May 17, 2017

Federal Trade Commission
Office of the Secretary
600 Pennsylvania Avenue N.W.
Suite CC-5610 (Annex B)
Washington, D.C. 20580

By electronic submission

Re: Hearing Health and Technology – Workshop, project No. P171200

Dear Sir or Madam,

Amplifon Americas ("Amplifon") appreciates the opportunity to provide comments on competition, innovation and consumer protection issues relating to hearing health care in the United State. Amplifon applauds the Federal Trade Commission ("FTC") for encouraging evidence-based discussions on these important topics, which impact our hearing-impaired population.

Amplifon is part of the Amplifon Group, a worldwide leader in the distribution of hearing care solutions. Amplifon is also the parent company to three of North America's most prominent and respected providers of hearing instruments and services: Miracle-Ear, Amplifon Hearing Health Care (formerly HearPO), and the Elite Hearing Network. Together, these companies have helped tens of millions of people in North America overcome their hearing loss, through innovative products, superior customer service, and convenient locations. Moreover, since 1990, Miracle-Ear has supported its commitment to helping people with hearing loss through the Miracle-Ear Foundation, which has donated more than 10,000 hearing aids to over 6,000 individuals nationwide.

Amplifon recognizes and agrees that finding a balance between health outcome, consumer safety, and accessibility-affordability of hearing care solutions is important. As policymakers explore new models for hearing care, Amplifon believes that the discussions should involve evidence-based, consumer-centric arguments centered on three pillars: health outcome, consumer safety, and accessibility-affordability.

1. Health Outcome and Consumer Safety

The current discussions around new models for hearing care revolve around the proposal to create a category of over-the-counter ("OTC") hearing aids.[1] These proposals do not involve a shift in technology; rather, they require a change in the delivery model for hearing instruments. OTC medications are offered because people are assumed to be capable of self-diagnosing and, therefore, self-selecting and

[1] See PCAST 2015, NAS 2016, Over-the-Counter Hearing Aid Bill of 2017

self-managing the appropriate solution for their medical condition.[2] Limited data about the ability of consumers to self-diagnose hearing loss and to self-select the appropriate hearing care solutions are available. As discussed below, the few available data raise concerns about an over-the-counter approach for hearing healthcare.

a. Inability to self-diagnose the degree and laterality of hearing loss

A consumer study developed in the United States by Dr. Tedeschi and Ms. Kihm to mimic a self-administered approach to hearing aids found that the majority of consumers are unable to self-diagnose their degree and laterality of hearing loss.[3]

As concerns the severity of their hearing impairment, all participants reported having either a mild or a moderate loss. However, the pure-tone, air-conduction hearing test determined that only about half correctly identified within the mild-to-moderate range. Out of the remaining half:

- About four-in-ten individuals had a hearing loss more severe than moderate
- One-in-ten had normal hearing.

In addition, only one-quarter of the participants correctly differentiated the degree of their hearing loss between mild and moderate. The same individuals were also asked to determine if their hearing impairment was unilateral or bilateral. Only half correctly self-reported the laterality of their loss.

When examining the overall ability of these individuals to self-report their mild-to-moderate hearing loss and the laterality of their impairment, **only one-in-four (25%) could correctly self-diagnose their hearing loss**. **Three-out-of-four individuals (75%) were not able to correctly self-report their impairment.**

In addition, after the in-person interviews before the beginning of the trial period about 13% of individuals were referred to a physician or an ENT for a condition that required timely referral to medical assistance. None of those customers self-identified their medical condition and the need to visit a physician. In other words, medical conditions such as ear infections (treatable with antibiotics), foreign objects in the ear, excess build-up of cerumen (that requires removal), or even more serious pathologies, such as an otologic or neurologic pathology, might go untreated when a consumer recognizes a hearing loss and thinks that it can be remedied through an OTC hearing aid.

b. Inability to self-select their hearing solution

In the same study, participants were also asked to select a hearing instruments, among a selection of 15 Personal Sound Amplification Products (PSAPs) and ready-to-wear hearing aids. A profile page was created and showed to the participants for each of the products; these pages included a photo, the price, and some technical features (e.g. style, battery type and life, maximum output, peak frequency, feedback cancellation, noise reduction, volume control, and Bluetooth capabilities). The profile pages and the product selection happened through an online survey that participants took at their home.

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[2] "Principles and Practice of Pharmaceutical Medicine, 2nd Edition", Edited by L.D. Edwards, A.J. Fletcher, A.W. Fox and P.D. Stonier, 2007, John Wiley & Sons, Ltd ISBN: 978-0-470-09313-9 p. 180

[3] "Implications of an Over-the-Counter Approach to Hearing Healthcare: A Consumer Study", Dr. Thomas J. Tedeschi, AuD, and Janette Kihm, published on December 22, 2016, The Hearing Review online. See Attachment for full details.

The process revealed several interesting insights on how consumers approach the selection of hearing instruments to treat their perceived mild-to-moderate hearing loss. First, **one-in-five (20%) selected a hearing instrument with a maximum output of a 120 dB or higher**; the safe listening time for sounds at this level is 9 minutes, according to the World Health Organization[4]. Due to safety concerns, the researchers did not deliver these devices and asked participants to make a second selection.

The study also investigated how familiar consumers were with the different features noted for each product. **Most consumers were familiar with only the most basic and intuitive features**: style/type, volume control, battery life and battery type. Two-in-five knew what noise reduction was; less than one-third were familiar with features such as feedback cancellation, Bluetooth compatibility, maximum output or peak frequency. **Among those who did not know exactly what the term meant, the vast majority either relied on their understanding of the terms or selected a device without knowing the meaning of the terms.** Only a small portion did some research to answer questions and make a decision.

As a consequence, hearing instrument style, price, and appearance were the three primary factors considered by the participants when selecting their device. With regard to price, not all participants were looking for the lowest-priced option. During in-person interviews, participants explained that they saw price as an indicator of quality and avoided the lowest-priced options because they felt low cost was a sign of poor quality. Conversely, **features that have a direct impact on performance of the hearing device were less likely to be considered**. This was likely due to a lack of familiarity or knowledge concerning these features.[5]

c. Inability to self-diagnose and self-select led to lower usage and satisfaction

The inability to correctly self-diagnose and self-select the appropriate solution appears to have negatively impacted the participants' experiences. **Less than one-third (28%) of the individuals that tried the OTC approach used the instrument daily**, with an average of about 8-8.5 hours per day. **When participants received the support of a hearing care professional, the daily usage rose to two-thirds (67%)** and the average usage time for individuals wearing the device daily increased to 11.4 hours. Hearing instrument usage is a strong predictor of satisfaction with the hearing solution. In fact, at the end of the study **consumer satisfaction with OTC was 48%, while satisfaction rose to 83% when the participants were supported by a hearing care professional** and benefitted by longer usage[6]. Please refer to the Attachment for a comprehensive overview of the results of the study.

