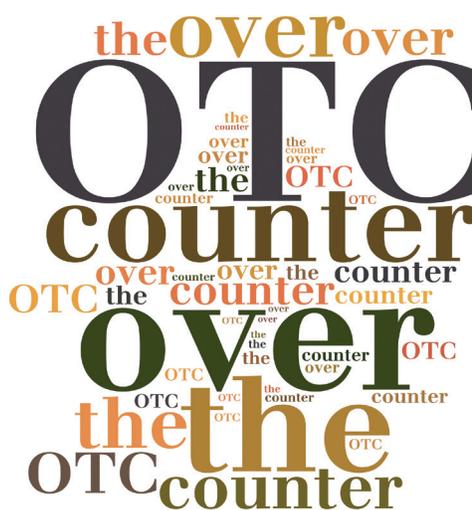


OVER THE COUNTER HEARING AIDS

OPINIONS & PERSPECTIVES 2018

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and

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Views discussed in this article are the opinion of Oticon Inc. and do not necessarily reflect IHS' policy and stand on OTC issues.

Summary: Although we certainly expect the new OTC law to create headlines and news with regard to greater access to, and increased affordability of, hearing aids, we do not anticipate vast changes in the practice of audiology or hearing aid dispensing. Further, we do not expect the advent of OTC hearing aids to significantly change market penetration for people with mild to moderate hearing loss in the United States. With due respect to the as-of-yet unknown rules and regulations which the FDA is developing, we maintain that the very best pathway to success for a person with hearing loss, listening difficulty and/or

communication disorders, to maximally manage their hearing, listening and communication needs, is to acquire excellent products, facilitated via a licensed hearing healthcare professional.

In this article, we will review how access and affordability have been responsibly addressed through the prevailing professional dispensing model for patients seeking solutions to hearing, listening and communication problems.

Indeed, access and affordability are already here.

To be clear, we (Oticon Inc.) have no plans to sell an OTC product in the United States. Entering the OTC market is inconsistent with our vision of the best path forward for people with hearing loss. Rather, our intention is to continue to support the hearing healthcare provider and the well-established professional hearing healthcare pathway, as we have done for decades.

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education quiz on page 55.

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On August 19, 2017, the President of the United States signed into law the Food and Drug Administration (FDA) Reauthorization Act (RA) of 2017. The FDARA includes the Over the Counter (OTC) Hearing Aid Act to provide greater accessibility to, and affordability for, hearing aids, via OTC hearing aids for people with “perceived” mild-to-moderate hearing loss, without involvement of a hearing care professional (HCP). The FDA is charged with creating the guidelines within 36 months of the law’s signing. The Over-the-Counter Hearing Act of 2017 has been one of the most

indeed, OTC is functionally already here. Today, any patient can easily find, purchase and acquire a product labeled “hearing aid” without seeing an HCP.

It is our belief that although the FDA’s new OTC category (when completed) will allow for the entry of new high-tech and low-tech, low-cost and mid-cost hearing aids, it appears unlikely to significantly alter the adoption rate of hearing aids among people with mild-to-moderate hearing loss.

In a recent survey (HealthyHearing.com,

Although we cannot know with certainty, it seems the new OTC category and pathway will encourage *some* people to try OTC hearing aids, from which some may benefit. Perhaps others will see the benefit of hearing healthcare and seek superior, hearing aids delivered by an HCP. However, the OTC initiative may ultimately deter some people from hearing healthcare, as they may become dissatisfied or discouraged and ultimately reject hearing aids.

Oticon’s product design process allows the HCP to customize the hearing aid fitting to deliver the best outcome. We understand and support professional consultation, counseling, hearing aid fitting and selection, appropriate education and training, aural rehabilitation, as well as responsible sales, maintenance, warranty, and service. From our perspective, the interaction between the patient and the HCP has been and remains, a critically important component within the hearing aid acquisition process. That is, HCPs are licensed professionals who deliver medical devices to address a medical condition.

Oticon’s viewpoint is clear.

Hearing loss requires professional attention and management for maximal and multi-focal benefit (i.e., hearing, listening, increased social interaction, decreased depression, decreased anxiety, potential cognitive benefits and more). Hearing care is Healthcare™ and hearing loss is a medical condition maximally addressed by licensed HCPs.

Although we support the majority of the PCAST recommendations, and

polarizing and controversial bills ever to impact the hearing aid industry.

