Federal Trade Commission
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SUBJECT
Hearing Health and Technology – Workshop, Project No. P171200

Hearing science and advances in technology can today offer new ways to provide hearing care and address the unmet need of millions of Americans with hearing loss. Innovative, high-quality, lower-cost hearing products, leveraging the speed and scale of the consumer electronics industry, can be made today. The computing power of smartphones and modern understanding of hearing loss can today enable systems that fit hearing aids without professional intervention.

To make this possible, it is essential to enable manufacturers to sell directly to the customer. A direct-to-consumer approach reduces cost, increases access, and importantly creates a direct relationship between the customer and the manufacturer which drives innovation. But regulatory barriers stand in the way: there is no clear regulatory pathway at FDA for direct-to-consumer hearing aids, and nearly all states have rules effectively inhibiting modern direct-to-consumer sales channels and requiring a license to sell hearing aids.

With a clear pathway to market, companies like Bose could apply technology and a customer-first approach to innovate and produce high-quality, desirable products that will be accessible to the millions of people with hearing loss that are not currently using hearing aids.

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Why OTC Hearing Aids Will Work

An OTC hearing aid works based on two fundamental building blocks: first, the technology used to build hearing aids (speakers, microphones, chipsets, processing algorithms) is now broadly available to allow new innovative manufacturers to enter the market, and second, scientific and technical advances enable smart systems that allow the user to easily adjust the sound of the world until he or she can hear better. Much like focusing a camera or binoculars, or tuning in a radio station, with the right tools and technology an individual is completely capable of finding the settings that puts the world into better focus.

Hearing Aid Fitting: Traditional Fitting

To understand why self-fitting is both possible and critical to addressing the unmet need, it is important to understand the traditional fitting process. "Fitting" a hearing aid is the process of setting a hearing aid to provide appropriate amplification across different frequencies to enable better hearing. Unlike reading glasses, to which this new category is often compared, even with an ideal fitting hearing aids cannot fully restore hearing: instead they allow users to make better use of the hearing capability they have. Unlike prescription eyeglasses, for which there is a single prescription that provides optimal vision correction, there is a broad range of hearing aid settings that provide benefit to a hearing aid user, and those settings may change according to the user's preferences and sound environment. But like all eyeglasses, customers can easily recognize when a setting improves their hearing.

In traditional hearing aid fitting, the dispenser relies on an audiogram and the customer's feedback to determine the best fit. A dispenser will begin by taking an audiogram, which will show the customer's ability to hear at different frequencies. Programming software provided by the hearing aid manufacturer takes the audiogram as input, and automatically adjusts the hearing aid to settings that are generally appropriate for that audiogram (making sounds louder at the frequencies where the user has hearing loss). After this, the dispenser may further adjust the device based on the customer's feedback until the customer is satisfied with how it sounds. Motivated customers return after using the hearing aid in different environments to ask for adjustments, often multiple times, because they have no way of adjusting their own devices. The process works, but it is very costly in time and money, and is not currently serving the large majority of people with hearing loss.

It is important to note that under state laws today, the person performing this fitting is required to have only a dispenser's license, not a degree in audiology. Current debate often conflates the hearing aid dispenser with an audiologist, and while there are many highly skilled licensed dispensers today, it is a mistake to assume that licensure equates with the expertise associated with an audiologist. Audiologists must complete a four-year graduate program leading to a doctorate of audiology degree. By contrast, many state licensure laws for hearing aid dispensers require only a high school degree, an exam, an apprenticeship or short course, and continuing education. Audiologists are highly trained experts in hearing, but a degree in audiology is not required to sell hearing aids.

Hearing Aid Fitting: Self-Fitting

The software tools and process described above are complex and the general population would not be able to self-fit a hearing aid using those standard approaches. Even the dispenser would find it difficult to start from scratch, which is why manufacturer software provides an initial fit based on the audiogram.
Self-fitting is possible, despite the complexity described above, because the patterns and causes of hearing loss are not random and are well understood. In the United States population, well over 90% of hearing losses are well represented by just 6 audiograms (women) and 12 audiograms (men) (Ciletti & Flamme, 2008). Successful smart fitting systems can use this audiogram demographic data to help users quickly get to the settings most likely to be beneficial, either by way of presets or adjustable fittings based on these patterns. These smart systems can use the computing power of smartphones to create simple user interfaces that control complex fitting parameters without requiring any audiological expertise in the user.