The importance of custom fitting and support performed by a hearing care professional is also confirmed by a recently published placebo-controlled, double-blind, randomized clinical trial developed by Humes at al. at the University of Indiana. The study compared the outcome of three patient groups who were fitted with the same hearing aid model: the first group (AB) was supported by an audiologist applying the audiology best practice; the second one (CD) self-managed their hearing care; the third one was a placebo group who was fitted with a hearing aid with no real amplification. The results suggested

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[4] "Make Listening Safe", World Health Organization, 2015

[5] See Ref. 3

[6] See Ref. 3

that were no significant differences between AB and CD on five of the six outcome measures; however, there was a **significant difference in patient satisfaction between the group supported by an audiologist (AB: 81%) and the group who self-managed their hearing care (CD: 55%)**. Consequently, a much smaller percentage of individuals in this second "over-the-counter" group were willing to purchase a hearing aid. At the end of the trial period, 83% of participants in the AB group planned to keep their hearing aids compared to only 2% in the CD group.[7]

d. Importance of hearing care professionals for health outcome and consumer safety

These results are not surprising. Hearing care professionals play an active role in driving health outcome and consumer safety for hearing impaired individuals by ensuring that:

- Hearing aids are the best health solution for the individual's hearing impairment through a physical ear examination and a comprehensive hearing evaluation;
- The appropriate hearing aid technology is selected and fitted to the individual's hearing loss and needs by considering multiple health hearing conditions, including the degree of loss compared to normal hearing (through the audiogram) as well as diminished frequency resolution (difference in pitch), diminished temporal resolution (timing), and/or diminished dynamic range, which is loudness perception (range between softest and loudest sounds);
- Each patient is supported by an individual process of rehabilitation and adaptation of the brain to the "new normal" of processing sounds again.

During the recent FTC Public Workshop,[8] several participants recognized the outstanding consumer safety and health outcome achievements of the current hearing care model, which is associated with the support of licensed professionals.

The importance of hearing care professionals is also widely recognized by consumers. MarkeTrak surveyed approximately 900 individuals who have hearing difficulties and own a hearing aid. Their satisfaction with hearing aids was at 81% overall and 91% for those who purchased in the last year; consumer satisfaction with hearing care professionals was at 95%. The same survey showed an 87% satisfaction rate for 600 individuals who had hearing difficulties, visited a hearing care professional but did not purchase a hearing aid.[9]

In the study developed by Tedeschi and Kihm, at the end of the OTC experience individuals were asked how useful did they think it would have been to have had some assistance from a professional. The vast majority (90%) felt that having some assistance would have been at least somewhat useful; many (38%) said it would have been very useful.[10]

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[7] "The Effects of Service-Delivery Model and Purchase Price on Hearing-Aid Outcomes in older Adults: A Randomized Double-Blind Placebo-Controlled Clinical Trial", Humes et al. , American Journal of Audiology, March 2017. Available at: http://aja.pubs.asha.org/article.aspx?articleid=2608398

[8] "Now Hear This: Competition, Innovation, and Consumer Protection Issues in Hearing Health Care". Washington, DC, April 18, 2017 Documentation available at: https://www.ftc.gov/news-events/events-calendar/2017/04/now-hear-competition-innovation-consumer-protection-issues

[9] "An Introduction to MarkeTrak IX: A New Baseline for Hearing Aid Market", The Hearing Review 2015:22(6):16, available at: http://www.hearingreview.com/2015/05/introduction-marketrak-ix-new-baseline-hearing-aid-market/

[10] See Ref. 3

A recent survey investigated the willingness of consumers to forgo some of the services typically associated with the traditional hearing care delivery model; the results were quite similar. The vast majority (over 93%) of respondents answered that a hearing care professional would be "absolutely" or "very" important to select, fit and program their hearing device; with over 60% saying that a hearing care professional would be "absolutely important."[11]

2. Accessibility and Affordability to hearing care solutions

The proposal for an OTC category of hearing aids aims at addressing the issue of low hearing aid adoption. As discussions around changes to hearing care models continue, it is useful to consider whether the "fix" of an OTC category really addresses the problem of low hearing aid adoption.

a. Hearing aids adoption rate into perspective

Statistics show that approximately 30% of those who self-report hearing loss in the United States use a hearing aid.[12] Such statistics do not mean that 70% of individuals who need hearing aids do not benefit from them. An economic model developed by Amlani takes into consideration the fact that conventional adoption rates include all listeners who perceive some form of hearing difficulty and fail to take into consideration that some of these individuals would not benefit from a hearing aid (e.g. they have losses with a conductive component, would be better served with cochlear implants, etc.).[13] Based on this consideration, Amlani focused on a "practical adoption rate" for hearing aids and estimated that approximately half of listeners with hearing difficulties would not benefit from a hearing aid.

This is confirmed by statistics from several European countries where a medical prescription from an ENT is required to receive a hearing aid. Only 50% of those who self-report a hearing loss receive a medical referral for a hearing aid fitting in these countries (including the United Kingdom, France, Germany, Italy, Denmark, Switzerland).[14]

b. Barriers to hearing aid adoption

The assumption that OTC will increase adoption rates is largely premised on the idea that it will make hearing aids more affordable. This assumes that cost is the main barrier to hearing aid adoption. This assumption does not seem to be supported by data, especially for the population affected by milder

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[11] "OTC hearing aids – survey says consumers aren't sold", B. Plotnick and P. Dybala, Healthy Hearing, April 6, 2017. Available at: http://www.healthyhearing.com/report/52742-Otc-hearing-aids-survey-says-consumers-aren-t-sold

[12] "An Introduction to MarkeTrak IX: A New Baseline for Hearing Aid Market", The Hearing Review 2015:22(6):16

Available at: http://www.hearingreview.com/2015/05/introduction-marketrak-ix-new-baseline-hearing-aid-market/

[13] "Myths about the Hearing Aid Market", A. M. Amlani, PhD, Department of Speech and Hearing Sciences, University of North Texas, 2010.

Available at: http://ord1.audiologyonline.com/content/11600/116b43/mythshandouts.pdf

[14] EuroTrak 2015, Anovum

hearing loss. A 2007 survey[15] investigated the reasons for adult non-adoption of hearing aids by decile of hearing loss, finding that:

- **For the lower three deciles of hearing loss, the main reasons for non-adoption were perception of hearing loss** ("loss is too mild") for 85%+ of consumers **and lack of need** ("hear well enough in most situations") for 70-75% of consumers. In this segment, only about one-third of non-owners cite any type of financial-based reasons;
- For the top three deciles of hearing loss (i.e., more severe hearing losses), financial reasons are cited by 60-65% of individuals ranking second as the primary reason for not purchasing hearing aids (still after perception of hearing loss).

