

New FDA Proposal for OTC Hearing Aids: Impact on Consumer Adoption and Industry Economics



Executive Summary from Nancy M. Williams, Auditory Insight Founder and President

The FDA's proposed rule to create a new regulatory category for over-the-counter (OTC) hearing aids will have profound implications for hearing healthcare.

The FDA has designated a maximum output level (essentially the loudest sound the hearing aid can deliver) that will ensure that OTC hearing aids are effective for the majority of people with hearing loss. Recent entrants into hearing healthcare—**large consumer brand companies including Apple and Bose, start-up innovators, and payers including United Healthcare—have the strategic interest and resources to capitalize on OTC regulations.**



Therefore, we expect to see an OTC hearing aid category characterized by **better awareness of hearing loss, more product and service innovation, lower prices, and greater adoption** than the traditional hearing aid category. Over the medium-term, the entire hearing aid industry most likely will have a far different structure than it does today.

Auditory Insight is releasing this special commentary in response to the FDA's publication of its long-awaited proposed rule on October 20. The top-line implications of the proposed rule merit this special commentary.

We are currently working on a detailed analysis, which will be published as our Q4 Research Note. The note will expand upon this commentary and discuss how the new OTC category could potentially interact with legislation before Congress on Original Medicare coverage of hearing aids.

We look forward to discussing this commentary with our valued clients.

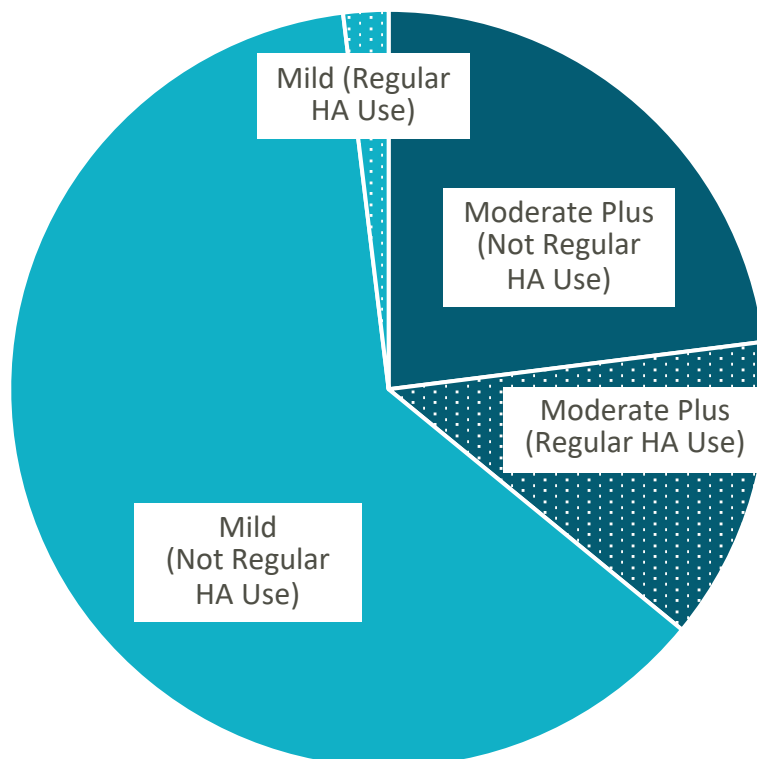
Significance of the Maximum Output Limit

The proposed rule spells out requirements for labeling, design, and electroacoustic performance for OTC hearing aids, as well as the preemption of state regulations governing the sale of hearing aids. Our belief, however, is that one of the proposed rule's **most significant items is the maximum output limit of 120 dB SPL for an OTC hearing aid**, provided that the aid contains compression technology (e.g., the ability to soften incoming loud sounds) and a user-controlled volume adjustment.

The agency's ruling intends to strike a balance between safety and effectiveness, with attention to consumer satisfaction and use of the devices. Coupled with the FDA's decision not to limit hearing aids' decibel gain, this rule ensures that OTC hearing aids should perform well for not only people with mild hearing loss, but also moderate.

People with moderate hearing loss are currently a core segment for hearing aids. Less than 5% of adults 50 and older with a mild hearing loss regularly use a hearing aid, while over one-third with a moderate-plus hearing loss do so. Therefore, OTC hearing aids will fit many consumers who traditionally have purchased hearing aids manufactured by the five global hearing aid companies and sold through the audiologist and dispenser channel.

Total U.S. Potential Opportunity of People with Hearing Loss 50 and Older



Source: Auditory Insight analysis

Three Sets of Players Likely to Capitalize on the New OTC Category

Three sets of recent entrants into hearing healthcare possess the strategic interest and resources to capitalize on the opportunity to provide OTC hearing aids for people with both mild and moderate hearing loss. These players will be critical to develop the new OTC category. As we have noted, when prescription categories go OTC, [the main brake on development is inertia in behavior](#). New OTC categories require sustained investment to create awareness and acceptance among consumers and primary care professionals. In this case, an important component of developing acceptance is addressing stigma.

Companies with strong consumer brands

In 2020, **Apple** launched the ability for the AirPods Pro to provide customized amplification based on a consumers' unique hearing patterns as reflected in their audiogram; more recently the company has augmented its offering with Conversation Boost, to enable better hearing in noisy situations. Earlier this year, **Bose**, armed with its pristine brand reputation, launched their FDA-cleared hearing aids, SoundControl. Not to be outdone, **Best Buy** launched a Hearing Solutions section to their website in the fall, complete with an online hearing assessment. And all the while, **Costco** has been steadily growing its share of the hearing aid market.

Start-up innovators

Smaller companies such as Lexie Hearing and Olive Union have been innovating in product design and service delivery, creating an opportunity for the large players to make **strategic investments** to augment their go-to-market strategy.

Payers

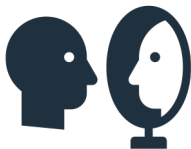
United Healthcare's **UHC Hearing** offers a hybrid experience, delivering hearing aids to the home and performing adjustments with virtual care. Fully [88% of Medicare Advantage payers](#) have some hearing benefits, while 75% of them have OTC benefits, groundwork for payers to improve coverage of hearing care.

Implications of Proposed Rule

We believe that these three sets of players will leverage an OTC hearing aid category, including the maximum output limit, to create the following changes:



- **Innovation** in hearing aid form factors, sound quality, fitting technologies, and add-on services



- Investment to develop **awareness and acceptance** of hearing loss, hearing protection, and hearing treatment, among consumers and primary care professionals, especially addressing stigma



- Considerably lower hearing aid prices, with a pair of OTC hearing aids retailing for about \$500 on average, compared to \$5,500 for a pair of traditional hearing aids from audiology and ENT hearing aid clinics today



- An increase in the overall adoption rate from the 15% of people who regularly use a hearing aid today (assuming innovation, greater awareness, and lower prices)



- An OTC category characterized by significantly **higher volume** than the remaining prescription hearing aid category, with the economics of the entire hearing aid industry potentially very different than today

We look forward to expanding our viewpoint in our Q4 Research Note.

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