Once an effective user fitting interface is provided, the user has a powerful advantage over the dispenser: users directly experience the changes to their hearing in the environments that matter most to them. Users then need no expertise, just the ability to adjust or cycle through different settings (without the need to understand the background processing) until they find ones that sound good in each situation. Early studies of one method developed by researchers at Bose indicate users can find settings similar to those that would be chosen by an audiologist within 20 seconds. In addition, when making blinded comparisons of their self-chosen settings with standard audiogram-based fittings, 72% of the time those same users liked their own settings as well or better than the standard ones (Van Tasell et al., 2014).

Further, research demonstrates that even simple self-fitting systems work. In a recent NIH funded randomized placebo controlled trial (Humes et al., 2017), users were presented with three hearing aids, each preset to fit one of the most common audiograms associated with mild to moderate hearing loss. The users had only general instruction materials on how to use the hearing aids and could adjust only the overall volume of the device. To decide which hearing aid was best, the users tried each in succession, without professional guidance. Despite this very simplistic fitting method, users achieved a level of benefit equivalent to standard-of-practice care and professional, customized, fitting. This is a clear indication that there is a range of settings throughout which people will achieve benefit from their hearing aids: it is not necessary to arrive at a single setting for an individual user to achieve meaningful benefit.

Other published reports of self-fitting hearing aids have shown that rudimentary self-fitting systems that allow the user to customize only a few parameters provide results comparable – and sometimes preferable – to fitting by a professional (Elberling & Vejby-Hansen, 1999; Moore et al., 2005; Dreschler et al., 2008; Keidser et al., 2008; Zakis et al., 2007). More recently there has been greatly increased research activity in the area of self-fitting, largely due to a National Institute on Deafness and Other Communication Disorders (NIDCD) funding initiative on hearing aid affordability and accessibility. At the 2017 meeting of the American Auditory Society there were four reports of NIDCD-funded research that concluded self-fitting methods provided equivalent or better outcomes than standard fitting methods, and none that reported negative results (Humes et al.; Lithgow et al.; Nelson et al.; Pavlovic et al., 2017). The authors of a recent summary article on self-fitting hearing aids (SFHAs) noted that there has been an explosion of research on self-fitting devices and methods just in the last 5 years, and that results have been sufficiently positive that they expressed the following opinion: "Overall, we believe that in developed countries, the SFHA will soon challenge providers of hearing

health care to change the structure and content of their services, governments and other bodies to reconsider the metrics used to judge outcomes and the need for funding, and university programs to change the training of audiologists. In developing countries, the app-driven SFHA should have a bright future among those who can afford a smartphone and can access the Internet" (Keidser & Convery, 2016).

Other market experiments showing the ability to effectively self-fit are proceeding in the form of smartphone apps that use the microphone and signal-processing power of the phone itself. Smartphone apps can function as self-fitted hearing aids when combined with consumer-grade earphones. One recent investigation showed that, when compared with conventional hearing aids that had been fit to research participants according to state-of-the-art professional fitting, the two smartphone apps yielded equivalent speech understanding in noise, higher user perceived benefit, and better satisfaction in terms of adjustability (Amlani et al., 2013). Taken together, this is convincing evidence that users can easily learn to manipulate an effective user interface to achieve benefit as good as that obtained with a conventionally-fit hearing aid. Self-fitting may even yield superior outcomes if the user can continually revise the fitting as he/she grows accustomed to amplification, and in different settings.

