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# Affordable and Accessible Hearing Healthcare Interventions in the United States: A Literature Review and Prospective Analysis

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AFFORDABLE AND ACCESSIBLE HEARING HEALTHCARE INTERVENTIONS  
IN THE UNITED STATES: A LITERATURE REVIEW AND PROSPECTIVE ANALYSIS

by

GARRETT THOMPSON

A capstone research project submitted to the Graduate Faculty in Audiology in partial fulfillment  
of the requirements for the degree of Doctor of Audiology, The City University of New York

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This manuscript has been read and accepted by the Graduate Faculty in Audiology in satisfaction of the capstone research requirement for the degree of Au.D.

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## ABSTRACT

### AFFORDABLE AND ACCESSIBLE HEARING HEALTHCARE INTERVENTIONS IN THE UNITED STATES: A LITERATURE REVIEW AND PROSPECTIVE ANALYSIS

by

GARRETT THOMPSON

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Age-related hearing loss is a significant public health concern with serious and far-reaching consequences including: social isolation, depression, faster cognitive decline, and increased risk of falls. Hearing loss is a widespread condition, it is in fact a leading cause of disability among older people. Hearing aids, the primary intervention for adults with hearing loss, are costly and inaccessible to many patients who need them. Among other reasons, these factors have led to a low uptake rate among the adult population; only one in seven adults who could benefit from wearing hearing aids utilizes them. Given the status quo of high quality but expensive hearing healthcare intervention and meager hearing aid usage, the need for alternative and innovative models is paramount. The goal of this paper is to discuss the prevailing hearing healthcare model, consider top-down forces that are driving change in this space, explore the alternative models that are currently or soon to be available, predict future innovations based on the available literature, and examine the evolving role of the audiologist in this context.

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## INTRODUCTION

Age-related hearing loss (ARHL) is insidious: its onset is gradual, its presence is often considered a benign aspect of aging, and its effects are consequential (Blustein & Weinstein, 2016). ARHL is associated with social isolation, depression, faster cognitive decline, and increased risk of falls; if left untreated, it is a significant public health concern with serious and far-reaching effects (Blustein & Weinstein, 2016). Hearing loss degrades communication with healthcare providers, leading to overall poorer healthcare quality (Mick et al., 2014). Even the more banal-sounding consequences such as chronic communication breakdowns, reduced workplace productivity, and reduced enjoyment of music can all lead to lower overall quality of life (Taylor, 2016). The widespread prevalence of ARHL is impactful, it is in fact a leading cause of disability among older people (Blustein & Weinstein, 2016). Despite the high quality of digital hearing aid technology, hearing aid uptake is small relative to prevalence, in large part due to cost and lack of accessibility. These factors underscore the need for alternative and innovative models (PCAST, 2015).

Audiological intervention for individuals with hearing loss (HL) offers the possibility of excellent outcomes as opposed to the negative outcomes of untreated HL (Swanepoel et al., 2010). Hearing aids (HAs), the primary intervention for adults with ARHL, are costly and inaccessible to many patients who need them (Fisher, et al., 2011). The average price of a pair of HAs, approximately \$4800, is out of the price range for many older adults (Fisher, et al., 2011; PCAST, 2015). While the Veterans Administration covers hearing aids for selected categories of veterans, Medicare and the vast majority of other insurance plans do not cover hearing aids, so patients typically pay

for the devices out of pocket (Blustein & Weinstein, 2016). Although the decision to use or not use HAs is multifaceted, individuals who could otherwise benefit from, but do not own hearing aids, often cite cost as the biggest barrier to acquisition (Fisher, et al., 2011; Kochkin, 2012).

In a large survey of hearing aid non-users, Kochkin (2012) asked participants which factors would motivate them to acquire hearing aids. Of over 50 factors that spanned financial, lifestyle, product performance, and psycho-social effects, three of the top four priorities were related to cost: 1) 100% insurance coverage for hearing aids, 2) money back guarantee, 3) more reliable/seldom breaks down, and 4) price not more than \$500. Furthermore, nearly half of the survey respondents who had severe hearing loss stated they would purchase hearing aids in the next two years if they were priced under \$500 (Kochkin, 2012). Kochkin (2007) also showed that patients who indicated they could not afford hearing aids, controlled for degree of hearing loss, had a median income of approximately \$40,000 less than those who stated price was not a barrier, suggesting that lack of affordability is not an imagined impediment but rather a real barrier to accessibility (Kochkin, 2014). In Fischer's (2011) recent population-based prospective study the majority of the 718 participants cited cost as a major deterrent to hearing aid use.

Factors beyond cost play a role in the decision making process of whether or not to acquire hearing aids (Blustein & Weinstein, 2016). Other factors include the perception that a hearing aid is not needed, the perception that the benefit would be relatively minor, negative reviews by hearing aid users they know, and the stigma of appearing old, weak, or disabled (Kochkin, 2007; Blustein & Weinstein, 2016). Stigma is

a particularly impactful barrier, as up to half of individuals who do not utilize hearing aids cite stigma as a major reason for their decision (Kochkin, 2007). Some combination of all these factors has led to a low uptake rate among American adults with hearing loss; only one in seven (17%) who could benefit from wearing hearing aids uses them (Chien & Lin, 2012).

Recent reports by the President's Council of Advisors on Science and Technology (PCAST) and the National Academies of Science, Engineering, and Medicine (NAS), as well as Big Box retail competitors are applying a great deal of top-down pressure on the hearing healthcare market (PCAST, 2015; NAS, 2016; Hosford-Dunn, 2017). Big Box retailers, most notably Costco, have entered the market at a drastically lower price point than the traditional hearing aid delivery model, changing the fundamental economics of the market and challenging the traditional model to adapt (Hosford-Dunn, 2017). PCAST and NAS reports have made a firm call for reform of the traditional hearing healthcare model for adults in the United States, emphasizing accessible, affordable, transparent, and quality healthcare as priorities (PCAST, 2015; NAS, 2016). This combination of powerful market and external forces will undoubtedly impact and shape the hearing healthcare landscape moving forward (Hosford-Dunn, 2017). The question is: will audiologists be disrupted and replaced, or can they evolve and thrive in this dynamic space?

The challenges laid out by the PCAST and NAS reports will not resolve themselves, in fact they will likely become more problematic in the near future (Clark & Swanepoel, 2014). If no changes are made, hearing healthcare may be fraught with the growing problems of an aging population, the extension of the human lifespan, the

geographical maldistribution of access, and a dearth of audiology professionals available to meet the increased demand for services (Clark & Swanepoel, 2014). The gap between available audiologists and services demanded will widen as the number of persons with hearing loss continues to increase at a faster rate than the number of audiologists entering the profession (Swanepoel, 2010). Alternative approaches to hearing healthcare are necessary as continuation of the status quo will lead to a significant deficit of available services, exposing the US adult population to the negative downstream effects of untreated hearing loss (PCAST 2015).

