



March 31, 2017

Federal Trade Commission
Office of the Secretary
600 Pennsylvania Avenue N.W.
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Washington, DC 20580

RE: Hearing Health and Technology – Workshop, Project No. P171200

The Hearing Industries Association (HIA) appreciates the opportunity to provide comments to the Federal Trade Commission (FTC) on the availability, accessibility, and adoption of hearing aids. As the national trade association of manufacturers of hearing aids, assistive listening devices, component parts, and power sources, HIA has a considerable interest in this issue. Our members consist of 17 companies representing approximately 30 hearing aid brands that constitute over 90 percent of the hearing aids sold in the United States on an annual basis. These companies spend over \$600 million per year on research and development for hearing aids. They collectively employ more than 6,000 engineers and scientists who work to develop sophisticated hearing aids and algorithms to process sound so that it resembles natural hearing with minimal power consumption. Further, HIA has long supported various efforts to inform consumers about hearing aids.

Our members are highly innovative and are consistently at the cutting edge of digital innovation; over the past decade, they have, among other developments, successfully miniaturized hearing devices through nanotechnology and flex circuitry,

developed Bluetooth and wireless features for content streaming, and linked hearing aids with smart phones to maximize performance in a wide variety of listening environments. Over the past three years, smart hearing aids have won the Consumer Technology Association’s CES “Best of Innovation Awards;” SXSW Interactive Innovation Awards & Edison Awards; Bluetooth Breakthrough Awards; German Design Awards; Good Design Awards; Red Dot Awards; and several other awards.¹ Despite these impressive achievements in innovation, some HIA members manufacture hearing aids that can be purchased for as little as \$500, including professional services.² Patients across the industry are receiving significantly more advanced technology for the same cost as a few years ago.

The hearing aid market is not the stagnant and outdated market that some recent reports would have one believe.³ While some non-owners are not aware of enhanced technology, the new practical functions and enhanced features are associated with increased satisfaction rates and usage.⁴ The year-over-year increase in hearing aid unit sales in 2016 rose to 8.6 percent from the traditional 4-5 percent, substantially increasing the number of people with hearing loss who benefit from using hearing aids. Satisfaction with current hearing aids is high and growing, with a 91 percent satisfaction rating for those obtained since 2014; 77 percent for hearing aids obtained between 2010 and 2013; and 74 percent for hearing aids obtained prior to 2010.⁵ Furthermore, overall satisfaction has increased from 74 percent in 2008 to its current level of 81 percent.⁶ Based on more

¹ HIA, Hearing Aid Industry Report (2017).

² See Costco for a variety of hearing aids made by various manufacturers, including ReSound, Siemens (Costco’s Kirkland brand), and others, starting at \$499, including professional services, <https://www.costco.com/hearing-aid-styles.html>.

³ See President’s Council of Advisors on Science and Technology, Letter to President Obama, 2 (Oct. 2015) (“PCAST Report”), https://obamawhitehouse.archives.gov/sites/default/files/microsites/ostp/PCAST/pcast_hearing_tech_letterreport_final.pdf.

⁴ Harvey B. Abrams, PhD, and Jan Kihm, MS, *An Introduction to MarkeTrak IX: A New Baseline for the Hearing Aid Market*, Hearing Review (May 15, 2015), <http://www.hearingreview.com/2015/05/introduction-marketrak-ix-new-baseline-hearing-aid-market/>.

⁵ *Id.*

⁶ *Id.*

than 30 years of data from MarkeTrak – a tracking survey of the hearing aid market – overall satisfaction with hearing aids is at its highest level ever. Better products and better experiences with hearing care professionals contribute to the improving satisfaction rates. It is clear that the hearing aid industry has made significant progress on both the technological and the consumer satisfaction fronts.

HIA appreciates FTC’s interest in the affordability and accessibility of hearing aids for all consumers. It is important, however, that affordability and accessibility do not come at the cost of safety or effectiveness. Hearing aids are, after all, medical devices intended to treat a disease or condition. To that end, HIA believes that all hearing aids, regardless of method of sale, should be required to comply with the general controls established by the Food and Drug Administration (FDA).

With Congress and FDA exploring an over-the-counter (OTC) model for hearing aids, HIA suggests that the new OTC delivery channel for hearing aids proposal may be effective only for a subset of patients. It is important to note that the proposed OTC model will not be a shift in technology, but only a new mechanism for delivering the product. The relevant question therefore is whether consumers can diagnose their own hearing loss and program their own hearing aids to best address their specific type and level of hearing loss or whether professional assistance is needed. With adequate FDA controls in place, OTC may be suitable to address mild hearing loss – where the consequences of ineffective treatment are low – but is not appropriate for the treatment of moderate or more severe hearing loss where the risks of failure and further delay in treatment are significantly greater.

The extent of hearing loss and its impact on different individuals varies significantly. There is no technology or product that can be sold as a “one-size-fits-all” hearing solution. Mild hearing loss, which is generally defined as difficulty hearing soft

speech or sounds,⁷ is more amenable to self-treatment than more severe degrees of hearing loss. HIA therefore believes that the risks of under-treatment or failed treatment leading to the potential abandonment of more effective hearing loss treatment is far greater for people with moderate hearing loss than those with mild hearing loss. Limiting OTC hearing aids to those with mild hearing loss only is consistent with the Consumer Technology Association's (CTA's) position as set forth in a recent press release, which states that "[t]he high cost of hearing aids, combined with the inconvenience and cost of doctor appointments, results in most adults with *mild* hearing loss not getting the hearing assistance they need" and further suggests that Personal Sound Amplifiers (PSAPs) – but more appropriately OTC hearing aids for the treatment of hearing loss – “can provide a less expensive, readily available array of products that can aid the millions of Americans living with *mild* hearing loss.”⁸ With two-thirds of all Americans with hearing loss having mild loss and only an estimated 12 percent of these people currently wearing hearing aids,⁹ OTC hearing aids could improve adoption rates in this population while presenting a favorable benefit-risk profile. Conversely, an estimated 50 percent of individuals with moderate hearing loss currently use hearing aids.¹⁰ This population, which is already utilizing hearing aids at a substantial rate, would be much less likely to be able to self-diagnose and self-manage with OTC hearing aids, and the impact of an erroneous treatment would be much greater.

Nevertheless, self-treatment will not be a panacea, even for patients with mild hearing loss. The CTA, the trade association for the consumer electronics industry and

⁷ Julia Calderone, *Hearing Loss: No More Suffering in Silence?*, Consumer Reports (Feb. 2, 2017), <http://www.consumerreports.org/hearing-aids/hearing-loss-no-more-suffering-in-silence/>. There is, however, complexity in this definition, as a patient may have one type of hearing loss in one ear and another in the other ear.

⁸ CTA, Press Release, CTA Applauds Bipartisan, Bicameral Effort to Bring Hearings Aids Over-the-Counter (Mar. 21, 2017) (emphasis added), <https://cta.tech/News/Press-Releases/2017/March/CTA-Applauds-Bipartisan-Bicameral-Effort-to-Bring.aspx>.

⁹ HIA, Final Report, MarkeTrak 9: A New Baseline, Estimating Hearing Loss And Adoption Rates and Exploring Key Aspects of the Patient Journey, slide 39 (Mar. 2015) (“MarkeTrak 9”).

¹⁰ There are varying classifications for degrees of hearing loss, and FDA combines “moderate” and “moderately severe” hearing loss into an all-encompassing “moderate” category. This would mean people with very significant 70dB hearing loss would be advised to purchase an OTC device. This is yet another reason why HIA believes that referring people who will know they have a “moderate” hearing loss to purchase an OTC device is not sound policy.

PSAP manufacturers, speculates that self-treatment will act as a “gateway for consumers who may struggle with hearing in certain situations, but cannot afford the cost of hearing aids and related medical visits.”¹¹ But this is an untested hypothesis, at least in the United States.¹² With the same evidence, one could conclude that ineffective self-treatment may lead some to frustration and further delay in getting effective therapy based on a belief that if an OTC hearing aid does not work, no hearing aid will work. And this possibility is of particular concern because of the variable nature of hearing loss – it is much more complicated than simply amplifying sounds – and the complexity and critical importance of proper and customized programming and fitting of the device (collectively known as “fit” in the industry). It is expected that many patients will not be successful with self-fit OTCs.¹³

These caveats notwithstanding, HIA supports the endeavor to reduce the barriers to access hearing loss treatment. Regardless of the method of sale, HIA members will continue to design and innovate to improve the quality of life of individuals with hearing loss. HIA’s position is one that emphasizes consumer safety, not market protectionism. Consumers will not benefit by getting easier access to lower cost hearing aids that are unsafe or ineffective.

¹¹ Comments of CTA, Docket No. FDA-2013-D-1295, 5 (May 6, 2016).

¹² In South Korea and Japan the results were the opposite. Both countries allow OTC hearing aids, and both countries have low adoption and satisfaction rates.

¹³ National Academies of Sciences, Engineering, Medicine, *Hearing Health Care for Adults: Priorities for Improving Access and Affordability* 35 (June 2, 2016) (“NAS Report”); see also discussion, *infra*, at pg. 12-13; Larry Humes et al., *The Effects of Service-Delivery Model and Purchase Price on Hearing-Aid Outcomes in Older Adults: A Randomized Double-Blind Placebo-Controlled Clinical Trial*, 26 *Am. J. Audiology* 53 (Mar. 2017) (“CD service-delivery model [self-selected pre-programmed high-quality hearing aids via an OTC model] was efficacious, with similar effect sizes. However, CD group had a significantly ($p < .05$) lower satisfaction and percentage (CD: 55%; AB: 81%; P: 36%) likely to purchase hearing aids after the trial).

I. Background

A. Hearing loss is a medical condition.

As noted, HIA and its members support greater access to hearing aids. Hearing aids are the treatment of choice for the vast majority of adults with hearing loss, and they play a critical role in improving communication function and quality of life. The scientific literature shows that untreated hearing loss is associated with social isolation, loss of independence, depression, dementia, and increased risk of falls.¹⁴ Though hearing loss is a common corollary to aging, its impact can be serious.

Hearing loss is a multifactorial condition, which requires a complex and skill-based approach to its treatment. There is a significant sensorineural component to hearing loss suffered by the vast majority of adults. Increasing audibility alone is often not sufficient to resolve their complex communication issues.¹⁵ In addition to diminished audibility, hearing loss often involves diminished frequency resolution (difference in pitch), diminished temporal resolution (timing), or diminished loudness perception (range between softest and loudest sounds). Some hearing loss is also situational: discussions of hearing loss include not just idiosyncratic etiologies, but different levels of loss and audibility in differing settings. Hearing aids incorporate advanced signal processing algorithms that are designed to address the complex interactions between a damaged sensory organ, the desired input speech signal, and interfering environment sounds. Consequently, expertise in the selection, fitting and programming of these devices, as well as counseling patients in the likely benefits and limitations of amplification, is often critical for optimizing treatment outcomes.¹⁶

¹⁴ Seniors Research Group, *The Consequences of Untreated Hearing Loss in Older Persons*, Nat'l Council on the Aging (May 1999); Stig Arlinger, *Negative Consequences of Uncorrected Hearing Loss—A Review*, 42 Int'l J. of Audiology 2S17 (July 2003); NAS Report, *supra* n.13, 273-74.

¹⁵ Calderone, *supra* n.7.

¹⁶ Humes et al., *supra* n.13.