Key Technological Developments

Scientific and technical capabilities now exist to fully support the sale of hearing aids directly to consumers. This was not the case when the current regulations governing the sale of hearing aids were enacted in 1977. At that time it was essential that a professional be personally involved in the sale because (1) almost all hearing aids were custom fabricated or used custom-fabricated earpieces and required an experienced professional to take a custom ear impression; and (2) there were no digital or digitally-programmable hearing aids, and therefore customization of the hearing aid's sound processing to the user's hearing loss had to be done by a professional via screw driver adjustable controls on the hearing aids.

In addition, most of the scientific underpinnings necessary for development of effective and safe OTC hearing aids were missing. For example:

- Major discoveries had not yet been made that would lead to a new understanding of how the damaged inner ear processes sound, and therefore there were no effective signal processing strategies designed on the basis of hearing science principles. Hearing aids could only amplify all sounds – whether loud or soft – with the same amplification. The only customization that was possible was to provide more amplification in frequency regions where the hearing loss was more severe, via crude adjustments equivalent to bass/treble controls.
- The science of hearing aid fitting was in its infancy, and there was no agreement on how to customize amplification to hearing loss, or even on whether it should be done at all. The first article describing a research-based fitting method for hearing aids had just been published (Byrne & Tonnisson, 1976).
- Hearing aids did only analog signal processing. There were no advanced features – such as feedback cancellation, noise reduction, and multi-microphone directionality – to make it easier to fit hearing aids on a wide range of hearing losses.

- The first smartphone would not appear for 30 years; consumers therefore had no means in their hands to effect adjustments to a hearing aid while wearing it and hearing the effect. Today smartphones provide such a platform.

In the years since 1977, scientific and technical advances have effectively overcome all obstacles to OTC hearing aids that then existed. The most important developments have been:

- Research carried out during the 1980s and 1990s on the pathophysiology of hearing loss resulted in the realization that the healthy inner ear acts as an amplifier for soft sounds, but not for loud ones (Neely & Kim, 1983; Brownell et al., 1986; Ruggero & Rich, 1991; Ashmore et al., 2010). The most common type of hearing loss reduces or eliminates the effectiveness of the ear's amplifier, so that most people with hearing loss have trouble hearing soft sounds, while their perception of loud sounds remains relatively normal.
- The understanding of the healthy ear as a non-linear amplifier quickly led to much improved hearing aid signal processing, in particular the wide dynamic range compression (WDRC) processing that is ubiquitous today (Barfod, 1978; Dreschler, 1992; Hickson, 1994; Dillon, 1996). WDRC is designed to provide amplification for soft sounds – where the ear's natural amplifier no longer works well – but very little or no amplification for loud sounds, where perception is relatively normal.
- Advances in effective hearing aid signal processing in turn gave rise to several research-based methods for customizing the signal processing in the hearing aids to the user's hearing loss (Byrne & Dillon, 1986; Cornelisse et al., 1995; Keidser et al., 2011). Both the programmability and the sophisticated signal processing were made possible by the development of digital hearing aids, which appeared in the late 90s.
- The development of effective feedback cancellation algorithms for digital hearing aids made it possible to achieve sufficient gain before feedback, without the necessity for custom earpieces, so that even persons with moderate to severe hearing losses can effectively use a non-custom hearing aid.
- Mobile phones and other handheld devices can support sophisticated expert systems to help users easily and accurately program their hearing aids using the standard wireless protocols available in their personal consumer devices.

In 1977 the FDA Commissioner affirmed that "in the final analysis the hearing aid user is the person best qualified to determine whether or not a hearing aid is useful and efficacious for its intended purpose" (Fed Reg 42, 1977). But at the time neither the means to make the user part of the fitting process, nor a scientific basis for doing so, existed. It is clear that now the means do exist to enable accurate self-programming of hearing aids, and that effective methods have already been designed and tested. If the FDA establishes the new OTC category, we expect that it will enable considerable innovation in self-adjustment methods that allow a user to do direct self-adjustment without the need for an audiogram, as well as methods to allow the user to estimate his/her own audiogram and adjust from there.

OTC Hearing Aids Are Safe

In 1977, the FDA Commissioner noted that "a hearing aid device is not an inherently dangerous device" (Fed Reg 42, 1977). That has proven to be true: FDA reported at its recent workshop that there have been no corrections or removals of hearing aid devices in recent years (see FDA's April 21, 2016, public workshop on "Streamlining Good Manufacturing Practices (GMPs) for Hearing Aids"). Thus, as with other products that have been switched to OTC status after a long history of safe use, it is time for products that are otherwise identical to conventional hearing aids to be made available OTC as long as they are accompanied by tools that FDA concludes can help a consumer self-fit the device.

While it is generally accepted that the hearing aid device itself is inherently low risk, some have expressed concern about the potential for users to over-amplify with their hearing aids and thereby cause hearing damage. There are several compelling reasons to conclude that this risk will be effectively mitigated in OTC hearing aids.

First, FDA will determine, based on scientific evidence and as part of its rule-making activity to establish standards for OTC hearing aids, appropriate output limits to protect a user's hearing.

Second, users are unlikely to overamplify their hearing aids because it would be undesirable: few people would want to listen to a conversation or other environmental sounds at excessively high volume. Furthermore, the seminal research on hearing aid prescriptive fitting, in which the gain settings preferred by users in their everyday use in the field were observed, reported that with remarkable consistency users set their volume controls to provide gain equal to about half their hearing losses (Byrne & Fifield, 1974; Byrne & Tonnisson, 1976). There is no reason to expect that users who are selecting their own gain in an OTC hearing aid would behave differently or less consistently. In fact, the recent body of published evidence on gain preference by hearing aid users shows that users are unlikely to set their own gain at levels higher than those prescribed by the hearing aid prescriptive fitting methods in general use by hearing professionals (Leijon et al., 1984; Mueller, 2005; Keidser et al., 2008; Hornsby & Mueller, 2008).

Third, modern hearing aid signal processing provides gain for soft sounds, but provides little or no gain for loud sounds, and there is no evidence whatsoever that modern hearing aid signal processing causes damage to hearing.

It is therefore not surprising that there are very few reports in the literature of hearing damage caused by hearing aids. The reports that do exist almost all are anecdotal or pertain to very few users and describe subjects who had severe hearing losses and wore high-gain hearing aids that were providing linear amplification instead of today's standard WDRC amplification. For a comprehensive review of these issues see Staab (2013a-e).

OTC Hearing Aids Will Be Technologically Sophisticated

Effective methods for hearing assistance are well-understood, and excellent signal-processing solutions are available off the shelf to any manufacturer who desires to design and build high-quality hearing aids. All the features of "premium" hearing aids – e.g. feedback cancellation, noise reduction, wind noise reduction, multichannel compression amplification, directional processing – can also be found in CE products. By the

same token, hearing aid manufacturers are taking advantage of CE advances, most notably in the area of wireless technology, to make their products perform more of the functions once found only in CE devices, e.g. audio streaming, telephony, and wireless control. The reality is that the technologies of hearing aids and CE devices are converging rapidly, and therefore the primary difference between them is or soon will be regulatory, not technological.

Conclusion

The science and technology are ready today for OTC hearing aids. Two premier independent groups, NASEM and PCAST, have carefully studied the policy implications and concluded that the time for OTC hearing aids is today. The great unserved need of millions of Americans is only growing with time as our population ages. OTC hearing aids will not fix this problem on their own, but unleashing the innovation and scale of new OTC products in this space will make important contributions towards the hearing health of people across the country.

Appendix II: References

Abrams, H (2015): MarkeTrak 9 (MT9) A New Baseline. http://www.audiology.org/sites/default/files/conferences/Final%20MarkeTrak%209.9.16.15.Harvey%20Abrams.pdf.

Abrams H, B Edwards, S Valentine, & K Fitz (2011): A patient-adjusted fine-tuning approach for optimizing hearing aid response. Hearing Review, 18(3):18-27.

Amlani, AM, B Taylor, C Levy, & R Robbins (2013): Utility of smartphone-based hearing aid applications as a substitute to traditional hearing aids. Hearing Review, Dec: 17-22.