#### TOP-DOWN FORCES

Top-down forces are applying significant pressure to the hearing healthcare market, particularly pricing pressure created from the entrance of Big Box stores into the hearing aid retail market and recommendations of regulatory change from two separate federal committee meetings. (PCAST, 2015; NAS, 2016; Hosford-Dunn, 2017). Pricing pressure from new competition, a market force, and the threat of government regulation, an external economic force, both arose in reaction to inefficiencies in the traditional hearing healthcare delivery model (PCAST, 2015, NAS, 2016).

Costco has embraced the sale of low-cost premium hearing aids in their stores, increasing their internal hearing aid centers (a store-in-store concept) considerably since the mid-90s (Hosford-Dunn, 2017). As the number of their hearing aid centers have significantly increased, so too has hearing aid revenue. From 2010-2015, it is estimated that hearing aid sales growth was 20% year-over-year, much greater than the overall industry growth of 3-4%. It is estimated that in the US in 2016 Costco sold 350,000

hearing aids (Hosford-Dunn, 2017). They now account for about 10-12% of the all hearing aids sold in the US, and they continue to gain market share (PCAST, 2015; Hosford-Dunn, 2017). The cost of a pair of Costco-brand premium technology hearing aids (which are produced by a mainstream manufacturer) is one-third of the average pair purchased in the traditional market (PCAST, 2015). With such a dramatic price advantage and extraordinary volume, pressure is being applied to the more traditional distribution channels (Hosford-Dunn, 2017).

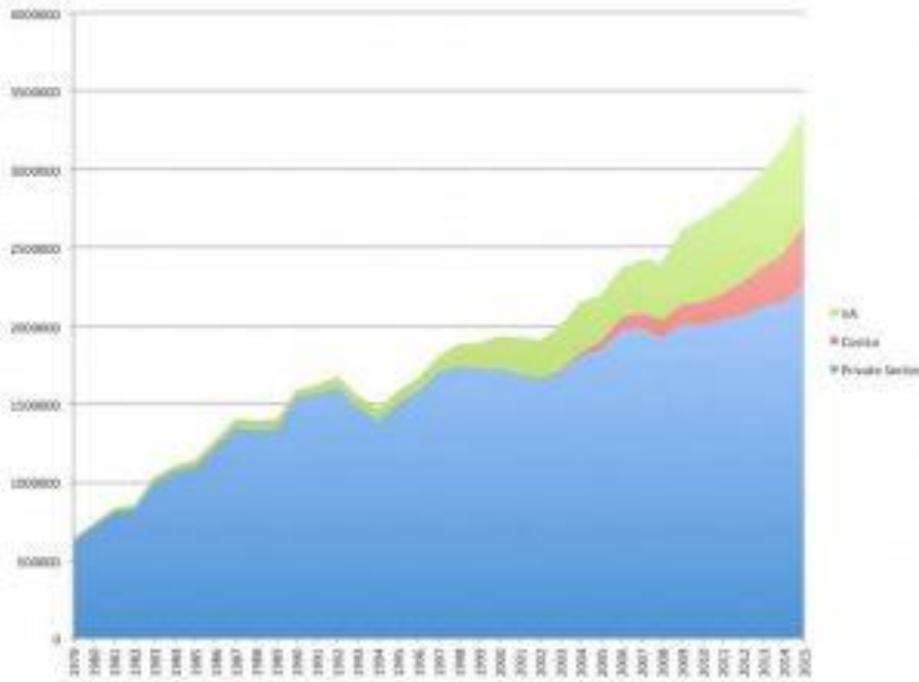


Figure 1, US Hearing Aid Sales Growth for Private Practices, Costco, and Veterans Affairs Medical Centers (Hosford-Dunn, 2017)

As seen in Figure 1 the overall hearing aid market is growing at a healthy rate, and the growth of Costco (pink) outpaces the market as a whole.

Economic theory suggests that as the price of a good's substitute declines so too does the price of the good; the demand schedule contracts and prices drop at all levels of demand. Due to cheaper prices, a requisite increase in consumption is expected. Costco hearing aids can be considered a substitute to the traditional hearing aid delivery model; as Costco hearing aid sales continue to thrive in the years to come, one can expect the average price of traditional hearing aid delivery to decline (Hosford-Dunn, 2017). This effect is evident in recent years, as the average price of hearing aids has declined relative to inflation since 2012 (Hosford-Dunn, 2017). With depressed prices, one can also expect a requisite increase in the consumption of hearing aids in the traditional market. Market data are consistent with this expectation, recent years have shown healthy growth in private sector hearing aid sales: 3.4% in 2014, 7.8% in 2015, and 9% in 2016 (Hosford-Dunn, 2017). Given the declining prices of traditional delivery hearing aids and concurrent influx of new baby boomer patients, one can expect that audiologists will be serving a significantly greater number of patients per hour in the years to come; they would be wise to consider a model with a lower price point that can handle an increased patient load.

The recent PCAST and NAS groups examined the state of hearing healthcare in the United States, producing several findings and recommendations (See Table 1 below, organized loosely by topic by the author). The reports emphasize that ARHL is a substantial public health concern and that the importance of accessible, affordable, and

quality healthcare are priorities for reforming hearing healthcare for adults in the United States (PCAST, 2015; NAS, 2016).

Table 1, Summary of Findings and Recommendations from the President’s Council of Advisors on Science and Technology (PCAST) and the National Academies of Sciences, Engineering, and Medicine (NAS) (PCAST, 2015; NAS, 2016)

President’s Council of Advisors on Science and Technology (PCAST)	National Academies of Sciences, Engineering, and Medicine (NAS)
<ul style="list-style-type: none"> <li>• Age-related hearing loss is a substantial national problem</li> </ul>	<ul style="list-style-type: none"> <li>• Hearing is vital to communication, health, function, and quality of life</li> <li>• Hearing loss is a public health and societal concern</li> </ul>
<ul style="list-style-type: none"> <li>• Recommend that, analogous to the “Eyeglass Rule,” FTC require audiologists and hearing aid dispensers to provide customers with a copy of their audiogram and the programmable audio profile for a hearing aid fitting at no additional cost</li> <li>• Recommend that, similar to the “Contact Lens Rule,” FTC should define a process by which patients may authorize hearing aid vendors (in-state or out-of-state) to obtain a copy of their audiogram from any audiologist who performs such a test</li> </ul>	<ul style="list-style-type: none"> <li>• Empower consumers and patients in their use of hearing healthcare, including access rights to audiograms and hearing aid programming history</li> <li>• Standards for an open-platform approach to hearing aid programming, so no device can be locked</li> <li>• Individuals need to be alert to their hearing health</li> <li>• Improve population-based information on hearing healthcare</li> </ul>
<ul style="list-style-type: none"> <li>• Current distribution channels create barriers to access</li> <li>• The frequent practice of audiologists bundling service fees with device cost reduces access and affordability</li> <li>• Audiologists that are vertically integrated and offer a limited number of manufacturers’ hearing aids limits access</li> </ul>	<ul style="list-style-type: none"> <li>• Many people do not have access to hearing healthcare options or can’t afford them</li> <li>• Improve access to hearing healthcare for underserved and vulnerable populations, including through the use of telehealth</li> <li>• Promote individual, employer, private sector, and community-based actions to support and manage hearing health and effective communication</li> </ul>
	<ul style="list-style-type: none"> <li>• Promote hearing healthcare in wellness and medical visits for those with concerns about their</li> </ul>