In addition to the complexity of the medical condition itself, there are other non-cost barriers to hearing aid access. A study of the dynamics of hearing aid acquisition in the United States hearing impaired population showed that individuals with self-reported hearing difficulties wait, on average, 4.8 years from acknowledgement of a hearing problem until they take action.¹⁷ While some attribute this delay simply to cost, research shows that other non-cost factors play a greater role.¹⁸ For example, those with self-reported mild hearing difficulty often report that they do not believe that their hearing loss is severe enough to warrant a hearing aid.¹⁹ Others report that they will wait until their doctors tell them hearing aids are necessary – a conversation that does not happen frequently enough.²⁰ Patients who experience difficulty in some but not all situations may believe that they may not yet “need” hearing aids.²¹ While cost appears to become the primary barrier among those individuals who report more severe hearing difficulties, a recent study shows relatively little price sensitivity even with a six-fold difference in cost.²² HIA supports lower costs and greater accessibility to hearing aids, but notes that other factors will play an even larger role in influencing hearing aid adoption rates.

B. Hearing aids are medical devices.

Any product “intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease” or “to affect the structure or any function of the body of man or other animals, and which does not achieve [any of] its primary intended purposes through chemical action” is a medical device under the

¹⁷ MarkeTrak 9, slide 162.

¹⁸ Abrams and Kihm, *supra* n.4.

¹⁹ MarkeTrak 9, slide 133.

²⁰ MarkeTrak 9, slides 59, 133; NAS Report, *supra* n.13, at 79-80. MarkeTrak 9 does show that about 20 percent of adults report being asked about their hearing during their most recent physical examination, which is an increase.

²¹ MarkeTrak 9, slide 133; Calderone, *supra* n.7.

²² Humes et al., *supra* n.13.

Federal Food, Drug, and Cosmetic Act (FDCA).²³ FDA classifies devices based on their level of risk.²⁴

Currently, air conduction hearing aids are classified as a Class I device, the lowest risk classification.²⁵ Those that incorporate wireless or bone conduction features are considered Class II, or moderate risk devices.²⁶ Class II devices require greater regulatory controls to provide reasonable assurance of safety and effectiveness. Approximately 88 percent of hearing aids sold in the United States in 2016 contained wireless features and were therefore categorized as Class II devices. Regardless of classification, all hearing aids are subject to the Quality System Regulations (QSRs),²⁷ as well as other general controls, such as establishment registration, device listing, labeling requirements, reporting, and correction and removal notification requirements. FDA regulations also require all medical device labeling or promotional claims to be supported by valid evidence.

In addition to federal requirements, hearing aids are subject to various state requirements. While requirements vary by state, most states mandate a 30- or 60-day trial period during which a full refund may be obtained by a purchaser.²⁸ Also, most states have provisions governing notice, contracts, device descriptions, and include services to ensure provider accountability.²⁹ Hearing health professionals must be licensed.

²³ FDCA § 201(h), 21 U.S.C. § 321(h).

²⁴ *Id.*; see also FDCA § 513, 21 U.S.C. § 360c.

²⁵ 21 C.F.R. § 874.3300(b); FDA, What does it mean for FDA to “classify” a medical device? (last updated Dec. 28, 2015), <https://www.fda.gov/AboutFDA/Transparency/Basics/ucm194438.htm>.

²⁶ FDA, What does it mean for FDA to “classify” a medical device? (last updated Dec. 28, 2015); 21 C.F.R. § 874.3305(b).

²⁷ See 21 C.F.R. Part 820.

²⁸ See, e.g., Alaska Stat. §§ 08.55.050, 08.55.110; Cal. Bus. & Prof. Code § 2539.4, Cal. Civ. Code §§ 1793.02, 2538.35; Ill. Admin. Code tit. 77 §§ 682.110, 682.115, 225 Ill. Comp. Stat. 50/6.

²⁹ *Id.*

C. PSAPs are not hearing aids.

Only devices intended to treat hearing loss are considered hearing aids, which excludes PSAPs. PSAPs are intended only for non-hearing impaired consumers. They are designed to accentuate sounds in specific listening environments, such as bird watching or hunting, but they are not intended for everyday use or to correct hearing loss.³⁰ As recognized by the National Academy of Sciences (NAS), “PSAP manufacturers and distributors are not supposed to be offering their products for the purpose of compensating for hearing loss. This legal and regulatory distinction between hearing aids and PSAPs might not be readily apparent to users, and it might not be fully respected by PSAP sellers who explicitly or implicitly offer their products to compensate for hearing loss.”³¹ But because PSAPs are not intended to diagnose, treat, cure or mitigate disease and do not alter the structure or function of the body, they are not devices as defined in the FDCA. As such, FDA has very limited regulatory authority over PSAPs, and PSAPs are not subject to regulatory controls or premarket notification.

The distinction between a hearing aid and a PSAP is an important one for protecting patients. The products are not interchangeable and cannot be considered as such. The embedded chip technology in a hearing aid is much more sophisticated than that of the standard PSAP currently marketed; directional measurements, compression ratios, frequency manipulations, and feedback management all require sophisticated intervention. PSAPs are designed to amplify only and therefore *cannot* be used to treat sensorineural hearing loss. Because PSAPs are not intended to treat hearing loss, they cannot be fitted or tailored to an individual’s specific communication requirements.

³⁰ FDA, Guidance for Industry and FDA Staff: Regulatory Requirements for Hearing Aid Devices and Personal Sound Amplification Product (Feb. 25, 2009), <https://www.fda.gov/MedicalDevices/ucm127086.htm>.

³¹ NAS Report, *supra* n.13, at 189.

Furthermore, because PSAPs are not medical devices, they are not subject to safety and efficacy oversight or regulatory controls.³² FDA has no authority to require that a PSAP be recalled should patient safety issues arise or PSAPs be ineffective. Nor does a PSAP manufacturer need to inform FDA of a recall. PSAP manufacturers are not even required to submit a report should their product injure a consumer.³³ FTC itself has said “[i]f your hearing is impaired don’t use a PSAP as a substitute for a hearing aid. That may delay the diagnosis of a potentially treatable condition, and cause more damage to your hearing.”³⁴ The NAS Report recommended maintaining the distinction between PSAPs and hearing aids “to ensure that consumers with hearing loss receive the benefits relating to quality, performance, compatibility, and labeling envisioned under the OTC wearable hearing device category.”³⁵

II. FTC’s Questions

FTC has posed five questions designed to help foster an understanding of the competitive landscape associated with hearing aids. FTC has said that its goal is to encourage an accessible and innovative hearing aid market. HIA agrees with this objective. Based on our members’ extensive experience in the market, HIA addresses each FTC question in turn.

A. What information about hearing technology and related health care services is available to consumers who may be shopping for these goods and services? How useful do they find this information?

³² Unless the PSAP is an electronic product that emits sonic vibrations and is subject to the electronic product provisions of the FDCA that also apply to non-device products. See FDCA §§ 531-542 (21 U.S.C. §§ 360hh-36ss); NAS Report, *supra* n.13, at 180.

³³ And this is indeed a risk. According to a recent Consumer Reports article, “these devices have the potential to cause additional hearing damage by overamplifying sharp noises, such as the wail of a fire engine” and “[PSAP machines that cost less than \$50] don’t seem to help much—if at all—and could actually further diminish your ability to hear.” Julia Calderone, *Can PSAPs Help Your Hearing?*, Consumer Reports (Feb. 2, 2017), <http://www.consumerreports.org/hearing-ear-care/can-psaps-help-your-hearing/>.

³⁴ FTC, *Sound Advice on Hearing Aids*, 2 (Sept. 2010), http://www.devicewatch.org/reports/ftc_hearing_aids.pdf.

³⁵ NAS Report, *supra* n.13, at 192.

Because hearing loss is a medical condition, much of the information about hearing technology and health care services is obtained through physicians, audiologists or hearing instrument specialists (collectively “hearing health professionals”). Industry has made a concerted effort to increase available informational resources for consumers. To that end, HIA’s educational arm, the Better Hearing Institute (BHI), has engaged in a consumer education effort to help people with hearing loss stay active and connected. Supported by the hearing aid industry for over 40 years, BHI conducts the only longitudinal survey of people with hearing loss including both hearing aid users and non-users. This study is the only available source of longitudinal data about attitudes toward hearing aids. The data are disseminated through an array of media sources, both internet and print. BHI also publishes on its website a plethora of materials about both hearing loss and hearing aids, including a Guide to Buying Hearing Aids, and a Guide to Talking to Physicians About Hearing Loss is forthcoming shortly.³⁶ In the past few years, the number of views of the BHI website has jumped as millions of people rely on it as a source of hearing loss and treatment information.

BHI is not alone. Virtually every non-profit entity in the hearing industry has a thorough and substantive website on hearing loss and related technology, as does the federal government through the National Institute on Deafness and Other Communication Disorders (NIDCD) and the Centers for Disease Control and Prevention.³⁷ AARP, Inc., whose nearly 38 million members comprise a large proportion of hearing loss patients, offers comprehensive information on its websites, and authors a multitude of articles in its magazine and on its website.³⁸ Multiple other sources also make available information and resources. Consumer Reports, for example, publishes an extensive Hearing Aid

³⁶ BHI, Guide to Buying Hearing Aids (2010), http://clienthiadev.devcloud.acquia-sites.com/sites/default/files/hearingpedia/Guide_How_to_Buy_Hearing_Aids.pdf.

³⁷ See NICD, Hearing, Ear Infections, and Deafness, <https://www.nidcd.nih.gov/health/hearing-ear-infections-deafness>; CDC, What If I Already Have Hearing Loss, https://www.cdc.gov/nceh/hearing_loss/what_if_i_already_have_hearing_loss.html.

³⁸ See AARP Hearing Center, <http://www.aarp.org/health/conditions-treatments/hearing-resource-center/>.

Buying Guide, which includes sections dedicated to understanding hearing aids, important features, hearing aid provider selection, and shopping tips.³⁹ Consumer Reports even provides ratings for hearing aid models, comparisons between brands, and evaluations of PSAPs. Furthermore, all hearing aid manufacturers offer commercial websites containing consumer information and online hearing screening tools.

Despite the abundance of hearing technology and related hearing health care services information available to the consumer, some of that information may be difficult for consumers to understand without a learned intermediary. Adult-onset hearing loss is a complex condition, and the modern hearing aid represents state-of-the-art digital technology with hundreds of possible style-feature combinations. Consequently, consumers generally benefit from conversations with a hearing health professional to understand the complex nature of their particular hearing loss and associated hearing aid needs. Without this assistance, it is very difficult for the patient to discern which hearing aid will be most effective or which settings or programmable features to select in that hearing aid.

The nature of hearing loss is highly individualized.⁴⁰ Combining individual physical characteristics, such as the size, shape, and volume of the ear canal, with non-auditory factors such as cognitive function, motivation, manual dexterity, and family dynamics, creates a unique challenge.⁴¹ Situational hearing loss adds further complexity.⁴² Additionally, as described, there is a surplus of information available on hearing aids and health care; parsing through this information to decide which OTC hearing aid is appropriate would likely be challenging for many consumers. For this

³⁹ Consumer Reports, Hearing Aids, <http://www.consumerreports.org/cro/hearing-aids.htm>.

⁴⁰ Calderone, *supra* n.7 (“You can have two people with identical audiograms who have very different functionality”) (internal quotations omitted).

⁴¹ American Speech-Language-Hearing Association, Hearing Aids for Adults (last visited Mar. 24, 2017), http://www.asha.org/PRPSpecificTopic.aspx?folderid=8589935381§ion=Key_Issues.