The reality, however, is that OTC hearing aid acquisition is already available to patients in multiple forms and to date, OTC has had little impact on professional hearing aid dispensing. While preparing this article, we purchased multiple OTC hearing aids from three web sites. All products were labeled “hearing aids,” each cost less than \$600, and each was purchased without help or guidance from a HCP. This exercise was undertaken to highlight that,

2017) some 800 people were asked “If you needed a hearing test, how important do you think it would be to have an HCP thoroughly evaluate your hearing loss and make recommendations?” Ninety-four percent of respondents responded “absolutely important” or “very important.” Additionally, respondents were asked, “If you needed hearing aids, how important do you think it would be to have an HCP select, fit, and program hearing devices specifically for your needs?” Again, 94% responded, “absolutely important” or “very important.”



we support OTC protocols for people with mild hearing loss (26-40 dB HL), as we stated in the FTC hearings and via written HIA submissions to FTC and FDA, once a patient has been determined (by an HCP) to have a moderate hearing loss (41 to 70 dB HL), there exists an increased chance of medical, social, and cognitive issues, and we believe these people should be professionally evaluated and managed.

History of OTC in the USA

Of note, the lack of involvement of the HCP in the acquisition of hearing aids is not a new concept; previous distribution models have been challenged and continue to exist.

For example, for over four decades, Lloyd's has been selling hearing aids via mail order without involving HCPs. In fact, their web site states "the first company to offer discounted hearing aids through the mail, now offers those same discounts over the web! For over 45 years, Lloyds has helped people enjoy a better quality of life by solving their hearing problems. We're the real McCoy" (<https://lloydhearingaid.com/>). "Direct to Consumer" (DTC) hearing aid sales without professional involvement was challenged in 2006 by the Missouri Board of Examiners for Hearing Instrument Specialists. In that case, the 8th District Court of Appeals refuted and overturned the State of Missouri's ban of online hearing aid sales without HCP testing and fitting. The District Court of Appeals stated the federal FDA law pre-empts the state-based ban on the same (<http://caselaw.findlaw.com/us-8th-circuit/1432490.html>), allowing the retailer to continue to sell hearing aids without an HCP. In 2014, essentially the same outcome occurred with regard to Metx, LLC. Versus Wal-



Mart Stores, LLC. (<https://www.leagle.com/decision/infdco20140815f15>). Federal laws and state laws are sometimes in conflict, and one must be aware of all aspects and positions while searching for a resolution.

Do Consumers Have Sufficient Access to Hearing Aids?

There are over 17,000 HCPs across the USA, from which one may acquire professional hearing healthcare. The U.S. Bureau of Labor Statistics (2014) reported there are some 12,250 audiologists (although, not all those professionals engage in dispensing hearing aids) in the USA and some 9,050 hearing aid specialists (Staab, 2015; Windmill, 2011). Further, if one were to argue people with hearing loss need *more* access, we would have to ignore the reality that 88% of the USA population has access to the Internet (<http://www.internetworldstats.com/stats.htm>). Additionally, there are already thousands of shops (including Miracle-Ear, CVS, Costco, Sam's Club. . .) that already sell hearing aids, and innumerable web sites that provide OTC hearing aids.

Can Consumers Afford Hearing Aids?

One of the major misconceptions in the discussion about OTC is that all hearing aids cost over \$3000. In reality, consumers have access to many different price points in the current market starting from as low as \$50. Walmart.com (and many other web sites) currently sell hearing aids starting at approximately \$50 each. Calderone (2017) reports Costco sells hearing aids between \$500 and \$1500 each and there are more than 500 Costco outlets in the USA. Every major market in the USA has at least one Costco, and some have more than one (<https://www.statista.com/statistics/269769/costco-number-of-warehouses-worldwide/>). Grundfast and Liu (2017) report multiple brick and mortar locations where hearing aids can be obtained from \$500 each and various web sites sell OTC hearing aids from \$200 to \$500.