	hearing
	<ul style="list-style-type: none"> <li>Develop and promote measures to assess and improve quality of hearing healthcare services</li> </ul>
<ul style="list-style-type: none"> <li>Remove FDA’s regulation for medical evaluation or waiver of that evaluation prior to hearing aid purchase</li> </ul>	<ul style="list-style-type: none"> <li>Remove FDA’s regulation for medical evaluation or waiver of that evaluation prior to hearing aid purchase</li> </ul>
<ul style="list-style-type: none"> <li>Recommend FDA should approve a class of OTC hearing aids</li> <li>Recommend FDA should withdraw its guidance on PSAPs, allowing these devices to be marketed to help with hearing loss</li> </ul>	<ul style="list-style-type: none"> <li>Implement a new FDA device category for over-the-counter wearable hearing devices</li> </ul>
<ul style="list-style-type: none"> <li>The market for hearing aids is characterized by low innovation</li> </ul>	<ul style="list-style-type: none"> <li>Evaluate and implement innovative models of hearing healthcare to improve access, quality, and affordability</li> </ul>
<ul style="list-style-type: none"> <li>The market for hearing aids is characterized by high cost, linked to the noncompetitive hearing aid market and inefficient distribution channels</li> </ul>	<ul style="list-style-type: none"> <li>Improve affordability of hearing healthcare by actions across federal, state, and private sectors</li> </ul>

The PCAST panel’s analysis of the hearing aid market and ARHL generated multiple reasons for the low uptake of hearing aids, most prominently being the lack of access and affordability of hearing healthcare (PCAST, 2015). Cost was cited as the single largest barrier, referring to a Strom (2014) survey that revealed the average price of a single hearing aid to be \$2,363. The authors note that most individuals need two hearing aids, doubling the cost to over \$4,700 (PCAST, 2015). The same survey (Strom, 2014) shows that the median pair of premium technology level RIC-style hearing aids (the most popular on the market) is \$6,000. PCAST reports that 64% percent of people with the most serious hearing loss reported that they could not afford a hearing aid (2015). By the estimation of the Council, cost is the key barrier to hearing aid use because: Medicare and other insurance plans rarely cover hearing aids, the hearing aid

manufacturing industry is highly concentrated, and because hearing aid distribution channels are inefficient (PCAST, 2015).

The PCAST report indicated that the lack of Medicare coverage originated in the 1966 Medicare amendments to the Social Security Act, which bar the coverage of hearing aids (Whitson & Lin, 2013; PCAST, 2015). Advocacy groups have long called for broader coverage of assistive devices that would help people living with hearing loss (Whitson & Lin, 2013). The President's Council states that the reason subsequent legislative attempts to change this have failed is due to the high incidence of hearing loss and high cost of hearing aids, suggesting that if the cost was reduced there would be the possibility of changing Medicare coverage rules for hearing aids (PCAST, 2015). Given present-day understanding of the long-term and public health effects of hearing loss, and furthermore the societal and healthcare costs incurred by not enabling individuals to access assistive devices, Medicare coverage policy may need reconsideration (Whitson & Lin, 2013).

The hearing aid manufacturing industry is considerably concentrated; following a wave of acquisitions, just six hearing aid manufactures account for 98% of global production (PCAST, 2015). While comparable consumer electronics have decreased in price dramatically over the last two decades, hearing aids have not (Blustein & Weinstein, 2016). There is considerable evidence that hearing aids can be profitably sold at drastically lower cost than they currently are; for example the Veteran's Affairs hospital system, which accounts for a large proportion of all hearing aid sales in the US, purchases HAs from the same manufacturers for about \$400 per unit (PCAST, 2015). The price of premium hearing aids from Costco is about one-fourth of the average

traditional delivery premium HA price (Strom et al., 2014; PCAST, 2015; Hosford-Dunn, 2017). It is rudimentary economics that monopolistic or oligopolistic market concentration creates significant pricing power for those firms, and welfare loss for consumers (Cowling, 1978).

The President's Council also points to inefficiencies in hearing aid distribution channels as a reason for both high cost and inaccessibility (PCAST, 2015). They point out the inefficiencies in the common practice of bundling the cost of the hearing aid with the cost of professional services; and the Council suggests that this method is opaque to consumers, that not all consumers use the services, that consumers are locked into using that audiologist, and that it increases overall cost (PCAST, 2015). Another inefficiency is that of vertical integration, as some audiologists or dispensers preferentially sell certain manufacturers based on close business relationships or incentivized arrangements; this is not transparent to the consumer and reduces their access to a full range of hearing aid options. Hearing aid manufacturers consistently acquire smaller companies and do not change the brand name, creating a false sense of options to consumers and a sense of competition in the market when there is very little (PCAST, 2015). Nor do they tell the consumer that the practice is owned by a manufacturer. Finally, the report touches on the fact that hearing aid technology level prices vary widely, even though research suggests that premium and basic technology levels offer comparable levels of hearing improvement (Cox et al., 2014; PCAST, 2015). When comparing premium and basic technology, no differences were found in speech understanding, listening effort, hearing-related QOL, or patient preference (Cox et al., 2016; Johnson et al., 2016). As seen in Figure 2 (Strom, 2014), the cost difference between technology levels is sizeable, a pair

of premium aids is approximately \$2,600 (77%) more expensive than basic aids.

Although peer-reviewed evidence for better performance is scant, premium aids are dispensed over one-third of the time (37%), meanwhile basic technology levels aids are the least frequently dispensed, at only 19% of the total (Cox et al., 2014; Strom, 2014).

2013 REPORTED PERCENT UTILIZATION OF THREE TECHNOLOGY/PRICE LEVELS				
	Economy	Mid-Level	Premium	
Average	19.1%	43.9%	37.0%	
Median	15%	45%	30%	
2013 REPORTED AVERAGE (AND MEDIAN) HEARING AID PRICES				
	Economy	Mid-Level	Premium	Weighted Avg*
RIC/RITE	\$1694 (\$1575)	\$2220 (\$2250)	\$2993 (\$3000)	\$2399
BTE	\$1580 (\$1500)	\$2155 (\$2200)	\$2769 (\$2900)	\$2325
ITE	\$1600 (\$1500)	\$2166 (\$2200)	\$2757 (\$2895)	\$2323
ITC	\$1716 (\$1575)	\$2197 (\$2210)	\$2861 (\$2900)	\$2344
CIC/IC	\$1695 (\$1670)	\$2294 (\$2250)	\$2958 (\$3000)	\$2417
Total Weighted Avg*	\$1657	\$2196	\$2898	\$2363

Figure 2, Average Utilization and Cost of Hearing Aid Styles and Technology Levels (Strom, 2014)

Following rigorous analysis, the President’s Council made several recommendations that they suggest will improve accessibility and affordability. They purport that modest regulatory changes could result in a dramatic reduction of the inefficiencies that currently exist (PCAST, 2015). They recommend that:

1. The Food and Drug Administration (FDA) should designate a new and distinct category for “basic” hearing aids that are intended to address ARHL, and to make them available over-the-counter.
2. FDA should withdraw its draft guidance on PSAPs, instead broadly defining them as devices intended to augment, improve, or extend the sense of hearing.