⁴² Donald J. Schum, PhD, *Situational Performance of Noise Reduction and Directionality*, Audiology Online (May 16, 2011), <http://www.audiologyonline.com/articles/situational-performance-noise-reduction-and-830>.

reason, significant hearing loss is a medical condition that is not readily susceptible to self-treatment. HIA therefore does not support OTC access for moderate or more severe hearing loss, as the risks of ineffective treatment are high.

A recent placebo-controlled, double-blind, randomized clinical trial illustrated the advantages of consultations with a hearing health professional in the hearing aid selection and fitting process. The study and associated paper by Larry Humes et al. compared different service-delivery models among participants with hearing loss. The results suggested that there were no significant differences between the two approaches on five of the six outcomes – the exception, however, was the critical measure of satisfaction. Satisfaction significantly increased for those participants who initially received OTC devices following additional treatment under the audiology best practices (AB) model in which the patients received assistance from audiologists.⁴³ While 81 percent of the participants who were assigned to the AB group said they would keep their hearing aids, only 55 percent of the participants in the OTC group said the same.⁴⁴ At the end of the initial six-week trial, 44 of 53 (83%) in the AB group actually purchased their hearing aids compared to only 1 of 51 (2%) in the OTC group. Following the six-week trial, 49 participants in the OTC model participated in an additional four-week trial that included professional adjustments to their OTC hearing aids before deciding to purchase. Notably, after four weeks of assistance from an audiologist, the percentage of willing purchasers in the OTC group jumped significantly.⁴⁵

It should be stressed that the research participants in both the AB and OTC groups received baseline audiologic evaluations and the same high-end, commercially-available digital hearing aids – conditions that *will not* occur in the real world of OTCs. The authors wrote, “The observation that the CD participants self-select hearing aids that are

⁴³ Humes et al., *supra* n.13. Of note, the study used only technologically-advanced hearing aids.

⁴⁴ This group was not fully representative of an OTC group, e.g., the patients were evaluated by a hearing professional against study inclusion/exclusion criteria.

⁴⁵ *Id.*

somewhat under-powered may explain some of the inferior outcomes observed in this group compared to the AB participants.”⁴⁶ And while HIA agrees that affordable and accessible hearing aids are clearly in the best interests of the consumer, HIA also believes that the best hearing aid for a consumer is the one that is worn.

B. How are hearing aids and other forms of hearing technology commonly distributed and sold? To what extent are new sellers of hearing devices, as well as new methods of distribution and sales, affecting the range of goods, services, and prices available to consumers?

As previously noted, hearing aids have traditionally been sold and distributed through hearing health providers. But the market has been expanding to include alternative types of providers, leading to increased access to hearing aids at lower costs.

Most notable is the addition of “big box” stores to the hearing aid market. Warehouse stores, like Costco and Sam’s Club, have implemented “Hearing Aid Centers” to offer the full array of hearing health services at value pricing. Big box stores now account for at least 10 percent of the private United States hearing aid market, and their market share continues to grow.⁴⁷ All of these stores provide safe and effective FDA-compliant hearing aids while providing increased economical access. These stores have been able to bring down costs for consumers while providing professional services, warranties, and advanced technology. Other types of distributors, such as pharmacy chains, have announced they are considering entering the market to provide professionally-fit hearing aids as well.⁴⁸

⁴⁶ *Id.* at 75.

⁴⁷ *US Hearing Aid Unit Sales Increased by 8.7% in 2016*, Hearing Review (updated Feb. 9, 2017), <http://www.hearingreview.com/2017/01/us-hearing-aid-unit-sales-increased-8-7-2016/>.

⁴⁸ *See, e.g.,* Laura Northrup, *CVS Will Experiment With Selling Glasses and Hearing Aids in Some Stores*, *Consumerist* (Oct. 5, 2015), <https://consumerist.com/2015/10/05/cvs-will-offer-glasses-and-hearing-aids-in-stores-as-pilot-project/>.

Additionally, the internet has opened up other avenues of sales that increase access to services and lower prices of both goods and services. For example, the internet has made it easier to locate and identify service providers, and patients in underserved areas can consult with hearing health professionals on the phone or through webcasts to address issues with hearing aids. And some companies have adopted a direct-to-consumer model of sales through the internet.⁴⁹ This model requires the submission of an audiogram conducted by a hearing health professional or a programming kit at an additional cost, but proper fit remains an issue. Other companies, like Hearing Planet, are researching ways to make online consultations work as technology continues to evolve. These new sales and distribution models are indeed having a positive impact on the accessibility of hearing aids.

As a consumer-electronic product rather than a medical device, PSAPs do not follow the traditional hearing aid sales distribution model. As long as they are not marketed to treat hearing loss, there are no restrictions or requirements governing the sale of PSAPs. PSAPs are generally sold directly to consumers without regard to fit or suitability for meeting that consumer's needs. Their sole mode of action is amplification. While they are indeed more easily accessible in that the consumer does not need to be examined by a hearing professional, they come with none of the same protections. There is no mandatory return or warranty period, no recordkeeping, no quality enforcement, and no FDA oversight of recall procedures for most PSAPs.

Illustrating the potential downside of increasing accessibility while sharply diminishing oversight, the measured output of some PSAPs indicate they may pose a risk to hearing due to their high decibel levels.⁵⁰ They also have been known to exacerbate existing hearing loss.⁵¹

⁴⁹ See, e.g., iHear Hearing Solutions, <http://iheardmedical.com/hearing-solutions#comparisonChart>.

⁵⁰ See European Association of Hearing Aid Professionals (AEA)/European Federation of Hard of Hearing People (EFHOH), Paper on the potential risk of using 'Personal Sound Amplification Products' PSAPs (Dec. 2015).

⁵¹ Calderone, *supra* n.33.

Yet the greater threat comes from the opportunity costs. Patients who use a PSAP forego the chance to receive effective hearing loss therapy. This, in turn, can mean greater social isolation and increased medical risks. Based on a bad PSAP experience, these patients run the risk of assuming that hearing aids do not work and may decide to defer or forego treatment altogether.⁵² FTC can help address this by ensuring that only clear, truthful, and non-misleading claims are made with respect to PSAPs.

It is important to recognize that the cost of hearing aids has long varied widely. A commonly repeated misconception is that hearing aids cost consumers between \$2,300 and \$2,800 each.⁵³ According to Consumer Reports, consumers can find a custom-fitted hearing aid including service for as little as \$500.⁵⁴ Only approximately one-third of this cost is for the device itself. The other two-thirds of the cost are associated with a multitude of crucial hearing aid-related evaluation and treatment services provided by the hearing professional, including multi-year follow-up care to adjust and maintain the devices as needed.⁵⁵ And, as noted, consumers currently receive sophisticated and advanced technology without corresponding increases in cost.

Hearing loss is a process, not a single event; hearing aids therefore need to be adjusted over time, and patients need to be monitored as hearing evolves. Without a post-purchase services package, consumers will need to pay for professional services as discrete, separate costs. The potential impact of needing to pay separately for

⁵² See AEA/EFHOH, Paper on the potential risk of using ‘Personal Sound Amplification Products’ PSAPs (Dec. 2015). There is no evidence to show that this scenario is any less likely than the suggestion that PSAPs will serve as a gateway to further hearing assistance.

⁵³ See PCAST report, *supra* n.3.

⁵⁴ Consumer Reports, Hearing Aid Buying Guide (Sept. 2015).

⁵⁵ Cathie Gandel, *Why Do Hearing Aids Cost So Much?*, AARP (Oct. 3, 2016), <http://www.aarp.org/health/conditions-treatments/info-2016/hearing-aid-costs-prices-cs.html>; see also, Harvey Abrams, *So You Say You Can Make a \$100 Hearing Aid? Go Ahead!*, Hearing Health and Tech. Matters (July 10, 2013), <http://hearinghealthmatters.org/hearingeconomics/2013/you-say-you-can-make-a-100-hearing-aid-go-ahead/>.

professional assistance is unclear, but incurring a cost for each transaction may serve as a new barrier to getting help when needed.

With the adoption of an OTC channel, hearing aids will be available without any accompanying professional services. At this time, it is unclear how – or whether – consumers will seek assistance if their purchase does not meet their needs. If, for example, an individual who purchases an OTC hearing aid needs to pay for the services of a hearing health professional to resolve a fitting issue, they may forego the repair or adjustment. This could lead to underutilization, poor utilization, or non-use and subsequent reluctance to pursue professionally fit hearing aids in the future. On the other hand, the low cost of the OTC hearing aid relative to professionally selected and fit hearing aids may be offset by those additional fees for post-purchase professional services. The purchase of a hearing aid is typically the start of a process which involves multiple adjustments and an investment of time. Data show that there are multiple adjustments even with professional assistance in hearing and selection fitting.⁵⁶

While the hearing aid distribution model is changing, experience has shown that it is questionable whether simply reducing costs and increasing access through OTC delivery channels will lead to greater hearing aid adoption by individuals with mild hearing loss. In Japan and South Korea, for example, OTC hearing aids and PSAPs are readily available through the internet and other non-traditional channels. HIA's member companies market the same technologies in these countries through their OTC models, but despite their technologically savvy customer base, adoption and satisfaction rates remain much lower than in the United States.⁵⁷ The United States hearing aid market, as it currently stands, has an adoption rate of 30 percent while the adoption rates are only in

⁵⁶ Sergei Kochkin et al., *MarkeTrak VIII: The Impact of the Hearing Healthcare Professional on Hearing Aid User Success*, 17(4) Hearing Review 12 (2010), <http://www.hearingreview.com/2010/04/marketrak-viii-the-impact-of-the-hearing-healthcare-professional-on-hearing-aid-user-success/>.

⁵⁷ Study by Anovum (Zurich) on behalf of Japan Hearing Instruments Manufacturers Association (JHIMA) (“JapanTrak 2015”), slides available at http://www.ehima.com/wp-content/uploads/2016/02/JAPAN_Trak_2015-1.pdf.

the 40 percent range even in countries where hearing aids are provided at no cost through the national health care system. In the United Kingdom and Norway, for example, adoption rates are 41 percent and 42.5 respectively.⁵⁸ (In the United States, the adoption rate is estimated to be 50 percent for patients with moderate hearing loss.) A 2014 study released by CTA showed that the most common reason for consumers with “a little trouble hearing” not to seek medical care was not cost, but that their hearing difficulties were not bad enough to warrant action.⁵⁹ Demand, it seems, is very unresponsive to cost.⁶⁰ With one of the highest satisfaction rates in the world (81 percent),⁶¹ it is entirely possible that the increased nominal affordability and accessibility of OTC devices, relative to traditional hearing aids, may not result in greater adoption in the United States for the very population to which they are targeted: individuals with mild hearing loss

C. How are innovations in hearing technology – including hearing aids, personal sound amplification products (PSAPs), and other devices and platforms – changing the competitive landscape and expanding the range of viable options to ameliorate hearing loss? What other innovations and developments are on the horizon?

HIA believes that “disruptive” distribution models have already had a dramatic impact on hearing aid affordability and accessibility. Innovation in technology is a core characteristic of the hearing industry, but not as a result of new device platforms. While some outdated and erroneous stereotypes persist,⁶² hearing aid manufacturers are consumer-directed medical device developers who have been consistently advancing and

⁵⁸ Søren Hougaard et al., *EuroTrak + JapanTrak 2012: Societal and Personal Benefits of Hearing Rehabilitation with Hearing Aids*, Hearing Review (Mar. 7, 2013), <http://www.hearingreview.com/2013/03/eurotrak-japantrak-2012-societal-and-personal-benefits-of-hearing-rehabilitation-with-hearing-aids/>.