As many hearing care professionals experience daily, while price (and lack of coverage) may play a role in individual decisions, overall the main reasons for non-adoption are still minimization of need and stigma.

In conclusion, we have doubts that the proposed OTC approach would ensure consumer safety and health outcome and that it would increase adoption of proper hearing care solutions. In fact, evidence does not exist to support these statements; on the contrary, some evidence suggests that caution needs to be taken when considering changing the current hearing care delivery model. While the goal of increasing access to and affordability of hearing care solutions for adults with mild-to-moderate hearing loss is laudable, more study and reflection is needed to properly evaluate (1) potential, unintended consequences such as increasing the number of people who do not seek medical help when needed as well as (2) whether the OTC approach would actually accomplish the goal of increasing adoption, address the needs of individuals who do not adopt hearing aids, and/or negatively impact the "gold standard" model in place today. As an organization, we are very supportive of fact-based discussions around health care policy models; for this reasons, we are willing to dedicate our resources to efforts that go in this direction.

Yours truly,

Heinz Ruch
President/CEO
Executive Vice President Amplifon Americas

[15] "MarkeTrak VII: Obstacles to adult nonuser adoption of hearing aids", S. Kochkin, The Hearing Journal, April 2007 – Volume 60 – Issue 4 – p 24-51. Table 5. Available at:
http://mobile.journals.lww.com/thehearingjournal/Fulltext/2007/04000/MarkeTrak_VII__Obstacles_to_adult_non_user.7.aspx

Attachment to:
Federal Trade Commission Public Comment

OTC Hearing Instrument Pilot Study

May, 2017

amplifon™

AZ Marketing Research, Inc.

Agenda

- Study Overview: Objectives and Design
- Key Findings:
  - Ability to self-diagnose and self-select hearing solution
  - Comparison of OTC and Traditional Approaches

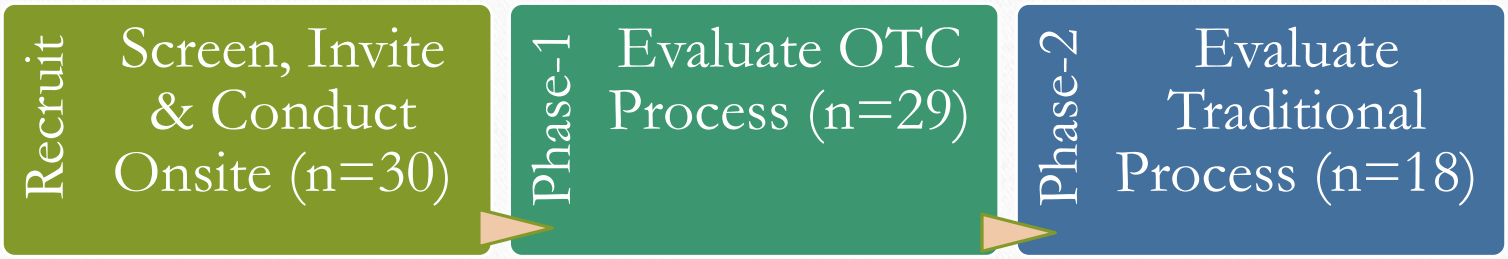
Study Overview

Objectives & Design Considerations

Pilot Study

- Study commissioned in response to the suggestion that FDA create category of "basic hearing aids" approved for OTC sales
- Goal was to provide insight on the following (to evaluate assumptions in the proposal):
  1. How well can individuals diagnose and classify their loss (and identify red flag conditions)?
  2. In an OTC environment, how well can individuals select an instrument and get started using it?
  3. How effective/satisfying is this category of instruments for average consumers?
  4. How does the OTC experience compare to the traditional process?
- Define and test a study design that could be replicated in other markets.

Multi-Step Study



- ✓ Screened to meet target requirements
- ✓ Given hearing evaluation
- ✓ Debriefed on product self-selection and provided with product/instructions for study

- ✓ Used products in OTC environment (as if shipped directly)
- ✓ Evaluated process/products at:
  - ✓ 3-weeks
  - ✓ 6-weeks

- ✓ Got evaluated and got fitted for hearing aids (with support from professional)
- ✓ Evaluated process/products at:
  - ✓ 3-weeks
  - ✓ 6-weeks

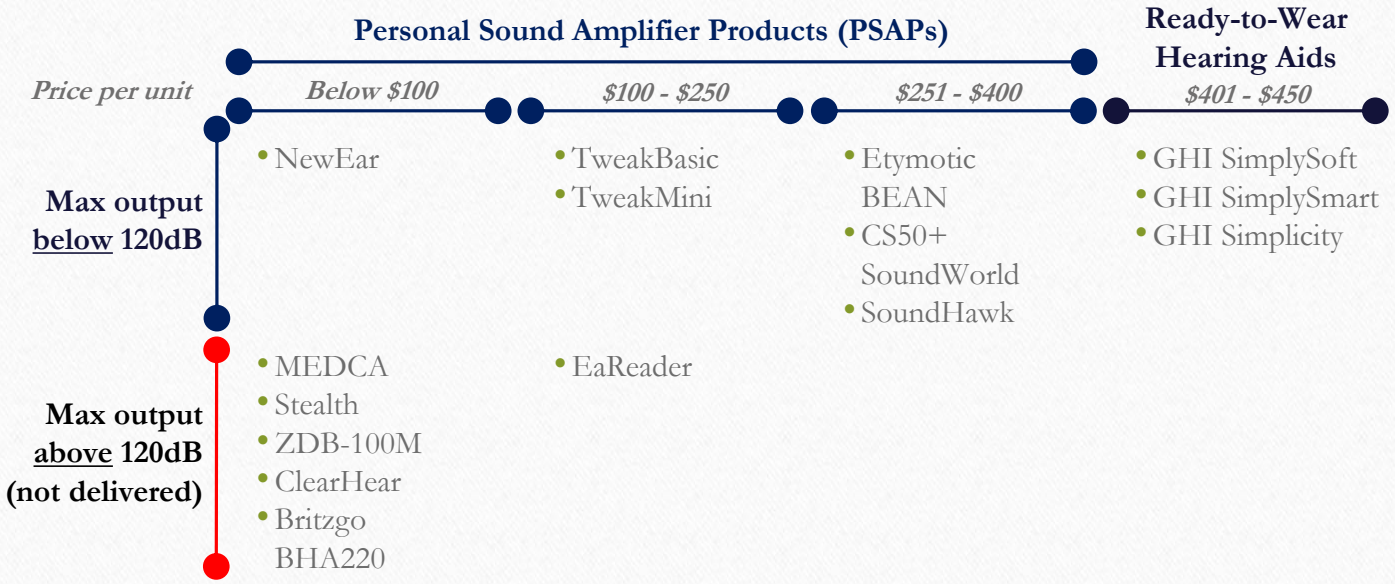
Target Market Screening Criteria & Process