3. The Federal Trade Commission (FTC) should require audiologists and hearing aid dispensers to provide customers with a copy of their audiogram, analogous to its “Eyeglass Rule.”
4. FTC should define a process by which patients may authorize hearing aid vendors (in-state or out-of-state) to obtain a copy of their audiogram from any audiologist who has performed such a test on them, at no additional cost to the consumer; analogous to its “Contact Lens Rule” (PCAST, 2015).

All four PCAST recommendations could be implemented without legislative action (Blustein & Weinstein, 2016).

The analysis and recommendations of the National Academies of Sciences (NAS) report mirrored the PCAST report in several ways and provided additional recommendations, as well. The NAS group concurred that hearing is vital to communication, health, function, and QOL, and that ARHL is a public health and societal concern (NAS, 2016). They were in agreement that the main considerations of the government should be improving access and affordability, and that creating a new category of OTC HAs was the recommended approach (NAS, 2016). They echoed that patients deserve the right to their hearing test results, free of additional charge, and that an open-platform approach to hearing aid programming that does not lock any devices is beneficial to consumers. Additionally, they encourage hearing healthcare providers to develop and promote measures to assess quality of hearing healthcare and to innovate their delivery models (NAS, 2016).

In response to the PCAST and NAS reports, and the shortcomings in the current state of hearing healthcare, Senators Elizabeth Warren (D-MA) and Chuck Grassley (R-IA) have proposed a bill to make the recommendation of an OTC hearing aid category a legislative reality (Warren & Grassley, 2017). The Senators reiterate several points made in the PCAST and NAS reports, including that a hearing aid geared towards individuals with mild-to-moderate hearing loss can be safely made available over the counter. They also recommend that the FDA should revise its guidance on so-called personal sound amplification products (PSAPs), allowing them to be marketed as devices designed to address hearing loss (Warren & Grassley, 2017). PSAPs are sound amplifying devices that are legally intended to be used by individuals with normal hearing who want assistance in difficult listening situations, although they can be helpful for people with hearing loss (Blustein & Weinstein, 2016).

The Senators purport that these actions will substantially lower cost and increase access to hearing technologies for millions of Americans (Warren & Grassley, 2017). Anecdotally this alternative direct-to-consumer approach might improve access and affordability however evidence is mixed regarding the advantages relative to outcomes. From the scant evidence regarding people's ability to successfully use and manage OTC devices, we know they commonly have difficulty with basic tasks such as inserting the device correctly in the ears; consumers also state a preference for the involvement of a trained professional (Convery et al., 2016). An OTC delivery model would likely remove the audiologist from the hearing aid evaluation and fitting, which inherently changes how consumers will interact with these devices. However, the fact remains that patients would still need to learn how to self-manage their hearing loss if negative outcomes and the

associated anxiety are to be avoided (Hogan et al., 2015). A review of the available body of evidence on outcomes of a direct-to-consumer hearing aid model, as well as patient's perception of such a model may shed light on the advantages and disadvantages of this new form of service delivery.

## ALTERNATIVE MODELS

There are limited studies that evaluate the efficacy of direct-to-consumer (DTC) or over-the-counter (OTC) hearing aids; but the few that do exist are well-designed. In a placebo-controlled double-blind randomized clinical trial, Humes et al. (2017) investigated the efficacy of hearing aid intervention in older adults comparing three delivery methods: a traditional audiology best practices (AB) model, a consumer decides (CD) model, and a placebo. The CD model is related to an OTC model, in that the consumer manages the process on his own with no involvement from a professional; but it likely does not precisely emulate an actual OTC consumer process (Humes et al., 2017). The CD group watched an instructional video and was provided a booklet on the self-fitting process, at which time they were allowed to trial as many as six hearing aids to determine which of three sound profiles they preferred. The hearing aids were pre-loaded with four programs of varying loudness, for the participant to self-adjust after the selection session, if necessary. Although there are similarities to a potential OTC model, the fact that participants could trial multiple sound profiles is likely not realistic for purchasing an OTC device. The CD group was thoroughly tested and monitored in a clinical setting, which could have affected the perception of success of the CD process. Additionally, 42% of potential participants were rejected because they did not meet the

selection criteria; in the real world this group would likely not remove themselves from OTC consideration (Humes et al., 2017). As several of these factors are not typical of the way OTC hearing aids are currently dispensed, the generalizability of this study is limited.

Participants in this study were 154 adults 53-83 years old with mild to moderate, bilateral, symmetrical, sensorineural hearing loss (SNHL), with no previous experience with hearing aids. Baseline testing was performed before and outcomes measures were obtained at the end of the six week trial. Outcome measures included the Hearing Handicap Inventory for the Elderly (HHIE), the Connected Speech Test (CST), the Profile of Hearing Aid Performance (PHAPglobal), and the Hearing Aid Satisfaction Survey (HASShaf). High-end digital mini-BTE (behind-the-ear) hearing aids were used for all participants. For the placebo group, the HAs were programmed to a zero dB insertion gain acoustical transparency, meaning they provided no amplification whatsoever. For the AB and CD groups, basic features were enabled including: directional microphones, dynamic feedback suppression, and noise reduction. In the AB group, HAs were programmed to the NAL-NL2 prescriptive formula and matched to targets using Real Ear Measure verification. The CD group was given the option of three different hearing aids, each programmed to match the most common hearing loss configurations in older adults. (Humes, et al, 2017).

Results revealed that the AB model was significantly better than the CD model for improvement in HHIE, PHAPglobal, and HASShaf. Both the AB and CD models were efficacious, meaning they each showed significant benefit relative to the unaided condition in terms of HHIE, PHABglobal, HASShaf, and CST scores. The authors point

out that the CD model yielded only slightly poorer effect sizes than the AB group. Interestingly, even though the placebo intervention was not statistically better than the unaided scores, 39% of participants expressed a desire to keep the placebo devices (Humes, et al, 2017).