⁵⁹ CTA, *Personal Sound Amplification Products: A Study of Consumer Attitudes and Behavior*, CEA Market Research Report, 6 (Aug. 2014), <https://www.cta.tech/cta/media/policyImages/policyPDFs/Report-Personal-Sound-Amplification-Products-A-Study-of-Consumer-Att.pdf>.

⁶⁰ See Humes et al., *supra* n.13.

⁶¹ Abrams and Kihm, *supra* n.4. The satisfaction rate is 91 percent for hearing aids purchased in the past year.

⁶² See, e.g., PCAST Report, *supra* n.3, at 2, which describes potential innovations in hearing aids technology, most of which have already been adopted.

implementing new and innovative technology. Over the past 15 years, hearing aid manufacturers have been early adopters and developers of numerous new technologies, such as noise-reduction, frequency shifting, miniaturized directional microphones, 3D printing to manufacture customized hearing aids and earmolds, and nanotechnology, which has enabled the integration of the most advanced signal processing features into devices no larger than the small digit of the pinkie. Many hearing aids now are equipped with wireless technology allowing communication between the user's two hearing aids, smart phones, TVs, and entertainment systems. Some technology companies have even sought out hearing aid manufacturers for advice on adopting these technologies into hearables.⁶³

The current competitive landscape and investment in research and development within the industry drives these technological advancements. There are currently six major manufacturers of hearing aids with additional sources from other technology industries – more major participants in the industry than cell phone manufacturers or telephone carriers. As noted, these entities employ thousands of engineers and scientists to develop sophisticated hearing aids and algorithms to process sound instantaneously, classify these sounds, and produce the highest level of audibility, sound quality, and spatial perception (i.e., localizing sound) that resembles natural hearing – all with minimal power consumption. Competition is rampant and has been responsible for driving down the cost of advanced technologies so that consumers have access to more features for the same or lower price. With internal market forces pressuring the hearing aid industry to advance, PSAPs are not the impetus of technological innovation.

Innovation has not been limited to technology. Increasing numbers of manufacturers are investing in the development of tele-health, which has resulted in the ability to remotely program and troubleshoot hearing aids as well as provide consultation, post-fitting education, counseling and rehabilitation services without requiring the patient

⁶³ For example, hearable companies have asked Starkey for help in developing hearing technology.

to travel to the clinic.⁶⁴ Additionally, dozens of chain retailers and independent clinics compete for customers, allowing consumers the opportunity to shop around for better prices and service.

Although hearing aid technology has advanced in recent years, no technology has yet been developed that would eliminate the critical role of the hearing health provider in ensuring the proper selection, fit, and follow up to provide optimal outcomes for individuals with hearing loss. A major issue that is difficult to overcome is the heterogeneous nature of hearing loss. It is unlike vision loss, where one or two simple parameters (diopters and astigmatism) are easily measured and identified. Two people with the same audiogram may have completely different hearing profiles and requirements based on their individual communication needs, pathophysiology, cognitive function, response to amplification, and a myriad of other psychosocial and demographic considerations.⁶⁵ For OTC hearing aids to be successful, it is critical that new self-diagnostic tools be developed that go far beyond the simple pure tone audiogram, which hearing experts consider a severely impoverished indicator of auditory system function. Illustrating the technical progress already occurring, an at-home hearing test was cleared for OTC use by FDA in 2016.⁶⁶ Yet professional and skilled care remains a necessary component for the success of most users, as the FDA clearance requires that the consumer take the results of the test to a hearing health professional.

As FTC made clear in its 2016 Enforcement Policy Statement on Marketing Claims for OTC Homeopathic Drugs, OTC products are intended for “self-limiting

⁶⁴ See, e.g., iHear, Press Release, iHEAR Announces EarPiNG - A New Telehealth Service to Remotely Customize Hearing Aids by Hearing Professionals (Nov. 10, 2016), <http://www.prnewswire.com/news-releases/ihear-announces-earping--a-new-telehealth-service-to-remotely-customize-hearing-aids-by-hearing-professionals-300360445.html>.

⁶⁵ Calderone, *supra* n.7 (“You can have two people with identical audiograms who have very different functionality”) (internal quotations omitted).

⁶⁶ iHear, Press Release, iHear Medical Receives Landmark FDA Approval for the First OTC Home Hearing Test (Jan. 4, 2016), <http://iheardmedical.com/ihear-medical-receives-landmark-fda-approval-for-the-first-over-the-counter-home-hearing-test/>.

disease conditions amenable to self-diagnosis of symptoms and treatment.”⁶⁷ Likewise, OTC hearing aids need to address self-diagnosis and self-treatment. Without the development of new tools that help to achieve these goals, OTC hearing aids may be easier to purchase, but will not adequately address patient needs.

D. To what extent are hearing aids, PSAPs, or “hearables” interoperable with different adjustment or programming tools, as well as other technologies and communications systems? What standard setting efforts are underway and how might standard setting further competition and innovation (or fail to do so)?

As with miniaturization and advanced signal processing, the hearing industry has been innovative in furthering the goals of interoperability and standardization. Not too long ago, clinicians were required to load proprietary fitting software onto their office computers that would communicate with manufacturer’s hearing aids through proprietary interface hardware unique to each manufacturer. Today, all of the fitting software resides on a single platform, NOAH, which communicates with the hearing aid firmware either wirelessly or via a common interface.⁶⁸ PSAPs or “hearables” are not interoperable with standard hearing aid technologies or communication systems like NOAH, as they are consumer electronics rather than medical devices. In fact, there is no way of knowing how many PSAP manufacturers exist,⁶⁹ the type of technology they use, how they could be designed to be interoperable with other devices, or whether the PSAP manufacturers would cooperate in the development of interoperability standards.

⁶⁷ 81 Fed. Reg. 90,122, 90,122 (Dec. 13, 2016).

⁶⁸ Ariane Laplante-Lévesque et al., *Hearing Device Manufacturers Call For Interoperability and Standardization of Internet and Audiology*, 25 Am. J. Audiology 260 (Oct. 2016), <http://aja.pubs.asha.org/article.aspx?articleid=2573084&resultClick=3>.

⁶⁹ The FDCA requires hearing aid manufacturers to register. This enables FDA and the public to know the identity of all 99 establishments registered as hearing aid manufacturers. As consumer products, PSAP manufacturers do not register with FDA.

In contrast, evidence of the hearing industry’s commitment to the goals of interoperability and standardization can be found in a recent publication co-authored by representatives from each of the major manufacturers that describes the importance of interoperability.⁷⁰ Interoperability could lower research and development costs for manufacturers, as well as save time and increase functionalities, which could further reduce costs for consumers and increase accessibility.⁷¹ Safety and data privacy are also protected with the proper interoperable system.⁷²

The differences between hearing aids and PSAPs are not merely technology-related. There is also a fundamental regulatory distinction. Hearing aids are subject to FDA and international standards. Thus, all hearing aid manufacturers must adhere to FDA QSRs and any specific standards codified in FDA regulations for hearing aids.⁷³ FDA, the hearing aid industry, and other parties worked collaboratively to establish these standards. FDA also established “special controls” for wireless hearing aids.⁷⁴ The combination of the standards and regulations has ensured a high level of safety with very few reported adverse events. Hearing aid manufacturers often credit these regulatory requirements for their excellent safety record.

PSAP manufacturers, on the other hand, have proposed industry-developed, voluntary compliance standards not subject to enforcement by a regulatory body. Voluntary standards, such as CTA standards, are of questionable value. For example, the absence of a CTA Safety Seal will not likely be noticed by consumers of PSAPs; in contrast, consumers are more likely to be aware of FDA oversight. Furthermore, consumers need not even be aware that FDA regulates hearing aid safety and efficacy to

⁷⁰ Laplante-Lévesque et al., *supra* n.68.

⁷¹ *Id.*

⁷² *Id.*

⁷³ 21 C.F.R. §§ 874.3300, 874.3305, 801.420(c)(4).

⁷⁴ *Id.* § 874.3305(b). FDA took this step over concerns that this new technology could present risks to patients and third parties.

gain the benefits of that oversight. Conversely, voluntary PSAP standards would not be legally enforceable by FDA.

In terms of their effect on competition and innovation, there is no evidence to suggest that requiring adherence to FDA regulations, including QSRs, or existing standards by future OTC manufacturers will have a negative impact on competition. Indeed, competition among the manufacturers in the traditional hearing aid space is robust and fierce; it has led to technological breakthroughs while at the same time reducing the cost of manufacturing.

E. To what extent might existing federal and state regulations be modified or streamlined to better accommodate new technologies and business models, consistent with promoting competition and innovation while meeting legitimate consumer protection objectives?

HIA understands the need to revisit federal and state regulations to accommodate new technology and business models, but emphasizes that it is important not to lose sight of the need to ensure safety and effectiveness. Accessibility and affordability are important goals, but increasing access to unsafe or ineffective hearing aids will not benefit patients. For this reason, if FDA were to create an OTC hearing aid category, HIA would support modification of federal rules to enable the sale of such devices *as long as OTC hearing aids are not intended for hearing loss more severe than mild and as long as FDA general controls apply.*

FDA general controls would require all hearing aid manufacturers to register and list devices with FDA, as well as comply with QSRs. All FDA labeling requirements, electromagnetic capability (EMC) standards, and any standards implicating safety should be retained for OTC hearing aids. Based on a survey of members, the addition of these requirements should not measurably impact consumer prices; for a \$1000 hearing aid,

HIA estimates the cost of QSR compliance is approximately 20 cents. The longevity of quality-controlled devices should exceed that of devices without such requirements, so consumers may also see long-term savings accrue from robust quality systems.

Additionally, HIA strongly believes that FDA review of a premarket notification for a manufacturer's initial hearing aid device would help ensure device safety and effectiveness. FDA can establish guidance documents that would clearly state the data needed to support this 510(k), facilitating entry into the market. Subsequent hearing aids by the manufacturer would be 510(k) exempt and could be marketed without FDA review, absent changes that under FDA's regulation would require a 510(k).

Furthermore, FDA should strongly incorporate consumer comprehension into its analysis of OTC hearing aids. It is imperative to ensure that consumers can understand the directions and conditions for OTC hearing aids. FDA studies have shown that consumer comprehension is a major barrier to the effective use of all medical devices. If a complex medical device is to be available to consumers without a learned intermediary, it is essential to the safe and effective use of the device that consumers can adequately understand and follow the directions on the labeling. FDA routinely requires consumer comprehension studies of OTC drug products and home-use medical devices.⁷⁵ FDA can set clear expectations for how these studies should be done. FDA can also provide guidance on the data needed for effective home testing that is the *sine qua non* for OTC hearing aids.

FTC also has a role to play in regulating hearing aids, particularly if state laws designed to protect consumers are preempted. If that were to occur, consumers will lose

⁷⁵ FDA, FDA CDRH Public Workshop: Guidance on Medical Device Patient Labeling (Sept. 29, 2015), <https://www.fda.gov/downloads/MedicalDevices/NewsEvents/WorkshopsConferences/UCM465733.pdf>; FDA, Device Labeling Guidance #G91-1 (Mar. 8, 1991), <https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm081368.htm>; FDA, Guidance for Industry: Label Comprehension Studies for Nonprescription Drug Products (Aug. 2010), <https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM143834.pdf>.

certain important protections. These state laws include mandatory warranty periods in which consumers have 30 or 60 days, depending on the state, to return a hearing aid for a full refund.⁷⁶ State regulations also mandate that distributors provide detailed contact, device, and contractual information in an effort to ensure accountability.⁷⁷ If these state protections were to be preempted in order to facilitate OTC hearing aids, FTC should address how to maintain consumer protections. It would indeed be ironic if efforts to increase accessibility and lower costs resulted in consumers losing important state protections that now exist.

