

# Disruptive Hearing Technologies and Mild Sensorineural Hearing Loss I: Accessibility and Affordability Issues

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## ABSTRACT

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Limited accessibility to and affordability of hearing health care (HHC) and hearing aids (HAs) are two reasons why people do not seek treatment for their hearing losses. This article is the first in a series of two and discusses affordability issues (i.e., billing models, cost-effectiveness, insurance coverage, and reimbursement) related to and provides a historical context for the Over-the-Counter Hearing Aid Act of 2017. This piece of legislation supports development of a new class of over-the-counter HAs that represents a disruptive technology that may transform the HHC industry by reducing costs specific to the device. A discussion of ethical issues and the importance of using evidence-based practice guidelines set the stage for the second article in this series, which reviews relevant research on issues pertaining to persons with mild hearing loss.

**KEYWORDS:** hearing aids, over-the-counter, direct-to-consumer, hearing loss, adult, insurance, health-related quality of life

**Learning Outcomes:** As a result of this activity, the participant will be able to: (1) discuss multifaceted affordability issues in hearing health care; (2) summarize recent events in the development of over-the-counter hearing aids; and (3) apply evidence-based practices with over-the-counter hearing aids.

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Presently, there is a growing number of persons in the United States and the world who suffer from the insidious negative effects of untreated sensorineural hearing loss (SNHL), which is the third most common chronic health concern facing seniors.<sup>1</sup> Over 36 million or 17% of adults in the United States self-report some degree of hearing loss.<sup>2</sup> For those between the ages of 65 and 74 years, approximately 25% have a self-reported hearing deficit, which increases to 50% among those 75 years or older.<sup>2</sup> With the number of older American adults expected to increase from 48 million to 88 million by 2050,<sup>3</sup> in addition to an increase in the number of younger persons experiencing communication difficulties,<sup>4</sup> hearing loss is a growing public health concern that has garnered considerable interest in the past decade.

In addition to increased prevalence, the consequences of untreated SNHL are of great concern for many older adults. SNHL is associated with depression,<sup>5</sup> anxiety,<sup>6</sup> social isolation,<sup>7,8</sup> and poorer cognitive function and incident dementia.<sup>9,10</sup> Even mild sensorineural hearing loss (MSNHL) has been associated with a threefold increase in risk for falls.<sup>11</sup> If left untreated, hearing loss can affect the safety and independence of older adults by impeding self-care and management of other co-occurring disorders. MarkeTrak VIII found that a significant proportion of individuals with mild hearing loss who reported their communication problems to their family doctors were told that hearing aids (HAs) would not help (18%) and to wait and be retested (31%) before pursuing amplification.<sup>12</sup> If true, that type of misinformation could further delay people with hearing loss from addressing their communication difficulties and pursuing amplification. By addressing untreated SNHL as a public health priority, practitioners can promote the productivity and independence of older adults, thereby mitigating associated economic and caregiver burdens, as well as addressing poorer health-related quality of life (HRQoL) issues. Unfortunately, many people wait as long as 10 years after first noticing a hearing problem, when it is often in its mild form, before they seek help.<sup>13</sup> It is important for all persons, particularly those with MSNHL, to have access to affordable hearing health care (HHC) early in the help-

seeking journey. It is also important for people to have early positive experiences with HHC providers and treatment to foster and promote consistent and life-long HA use.

The economic burden of untreated SNHL is significant and is estimated to be \$750 to \$790 billion globally.<sup>14</sup> The most common treatment for SNHL is HAs, which are expensive and can impose a significant financial burden on many families, especially seniors. The average bundled cost of an HA is about \$1,800, while the component costs are estimated to be less than \$100.<sup>15</sup> Considering that HAs typically are replaced about every 3 to 5 years, costs for HAs can easily exceed \$10,000 over a lifetime and are among the largest expenditures for seniors, third only to purchasing a car or home.<sup>15</sup> It is estimated that over 30% of seniors live at 200% or more below the poverty level,<sup>16</sup> a figure that is expected to increase in the coming years. The affordability of HAs is often problematic for persons of low socioeconomic status who may have poor health and may not have private insurance coverage to meet their general health and HHC needs.<sup>17</sup> In addition, African American and Hispanic individuals have low rates of HA use.<sup>17</sup> Although Medicare covers hearing testing, it does not cover treatment including HAs, and most Medicaid coverage for adults typically does not include HAs. Untreated SNHL has been associated with low salaries and unemployment or underemployment.<sup>18</sup> Seniors and minorities are not alone in this problem as MSNHL can impact young to middle-aged adults during their most productive and child-rearing years. People of any age with MSNHL may believe that their hearing losses are not severe enough to warrant purchasing HAs for their communication problems, and may believe that they can just get by and postpone seeking help until their problem gets worse. Presently, the HHC system is overburdened and is not able to meet all the needs of many persons with hearing loss. This article is the first of a two-part investigation and discussion of challenges and disruptors to the traditional professional model of HHC, particularly how HAs are provided, and looks at ways to help make HHC more accessible and affordable to persons with hearing loss. These articles address issues (e.g., billing, delivery

models, and value-based service) that directly impact the accessibility and affordability of HHC and HAs for the American public with a focus on MSNHL.