Ashmore J, P Avan, WE Brownell, et al. (2010): The remarkable cochlear amplifier. Hear Res, 266: 1-17.

Barfod J (1978): Multichannel compression hearing aids: Experiments and consideration on clinical applicability. In Sensorineural Hearing Impairment and Hearing Aids (eds. C Ludvigsen & J Barfod). Scand Audiol, Suppl 6: 315-340.

Brownell, WE, CR Bader, D Bertrand, & Y Ribaupierre (1986): Evoked mechanical responses of isolated cochlear outer hair cells. Science, 227: 194-196.

Byrne, D, & H Dillon (1986): The National Acoustic Laboratories' (NAL) new procedure for selecting the gain and frequency response of a hearing aid. Ear & Hearing, 7(4): 257-265.

Byrne, D, & D Fifield (1974): Evaluation of hearing aid fittings for infants. Br J Audiol, 8: 47-54.

Byrne, D, & W. Tonnisson (1976): Selecting the gain of hearing aids for persons with sensorineural hearing impairments. Scand Audiol, 5: 51-59.

Ciletti, L. and G.A. Flamme (2008). Prevalence of hearing impairment by gender and audiometric configuration: results from the National Health and Nutrition Examination Survey (1999-2004) and the Keokuk County Rural Health Study (1994-1998). Journal of the American Academy of Audiology, 2008. 19(9): p. 672-85.

Committee on Accessible and Affordable Hearing Health Care for Adults (2016): Hearing Health Care for Adults Priorities for Improving Access and Affordability. The National Academies Press. http://www.nap.edu/23446.

Cornelisse, LE, RC Seewald, & DG Jamieson, (1995): The input/output formula: A theoretical approach to the fitting of personal amplification devices. J Acoust Soc Am, 97(3): 1854-1864.

Dillon, H (1996): Compression? Yes, but for low or high frequencies, for low or high intensities, and with what response times? Ear Hear, 17: 287–307.

Dreschler, WA (1992): Fitting multichannel-compression hearing aids. Audiology, 31: 121–131.

Dreschler, WA, G Keidser, E Convery, & H Dillon (2008): Client-based adjustments of hearing aid gain: The effect of different control configurations. Ear & Hearing, 29(2): 214-227.

Elberling, C, & K Vejby Hansen (1999): Hearing instruments: Interaction with user preference. In *Auditory Models and Non-Linear Hearing Instruments*, Proc 18th Danavox Symposium (eds. AN Rasmussen, PA Osterhammel, T Andersen, & T Poulsen), 341-347.

Federal Register (1977) Part 801: Hearing Aid Devices, Professional and Patient Labeling and Conditions for Sale, Vol 42 No. 31, Feb 15 1977, 9286-9296.

Hickson, LMH (1994): Compression amplification in hearing aids. Am J Audiol, 3: 51-65.
Hornsby, BW, & HG Mueller (2008): User preference and reliability of bilateral hearing aid gain adjustments. J Am Acad Audiol, 19(2): 158-170.

Humes, L, S Rogers, T Quigley, et al., (2017): The Effects of Service-Delivery Model and Purchase Price on Hearing-Aid Outcomes in Older Adults: A Randomized Double-Blind Placebo-Controlled Clinical Trial. American Journal of Audiology 26: 53-79.

Humes, L et al (2017): Hearing Aid RCT Comparing Best-Practices and OTC Service Delivery. Paper presented at annual meeting of American Auditory Society, Scottsdale, AZ, March 3, 2017.

Humes, L, & F Bess (1981): Tutorial on the potential deterioration in hearing due to hearing aid usage. J Speech Hear Res, 46: 3-15.

Keidser G, and Convery, E (2016): Self-Fitting Hearing Aids: Status Quo and Future Predictions. Trends in Hearing Vol. 20: 1–15.

Keidser, G, A O'Brien, L Carter L, M McLelland, & I Yeend (2008). Variation in preferred gain with experience for hearing-aid users. Int J Audiol, 47(10): 621-635.

Keidser, G, H Dillon, M Flax, T Ching, & S Brewer (2011): The NAL-NL2 prescription procedure. Audiol Res, 1e24: 88-90.