Consumer electronic products and other non-medical devices should remain prohibited from advertising that their products are designed to treat hearing loss. Permitting consumer electronic products to advertise for hearing loss would be akin to complete deregulation of the industry. FTC can play an important role here as well. Since PSAPs are not devices, they are not subject to FDA regulation (although FDA can intervene if PSAP manufacturers do promote their products in a manner that renders them devices). FTC regulation of false or misleading claims, regardless of whether they make medical device claims or general amplification claims, would help protect consumers.

The consumer electronics market operates very differently from the medical device market. As such, there are serious risks associated with the development of PSAPs to treat hearing loss. New consumer electronic technologies are often disseminated at an early stage through beta tests to accelerate, commercialize, and gain feedback, but this model is not appropriate for a medical product. Medical devices are carefully tested for safety and efficacy before being commercialized; consumer product testing is primarily directed toward performance, not safety. And FDA regulates the investigational studies of new devices.⁷⁸ Thus, PSAPs need to be treated only as

⁷⁶ See, e.g., Alaska Stat. § 08.55.110; Cal. Civ. Code § 1793.02; Ill. Admin. Code tit. 77 § 682.115.

⁷⁷ See *supra* n.28.

⁷⁸ 21 C.F.R. Parts 50, 56, and 812.

amplification devices, not as substitutes for hearing aids, and this requirement must be enforced.

Complete deregulation of the hearing aid industry should not be considered a viable option. Past experiments with deregulation have shown that the unregulated hearing aid market does not work. Prior to hearing aid regulation, an FDA Task Force in 1976 investigated hearing aids and discovered that many of the hearing devices sold “basically didn’t work.”⁷⁹ In 1985, Colorado experimented with deregulation of hearing aid sales and determined that complaints filed for hearing aids jumped from an average of 14 per year to 100.⁸⁰ The most common complaints included refusal to provide legally mandated refunds, problems with fittings and repairs, and contract and fraud issues. Colorado eventually decided to reinstate licensing requirements for hearing aid distribution.⁸¹ Complete deregulation of OTC hearing aids would be likely to result in a recurrence of the same behaviors and problems. And with the internet, it would be easier to commit fraud and confuse people than before.

III. Conclusion

HIA appreciates the opportunity to provide comments on this very important issue. HIA’s main concern is that hearing aids continue to be treated as medical devices to ensure the safety and effectiveness of treatment for hearing loss patients. HIA supports the effort to promote innovation in the field of hearing technology and increase access for consumers. HIA believes that the new distribution models and new informational resources are helping to advance these goals. HIA applauds the efforts of the FTC and FDA to work together to ensure more accessible and affordable hearing loss treatment for all.

⁷⁹ FDA, Transcript from Streamlining Good Manufacturing Practices for Hearing Aids Workshop, 12 (Apr. 21, 2016) (Statement of Commissioner Robert Califf), <https://www.fda.gov/downloads/MedicalDevices/NewsEvents/WorkshopsConferences/UCM502750.pdf>.

⁸⁰ *Id.* at 183-84.

⁸¹ *Id.* at 185.

Once again, HIA emphasizes the importance of safety and efficacy in the hearing aid industry. The health of the patient must be foremost; only after assuring safety and efficacy can the discussion about cost proceed. For this reason, HIA believes that OTC hearing aids subject to regulatory controls may be an effective cost-reducing option for those with mild hearing loss, but strongly encourages limiting the category to *only* those with mild hearing loss. As noted, the hearing aid industry has evolved from both a technology and consumer accessibility standpoint and will continue to do so, but regulatory oversight remains paramount in ensuring consumer satisfaction and protection.

Exhibit A



Hearing Technology Industry
Impact Report
2017

Contents

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The Hearing Industries Association

Unfettered imagination, perseverance, and the unrelenting desire to help people with hearing loss have been the most powerful forces fueling advancements in hearing aid technologies.

Helen Keller once wrote, “Blindness separates people from things; deafness separates people from people.”

The people who have made the creation of advanced hearing technologies their life’s work understand that.

Behind every discovery, behind every breakthrough, behind every incremental advancement has been a sustaining sense of purpose: To keep those challenged with hearing loss connected to life, to the world, and to the people around them.

The Hearing Industries Association (HIA) is proud to share this impact report with you. It lays out our industry’s work. And it shines a light on the lead we have taken over the past four decades to harness breakthroughs in scientific understanding and wed them with the power of imagination and ingenuity to help millions of people with hearing loss live fuller lives.

This report takes a close-up look at eight of our member companies: Cochlear, EarLens, GN Resound, Oticon, Sivantos, Sonova, Starkey, and Widex.

First, the report offers a snapshot of the depth and breadth of their new technologies, as reported in the media. It goes on to talk about their groundbreaking partnerships and future plans. Importantly, it spotlights what their customers are saying. And finally, it gives a glimpse of some of the many awards earned through years of work and dedication.

The pages of this report tell the untold story of an industry that has pushed the frontiers of knowledge and technology to help millions of people better hear the world—and to remain an important part of it.



“That’s the untold story of hearing aid development: All along, we’ve been at the forefront of technological advancement, applying new ideas in engineering, science, and technology in groundbreaking ways, ahead of other industries. We’ve been pioneering smaller, increasingly powerful, ever-more capable devices to help people compensate for a serious and intricate sensory loss. And we were doing it long before other industries cared, and long before hearing loss ever made headlines. The fact is, an unrelenting drive to help people struggling with hearing loss is in our DNA, and we’ll keep advancing hearing aid technologies for as long as innovation is possible.”

Carole Rogin, President, Hearing Industries Association (HIA)

Introduction

More than 10 million people in the U.S. use hearing aids.

Hearing aids have morphed into tiny, personalized, high-tech computers that can do amazing things to help people with hearing loss. But it wasn't always that way. And it was never a clear path. It took decades of research and development—trial and error—by the industry to dramatically advance hearing aid technologies. Just think, the first electric hearing aid was invented in 1898. The first all-transistor hearing aid was invented in 1952. And the first commercial digital hearing aid came out in 1987.

Breakthroughs in electronics, microelectromechanical systems (MEMS), and their manufacturing processes fueled more recent advancements in hearing aids. Often, hearing aids were the first commercial devices to apply these developments.

At every turn, the industry seized upon novel scientific ideas and engineering applications to move hearing aids forward. Eventually, miniaturized hardware enabled engineers to pack more amplification and signal processing power into small, wearable housings. And these devices were fitted and programmed for the individual's specific hearing loss, by frequency and lifestyle needs. In essence, personalized medicine has always been at the core of how quality hearing aids work.

Today, breakthroughs are happening at an accelerated rate. And the most current emerging technologies are giving new hope to the roughly 40 million Americans facing hearing problems.

Since the launch of digital hearing aids, connectivity has been the overriding disruptive technology. And it's paving the way for new hearing aid models and experiences. Bluetooth-enabled hearing aids are empowering wearers with added control over their device and listening environment; and new functionalities are enabling wearers a multitude of lifestyle conveniences.

In short, the newest hearing aids are not just compensating for a hearing loss. They are enhancing wearers' lives, connecting their ability to hear to the personal devices that organize their days and power the world around them.

Looking ahead, the possibilities for even further advancement in hearing technologies remain endless. And it was over 40 years of work, ingenuity, and an unwavering vision by the hearing aid industry that paved the way.

Our Companies & Awards

Technological achievement inspires even more technological achievement. Each and every year the hearing aid industry builds on that momentum to develop ever-better hearing aids to keep people with hearing loss connected with life.

People often make the mistake of thinking that hearing loss is a simple, mechanical sensory loss that can be remedied as easily as picking up a pair of “cheater” reading glasses at a local supermarket. But it’s not.

The fact is, hearing is an extremely complex sense that involves a multifaceted interplay of sound and neural signals within the ears and several areas of the brain. The complexity of treating hearing loss is heightened by the challenging environment within the ear canal where hearing aid technologies need to function.

The challenge is great. But the advancements have been tremendous.



Cochlear®

Hear now. And always



The difference is clear.



Recent Awards



reddot design award



Red Dot Award: Product Design 2015

Cochlear

Cochlear's Baja 5 Sound Processor won the Red Dot Award: Product Design 15 in the world's most important competition for product design. International experts assessed 4,928 entries from 56 countries across different industries, ultimately awarding the Baha 5 Sound Processor the sought-after Red Dot seal of quality and noting that "[t]his sound processor is a highly successful translation of modern technology into an exceptionally compact design."

Read More:

www.red-dot.de/pd/online-exhibition/work/?code=26-00436-2015&y=2015&c=167&a=0&lang=en

medGadget



Best Medical Technology 2015

Earlens

Named one of the "Best Medical Technologies" in 2015 by medGadget, an independent publication that reports on medical technology from around the world.

Read More:

www.medgadget.com/2015/12/best-medical-technologies-2015.html



CES Best of Innovation Award 2017

GN Resound

The ReSound ENZO smart hearing aid wins the 2017 CES Best of Innovation Award for Accessible Tech.

Read More:

www.readitquik.com/news/utilities/the-ces-best-of-innovation-award-goes-to-resound-enzo-for-accessible-tech/



CES Best of Innovation Award 2017

Oticon

Oticon Opn™, the world's first internet-connected hearing aid, captured awards in the prestigious CES 2017 Innovation Awards in two categories – "Tech for a Better World" and "Wearable Technologies." Opn is the world's first internet connected hearing aid and a groundbreaking technological achievement. Oticon's newest BrainHearing™ solution offers a range of powerful features to benefit people with hearing loss, including the ability to connect seamlessly to smart devices and smartphones and manage the challenge of noisy environments with multiple speakers – a problem even the most advanced hearing devices of today can't solve.



CES Innovation Awards Honoree 2017

Sivantos

Signia Hearing Aids Named as CES 2017 Innovation Awards Honoree. Cellion, which is built on Signia's advanced primax technology platform, is the world's first lithium-ion inductive rechargeable hearing aid. Its high-capacity power cell is completely sealed into the hearing aid's housing and provides up to 24 hours of continued use with unlimited Bluetooth® streaming on a single charge.



GERMAN
DESIGN
AWARD
WINNER
2017



German DESIGN AWARD 2017

Sonova

The Roger Pen is an advanced wireless microphone for hearing aid users and cochlear implant recipients. With its inconspicuous design, it mimics a pen in shape and looks more like a stylish device than a medical instrument. The Roger Pen was selected to receive the coveted seal of design excellence in the category of Medical, Rehabilitation and Health Care by an international, high-profile jury of design professionals, press members and academics

Read More:

www.phonak.com/com/en/press/german-design-award.html



EDISON AWARDS
INNOVATIONS & INNOVATORS



Winner of the SXSW Interactive Innovation Award for Wearable Tech

Starkey Hearing Technologies

Halo 2 was honored for its ability to merge audiological advances with mobile technology to provide a hearable technology built for better hearing and active living. Featuring revolutionary quad-core twin compressor technology, a unique music algorithm and high-definition operating system, Halo 2 enables high-definition sounds and speech audibility across life's changing landscapes. Additionally, Halo 2 was also honored for its destigmatizing effect.