## AFFORDABILITY ISSUES

### Billing Models for Hearing Health Care Services and Hearing Aids

There are several challenges to increasing access to and affordability of HHC services and HAs for persons with SNHL. Although seniors with Medicare and/or Medicaid have coverage for hearing testing, most adults and seniors are left without coverage for other HHC services and HAs. For the purposes of the present articles, the three typical options for payment models are defined as the following:

- *Bundled billing*: Patients are presented with a consolidated price for hearing devices (e.g., HAs and ear molds) and associated services (e.g., hearing and HA evaluations, cerumen management, and all in-office and in-warranty repairs). The fees are either billed to insurance (not commonly covered) or paid privately by patients at the time of service or over a specified period. (Note: a hearing test specifically for the purpose of fitting an HA is not covered by Medicare, which is why a provider may decide to bundle it into the other services. However, any hearing test for the purpose of evaluating hearing status, possible change in hearing, or to rule out/identify medical issues causing hearing loss is typically covered.)
- *Itemized billing*: Patients are provided with detailed prices with line items for HAs, ear molds, and each associated diagnostic or rehabilitation service, which are either billed to insurance (rarely covered) or paid privately by patients at the time of service or over a specified period.
- *Unbundled billing*: Patients are only billed for the devices and services rendered on the date of service, and subsequent services and follow-up visits are billed separately as patients need them. Fees are either billed to insurance (rarely covered) or paid privately by

patients at the time of service or over a specified period.

Some have proposed that unbundling of HA costs from services might help in advocating for HA coverage through Medicare.<sup>19</sup> Others<sup>20</sup> have provided frameworks for implementing unbundled or itemized billing practices and proposed a model with both time (i.e., hourly rate for services) and case-complexity components similar to that used in evaluation and management (E/M) codes. E/M codes are a family of current procedural terminology codes<sup>21</sup> that are used for patient encounters that do not include any other procedures, but instead cover the time and expertise used in clinical decision-making, case history, and/or preliminary examination (e.g., review of systems). Currently, these are reserved for use by physicians and require several body system evaluations to meet the criteria of different reimbursement levels. Windmill and colleagues speculated that lower upfront product costs would be more affordable to patients and offer them an opportunity to spread deferred costs over a longer period of time.<sup>20</sup> Ideally, unbundling or itemizing of costs might increase transparency to patients, insurers, and policy-makers and provide audiologists an opportunity to assign and show value for their provision of HHC. The traditional bundled model obscures the value of professional expertise and time spent by HHC providers because consumers associate the overall price with the device/technology only. However, some audiologists see problems with a totally unbundled model because they believe that many patients are unwilling to pay these costs through à la carte unbundled pricing structures and that they will choose to forego hearing tests, HAs, follow-up services, or auditory rehabilitation if payment is required every time they see their providers. A totally unbundled model is seen by many audiologists in private practice as being an unworkable option, while others indicate that revenue predictions of their proposed unbundled models are consistent with bundled models.<sup>20</sup> Currently, there are no published data comparing the behavior or attitudes of patients accessing a bundled and unbundled model of HHC that would allow us to answer this question. In addition, no published data exist comparing

the overall revenue collected from each of these models.

Physicians have faced similar issues and have tried to find ways to address these problems and gain some control over unstable conditions and shrinking medical reimbursement rates by converting their practices into concierge facilities where patients pay an annual fee to have access to their favorite doctors. Concierge physicians often do not accept assignment from or bill Medicare or private insurances for office visits or specific tests and procedures, which are billed separately from the annual concierge fee. Concierge physicians often refer their patients to other professionals and diagnostic facilities for X-rays, CT scans, blood tests, MRIs, and other special tests, which may be billed to insurance or paid privately. Concierge arrangements mean that patients are guaranteed access to their physicians whenever they need them and that doctors can dictate which and how many patients they can or will be comfortably willing to accommodate in their caseloads. According to the aforementioned definitions, concierge services would fall under an unbundled billing system. However, audiologists are unable to opt out of Medicare participation, which would prevent this type of concierge model.

Bundled, unbundled, and itemized pricing structures differ in their challenges, advantages, and disadvantages to various stakeholder groups, but should be explored with regard to their proprietary and financial feasibility, as well as their impact on audiologists' ability to provide sustainable, accessible, and affordable HHC services to their patients. Moreover, the potential effects of unbundling on patient satisfaction with and benefit from HHC services and HAs are unknown. