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# Exec Chat: Intricon CEO Bullish On OTC Hearing Aids

by [Brian Bossetta](#)

Scott Longval, CEO of medical device manufacturer Intricon, says the US FDA's proposal to allow over-the-counter sales of hearing aids without a prescription will benefit industry as well as those with hearing loss.

The US Food and Drug Administration recently [proposed](#) a rule change that will allow some hearing aids to be sold over the counter, in a move that many say is long overdue and could bring much-needed hearing help to many Americans.

The movement to sell hearing aids directly to consumers has been gathering steam for a while. In 2017, the OTC Hearing Aid Act authorized the FDA to establish an OTC category for the devices. The legislation stalled, however, until it was given new life in a July executive order signed by President Joe Biden. (Also see "[Sweeping Executive Order Puts Hearing Aids Over The Counter; Cracks Down On Internet Providers](#)" - Medtech Insight, 9 Jul, 2021.)

Now, with the FDA accepting comments through 19 January on its latest OTC proposal, the new OTC category is likely to go into effect in early 2022.

In an interview with *Medtech Insight*, Scott Longval, CEO of hearing aid company Intricon, says the proposal will likely drive down costs of hearing devices, which has been the chief impediment to people getting them.

Most sources estimate that some 30 million Americans have hearing impairment, yet only 20% of them use a hearing aid.

But in Longval's estimation, the problem is worse. "Actually, the statistics we are following indicate that more than 38 million Americans experience some degree of hearing loss and only 14% of them use a hearing aid," he says.

If Longval's assessment is accurate, the opportunities for device makers from direct OTC sales of hearing devices could be even greater.

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***“OTC sales of hearing aids will make them more common and inspire others to wear them – much like reading glasses.” – Scott Longval***

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However, as Longval notes, the proposal to sell hearing aids directly to consumers only applies to devices for mild to moderate hearing loss and not more complex devices, such as cochlear implants, which are designed to address more severe cases of hearing impairment.

Still, Intricon's research suggests OTC availability of hearings could make significant inroads in improving the hearing health of a lot of people. Putting the numbers into perspective, Longval says hearing loss is the third most common medical condition in the US, more prevalent than both diabetes and cancer. And as people continue to live longer, the population with hearing loss will only continue to rise, further expanding an already large and burgeoning market.

Longval, however, is not entirely convinced the OTC channel will only help those with mild to moderate hearing loss. “Actually, we believe the best technology will be needed for this OTC category; that means wireless-enabled hearing devices,” he says, noting that the FDA regulates these as moderate-risk class II exempt. “These are not basic devices – they are high-quality, high-technology hearing devices. Those with more severe hearing loss will use similar technology with increased power and output.”

But Longval is certain that direct OTC sales of hearing aids will get them to those who need them most by chipping away at the two biggest impediments to getting them in the first place – access and cost.

“If you look at other regions in the world where they have removed cost as a barrier to entry, such as the UK and Scandinavia, penetration rates are double that of the US,” Longval said. “We’re confident that the OTC channel will provide greater convenience, increased value, and easier access.”

Beyond access, however, the primary obstacle for many getting the devices they need remains the high price tag. On average, a hearing aid in the US is roughly \$2,400 per device – and as most needing devices have loss in both ears – Longval says a more typical cost jumps to nearly \$5,000.

On top of that, Medicare and most private plans do not cover hearing aids, making the out-of-pocket hit too hard for many Americans to take. Establishing an OTC channel for hearing aids will create a “more efficient distribution model,” in Longval’s view, which will foster competition as many companies will begin to manufacture products to fit within the OTC category, thus lowering costs.

But access and cost are not the only hurdles hearing loss sufferers must clear. There’s the stigma, especially for seniors – “the doddering old man” – and the misperception that trouble hearing equates to a lack of intelligence or that hearing aids make the wearer less attractive. And Longval believes the OTC channel can make a difference here as well. “OTC sales of hearing aids will make them more common and inspire others to wear them,” he said, “much like reading glasses.”

### **A Boon for Industry**

But consumers are not the only ones that stand to benefit from the FDA’s new regulations. Device manufacturers, such as Intricon, will benefit too as competition not only drives down costs but boosts innovation by opening the market to many companies looking to expand or enter the space.

For example, Longval says, self-fitting technology will allow consumers to program and adjust their devices remotely.

“In the end, what’s most important is that more people will be using hearing aids to enhance and improve their lives through reduced isolation, increased social engagement, and so many more health and wellness benefits,” he says. “This will drive growth in the industry.”

Despite the popularity of the FDA’s proposal to create an OTC category for hearing aids, some caution the move might have negative consequences, with the primary concern being the absence of professional guidance and need for testing prior to purchase. The skeptics say that patients who don’t consult an audiologist beforehand might not get the right device and could face issues such as inadequate audio levels or improper fit which could potentially worsen hearing loss.

While he understands these concerns, Longval feels they can be mitigated through a series of steps – “an ecosystem of care” – that can help the consumer navigate through the maze of options to find the right device.

This ecosystem, he says, includes the right combination of consumer education, the latest high-tech user-friendly tools, high quality devices, personalized customer care options, and return policies. This type of support structure will not only empower consumers to make the right choices for their hearing needs, Longval says, but will also help caregivers as well.

And while anyone with mild to moderate hearing loss stands to gain from the convenience of the OTC category, Longval believes that certain demographics, such as seniors in rural areas, where access to hearing health is limited, will gain the most from being able to walk into their local pharmacy or drugstore or go online and pick up a pair of affordable hearing aids.

“Many people in rural areas go untreated rather than use hearing aids,” he says. “The proposed OTC regulation enables greater accessibility by bring hearing health care to the consumer’s home instead of bricks and mortar.”