An earlier pilot study directly compared a simulated OTC model with a traditional hearing healthcare delivery (Tedeschi & Kihm, 2016). This study was designed to determine if individuals can properly self-diagnose and classify their hearing loss, as well as how satisfied they will be with an OTC model and how it compares to the traditional model. A sample of 29 individuals with self-reported mild-to-moderate hearing loss who are not using HAs or PSAPs were given the opportunity to choose one of PSAP of several that are commercially available (Tedeschi & Kihm, 2016). For six weeks they used these devices without professional involvement. Prices of the PSAPs that were offered ranged from \$100-\$450. Following that period, those who had hearing loss were invited to receive audiology best practice (ABP) intervention for another six weeks which included: a hearing evaluation, counseling, fitting and verification of hearing aids, instructional information, and aftercare services as needed (Tedeschi & Kihm, 2016). Ultimately, 18 individuals participated in this second phase. The design of this study was intended to mimic the sequence of a typical OTC consumer, moving from self-treatment to professional treatment, even if not in a realistic timeline (Tedeschi & Kihm, 2016). The authors note that of the 29 participants, four of them (13%) were referred to an ENT due to medical or audiological contraindications for hearing aid use; three of these individuals were eventually cleared for hearing aid use and participated in the study. In each phase of the study, participants were asked to evaluate the process twice. To the

question of accurate self-diagnosis, 15 of 29 (52%) correctly identified their hearing as mild-to moderate; of those who did so incorrectly, three had normal hearing and eleven had poorer than moderate hearing. Only 14 of 29 (48%) correctly identified their hearing as unilateral or bilateral.

When comparing the two delivery models in terms of levels of usage, 95% of the ABP group used the devices at least a few times a week; in the OTC group 59% of participants used them at least a few times a week. After the six week period, satisfaction with ABP was considerably higher than for OTC devices; 83% were at least somewhat satisfied compared to 48% for the OTC model. One in three of the ABP group were very satisfied, in the OTC group that number was one in ten. However, 52% of participants reported that the OTC device helped at least some of the time and they would recommend one to a friend; the willingness to recommend hearing aids to a friend is highly correlated to satisfaction (Kochkin, 2007). Also of note is that at the end of the OTC phase, 90% of participants felt that having some assistance from a professional would have been at least somewhat useful when getting used to the device. (Tedeschi & Kihm, 2016).

Kochkin (2014) conducted a large survey of traditional hearing aid (THA) users and direct-mail (DM) hearing aid users. In total, 1,721 THA users and 2,332 DM completed the 7-page survey. The THA sample was drawn from Kochkin's (2012) MarkeTrak VIII data, and the DM sample were customers of the largest US direct-mail hearing aid firm (Kochkin, 2014). The samples include individuals with a range of hearing loss configurations, income, and education levels; all participants were adults. DM hearing aids were not programmed to the hearing test of an individual, but rather were pre-programmed with amplification profiles that fit the most common hearing

losses; this is analogous to an OTC consumer experience. The THA group was also broken into ten audiology best practices (BP) deciles, where BP1 is a minimal hearing aid fitting protocol, BP10 is a comprehensive hearing aid fitting protocol, and BP5 is the median (Kochkin, 2014).

Results of the survey revealed that both THA and DM hearing aids were efficacious in that they both improved listening performance in various situations and improved quality of life (QOL). QOL was defined as the change in various areas that the consumer believed was due to his hearing aids, including: emotional health, mental ability and memory, physical health, relationships at home and work, social life, feelings about himself, ability to participate in group activities, sense of independence, sense of safety, confidence in himself, sense of humor, romance in his life, and overall ability to communicate more effectively in most situations (Kochkin, 2014).

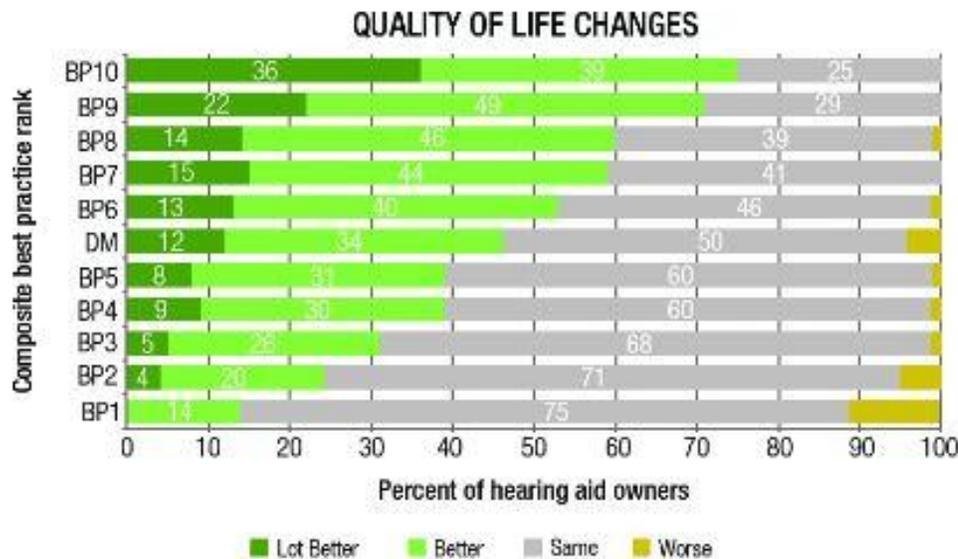


Figure 3, Quality of Life Changes Attributed to Hearing Aid Use, Comparing Direct-Mail and Traditional Hearing Aid Fittings Ranked by Best Practices (Kochkin, 2014)

As seen in Figure 3, 46% of DM users perceived either “better” or “a lot better” QOL. Compared to QOL changes in the THA group, the best practices decile breakdown greatly impacted the results. Audiology services at or below the median BP decile produced no better QOL improvement than the DM delivery model; BP5 resulted in “better” or “a lot better” QOL in 39% of subjects, less than the 46% produced by DM. The most comprehensive fitting protocol, however, resulted in “better” or “a lot better” QOL in 75% of subjects, significantly higher than the DM users.

As a measure of value, Kochkin (2014) calculated the dollars spent for each percentage-point reduction in hearing handicap.

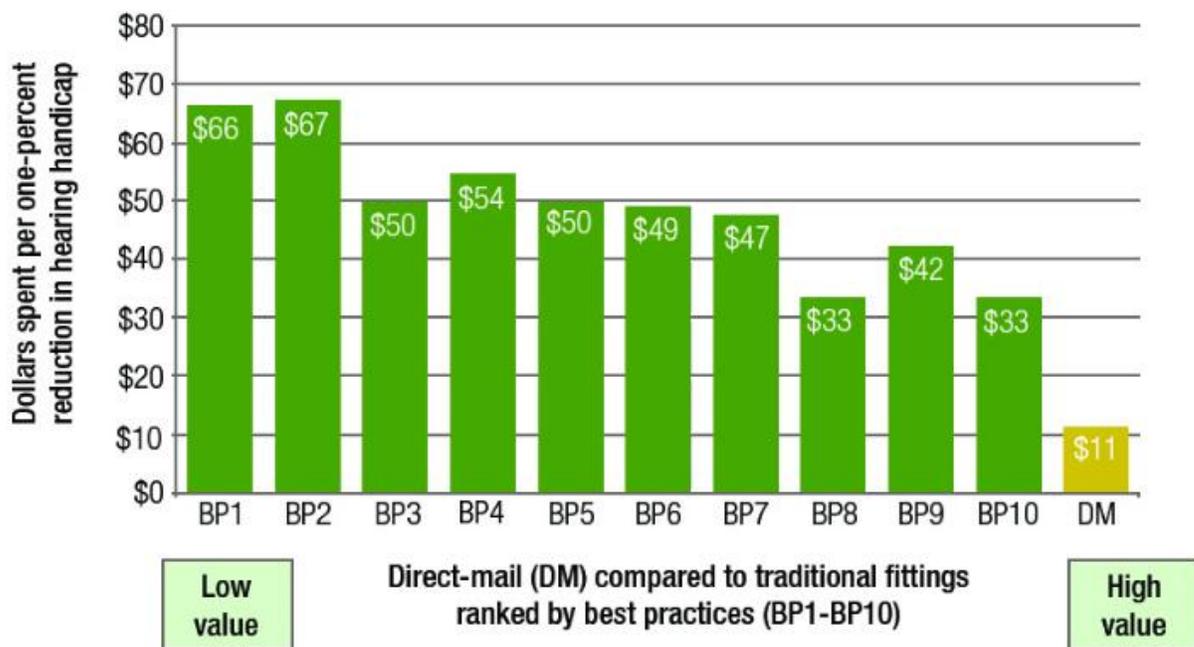


Figure 4, Value of Device Purchase, Expressed as Median Dollars Spent for Each Percentage-Point Reduction in Hearing Handicap (Kochkin, 2014)

As seen in Figure 4 above, DM users perceived higher value in the devices than the THA group as a whole and higher than even the most comprehensive BP service. Although the overall hearing handicap reduction was less than the THA model, because the cost was significantly less, the value of DM aids was greater (Kochkin, 2014).

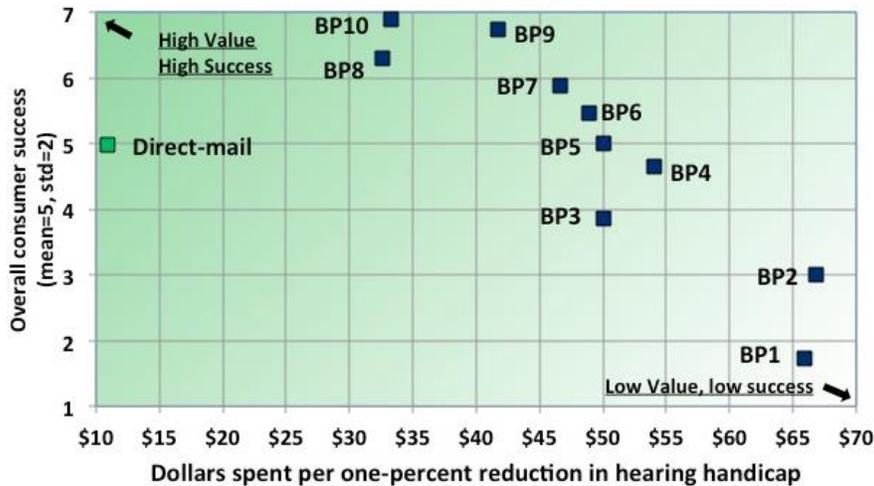


Figure 5, Overall Consumer Success with Hearing Aids as a Function of Value, Comparing Direct-Mail and Traditional Hearing Aid Fittings Ranked by Best Practices (Kochkin, 2014)

Figure 5, above, graphically displays consumer success as a function of value for each of the BP deciles and the DM aids. The results reveal that a DM model of hearing aid delivery is somewhat successful and has high value, while a comprehensive traditional fitting protocol (BP10) is highly successful and has moderate value. A median fitting protocol (BP5) delivers the same level of success as DM but offers nearly five times less value. Anything less comprehensive than a median fitting protocol delivers less success

than a DM paradigm. Overall, the Kochkin (2014) found that patient satisfaction was highly driven by perceptions of value.

Convery et al. (2016) sought to evaluate the performance of individuals as they attempted the complete process of self-fitting a hearing device. Mimicking the framework of an OTC experience, they used a commercially available product (SoundWorld Solutions RIC-style HA). The sample was comprised of 40 adults aged 50-88 years with mild to moderately-severe sensorineural hearing loss, half of which were experienced and half inexperienced hearing aid users; 24 participants brought a family member for assistance, as needed. Participants followed a set of written and illustrated instructions to perform the multi-step fitting procedure, and success was determined by whether they could complete the entire task (Convery et al., 2016).

Results revealed that 55% of participants were able to successfully complete the self-testing and self-fitting task. This is similar to the 58% of participants that were able to complete audiograms for both ears using in-situ audiometry in an earlier study by the same authors (Convery et al., 2015). Although success versus failure in this study (Convery et al., 2016) was based exclusively on the seven-step testing and fitting process, it should also be noted that only 16 participants (40%) were able to successfully navigate the process of pairing the devices to the tablet which was necessary for hearing testing and fitting (Convery et al., 2016). Interestingly, the individuals who received help from a family member were no more likely to complete the task than those who didn't. There was also no difference in success rate between the experienced and inexperienced group, although the types of mistakes differed between groups (Convery et al., 2016). The most frequent failure was due to poor insertion of the RIC earpiece in the ear, success on this

task was 77%; this is consistent with previous data from these researchers in which success rates for insertion were previously found to be 58% (2011) and 77% (2015). The authors note that participants who made mistakes in the self-fitting process were generally unaware that they had done so (Convery et al., 2016).

An important model to study on a national scale is the hearing aid market of Japan, where OTC devices are readily available in retail stores, on the Internet, and via mail order (Hougaard et al., 2013). In one particular study (Hougaard et al., 2013) hearing aid uptake was the lowest of all developed countries, 60% less than that of France, Germany, the United Kingdom, and the United States. Additionally, only 39% of hearing aid users were satisfied with their devices, compared to approximately 80% in the other developed countries (Hougaard et al., 2013).

Patient perception of a DTC model is also important to consider. In a semi-structured interview survey of 18 older adults (Chandra & Searchfield, 2016), the perception of internet-purchased HAs is mixed. Most participants were unaware that hearing aids can be purchased online. When the process was described to them, several themes emerged from participants' responses. They recognized potential benefits of purchasing aids online, such as perceived lower cost and increased convenience and physical accessibility. There were reservations, though, including whether and how clinical procedures would be performed in the assessment and fitting of hearing aids; procedures noted were hearing evaluation, fine-tuning of hearing aids, and physical ear mold modifications (Chandra & Searchfield, 2016). Participants also conveyed a general distrust of online retailers, which included a lack of trustworthiness, a lack of trust in the brand of hearing aid, and a fear of scammers. Several participants stated that they

preferred involvement of an experienced professional in the hearing aid fitting process, and they considered this type of expert advice and support to not be available in an online retail framework (Chandra & Searchfield, 2016).