Sample (n=30) provides reasonably stable estimates and solid directional insight for pilot

- Study framed broadly (about "health", with objective blinds during screening)
- Participant qualifications:
  - Seniors (60+)
  - With self-reported mild-to-moderate loss
  - Not currently using a hearing aid or PSAP
  - Had not evaluated hearing loss recently
  - Showed interest in a qualifying hearing instrument
- Interest in qualifying devices assessed using OTC market simulation process:
  - Shown profiles of 15 models varying on type/price and key features
  - 9 safe for trial (max output at <120 dB)
- On-site hearing evaluation conducted by a professional to:
  - Determine actual level of hearing loss
  - Ensure no red flag conditions were present
  - Results shared only after phase-1

OTC market simulated to allow consumer to choose & safely try products

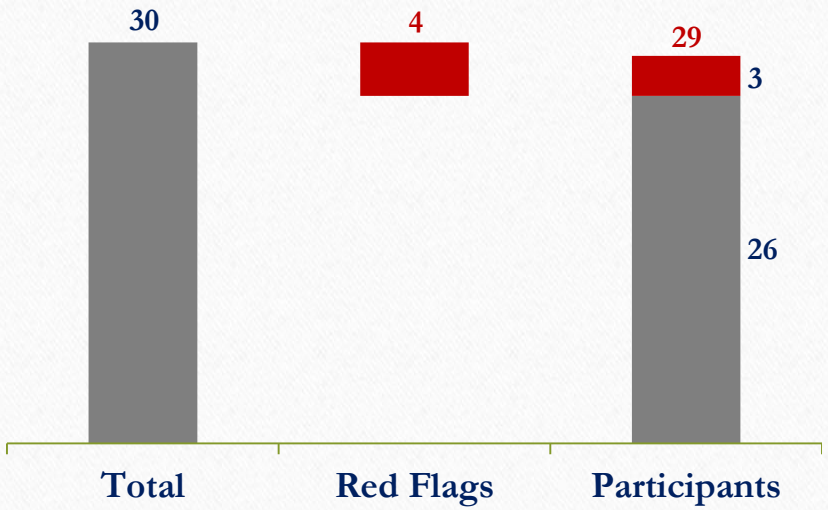
- Range shown varied on features & price; but not all allowed for trial
- Shown 15 product profiles: included photo, price and key technical features (e.g.: type, battery type and life, maximum output, peak frequency, etc.)



Ability to Self-Diagnose

Level & Type

4 (out of 30) participants were referred for red flag condition



- **Overall, 29 were cleared to participate in the study**
- **4 referred to physician/ENT for red flag condition:**
  - Outer ear infection (both ears)
  - Progressive HL; unilateral HL of sudden onset in last 90 days
  - Progressive HL in left ear; tube in right ear
  - Unilateral HL of sudden onset in last 90 days
- 3 obtained medical clearance and participated

29 individuals received hearing instrument to try & evaluate
simulating an OTC experience (with no HCP input or assistance)

Many consumers not equipped to precisely self-diagnose degree of hearing loss

		Self-Reported		TOTAL
		Mild	Moderate	
Hearing Test Results	No Loss (25 dB HL or less)	2	1	3
	Mild (26 – 40 dB HL)	2	0	2
	Moderate (41 – 60 dB HL)	8	5	13
	Severe or Profound (61-80 / 81+ dB HL)	3	8	11
TOTAL		**15**	**14**	**29**

3 with normal hearing self-reported hearing loss

15 able to self-diagnose a mild/moderate hearing loss; half of them (7) able to discriminate mild vs. moderate

11 with more severe loss self-report lower degrees (mild or moderate)

Comparison of self-reported level (overall) and type from results of hearing test performed by a hearing care professional on-site (before delivering any hearing instrument).
NOTE: For bilateral hearing loss, considered mis-diagnosed if degree HL wrongly self-reported for at least one ear

Most assume type of hearing loss is bilateral, but only about half (14) of participants correctly self-diagnosed

		Self-Reported			TOTAL
		Unilateral Loss	Bilateral Loss	Not sure of type	
	No Loss	1	1	1	3
Hearing Test	Unilateral Loss	0	5	0	5
	Bilateral Loss	4	14	3	21
TOTAL		5	20	4	29

3 with normal hearing self-reported hearing loss

4 not sure of type (mostly bilateral)

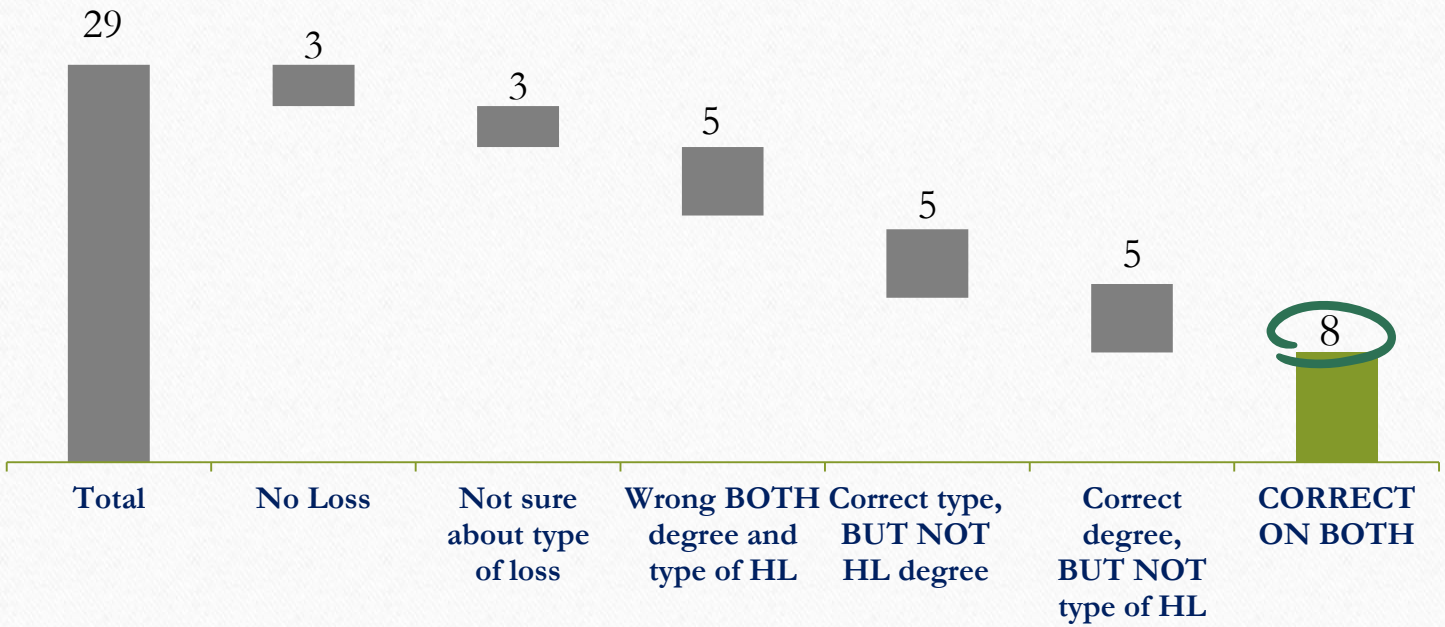
14 (out of 29) able to self diagnose type of hearing loss