Leijon, A, M Eriksson-Mangold, & A Bech-Karlsen (1984): Preferred hearing aid gain and bass- cut in relation to prescriptive fitting. Scand Audiol, 13(3): 157-161.

Lithgow, A, et al (2017). Comparison of Self-Adjusted Amplification and Own Hearing-Aid Response. Paper presented at annual meeting of American Auditory Society, Scottsdale, AZ, March 3, 2017.

Moore, BC, J Marriage, J Alcantara, & BR Glasberg (2005): Comparison of two adaptive procedures for fitting a multi-channel compression hearing aid. Int J Audiol, 44(6): 345-357.

Mueller, H (2005): Fitting hearing aids to adults using prescriptive methods: An evidence-based review. J Am Acad Audiol, 16(7): 448-460.

Neely, ST, & DO Kim (1983): An active cochlear model showing sharp tuning and high sensitivity. Hear Res, 9: 123-130.

Nelson, P, et al (2017). Listeners Prefer Self-Adjusted Gain Over Audiologist Settings in Blind Comparisons. Paper presented at annual meeting of American Auditory Society, Scottsdale, AZ, March 3, 2017.

Pavlovic, C, et al (2017). Evaluation of the 1:1 Communication Mode and of the Self-Fitting. Paper presented at annual meeting of American Auditory Society, Scottsdale, AZ, March 3, 2017.

President's Council of Advisors on Science and Technology (2015): Aging America & Hearing Loss: Imperative of Improved Hearing Technologies. https://obamawhitehouse.archives.gov/sites/default/files/microsites/ostp/PCAST/pcast_hearing_tech_letterreport_final3.pdf.

Ruggero, MA, & NC Rich (1991): Furosemide alters organ of Corti mechanics: Evidence for feedback of OHCs upon the BM. J Neurosci, 11: 1057-1067.

Staab, W (2013a): Hearing aids and further hearing loss? Part I: Does using hearing aids lead to further hearing loss? Hear Health Tech Matters, http://hearinghealthmatters.org/waynesworld/2013/hearing-aids-loss/.

Staab, W (2013b): Hearing aids and further hearing loss? Part II: Do hearing aids cause further hearing loss? Hear Health Tech Matters, http://hearinghealthmatters.org/waynesworld/2013/hearing-aids-hearing-loss-part-ii/.

Staab, W (2013c): Hearing aids and further hearing loss? Part III: Do hearing aids cause further hearing loss? Hear Health Tech Matters, http://hearinghealthmatters.org/waynesworld/2013/hearing-aids-hearing-loss-part-iii/.

Staab, W (2013d): Hearing aids and further hearing loss? Part IV: Potential deterioration in hearing due to hearing aid usage. Hear Health Tech Matters, http://hearinghealthmatters.org/waynesworld/2013/hearing-aids-hearing-loss-part-iv/.

Staab, W (2013e): Does using hearing aids lead to further hearing loss? Part V: Predicted PTS (Permanent Threshold Shift) from hearing aid use. Hear Health Tech Matters, http://hearinghealthmatters.org/waynesworld/2013/hearing-aids-hearing-loss-part-v/.

Van Tasell, D, Sabin, A, and Franck, K (2014): User self-adjustment of a simulated hearing aid using a mobile device. Paper presented at International Hearing Aid Research Conference, Lake Tahoe, CA, August 2014.

Zapala, D, S Dhar, D Nielsen, J Griffith, & S Kleindienst (2015): Managing disease risk in hearing healthcare delivery. Presentation to Institute of Medicine, Committee on Accessible and Affordable Hearing Health Care for Adults, Washington, DC, September 10. https://phhp-slhs.sites.medinfo.ufl.edu/files/2012/11/UF-IOM-DISEASE-RISK-PRESENTATION-.pdf.

Zakis, JA, H Dillon, & HJ McDermott (2007): The design and evaluation of a hearing aid with trainable amplification parameters. Ear & Hear, 28(6): 812-830