

OTC hearing aids: where are we now?

The 'Over-the-Counter Hearing Aid Act' of 2017 set in motion plans for a long-debated shift in the hearing care market. In 2021, the FDA released draft guidance which will allow hearing aids in the US to be sold direct to the consumer without the need for an audiologist. The finalised guidance was released on 16 August 2022. Whilst the legislation is specific to the US, the international market waits to see the impact the additional model of hearing care delivery brings. In 2017 *ENT & Audiology News* asked opinion leaders for their views on this controversial change*. Five years later, we have revisited the subject and asked today's opinion leaders: 'With the framework in place for OTCs to become available in 2022, and it being five years since the act was passed, what are your current thoughts on OTC devices?'. Here, they share their views.

* OTC hearing aids: the good, the bad and the ugly. *ENT & Audiology News* 2017;**26(3)**:86-8.



Sarah Sydlowski,
President, American Academy of
Audiology (AAA).

While the entry of OTC hearing aids will certainly change established delivery models, there is not compelling evidence that the desire of the public to do anything about their hearing loss has evolved. The introduction of new options for the management of hearing loss certainly necessitates that every stakeholder in the hearing industry consider their role and how they can be most effective in their care delivery, but the most important issue is first ensuring that the public understands the importance of hearing health, then that they have a clear path to access safe and effective care that improves their hearing experience and quality of life.

The best scenario for the evolution of hearing care is that the public recognise that hearing is inextricably connected to health and wellness. In that welcome circumstance, the market would expand exponentially, creating space for increased utilisation of devices from OTC to implant, without constraint of the existing market. The enhanced media attention on OTCs, combined with the recognition of the impact of social isolation and communication difficulties without visual cues highlighted by the recent pandemic, creates a previously unparalleled opportunity to elevate the importance of hearing care in the minds of the public. But it's an opportunity to improve access and outcomes that could be missed if more time is spent focused on the device and the delivery model than on reversing apathy to hearing loss.



Kate Carr,
President,
Hearing Industries
Association (HIA).



Stefan Zimmer,
Secretary General,
European Hearing
Instrument
Manufacturers
Association
(EHIMA).

EHIMA and HIA members strongly support broader consumer access to safe and effective hearing devices, whether over-the-counter (OTC) or prescription, in compliance with US regulations. Our members recognise that hearing plays a crucial role in healthy living and overall wellbeing, with a growing body of research demonstrating the costs and health risks related to untreated hearing loss.

We also recognise the important role of the hearing healthcare professional in providing guidance, advice, high-quality care, and overall consumer satisfaction. With the release of the new US regulations, we encourage consumers to take steps to understand their unique hearing loss and treatment options.



Karl Strom,
Editor in Chief,
Hearing Tracker.

I am an advocate of OTC hearing aids. However, in the short term, the finalisation of FDA rules for OTC hearing aids may not ‘open the floodgates’ to a new market as much as I hope or think. That’s because what we now call ‘hearables’ have been around for years, and online hearing aids (eg, Lloyds, HearingHelp Express, etc.) have been around for decades. With the notable exception of the Apple AirPods Pro, which would be equally successful *without* its hearing-aid-like features - few hearables are lighting it up in sales. The better dedicated ‘hearing enhancement’ devices - which might be represented by products like Nuheara Max Pro2, Jabra Enhance Plus, Lexie, Alango, and a handful more - already offer what OTC hearing aids will presumably be promising. As good as they are, these affordable and accessible devices have yet to make an identifiable impact on our market. In fact, some very good hearable companies might not still be around without outside funding. Several (e.g. Doppler, Bose SoundControl, etc.) have made early exits. Akin to the Silicon Valley lament that ‘Hardware is hard’, one could add that ‘Hearing is *really* hard’.

That’s not to say OTC hearing aids won’t be successful. Indeed, I think we’ll see some great innovations and successful products. Through the years, it should be fascinating to watch how these devices evolve and fit (or don’t fit) into different segments of both consumer electronics and hearing healthcare. But history places a *big* question mark on their timeline for success and/or if these products will be strictly dedicated to ‘better hearing’ or, like the AirPods Pro, predominate as attractive add-on features or apps within a larger constellation of hearables.

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Barbara Kelley,
Executive Director,
Hearing Loss
Association of
America (HLAA).

The Hearing Loss Association of America welcomes the final rules from the FDA and the opening of this new market. Many people who could benefit from hearing aids don’t get them for a variety of reasons, not only cost. Some people need situational hearing and might be willing to try a device to help them hear better at work, in a restaurant, and other challenging places. For certain people, a device readily available over the counter could be a first step to better hearing.

Consumers will need information and education about over-the-counter devices, who they are intended for and how they might work. Audiologists can play a role in helping people navigate the process, such as helping people with an OTC device, for a fee. This could be the start of a patient-centred approach to hearing care. Hearing loss usually progresses, and people usually end up in the good care of an audiologist with more advanced technology.

If seeing devices in the market drives people to treatment sooner rather than later, that is a progress. Over-the-counter hearing aids could be one step in making hearing health top of mind for people and understanding how critical it is to not ignore a hearing loss.



Lidia Best,
President, European
Federation of Hard
of Hearing People
(EFHOH).

Discussions around access to affordable hearing care and hearing aids is not a new topic within the European Federation of Hard of Hearing People. In response to our members requests, we have issued the Essen Declaration 2015. Since the Essen Declaration we have seen some progress, but not enough improvement in access to hearing aids and hearing technologies, despite the overwhelming evidence of significant return of investment when integrating hearing healthcare into universal healthcare strategies.

The arrival of the new category of the over-the-counter hearing aids (OTC-HA) in the United States is therefore a worrying development for the EFHOH members, as it could inspire European Health Ministers to stop including hearing aids and hearing care into national health strategies planning. For this and other specific reasons, outlined in our statement, the EFHOH Board urges European Member States and healthcare policy makers to take positive action and follow calls of Essen Declaration 2015 and London Declaration 2017 from hard of hearing associations in Europe.

You can read our statement on OTC-HA by scanning this QR code.



You may also wish to read the EFHOH comment with safety concerns on FDA OTC-HA proposals www.regulations.gov/comment/FDA-2021-N-0555-0451

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