- All of them had bilateral loss

Comparison of self-reported level (overall) and type from results of hearing test performed by a hearing care professional on-site (before delivering any hearing instrument).

About one-in-four able to correctly self-diagnose <u>type & degree</u>

- Considering only ability to discriminate between mild-moderate vs. any other degree



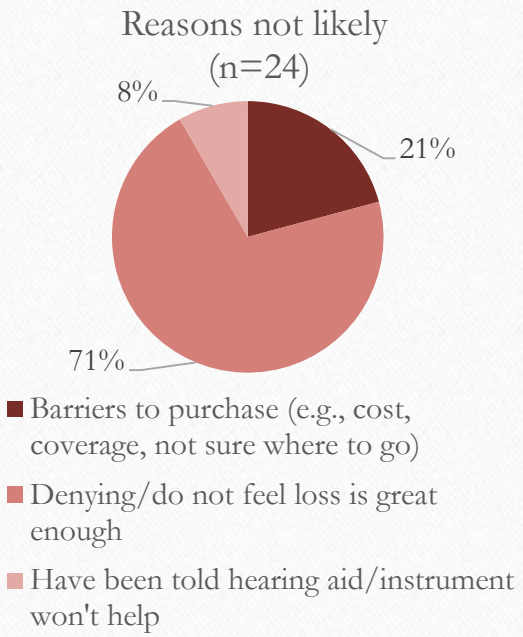
Comparison of self-reported level (overall) and type from results of hearing test performed by a hearing care professional on-site (before delivering any hearing instrument). NOTE: For bilateral hearing loss, considered mis-diagnosed if degree HL wrongly self-reported for at least one ear

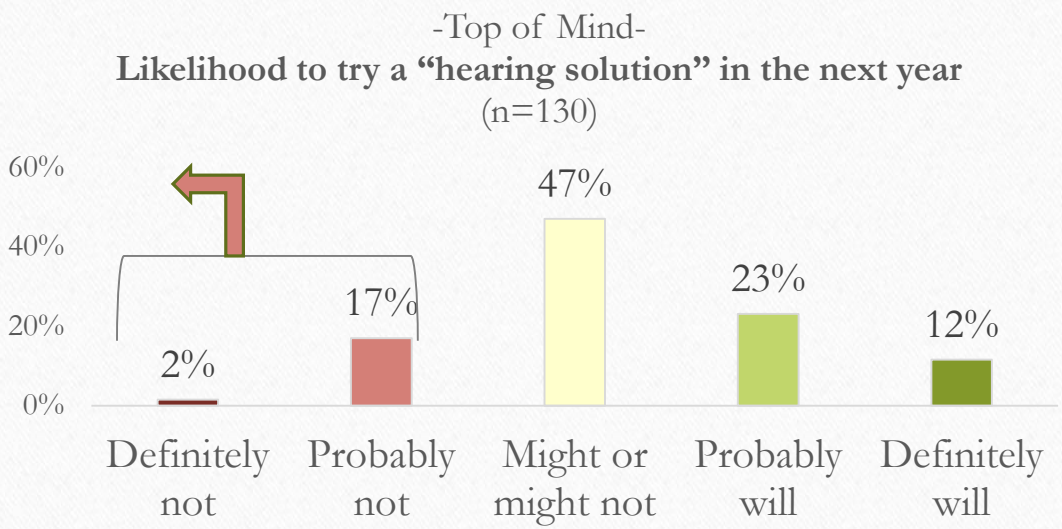
Ability to Self-Select

Knowledge Levels & Decision-Making

Among those who met basic criteria during screening process (n=130)