Similar results were found in a survey asking 80 older adults about their perception of a hearing aid which is self-fit without the involvement of an audiologist (Convery et al., 2011). Participants noted potential benefits such as increased convenience and the ability to self-adjust the device, however they also expressed a preference for professional guidance through the fitting process. About half of the participants responded affirmatively to all three of the following: that a self-fitting aid was a good idea, that it would be of personal benefit, and that it could be managed independently by the user (Convery et al., 2011). A recent survey (Plotnick & Dybala, 2017) of 809 adults was conducted to assess their opinion of a potential OTC hearing aid. The sample was adults aged 50 years and older, geographically and socioeconomically diverse, and most had little experience with hearing aids; this is thought to be emblematic of the market interested in low cost OTC hearing devices. The results indicated that 93.8% of survey respondents considered the involvement of a hearing care professional in the selection, fitting, and programming of a hearing aid to be either very important or absolutely important. Interestingly, 95.3% of respondents were only willing to spend \$200 or less on an OTC hearing aid (Plotnick & Dybala, 2017). Table 2, below, displays a selection of currently available direct-to-consumer hearing aids and PSAPs. The DTC market is, at this time, highly unregulated and unsupported by evidence-based data (Keidser & Convery, 2016).

Table 2, Selected direct-to-consumer products that are currently on the market

<b><u>Company</u></b>	<b><u>Website</u></b>	<b><u>Device Style</u></b>	<b><u>Price</u></b>	<b><u>Programming</u></b>
Audicus	www.audicus.com	RIC, non-custom ITE	\$500-\$700/ear	Professional audiogram
iHear Medical	www.ihearmedical.com	RIC, non-custom ITE	\$350/ear & \$69 for at-home test kit	At-home hearing test with provided kit
Soundworld Solutions CS-50	www.soundworldsolutions.com	RIC and bluetooth-like earpiece	\$350/ear, marketed as a monaural product	Pre-programmed profiles + app
Soundhawk	www.soundhawk.com	Bluetooth-like earpiece	\$299/ear, marketed as a monaural product	Pre-programmed single profile + app
Etymotic BEAN and T-coil BEAN	www.etymotic.com	Non-custom ITE (PSAP)	\$214-\$250/ear	Pre-programmed + volume control switch
Jacoti ListenApp	Apple App Store	Headphones/earbuds (Hearable)	Free	Patient-entered results

As seen in Table 2, several technologies can currently be purchased directly by the consumer including PSAPs, FDA-approved hearing aids, and even a free app that is a software-based hearing aid. Of the hearing aids, Audicus and iHear Medical have received considerable media coverage (audicus.com, 2017; ihearmedical.com, 2017). Audicus customers must obtain an audiogram from a professional, (e.g. an audiologist or ENT), and send the results to the company. The company programs the hearing aids based on the audiogram submitted by the consumer and mail the devices to the customer; volume adjustments can be made on the customer side via a smartphone app. Audicus

will not sell a hearing aid to consumers with selected red flag conditions including unilateral losses, and they explicitly suggest seeing your doctor or audiologist if you are experiencing difficulty hearing only on one side (audicus.com, 2017). The iHear system relies on the consumer performing an FDA-approved self-administered hearing test, the aids are then programmed based on this result. They also offer remote programming, purportedly by a licensed hearing professional (ihearmedical.com, 2017). iHear is backed by several Silicon valley investors having secured over \$14 million in venture capital funding, they've also partnered with Ameritas, a healthcare insurer with 6.4 million customers (IHear Medical, 2016; crunchbase.com, 2017).

Several PSAPs are on the market; the Soundworld Solutions CS-50, the Soundhawk, and the Etymotic BEAN have shown the strongest performance of the group (Smith et al., 2016). The Soundhawk and BEAN devices are delivered to the customer with one or more pre-programmed amplification profiles, and each has a means for the user to change the volume to their preference (Smith et al., 2016). Soundworld Solutions CS-50 is programmed based on a basic hearing test the consumer self-conducts (Smith et al., 2016). The Jacoti ListenApp is a software-based system that is available for free in the form of a smartphone app; it is approved by the FDA as a Class I Medical Device hearing aid (jacoti.com, 2017). The app allows the user to enter a recent audiogram or self-test their hearing within the software. Then, using the microphone of the smartphone, the app analyzes the nearby acoustic information and selectively amplifies frequencies based on the audiogram similar to how a hearing aid would. This technology can be used with conventional wired headphones or combined with wireless headphones, which more closely mimics the experience of using traditional hearing aids (jacoti.com, 2017). One

might consider this a “hearable,” a term originally describing wearable technology in the ear that allows for a variety of functions, for example streaming music or biometric tracking (Fabry, 2016). Whether these bonus functions are included or not, this kind of device setup would deliver many features of a basic hearing aid.

## PROSPECTIVE INNOVATIONS

In the past two decades, the cost of consumer electronics of every ilk have come down dramatically, but the cost of hearing aids has not (Blustein & Weinstein, 2016). The PCAST report described the hearing aid market as being characterized by high cost and low innovation (PCAST, 2015). Given the top-down effects of price pressure and regulatory change, one can expect significant changes and innovation in the market in the near future (PCAST, 2015; NAS, 2016; Hosford-Dunn, 2017). The traditional delivery model will need to evolve, particularly by adopting the practice of unbundling services from device costs (PCAST, 2015). New devices and interfaces will emerge as well; as smartphones and tablets become increasingly ubiquitous, they are likely to play a role in the future of hearing healthcare (Clark & Swanepoel, 2014). Mobile operating systems continue to become smaller and cheaper, their employment for audiological procedures such as audiometry is inevitable (Clark & Swanepoel, 2014). The burgeoning area of remote hearing aid programming is likely to play a transformative role in the future of rehabilitative audiology, as well (Clark & Swanepoel, 2014).

A predicted innovation in this space is that of the self-fitting hearing aid (SFHA), a device that enables the user to perform a hearing test with the device itself, which produces a prescribed hearing profile, without the need for additional equipment or

audiological support (Keidser & Convery, 2016). It was originally proposed as a solution to address the large unmet demand for hearing care in the developing world, but it could be utilized in developed countries as well (Keidser & Convery, 2016). In the last several years, self-fitting devices and apps have become readily available, in the future these technologies may merge, either in the unregulated or regulated markets (Keidser & Convery, 2016). In order for these new devices to be most effective they need a built-in hearing test that produces accurate threshold measurements (Keidser & Convery, 2016).