Read More:

www.finance.yahoo.com/news/starkey-hearing-technologies-halo-2-195235798.html



European Inventor Award (2012)

Widex

Widex has won the prestigious European Inventor Award 2012. The Danish hearing aid manufacturer came top of a strong field of 15 finalists for its ground-breaking CAMISHA technology – a sophisticated method of manufacturing individual hearing aid shells, earmolds and ear-pieces. CAMISHA stands for Computer Aided Manufacturing of Individual Shells for Hearing Aids. It uses laser technology to make an impression of the hearing aid user's ear canal and turns this data into a 3D computer model.

Read More:

<http://webfiles.widex.com/en/newsroom/2012/eiawinner/>

Additional Awards

Take a look at all our additional awards. The truth is, the hearing aid industry regularly wins many types of awards for leading-edge innovation focused on improving the lives of the millions of people with hearing loss.

Cochlear

German Design Award, German Design Council – Nucleus 6 System Graduate Employers 2016

Good Design Award, Australian International Design Awards – Nucleus Aqua+ 2015

Good Design Award, Australian International Design Awards – Nucleus 6 Sound Processor 2014

Good Design Award, Australian International Design Awards – Cochlear Codacs System 2014

Medical Design Excellence Awards – Cochlear Codacs Systems 2014

Powerhouse Museum Award – Nucleus CR110 Remote Assistant Fitting 2013

Medical Design Excellence Awards – Silver winner – Nucleus CR120 Intraoperative Remote Assistant 2013

Good Design Award, Australian International Design Awards – Nucleus CR120 Intraoperative Remote Assistant 2013

GN Resound Inc.

CES Innovation Award Honoree 2015

ReSound ENZO is the first super-power hearing aid on the market to bring Made for iPhone technology to people with severe-to-profound hearing loss. To support the processing performed by the brain, ReSound ENZO hearing aids continuously exchange data about the user's surrounding sound environment to optimize the hearing aid's settings. This is made possible by the most advanced version of the patented Surround Sound by ReSound™ technology resulting in maximized speech understanding even in challenging listening situations.

Read More: www.businesswire.com/news/home/20141112005260/en/Re-Sound-ENZO-Recognized-Innovation-Capabilities-%E2%80%93-Named

Bluetooth Breakthrough Awards Finalist 2015

GN ReSound Smart - An app that interfaces with GN's ReSound Linx hearing aid designed specifically for Apple iPhones, the GN ReSound Smart app lets users receive auditory information from their smartphone, including FaceTime audio, phone calls, music, podcasts and more. Additionally, users can interface with the app to adjust hearing aid volume, assign custom sound profiles for any geotagged location, and set up a "find my hearing aid" tracker that uses GPS to locate a lost unit.

Read More: www.cnet.com/news/2015-bluetooth-breakthrough-awards-finalists-announced/

Additional Awards

GN Resound Inc. (continued)

Good Design Award 2014

A winner at the 2014 good design award, the GN resound 'linx' is a bluetooth enabled hearing aid that connects wirelessly to smart devices. The instrument uses a unique noise processing strategy called surround sound, that emulates the function and performance of the human ear. This means the user can once again communicate effortlessly and enjoy rich, natural intonation. Another feature is the binaural directionality technology that helps the wearer understand speech in noisy situations by amplifying what they need to hear and reducing background noise. The binaural environmental optimizer also enhances this function as it ensures the product automatically regulates volume according to different environments.

Read More: www.designboom.com/technology/gn-resound-linx-hearing-aid-10-03-2014/

Sivantos

2014 CES Innovation Design & Engineering Awards Honoree

Read More: www.usa.bestsoundtechnology.com/news/press/11-12-13_remote-honoree/

2015 Gold Edison Award

Read More: www.usa.bestsoundtechnology.com/news/press/11-12-13_remote-honoree/

CES 2017 Innovation Awards Honoree

Read More: www.marketwired.com/press-release/signia-hearing-aids-named-as-ces-2017-innovation-awards-honoree-2186165.htm

Spark Gold Award

Read More: www.marketwired.com/press-release/signia-hearing-aids-named-as-ces-2017-innovation-awards-honoree-2186165.htm

Additional Awards

Sonova

Cannes Corporate Media & TV Awards 2016

Sounds are among the strongest triggers of memories. Sonova Holding AG, the world's leading provider of hearing solutions, has won a total of three awards at the Cannes Corporate Media & TV Awards for a short film, "Life without Limitations," about German junior soccer player Simon Ollert, and another short film describing multiple World Beard Champion Fritz Sendlhofer's "Sound Memories."

Red Dot Design Award 2016

Read More: www.phonak.com/in/en/press/red-dot-design-award.html

Red Dot Product Design Award 2010

Read More: www.phonak.com/content/dam/phonak/b2b/Press_Releases/en/Press_release_red_dot_award_MINI_EN.pdf

Red Dot Product Design Award 2011

Read More: www.audiologyonline.com/releases/dynamic-soundfield-loudspeaker-wins-red-2268

IF Design Award 2016

Read More: www.phonakpro.com/content/dam/phonakpro/gc_us/en/about_phonak/press_releases/2016/documents/phonak_if_design_award_english.pdf

British-Swiss Business Awards 2013

Read More: www.phonak.com/us/en/press/winner-at-british-swiss-business-awards.html

International Commercial Film Festival – Gold Award

Read More: www.sonova.com/en/features/my-dream-become-professional-soccer-player

European Excellence Award 2016 – Storytelling Category (Shortlisted)

Read More: www.sonova.com/en/features/my-dream-become-professional-soccer-player

Additional Awards

Starkey Hearing Technologies

Red Dot Design Award 2014

Good Design Awards 2015

Edison Award 2015 – Silver Award

Starkey Hearing Technologies, Minneapolis, Minn, announced that it has won an Edison Award for its Halo Made for iPhone hearing aid.

Read More: www.hearingreview.com/2015/04/starkey-halo-hearing-aid-wins-2015-edison-award/

Eureka! Award 2015

Read More: www.marketwired.com/press-release/signia-hearing-aids-named-asces-2017-innovation-awards-honoree-2186165.htm

Core 77 Design Award (runner up)

Starkey Hearing Technologies and Karten Design tackled the hearing aid stigma by introducing Halo™, a Made for iPhone® hearing aid engineered to coexist with the iPhone®, iPad® and iPod touch®.

Read More: <http://designawards.core77.com/Commercial-Equipment/32601/Starkey-Hearing-Technologies-Halo-Made-for-iPhone-Hearing-Aid>

Inc. Magazine Best in Class Design Award 2016

Read More: www.inc.com/magazine/201606/inc-staff/best-in-class-design-awards-2016-winners.html

The American Business Awards (Stevie Awards) 2016 – Technical Innovation of the Year, Bronze

Spark Awards 2016 – Gold Product Design Award

Widex USA

European Inventor Award 2012

Read More: www.hearagainamerica.com/widex-wins-european-inventor-award

Association of Independent Hearing Healthcare Professionals Awards 2012 – Best Technology, Best Individual Support, and Best Manufacturer

Read More: <http://webfiles.widex.com/en/newsroom/2012/aihhp/>

Widex first company in the world to become “WindMade” 2012

Read More: www.hearagainamerica.com/widex-wins-european-inventor-award

RedDot Award 2009 - World’s smallest hearing aid

Read More: <http://webfiles.widex.com/en/newsroom/2009/reddotaward/>

Danish Entrepreneur of the Year 2009

Read More: <http://webfiles.widex.com/en/newsroom/2009/winnerentrepreneuroftheyear2009/>

Widex first company in the world to become “WindMade” 2012

Read More: <http://webfiles.widex.com/en/newsroom/2012/windmade/>

Media Accolades

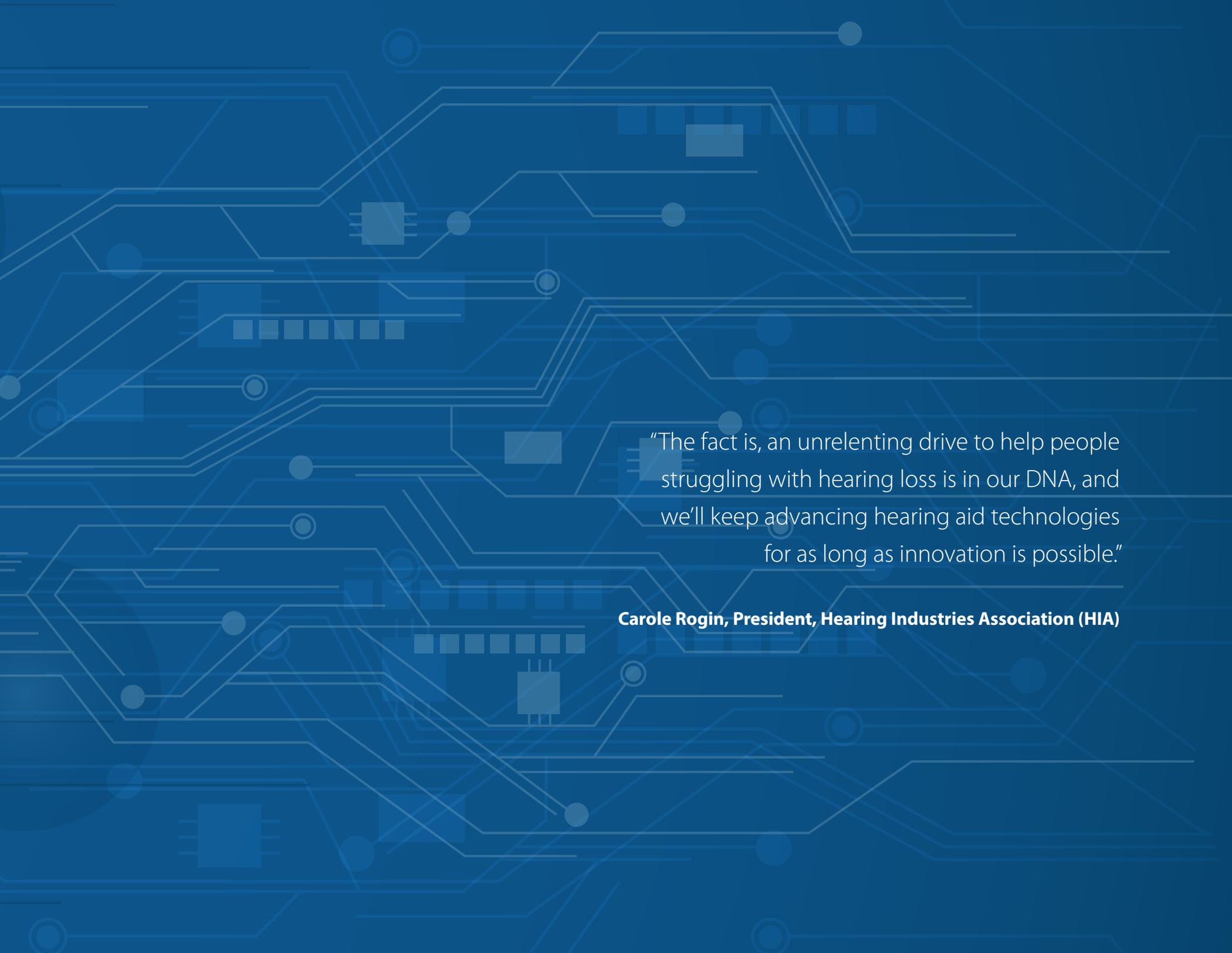
The hearing aid industry has reason to be proud. We're a small industry. But we've made a big difference.

Perhaps one of the best ways to demonstrate the positive impact our work has had on the lives of millions is to draw from the words of journalists.