Most had interest in a solution, but not all ready to commit

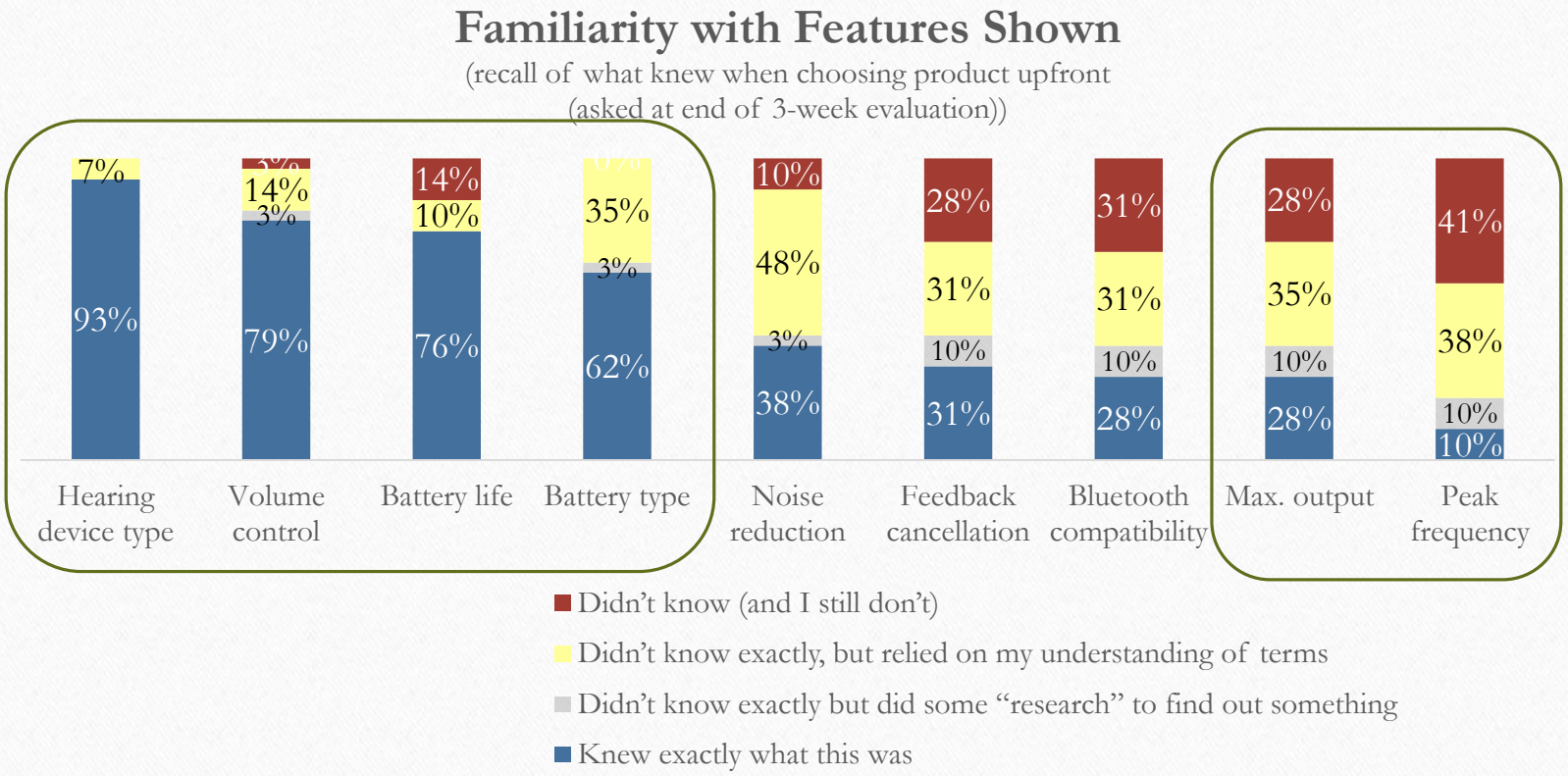




NOTE: "Hearing solution" was not defined in the question

Most respondents familiar with just the basics: type, volume control, batteries

- Few knew much about critical features, such as "peak frequency" and "maximum output".

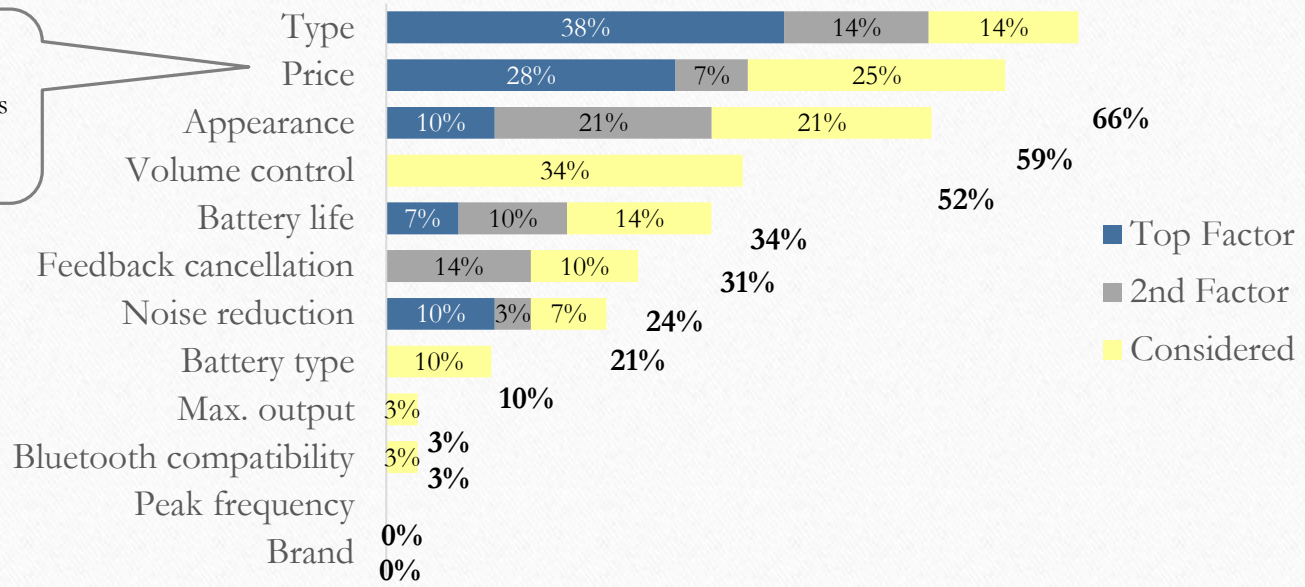


Hearing aid type, price and appearance were the main factors considered "at all"

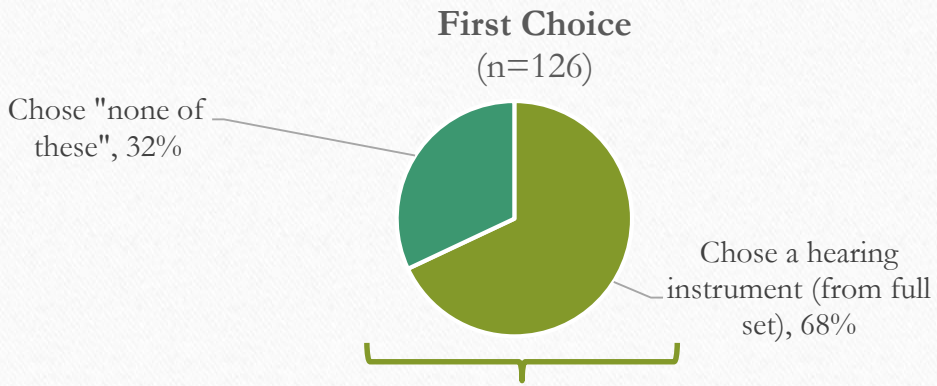
- Only three factors were considered by at least half (and were about the only factors considered top-2 in importance).
- Features that may impact performance were often not considered at all (likely driven by lack of familiarity/knowledge).

