the proposal

by [Brian Bossetta](#)

The FDA's recent proposal to allow hearing aids to be sold over the counter without a prescription has mostly been met with approval. Many Americans, however, are unaware of the plan.

Many Americans with trouble hearing never do anything about it. This is due, in large part, to the high cost of hearing aids and the hoops one must jump through – exams, fittings – to get them. But that could all change, with the US Food and Drug Administration set to approve the sale of hearing aids over the counter without a prescription or prior medical exam. (Also see "[No Prescription? No Problem: FDA Draft Rule Gives Green Light To OTC Hearing Aids](#)" - Medtech Insight, 19 Oct, 2021.)

Allowing consumers to purchase hearing aids directly at their local retail pharmacy or online – much like buying reading glasses – will go a long way in improving the quality of hearing, and of life, for many with hearing loss, according to Scott Longval, CEO at medical device manufacturer Intricon.

The FDA's proposed regulations to establish an OTC hearing aid category represents an important step in enhancing hearing health, said Longval. "We have long been in support of opening this market to the substantial number of Americans suffering from self-perceived mild-to-moderate hearing loss who previously could either not obtain a prescription, could not justify the cost, or could not afford prescription hearing aids."

And though the FDA's proposal only applies to low-risk, class I hearing aids and not more complex audio devices for severe hearing issues, the FDA and advocates of the proposal still believe direct sale of hearing aids has the potential to positively impact a large percentage of

Americans with difficulty hearing.

As Longval noted, hearing aids are not covered under Medicare or most private plans, which means most Americans must pay for them out-of-pocket. And with the average cost of a single device around \$2,400 – and a pair nearly \$5,000 – that’s simply out of reach for many Americans, so they do without. On top of that, there’s the stigma associated with hearing loss, especially for seniors. These factors help explain why of the 30 million or so Americans with hearing impairment – half of whom are older than 70 – only 20% use a hearing aid device.

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The consensus among industry and hearing health advocates is that direct sale of hearing aids will drive down costs by fostering competition in the marketplace.

Barbara Kelley, executive director at the Hearing Loss Association of America (HLAA), told *Medtech Insight* that her organization has been in favor of selling hearing aids directly to consumers for some time and advocated for the OTC Hearing Aid Act of 2017, which called for the FDA to establish an OTC category for hearing aids. That initiative stalled until it was revived by the Biden administration.

“This is one step closer to seeing OTC hearing devices on the market for adults with mild to moderate hearing loss,” Kelley said. “We hope to see many adults who qualify for these devices be encouraged to take that important step toward good hearing health.”

Hope Lanter, an audiologist at hear.com, said establishing a new category of OTC hearing aids could help millions of Americans with hearing loss. “Lower-cost hearing aids may act as a stepping-stone for those who need help but are reluctant to make a large commitment to medical grade devices,” Lanter said.

Lanter cautioned, however, that hearing loss is unique to each individual and those who might end up using OTC hearing aids should continue to seek professional guidance. “OTC hearing aids will not be shaped to a person’s hearing loss and, therefore, using them could actually cause

more damage.”

Jeffrey Regan, director of government affairs and public policy at the American Speech-Language-Hearing Association (ASHA), said he appreciates the FDA’s action, but also voiced concerns that OTC devices might not meet the necessary technical specifications to maximize safety and efficacy. “We also remain committed to advocating that these devices are appropriately marketed only to individuals who are 18 years of age and older,” Regan said, “and that anyone with any degree of self-perceived hearing loss be encouraged to consult with a certified audiologist or hearing health care professional.”

Public Lacks Knowledge of OTC Proposal; Wants Guidance

While the FDA’s proposal is meant to make hearing aids easier and more affordable to purchase, many Americans don’t even know about it, according to an [ASHA/YouGov poll](#), and those that do are uncertain about who the products are intended for or how they should be used. The poll also found that most Americans want professional guidance when it comes to their hearing health.

“It is critical that the public understands what these products can and cannot do – and who should be using them and how,” said ASHA board member Charles Bishop. “We don’t want people to further damage their hearing by purchasing a device that will over-amplify sound. We also don’t want to see people purchasing devices that are not strong enough for their hearing loss.”

In Bishop’s view, the public should be aware that audiologists remain a key resource even as OTC hearing aids become available.

“We’d recommend anyone with concern about their hearing get a hearing evaluation as a first step, even if they intend to purchase an OTC hearing aid,” he said, noting that a professional evaluation can rule out other medical issues that might be causing hearing loss, such as wax buildup or even a tumor on the hearing nerve.

Of the 2,030 US adults surveyed for the ASHA/YouGov poll, 87% said it would be important to have a professional diagnosis prior to buying a hearing aid, while 83% said it would be important to know the most appropriate technology for their hearing loss before purchase. A large majority, 84%, also felt it important to know the extent of professional support that would be available to them after purchase, such as adjustment to volume levels, speech clarity, and physical fit.

And even with hearing aids potentially becoming more affordable over the counter, the leading factor influencing the purchase of a hearing aid was not cost, the poll found, but the recommendation of a medical professional.

“People should also understand that, unlike hearing aids obtained by an audiologist, OTC products won’t come with a diagnosis of the cause and extent of their hearing difficulty; professional fitting and other customization of the device; and rehabilitation services that are often needed to adjust to life with a hearing aid.” – Charles Bishop

At the same time, the poll shows that most Americans do not even know about the proposal and the new category of OTC hearing aids. Only 29% had heard about the proposal, while 42% said they would be unwilling to purchase an OTC device.

According to Bishop, one of the more concerning aspects of the poll results is the public uncertainty about whether OTC hearing aids are for children. The poll found that 70% of adults were unsure if the OTC hearing aids were for children, and 58% were unsure if they were intended for those with mild to moderate hearing loss. And many surveyed were wary about the creation of this new OTC medical device category.

“These devices are not intended for children, and using them inappropriately could put children at risk for severe complications due to untreated ear disease; inadequate amplification that could result in significant language delays or disorders; and further hearing loss due to inappropriately high levels of amplification,” he explained. “People should also understand that, unlike hearing aids obtained by an audiologist, OTC products won’t come with a diagnosis of the cause and extent of their hearing difficulty; professional fitting and other customization of the device; and rehabilitation services that are often needed to adjust to life with a hearing aid.”