This snapshot of media coverage captures many of the technological breakthroughs our industry has brought to the market—and to people struggling with hearing loss.*

Our work continues.

*An appendix with a more extensive round-up of coverage appears at the end of this report.



"The fact is, an unrelenting drive to help people struggling with hearing loss is in our DNA, and we'll keep advancing hearing aid technologies for as long as innovation is possible."

Carole Rogin, President, Hearing Industries Association (HIA)

Media Accolades

Cochlear

“He attends a regular local elementary school... [and is] in a gifted program at another school. He’s in the 99th percentile for reading, several grade levels ahead, which makes his mother chuckle. ‘It’s kind of ironic that someone who started off so far behind has surpassed his peers in terms of language development,’ she says.”

www.healthyhearing.com/report/52673-Technology-meets-support-one-family-s-cochlear-implant-success-story

“Some people with hearing loss have the attitude that this is how I was born, I’ve lived with this, this is my burden,” Crawford said. “I can understand that. I had those feelings. But the difference [with Cochlear Implants] is incredible. It’s like a whole new world opened up.”

www.mlive.com/sports/saginaw/index.ssf/2016/07/implant_helps_former_coach_pla.html

“Before his implant, [his wife] said they couldn’t talk to each other when they went on dates because Cervi couldn’t hear her... It never really bothered her, but she, like Cervi, didn’t really know what she was missing. She said she cried the day the couple discovered Cervi’s hearing was at 70 percent after only three months [with his implant].”

www.greeleytribune.com/news/weld-rodeo-producer-hears-at-national-western-stock-show-for-first-time-since-receiving-cochlear-implant/



Healthy Hearing
BE PART OF THE CONVERSATION

mlive
.com

TheTribune

Media Accolades

EarLens

“For the millions of Americans with hearing impairment, hearing aids can significantly improve regular daily communications, as well as overall quality of life,” said William Maisel, M.D., M.P.H., deputy director for science and chief scientist in the FDA’s Center for Devices and Radiological Health. “People with hearing impairment now have a new option that may help improve their hearing by amplifying sounds over a broad spectrum of frequencies.”

www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm464839.htm

Sound waves are converted by the system to electronic signals, which are digitally processed, amplified and sent to the ear tip. A laser diode converts the signals into pulses of light, which shine onto a photodetector in the tympanic membrane transducer. This then converts the light back into electronic signals to transmit sound vibrations directly to the eardrum. In a 48-subject trial over 30 days, Earlens offered a 33% average improvement in word recognition.

www.fiercebiotech.com/medical-devices/earlens-raises-51m-to-launch-laser-based-hearing-aid-after-fda-nod

What we’re trying to do is build a channel in ENT, and we’ve got a proprietary differentiated technology that addresses some of the limitations associated with the existing air conduction hearing aids. Instead of using a speaker, like they all do to amplify sound, we actually use light to transmit sound and energy. If you think about a contact lens that sits on your eye, we’ve got a similar approach where we’ve got a contact lens that sits on the eardrum and we’ve got a laser that is housed into a custom ear tip and that shines onto the contact lens. .

www.massdevice.com/lessons-learned-building-acclarent-scratch-interview-bill-facteau-president-ceo-earlens/



Media Accolades

GN Resound Inc.

"Think of how stigma-reducing that is," says Laurel Christensen, ReSound's chief audiology officer. "You can control your hearing aids simply by doing what everybody else is doing today, playing with their iPhone... No one has to know you are adjusting your hearing aid."

www.forbes.com/sites/realspin/2016/12/15/hearing-the-benefits-of-globalization-in-your-ear/#48cfc2295264

"ReSound LiNX again underlines our core strength of bringing breakthrough innovations to the hearing impaired, making them consumers with choices rather than patients with challenges," GN CEO Lars Viksmoen said in a statement.

www.pcmag.com/article2/0,2817,2427590,00.asp

"Hearables" — the next "wearable" health trackers - are the next frontier in the convergence of healthcare and technology.

www.huffingtonpost.com/laurel-a-christensen-phd/how-mobile-phone-compatib_b_6374804.html

The logo for Forbes magazine, featuring the word "Forbes" in a bold, blue, serif font.The logo for PC Magazine, featuring the letters "PC" in a large, bold, red font, with the word "MAGAZINE" in a smaller, red, sans-serif font below it.The logo for The Huffington Post, featuring the words "THE HUFFINGTON POST" in a green, serif font, arranged in three lines.

Media Accolades

Oticon, Inc.

“The results for measuring peak pupil dilation were statistically significant ($p=0.04$), indicating a significant reduction in peak pupil dilation,” Behrens said. “These data demonstrate that Oticon’s Opn is the first hearing aid proven to make it easier for the brain, freeing up the cognitive resources for more recall.”

www.news-line.com/onenews.lasso?-Search=Action&-token.profession=NL&-token.target=onenews&-Table=webinfo&-MaxRecords=50&-SkipRecords=0&-Database=newsline&-KeyValue=25304

Opn is the world’s first internet connected hearing aid, creating a world of opportunities for connecting to smart devices and wearables,” Ole Asboe Jørgensen, Oticon’s VP of sales and marketing, tells us. “By designing recipes through the If This Then That (IFTTT) network, users can get really creative and add genuinely useful functionalities to their listening device. “We’ve seen examples such as receiving a message from a smart doorbell, an alert from a baby monitor, or automating a message to a loved one when a hearing aid is turned on each morning, but really the possibilities are endless.”

www.wearable.com/saves-the-day/wearable-tech-transforming-how-we-live-with-disabilities

The new hearing aid is the first to be part of the Internet of Things revolution. It can connect to smoke detectors and lighting systems. The device decreases the amount of effort that users have to exert to hear conversations, especially in noisy environments. Traditional hearing aids listen in a single direction at a time but the Oticon Opn can listen to several conversations at the same time while getting rid of background noise.

www.allaboutcircuits.com/news/internet-of-things-hearing-aid-oticon-opn/



WEARABLE



Media Accolades

Sivantos

You might think that all hearing aids are the same but in reality they're not. While they operate and offer similar functionalities, it is really the micro-processing chip — very similar to the brain — that distinguishes one hearing aid brand from another. Similar to how the brain controls every aspect of the human body; the primax chip contains nearly 20 million transistors and is capable of executing over 250 million instructions per second.

www.slashgear.com/signia-primax-insio-pure-hearing-aid-review-one-of-the-most-advance-wearable-devices-12446048/

SLASHGEAR

There are many hearing aid manufactures, but the Signia Pure hearing aids are a revelation in technology-driven innovation. Much like Tesla Motors is pushing the limits on autonomous driving, Signia is exploring the limits of autonomous 'listening'. It could be the start of a truly remarkable tech revolution for people dependent upon technology to help them with everyday tasks.

<http://www.forbes.com/sites/moorinsights/2016/10/27/hearing-aids-enter-the-autonomous-listening-age/#344b5e6a5f09>

Forbes

The good news: new technology is making smaller, better, smarter hearing aids that, in many cases, are invisible (they sit in the ear canal rather than behind the ear, which is where legacy products resided).

www.thestreet.com/story/13557707/1/why-hearing-aids-have-gotten-so-cheap.html

TheStreet

Media Accolades

Sonova

The study, published in the American Journal of Audiology, found people with moderate-to-severe hearing loss who used the Roger Pen could understand speech better than those with normal hearing at noise levels of 65 decibels (dB) and above.

www.reuters.com/article/us-sonova-hldg-device-idUSKBN0GY1RL20140903



At the core of Sonova's success thus far is its concentration and focus on innovation, says Hansjurg Emch, president of Advanced Bionics, a unit of Sonova. "Close collaboration in R&D to share the benefits of innovation across the company is at the core of Sonova's success. The complementary strengths of the Advanced Bionics and Phonak R&D teams were demonstrated by the development of a next-generation sound processor," he adds.

www.forbes.com/sites/genemarcial/2014/09/15/sonova-hearing-aid-with-smartphone-connectivity-catches-investor-attention/#4ee0ad4b4874

Forbes

"The new dual-core chip platform presented today is the result of many years of development work and provides the foundation for further substantial innovative hearing solutions from all of Sonova's product brands," Chief Executive Lukas Branschweiler said in a statement.

www.businessinsider.com/r-sonova-unveils-new-hearing-aid-technology-2014-10



Media Accolades

Starkey Hearing Technologies

We're reaching a new stage of how we interact with our devices. It's an excellent time to think about what tools we can build when we're in constant conversation with the machines around us. "It was a big blow to learn I was going deaf at such a young age, but through this project I've seen that actually I can use the situation I'm in to my advantage, and explore abilities that nobody else gets to experience," said Mr Swain.

www.independent.co.uk/life-style/gadgets-and-tech/one-man-hears-wi-fi-wherever-he-walks-9858488.html



"When people think about hearing technology, they don't think about small and stylish and wireless and superhigh quality audio," said Chris McCormick, Starkey's marketing chief. "When they hear about this tech, they say, 'I wish I'd done this five years ago.'"

www.cnet.com/news/apple-iphone-hearing-aid-tech-deaf-ios-accessibility-cochlear-starkey-bluetooth-watch/



Recreating hearing is an incredibly difficult task. Unlike glasses, which simply bring the world into focus, digital hearing aids strive to recreate the soundscape, amplifying useful sound and suppressing noise. As this changes by the second, sorting one from the other requires a lot of programming.

www.newscientist.com/article/mg22429952-300-the-man-who-can-hear-wi-fi-wherever-he-walks/?cmpid=ILC|NSNS|2016-GLOBAL-inlinelink&utm_medium=ILC&utm_source=NSNS&utm_campaign=inlinelink



Media Accolades

Widex USA

The hearing aid, called a biCROS system, works by adjusting for the loss of hearing in his failing left ear, like a normal hearing aid. But it also “tricks the brain” into believing his deaf right ear can hear. A wireless receiver on his right ear takes in the sound, and transmits it into his left ear, mimicking full hearing.

www.dnainfo.com/new-york/20140429/bed-stuy/bed-stuy-911-responder-gets-gift-of-hearing-thanks-good-samaritan-doc



Either on its own or as part of a hearing aid, the Widex Zen device technology trains the brain to break free of the tinnitus cycle by playing subtle—but more interesting and less frightening—sounds. Patients are distracted by the new sounds and learn to ignore the constant ringing of tinnitus. “It takes away some of that fear,” says Lezynski. “[Tinnitus] is always there, but with Zen, it kind of drops to the background.”

www.sarasotamagazine.com/articles/2015/6/1/13-new-medical-breakthroughs-in-sarasota-manatee

SARASOTA

“The finely detailed mold is scanned through a 3D scanner taking millions of measurements to create a “3D point-cloud” representing exactly the inside of a patient’s ear. The Invisible In-Canal (IIC) hearing aids allow for more sound to be collected naturally by the shape of the ear, and to flow down the ear canal as it would with unassisted hearing, improving the fidelity and range of sound. The fact that the shell is modeled so exactly on the user’s ear also prevents any noise from leaking out – so no more “whistling.”

www.cnn.com/2012/11/09/tech/hearing-aid-widex-3d-printing/



Addendum Media Coverage

Media Coverage

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CBS Denver

www.denver.cbslocal.com/2016/01/06/new-cochlear-implant-technology-gives-deaf-people-a-new-ea/

ChipChick

www.chipchick.com/2016/10/cochlear-limited-kanso.html

CNET

www.cnet.com/news/apple-iphone-hearing-aid-tech-deaf-ios-accessibility-cochlear-starkey-bluetooth-watch/