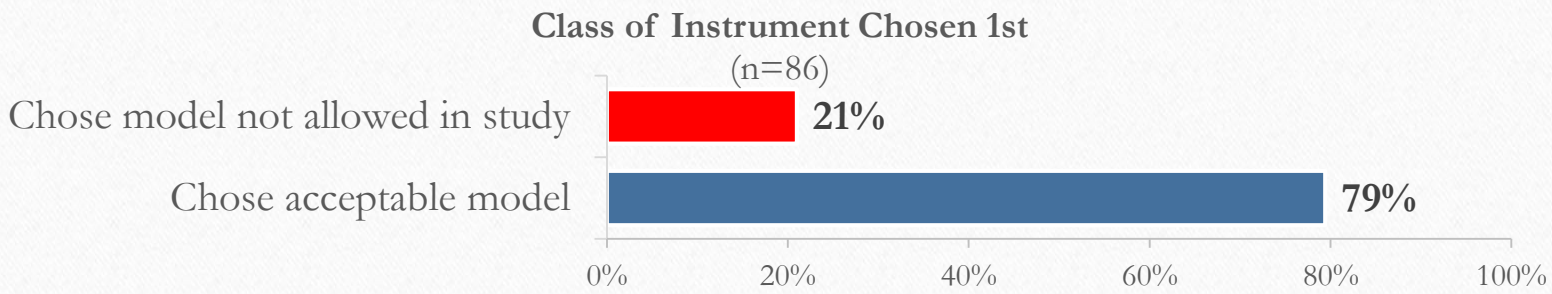
Features Considered When Choosing Product

- Most not looking for lowest price.
- Lower priced products avoided because price is indicator of quality



Most participants would try a product in OTC range; but one-fifth chose model with max. output of 120 dB or higher





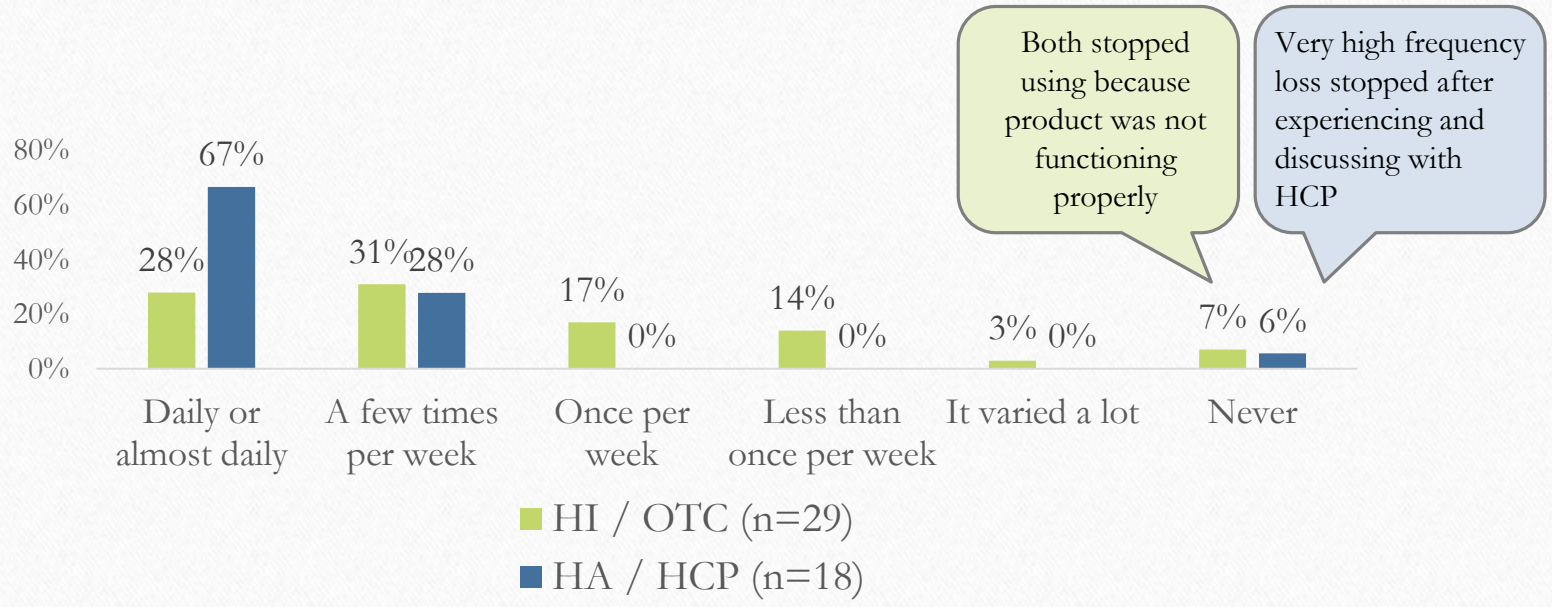
Comparison of OTC and Traditional Approaches

Part-1 & Part-2

Virtually all used their hearing aids a few times per week or daily

- HA/HCP daily use more than double than for HI/OTC product
- HA/HCP daily users had higher average hours per day (~11 vs. ~8 hours/day, respectively)

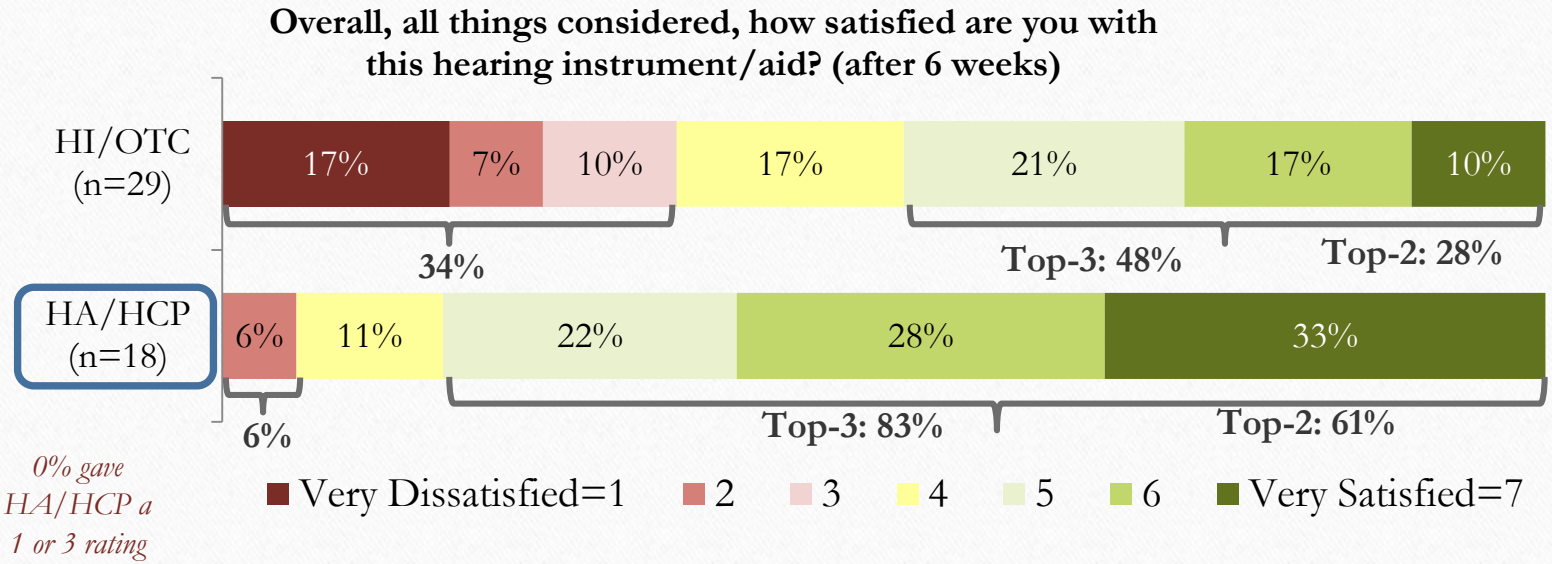
How often did you use the hearing instrument/aid?