Unfortunately, when the President's Council of Advisors on Science and Technology (PCAST, October 2015)

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quoted the “average price of one hearing aid was \$2,363, with premium models costing \$2,898,” this reference lacked substantial context. Specifically, the PCAST reference (Strom, 2014) stated the typical median hearing aid practice dispenses 20 units per month, and of note, 37% of those units were premium, 44% were mid-level and 19% were economy units (i.e., 63% were NOT premium). Further, the average weighted price for economy hearing aids was listed (page 5) at \$1,657, mid-levels were listed at \$2,196 and premiums were \$2,898. Thus, there was a price difference of more than \$1,200 between economy and premium products. Importantly, Strom notes (page 6) the respondents were asked “what was the very lowest price hearing aid the practice offered?” The average response to this query was \$1,025, and the median price was \$995. And of greater significance, 44% of respondents offered a lowest price option for less than \$800.

Therefore, it seems fair to say, the price of hearing aid acquisition varies tremendously and, currently, a pair of hearing aids can be purchased with professional services for less than \$1000. It seems apparent that despite highly variable price points, people tend to not move toward lower priced products, supporting the recognized value of the HCP (as noted below, see HealthyHearing.com).

Is Price the Primary Roadblock?

Valente and Amlani (May 2017) argue cost is not the major barrier to hearing aid acquisition. They reported the adoption rate for people with hearing loss who acquire hearing aids in the USA is about 33%. However, in

countries where hearing aids are fully or partially subsidized by the government, the adoption rate is not remarkably different from the USA. They note in Norway, Switzerland and the UK, where hearing aids are essentially free, the adoption rates are 42.5, 39, and 41% (respectively). However, even when hearing aids are free, 60% of people with hearing loss are unwilling to explore or acquire hearing aids. Valente and Amlani speculate that if the USA fully subsidized hearing aids, the penetration rate would not increase by more than 10%.

Valente and Amlani cited a recent study of more than 600 veterans who were screened and found to have hearing loss. They report fewer than 1/3rd of the 600 veterans complied with the recommendation to seek hearing aids and fewer than half of those (1/6th) adopted hearing aids, despite no out-of-pocket expense related to the acquisition of hearing aids. This example too, illustrates that removing the financial costs associated with hearing aids does not necessarily create increased interest or acquisition.

Finally, if one were to consider price the primary roadblock, we might query “How much would you be willing to spend on an OTC hearing device without professional support available?” This question was recently posed (www.healthyhearing.com) to some 800 people in 2017. Eighty-two percent said they would be willing to spend \$100 or less. This implies people are not willing to pay very much for a hearing aid without the involvement of an HCP. However, they are willing to pay higher prices for the services and expertise performed by licensed professionals, as indicated

by the MarkeTrak IX (MT9) survey. MT9 reported owners of hearing aids rate their satisfaction with their HCPs at 93%, and as noted above (see HealthyHearing.com, 2017) 94% of some 800 people responded that it was “very important” or “absolutely important” to include an HCP in their hearing healthcare to evaluate and make recommendations and select, fit and program hearing aids.

Are Audiograms Enough?

As indicated above, people with mild to moderate hearing loss often do not seek help – unless their hearing loss causes decreases in quality of life, communication difficulty, the inability to effectively function in work, social and/or recreational activities, or creates a specific problem substantial enough to initiate a solution.

That is, audiogram-based hearing loss, in and of itself, may not indicate enough difficulty (for some adults) to seek solutions. The fact that someone has hearing loss (per their audiogram) does not decisively make or break the case for hearing aids. To be clear, quality of life, listening assessments, listening needs, and individual perceptions and problems secondary to hearing loss are equally (or more) important than an audiogram. The role of the HCP is to accumulate all of this information and to use it to effectively guide the person with hearing loss to the solution which best meets their individual needs.

The National Academies of Science, Engineering and Medicine (NASEM, June 2016, <http://nationalacademies.org/hmd/reports/2016/Hearing-Health-Care-for-Adults.aspx>) reported for a “variety of reasons, many people

with hearing loss do not seek out or receive hearing healthcare. Estimates of hearing aid use are that 67 to 86 percent of adults (50 years and older) who may benefit from hearing aids do not use them...”

Simple measures of hearing thresholds, such as those demonstrated on audiograms are important, but are not the exclusive and decisive issue upon which amplification decisions are made.

