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Are Over-the-Counter Hearing Aids Good for Audiology in Canada?

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Unless you have been trapped in your sound booth for the past few years, you are no doubt aware that consumers are able to access hearing aid-like technology in a variety of ways. Some refer to these as over-the-counter (OTC) hearing aids, hearables, or perhaps a few other names spring to mind. Much of the discussion, and buzz, is coming from south of the border where the United States Food and Drug Administration (FDA) has been tasked with preparing guidelines for the distribution of OTC hearing aids in response to the OTC Hearing Aid Act that was signed into law back in August of 2017. The Act is designed to enable adults with mild-to-moderate hearing loss to access OTC hearing aids without the assistance of a hearing healthcare professional. Naturally, this should spark some questions among Canadian audiologists. Our OTC Interest Group from CAA certainly has a few. The biggest being: What do audiologists in Canada know about OTC hearing aids and what are their thoughts on their potential impact on audiology in Canada.

This article has two aims: (1) to review hearing device terminology related to over-the-counter hearing aids; and (2) to provide a brief history of medical device approval in the US as it relates to hearing aids. With this information, we hope that the readers will have a better understanding of the situation in order to develop an informed opinion about how OTC hearing aids might impact audiology in Canada.

With a goal of starting more dialogue, we'll be gathering your initial thoughts using an online survey found in a link below. To understand where we are today, it is of benefit to look at a little of the history involved. Fortunately, one of the authors (Steve Armstrong) has been deeply involved in worldwide hearing aid development for decades and has touched on the highlights as needed.

Hearing Device Terminology

Air conduction hearing aids will be the focus in this paper, mainly because we are not aware of anyone offering bone conduction hearing aids through anyone but a licensed professional (something that's not too likely to change in the near term). For completeness we have provided the description of a hearing aid below, and just to clarify, we aren't expecting most readers will have too much problem agreeing with it.

Hearing Aid

An ear level device that amplifies sound in an individualized way for each person's hearing loss. Hearing aids use signal processing to automatically adjust the level and relative levels of bass /treble along with limiting the output levels of loud sounds. They are designed to mitigate the impact of permanent hearing loss and are available for most types, degrees, and configurations of

hearing loss. In some provinces, obtaining one is a controlled act and therefore requires a prescription by an audiologist or physician.

From a US perspective, the FDA classifies air conduction hearing aids as Class 1 medical devices. All medical devices require something called a 510K— think of it as a lot of paperwork designed to back up claims of efficacy and safety. For hearing aid manufacturers who would like to release a new product, this adds extra time to the development and product release process.

Wearable

An electronic device with a micro-controller that is worn on the body and is part of the Internet of Things. Activity trackers worn on the wrist or chest are common examples of wearables.

Hearable

These products are essentially a hearing aid and wearable mashup. Most of the manufacturers interested in making hearables are likely to follow the voluntary Consumer Technology Association (CTA) Personal Sound Amplification Product (PSAP) test standard, not the one mandated for hearing aids. Current hearables barely achieve four hours of use on a single battery recharge, hence they are situational-use devices at best. It is also true that most hearables are acoustically configured as closed canal devices, which allows for more bass frequencies when streaming audio, at the risk of occlusion issues.

In contrast when targeting mild-to-moderate hearing losses, we frequently choose to have hearing aids that are of an open canal configuration. Even with wireless streaming our patients are used to much longer battery life.

Personal Sound Amplification Product (PSAP)

The term PSAP was created by the FDA. PSAPs are for situational use in relatively quiet situations (e.g., hunting, bird watching) and are not intended to mitigate the impact of permanent hearing loss. They are not regulated devices and are often available “over-the-counter” or without the need to see a hearing healthcare professional, much like reading glasses. PSAPs are intended for people who have normal hearing and need extra volume during certain activities.

Over-the-Counter Hearing Aids

Technically these don’t exist yet! At least not in the legal context of US FDA rules. According to the OTC Hearing Aid Act, these will be hearing aids that can be obtained by adults with a perceived mild-to-moderate hearing loss without the need to see a hearing healthcare professional for an assessment, recommendation or fitting. Of course, the lack of official rules has not held back some from using the term OTC when referring to what are actually PSAPs and Hearables. The quality and efficacy of the signal processing of these devices compared to hearing aids obtained through traditional channels is currently the topic of much investigation in the hearing industry.

History

FDA and Hearing Aids

As previously mentioned, the creation of the original Hearing Aid Act in 1977 lead the FDA to designate hearing aids as medical devices; complete with all kinds of regulatory oversight. Some number of years ago, the FDA began allowing hearing aids to be introduced without having to go through "premarket approval" of their 510K, assuming the new product did basically the same thing as the previous product and perhaps represented a small evolutionary improvement.

Note, eliminating the premarket approval requirement did not eliminate the paperwork, although it did shorten the product introduction cycle time. Any responsible company would still need to have their 510K documentation file standing at the ready, given that the FDA has the right to demand to inspect a 510k at any time with the understanding that it must be delivered within 48 hours. When manufacturers started introducing noise reduction algorithms (at the tail end of the analog days), the FDA took issue with some of the claims being made and requested proof of performance. As improved speech intelligibility in noise performance was as hard to find then as it is today, there was a real risk that the FDA would reinstate the premarket approval requirement.