HIA MT9 Market Study (2015) Comparison: All HA Owners (n=980) 72% wear daily (11.4 hours/day)

At 6-weeks, satisfaction with hearing aid is considerably higher than for HI/OTC

- Higher satisfaction rate and a much lower dissatisfaction level, for the HA/HCP compared to the HI/OTC



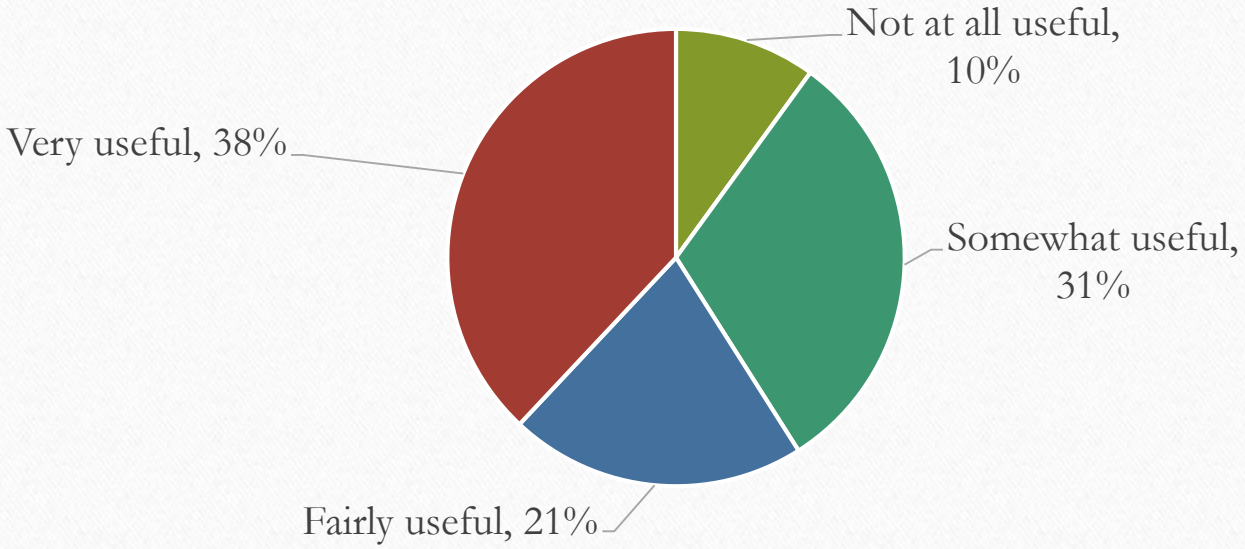
0% gave HA/HCP a 1 or 3 rating

HIA MT9 Market Study (2015) Comparisons:
- All HA Owners (n=980) Top-2%=73% & Top-3%=81%
- HA <=1 Year Old (n=340) Top-2%=76% & Top-3%=91%

At the end of the OTC experience, most felt having some assistance from a professional would have been useful (for many, "very useful")

- Asked at the end of the 6-week survey, after the overall satisfaction question on the OTC approach (before participant experienced the Professional Approach)

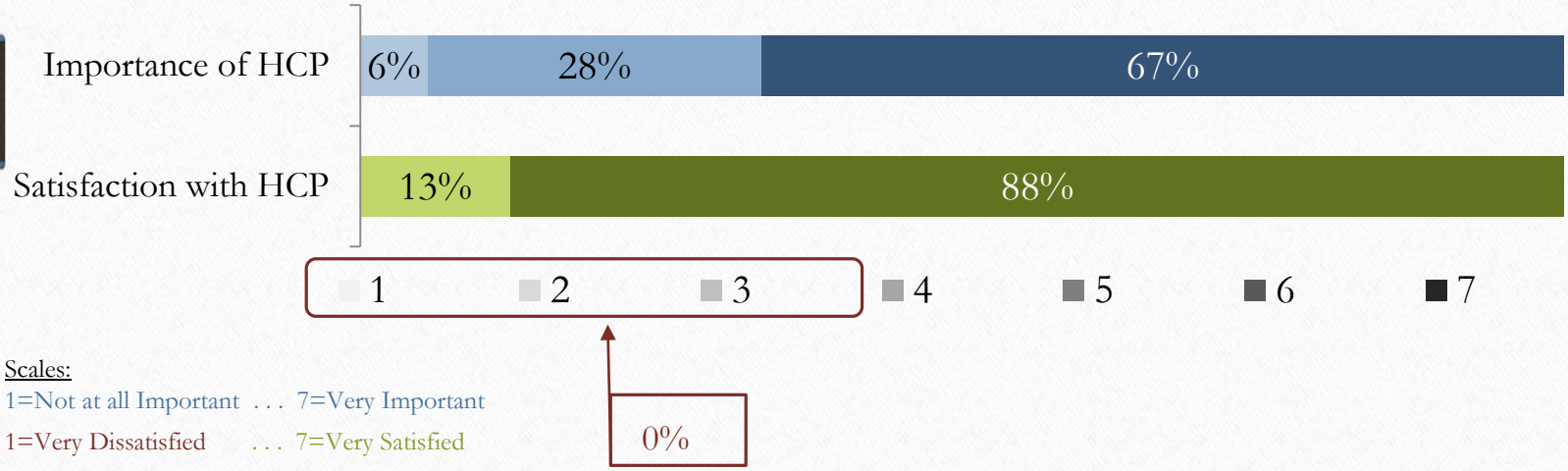
Thinking back, how useful do you think it would have been, if at all, to have some assistance from a professional when getting used to this hearing instrument?



At the end of the study, hearing care professional viewed as playing a significant role in process

- Virtually all valued input/guidance of hearing care professional overall
- Also gave rave reviews for counseling on selection and when acclimating to the hearing aid, for service during the fitting and for explanations about hearing condition/test and what to expect (not shown)

Importance/Satisfaction with HCP



Scales:
1=Not at all Important . . . 7=Very Important
1=Very Dissatisfied . . . 7=Very Satisfied

No one rated the importance of the HCP below a 5 nor the satisfaction with the HCP below a 6. These values are all "0%" and not shown.