The simplest method for performing threshold measurements without additional instrumentation is called in-situ audiometry, it is a hearing sensitivity air conduction threshold test that uses the receiver of a HA as the tone generating transducer (O'Brien et al., 2010). Hearing aid fittings are fundamentally based on frequency-specific hearing thresholds, therefore the validity of threshold results is essential for accurate fittings (O'Brien et al., 2010). There is strong evidence that in-situ audiometry, when administered by an audiologist, is as reliable and accurate as traditional air conduction audiometry (Smith-Olinde, 2006; O'Brien et al., 2010; Wong et al., 2011; Durisala, 2014; Convery & Keidser, 2015; Keidser & Convery, 2016). In-situ audiometry can produce artificially high low-frequency thresholds due to the leaking of low-frequency sound during testing (Keidser, 2011; Kiessling, 2015), however with proper correction factors this does not affect the accuracy of the results (O'Brien et al., 2010; Convery & Keidser, 2015; Keidser & Convery, 2016). Poor coupling of the earpiece has a significant negative effect on results, but can be overcome when the process is directed by an audiologist (Convery & Keidser, 2015). Perhaps the individual who assists with testing may not need to be an audiologist; a layperson trained to guide the patient along the steps of in-situ

testing could produce equivalent and valid results (Keidser & Convery, 2016; Convery et al., 2017).

There are challenges that remain for achieving accurate in-situ audiometry testing. Monitoring ambient noise levels is important, however it is possible to use the microphones on the HA itself to do so and pause testing if the ambient noise becomes too great (Keidser & Dillon, 2011). As in-situ testing only measures air conduction thresholds, detecting medical contraindications to HA use is a challenge (Clark & Swanepoel, 2014). However, a recent study by Convery & Keidser (2014) shows promising results for the detection of an air-bone gap (ABG) using air conduction alone. They suggest an ABG can be detected with reasonable accuracy by comparing the results of a speech-in-noise test to normed values of individuals with no known ABG. The accuracy of this procedure increases with larger ABGs, suggesting very few large ABGs would be missed (Convery & Keidser, 2014). Detection of asymmetrical losses, an initial contraindication for HA use, is also possible by using the non-test ear HA receiver to produce contralateral masking noise (Keidser & Dillon, 2011). Overall, the empirical evidence collected thus far and the emerging self-fitting products support the viability of a SFHA in terms of technical implementation of the required processes (Keidser & Convery, 2016).

It is predicted that future SFHA will consist of ear-level devices that wirelessly connect with a smartphone and provide assistance through an established telehealth infrastructure (Keidser & Convery, 2016). Telehealth is defined as the provision of healthcare services via information and communication technologies, and it is currently utilized by several branches of medicine and clinical healthcare including psychology,

radiology, dermatology, geriatric medicine, speech-language pathology, and audiology (World Health Organization, 2010). Telehealth providers can communicate with their patients using email, videoconferencing software, internet-connected tablets, and smartphones. The use of smartphone technology in healthcare, which is referred to as mHealth, is growing exponentially (Fiordelli et al., 2013). Several societal drivers have motivated the adoption of telehealth services, including: an aging population, a shortage of high skilled medical personnel, and changes in generational healthcare wants and needs (Doarn et al., 2008). Implementing a telehealth support infrastructure in tandem with SFHA or low-cost HAs could be a potential boon to the accessibility and affordability of hearing healthcare (Keidser & Convery, 2016).

## CONCLUSION

Age-related hearing loss is a substantial public health and societal concern (PCAST, 2015). The current market for hearing aids, the primary intervention for ARHL, is characterized by high cost and low innovation. The traditional delivery model of HAs provides quality but expensive healthcare and is marked by inefficiencies (PCAST, 2015). The PCAST and NAS groups have called for reform of the hearing healthcare marketplace, emphasizing the need for accessible, affordable, quality, and transparently-priced care. They made the recommendation that a new category of basic hearing aids should be established and made available to consumers over-the-counter (PCAST, 2015; NAS, 2016). United States Senators Elizabeth Warren (D-MA) and Chuck Grassley (R-IA) have proposed a bill to make that recommendation a legislative reality (Warren & Grassley, 2017). Underpinning the recommendation and bill is a public health

calculation, in which the benefit of accessible care for the masses outweighs the relative risk of foregoing a comprehensive audiological and medical evaluation for each patient (Blustein & Weinstein, 2016). The Senators reiterate several points made in the PCAST and NAS reports, including that a basic OTC hearing aid geared towards individuals with mild-to-moderate hearing loss can be provided safely (Warren & Grassley, 2017).

Along with government regulatory pressure, the traditional HA delivery market is being confronted by greater competition and pricing pressure from Big Box retailers, specifically Costco (Hosford-Dunn, 2017). Although it is quite certain that these powerful top-down forces will change the market from what it looks like today, it's not clear what specific changes will occur. Consumers understand the potential benefits of direct-to-consumer hearing aids, but they also express reservations and a preference for the involvement of an audiologist (Kochkin, 2014; Chandra & Searchfield, 2016; Plotnick & Dybala, 2017). If this consumer preference proves to be the case, audiologists will continue to see a large number of hearing aid candidates, and they should adjust their services to match the evolving needs of their patients. It would be wise of audiologists to embrace measures that increase transparency, accessibility, and affordability. These efforts should include, among others: the unbundling of services from device cost, championing the dispensing of basic technology for uncomplicated ARHL, interfacing with patients who are using OTC devices, and committing to best practice as the ultimate method of adding value.

There is good evidence that OTC devices will produce mixed results, helping a sizeable proportion of customers but leaving many others unsatisfied (Tedeschi & Kihm, 2016). From the relatively limited evidence that exists, the proportion of successful OTC

consumers, characterized as those that are at least somewhat satisfied or have at least moderate improvement in QOL, ranges from 39-58% (Hougaard, 2013; Kochkin, 2014; Convery et al., 2015; Convery et al., 2016; Tedeschi & Kihm, 2016; Humes et al., 2017). For individuals that are successful with the devices, OTCs represent a high value product that may improve hearing, reduce the handicap associated with hearing loss, and increase quality of life (PCAST, 2015). Although they have the potential to make a positive public health impact, OTC devices have significant weaknesses. The legislation and OTC devices themselves fail to overcome the stigma associated with wearing hearing aids or the difficulties that individuals in the target market have with dexterity problems, they will struggle manipulating small components and batteries. The focus on OTC devices fails to address the importance of family and community support networks and self-management of hearing loss in difficult listening situations (Hogan et al., 2015). Not only could this be a threat to the success of OTC devices, it could create distressed customers who further postpone the decision to see an audiologist for professional intervention.

Future audiologists should be prepared to augment the hearing healthcare of both satisfied and unsatisfied OTC users. For patients who are experiencing success with OTC devices, audiologists have a role in objectively documenting their status and adding value via counseling, real ear measures, speech in noise testing, and validation questionnaires. For OTC users who are not satisfied with their devices, the audiologist has a role in improving their performance and introducing them to services and devices that may provide more benefit including aural rehabilitation, hearing assistive technologies, and traditional hearing aids.

The only thing that is certain is that we do not know how hearing healthcare will evolve; audiologists would be wise to embrace the unknown, be flexible, serve the patient first and foremost, and follow the evidence-base wherever it leads.

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