Wireless Technology

The introduction of wireless technology also sparked challenges as this represented a significant change from previous technology, and manufacturers had not sought premarket approval, as is required under FDA rules. It all unfolded when a “certain” hearing aid manufacturer sought premarket approval of a product that included tinnitus masking, and happened to also have wireless technology; the FDA took notice of that later. Tinnitus maskers are considered Class 2 devices and are subject to more stringent requirements, including premarket approval (incidentally band aids are also considered a Class 2 medical device).

The FDA was concerned about the wireless aspect of this product from a safety perspective. Faced with a potential shutdown of all wireless product sales the manufacturers, as a group, countered that the wireless aspect was under the jurisdiction of the Federal Communications Commission (FCC), not the FDA. Since the wireless technology had passed all FCC requirements, they felt it did not require FDA permission. Discussions took place and the FCC, together with the FDA, decided that if a wireless hearing aid passed FCC radiation specifications, then it could be brought to market as a Class 2 medical device and eventually even the premarket approval requirement was relaxed.

Personal Sound Amplification Products (PSAPs)

In response to complaints about devices that seemed to resemble hearing aids that could be obtained online or through the mail, the FDA created a new category called PSAP, short for Personal Sound Amplification Product. The FDA regulates devices not products, so in essence they put wording together to describe something over which they do not lay claim to have regulatory oversight. See their Guidance document at https://www.fda.gov/MedicalDevices/ucm373461.htm

The voluntary PSAP testing standard (created by the Consumer Technology Association - CTA) is considerably different from the ANSI S3.22 Hearing Aid test standard, and is in some ways better, but it also has some flaws. For example, while it does specify maximum input referred noise, it does not specify how to configure the product when measuring it. However, it does specify the requirements from a bandwidth perspective to qualify to be labelled as a “wideband” product.

Overall, the PSAP standard strives to predict performance as would be measured on-ear. It makes use of correction factors to take 2cc data and move it into the ear simulator domain, then subtracts the unaided condition, like a CORFIG does.

Some PSAP providers have marketed their products as only intended to allow you to hear in some difficult situations, such as at home while listening to the TV, or out at noisy restaurants, or while driving a car. So much for hunting and bird watching.

The original PSAP Guidance document was viewed by many in the hearing aid manufacturing space as being too open to abuse. The FDA was in the midst of reworking that Guidance when events and initiatives occurred that resurrected the idea of creating an OTC category.

Medical Waiver

As part of their action with OTCs, the FDA started with eliminating the medical waiver requirement effective December 2016. When the Hearing Aid Rule was first created in 1977, it stated that a patient must obtain medical clearance before purchasing a medical device called a hearing aid. This was to protect patients from the unneeded expense of a hearing aid in situations where a medical procedure could treat the loss.

However, forcing someone to seek medical treatment goes against some religious beliefs, such as refusing a blood transfusion. This gave rise to the Medical Waiver, which was anticipated to be used infrequently, and only by those over 18 years of age. It is estimated that the Waiver, just prior to being discontinued, was being used in over 85% of adult hearing aid fittings! Logically, why would you want to burden the patient with a visit to a physician, who may contradict the recommendation of the hearing care professional. As such, the Waiver was useless, and the FDA made immediate changes in December of 2016 ending its need.

OTC Timeline

The FDA took input from the President's Council of Advisors on Science and Technology (PCAST), and the National Academies of Sciences, Engineering and Medicine (NAS) reports which lead to helping develop legislation that passed through both the House and Senate with good support. It was then signed into law by the President in August of 2017, starting the clock ticking.

The FDA was given until August 18h, 2020 to create a proposed rule defining an OTC class of hearing aids; their exact definition has yet to be determined. In fact, they have emphasized that products using the OTC label cannot exist yet. Check it out at https://tinyurl.com/yazmmcv8

Despite the lack of definition, the Consumers Technology Association has declared that the PSAP test standard they created, will be the standard for testing OTCs. Obviously premature, given the FDAs statement. Perhaps noteworthy is that the PSAP standard is based on closed ear canals. If OTC is intended to help those with mild-to-moderate losses presumably a good portion of those could be effectively satisfied by open canal technology.

Various professional organizations in the Hearing Healthcare arena have created a consensus paper with their input to the FDA regarding the OTC rule. It makes an interesting read, and can be found at https://www.hearing.org/news/Consensus_Paper_OTC_HA.pdf

Final Point

OTCs are coming. How they will be defined is not clear at the time of this writing. Currently, PSAPs and Hearables exist, and are available. Some speculate that PSAPs will simply become OTCs, but regulations have yet to be established so this is only conjecture.

Nevertheless, given the proximity of the US market to Canada, we cannot ignore this phenomenon, and a healthy discussion is probably the best course of action. We are very interested in your thoughts on OTC hearing aids and hope you will take the time to complete a survey which can be found at: Survey