Denver Business Journal

www.bizjournals.com/denver/news/2016/12/09/implants-a-sound-approach-for-many.html

Hearing Health & Technology Matters

www.hearinghealthmatters.org/betterhearingconsumer/2016/tipping-points-knew-hearing-aids-werent-enough/

KERA News

www.keranews.org/post/after-losing-her-hearing-baby-girl-making-her-mark-kindergarten

St. Louis Post Dispatch

www.stltoday.com/lifestyles/relationships-and-special-occasions/parenting/aisha-sultan/what-it-s-like-to-hear-again-a-world-opens/article_28d7667e-1fec-54dc-a8d6-8a38d4f14aa9.html

“My first experience was riding home after activation. I asked my wife what was that clicking noise. She informed me that it was the directional signal of the car. That was one of many sounds that I had not been hearing... At 88 years old, I feel rejuvenated! Now, I can actively participate in life. These past two years have given me such confidence and, more importantly, a renewed sense of purpose in my life.” **Fred Terry, 88, Cochlear Nucleus® recipient**

Read More www.connections.cochlearamericas.com/bimodal-hearing-rejuvenates-88-year-old-cochlear-implant-recipients-life/

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Earlens

3Ders.org

www.3ders.org/articles/20160907-3d-printed-hearing-aid-from-earlens-uses-non-visible-light-to-create-natural-rich-sound.html

3DPrint.com

www.3dprint.com/148449/earlens-3d-printed-hearing-aid/

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www.abc7news.com/health/earlens-hearing-aid-uses-laser-light-to-transmit-sound/1165619/

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www.assemblymag.com/articles/93573-mes-software-helps-manufacturer-of-revolutionary-hearing-aid

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www.fiercebiotech.com/special-report/earlens-2014-fierce-15

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www.hearingreview.com/2016/06/earlens-raises-51m-to-launch-light-driven-hearing-aid/

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<http://abc7news.com/health/earlens-hearing-aid-uses-laser-light-to-transmit-sound/1165619/>

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www.massdevice.com/earlens-wins-fda-510k-for-novel-hearing-aid/

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www.massdevice.com/lessons-learned-building-acclarent-scratch-interview-bill-fac-teau-president-ceo-earlens/

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www.medgadget.com/2015/10/earlens-contact-laser-based-hearing-device-receives-fda-approval.html

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www.medgadget.com/2015/12/best-medical-technologies-2015.html

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<http://medcitynews.com/2016/07/hearing-aids-and-ai/?rf=1>

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<http://www.medscape.com/viewarticle/851885>

Minneapolis/St. Paul Business Journal

www.bizjournals.com/twincities/news/2016/06/27/medtronic-backs-earlens-light-based-hearing-aid.html

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www.news-medical.net/news/20151009/FDA-allows-marketing-of-new-EarLens-Contact-Hearing-Device.aspx

Oh Gizmo!

www.ohgizmo.com/2015/09/02/5-bits-of-future-hearing-technology/

The Economist

www.economist.com/blogs/babbage/2012/12/hearing-aids

“Really love the fact that Earlens has just changed my life. Now I can hear what I really want to hear. Earlens seems to broaden how much I hear so I don’t have to hear it as loud, but I hear more.” **Carol L., California**

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www.appleinsider.com/articles/13/11/25/first-fully-integrated-made-for-iphone-hearing-aids-are-set-to-hit-the-market

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www.assemblymag.com/articles/92973-jet-dispenser-applies-epoxy-underfill-material-for-hearing-aid-assembly

The Blaze

www.theblaze.com/news/2015/02/25/iphone-app-lets-hearing-impaired-patients-take-it-up-an-octave-by-connecting-with-their-hearing-aids/

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www.chicagotribune.com/bluesky/originals/chi-hearing-aid-market-beltone-bis-20141006-story.html

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www.cnet.com/news/made-for-iphone-hearing-aids-aim-to-shake-stigma/

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www.cnn.com/2014/03/04/tech/innovation/apple-resound-hearing-aids/

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www.digitaltrends.com/mobile/apple-collaborates-on-worlds-smartest-hearing-aid/

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www.electronicweekly.com/blogs/gadget-master/gadget-watch/gadget-watch-resound-linx-bluetooth-smart-hearing-aid-2014-08/

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www.guardianlv.com/2014/03/apple-jumps-into-wearable-computers-with-smart-hearing-aid/

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www.macworld.com/article/2914374/5-outside-the-box-health-apps-for-apple-watch-that-go-beyond-heart-rate.html

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www.medicaldaily.com/resound-linx-made-iphone-hearing-aid-finds-growing-us-customer-base-273180

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www.mnn.com/green-tech/gadgets-electronics/stories/hearables-boomers-answer-to-the-hearing-aid

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www.nytimes.com/2014/04/24/technology/personaltech/app-controlled-hearing-aid-improves-even-normal-hearing.html?_r=0

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www.upi.com/Business_News/2017/01/05/CES-2017-Five-gadgets-to-help-consumers-get-healthy/4181483632323/

WLS-TV (online)

www.foxnews.com/tech/2014/03/19/apple-gn-resound-create-worlds-first-made-for-iphone-hearing-aid.html

VR-Zone

www.vr-zone.com/articles/denmarks-gn-resound-release-made-iphone-hearing-aids-next-year/65053.html

“When I played my first performance with the [ReSound] ENZOs, I was braced for distortion, but it never happened – everything was there to hear, from guitars and flutes down to the lowest note of my bass. For years I had to put up with hearing aid distortion in performance, and I am now faced with the happy task of relearning how music is supposed to sound.” **Rick Ledbetter**

Read More www.gnresoundblog.com/2015/10/28/resound-enzo-story-rick-ledbetter/

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Oticon, Inc.

All About Circuits

www.allaboutcircuits.com/news/internet-of-things-hearing-aid-oticon-opn/

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www.geektime.com/2017/01/08/oticon-offers-bluetooth-connected-hearing-aid-that-connects-to-alarms-and-doors/

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www.mdmag.com/news/2016/06/internet-things-hearing-aid-handles-noisy-environments

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“The Bluetooth technology is just awesome with cell phones and TVs.”

Robert

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Wendy Marty

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“When I go to restaurants, the Halo remembers the settings I had on at that specific location, so the next time I’m there it will know to project the sound of the person I’m having a conversation with over the background noise. I also have preferences set at home and when I’m on an airplane. There’s even a find-my-device feature to track down lost hearing aids.” **Daymond John**

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“Just a brief email to say how delighted I am with my new hearing aids you supplied and fitted. The Widex UNIQUE 440 is indeed a massive advance on my old hearing aids and the wind noise reduction element works a treat, and thanks to the custom made ear molds they’re very comfortable, even to wear all day. The way that they keep analyzing the sounds around you and keep changing to give you the best listening experience possible is amazing and doesn’t cause any issues. The functions that you programmed into them all work well...” **Martin Oakes**

Conclusion

Hearing loss is in the spotlight as it has never been before.

New research tying many other serious health issues to hearing loss has raised its importance in the eyes of public policy makers, the healthcare community, media, and even other industries.

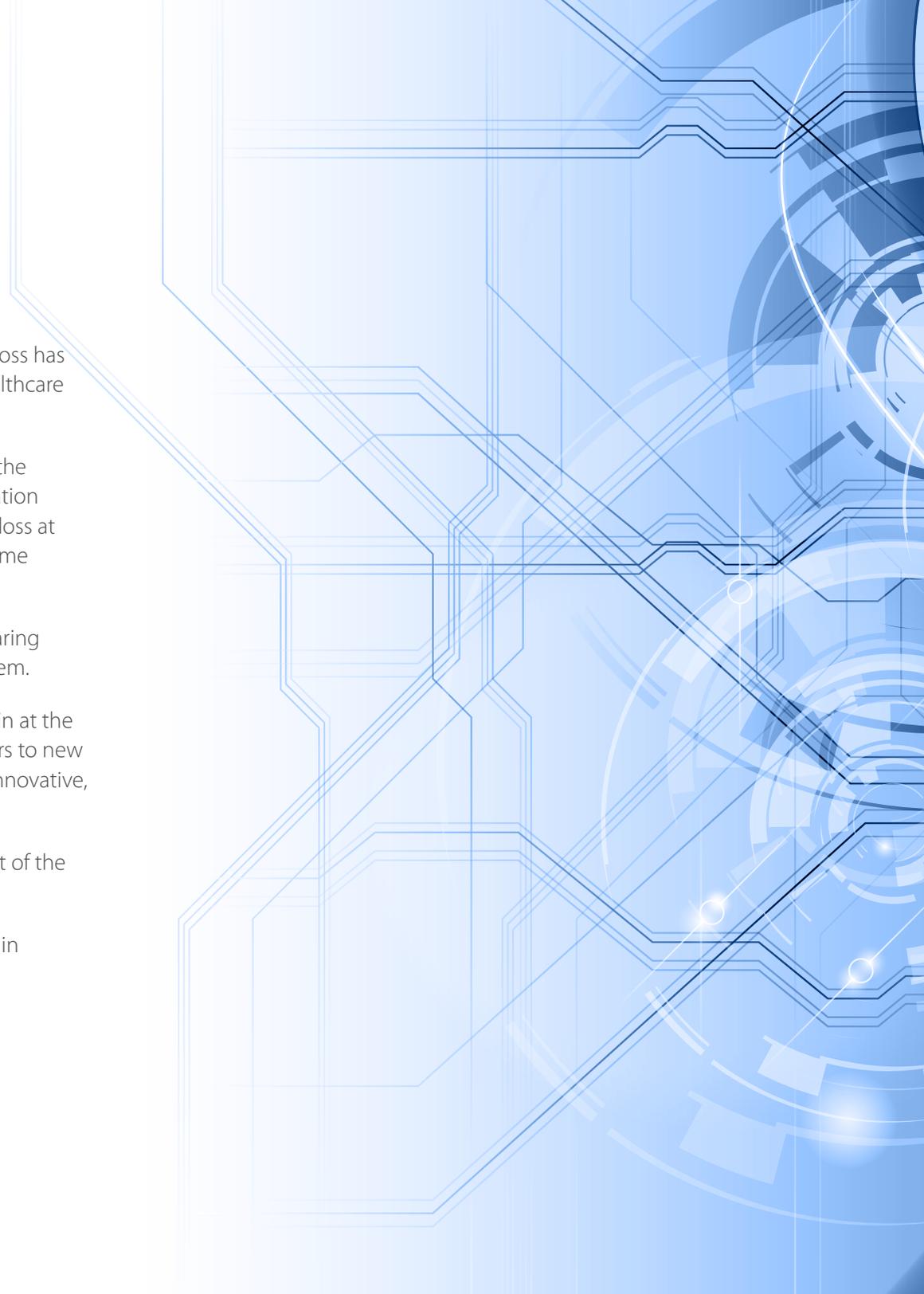
We, in the hearing aid industry, will continue to further advance the work we began more than 40 years ago. As the American population gets older—and as more people acquire noise-induced hearing loss at younger ages—the mission of the hearing aid industry will become even more relevant.

Our purpose has always been to keep those challenged with hearing loss connected to life, to the world, and to the people around them.

In this new era of understanding and engagement, we will remain at the forefront of technological advancement, pushing through barriers to new discoveries and bringing forth ever-improving, more and more innovative, life-enhancing technologies.

Keeping people with hearing loss connected and an integral part of the world is our life's work.

Our determination to bring forward even greater advancements in hearing aid technologies remains stronger today than ever.





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