Best Practices for Hearing Aid Dispensing

With the upcoming OTC pathway and category, we remain concerned that Best Practices might be compromised. That is, hearing aids fitted exclusively by audiograms do not fulfill the Best Practice recommendations of the American Academy of Audiology (AAA, 2006) or the American Speech Language Hearing Association (ASHA, 1998). Recently, Beck and Valente (2017) reviewed the “Greatest Hits” of Hearing Aid Dispensing Best Practices (Dr. Valente was the lead author for the working groups who developed the AAA and ASHA Best Practice Guidelines). Some factors which must be addressed to provide a Best Practice hearing aid fitting include: a thorough audiologic evaluation, a needs assessment (including unaided speech recognition in noise and perhaps an unaided questionnaire assessing the patient’s perception of his/her unaided performance in a variety of listening situations), a Hearing Aid Evaluation (HAE) to determine which hearing aids are most appropriate, ear mold selection, potential accessories (assistive listening devices and more) which best meet the needs of the individual, coupler measurements



of the selected hearing aids to verify adherence to manufacturer specifications (which include assessing the directional microphones and noise reduction), a Hearing Aid Fitting (HAF) appointment which includes real-ear measures (REM) and aided speech-in-noise testing, and validation measures to assess outcomes.

In brief, assessing and programming hearing aids based exclusively on audiograms is not in accordance with Best Practice guidelines. We’re hopeful that Best Practice considerations (as established by AAA, ASHA and briefly reviewed above) will be considered by the FDA (as it relates to labeling) to maximally address the needs of people with hearing loss with respect to their hearing care needs, options and preferences.

Potential Problems and Pitfalls

Other issues which are difficult to quantify with respect to OTC hearing aid acquisition include:

1. **Confusion for consumers/patients with regard to Personal Sound Amplification Products (PSAPs), OTC, and traditional hearing aids.** There exists limited data indicating

patients can self-diagnose, select, fit and program hearing aids effectively to solve their hearing, listening, and/or communication problems.

2. **Lost patients.** It is possible consumers purchasing OTC devices without an HCP may lose interest in hearing aids and may not seek additional help. The consumer who self-diagnoses and self-fits OTC products may think “I tried hearing aids, they didn’t work for me...”
3. **Unknown OTC impact.** There exists an overwhelming amount of literature relating and correlating untreated hearing loss to cognitive decline, auditory deprivation, increased anxiety, increased depression, increased stress, less social interaction and general decreases in overall health. Given the OTC model, there is no professional involvement, and the long term outcomes of OTC remain unknown.
4. **Poorly fit hearing aids.** Poorly fit and over-fit hearing aids (i.e., too much sound) may cause additional temporary and permanent problems such as: threshold shifts, tinnitus,

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aural discomfort, vertigo, dizziness, and more.

Discussion & Viewpoint

In brief, one could argue OTC and traditional hearing aid dispensing models represent different patient journeys. That is, although the products may or may not appear similar, the major difference in these journeys is the involvement of the licensed professional. The HCP's role is to test, assess, select, prepare realistic expectations, program, provide counsel, maintain products, and provide warranty services and more. As such, the value of the HCP cannot be overstated. Abrams (2015) reported the results of the MT9 national survey of 1000 hearing aid owners and 2000 non-owners. With regard to the hearing aid itself, Abrams reported satisfaction has increased from 74% to 81% in the last decade and satisfaction is even higher with newer hearing aids—at 85% for products four years old or newer. However, with specific regard to the HCP, satisfaction with hearing care professionals has also increased. Owners of hearing aids rate their satisfaction with their licensed professionals at a noteworthy 93%. At Oticon, we have maintained that the HCP's professional knowledge and expertise (testing, counseling, instrument selection, programming, aural rehabilitation protocols and more) are an essential factor in a contemporary hearing aid delivery system. To be clear, we (Oticon Inc.) have no plans to sell an OTC product in the United States. We have supported and will continue to support the critically important role of the HCP in the hearing aid acquisition process.

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Gary Rosenblum has been President of Oticon, Inc. since October of 2016. Prior to Oticon, Gary ran several medical device and consumer healthcare businesses for Fortune 500 companies including Johnson & Johnson, Abbott Labs, and Pfizer. Gary earned his MBA from Cornell University and his BA in Psychology and History from Washington University in St. Louis.



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As of 2018, with due respect to the changes occurring around us and the as-of-yet unknown rules and regulations which the FDA is developing, we underscore and maintain that the very best pathway to success for a person with hearing loss, listening difficulty, and/or communication disorders, to maximally manage their hearing, listening, and communication needs, is to acquire excellent products, facilitated via a licensed healthcare professional. ■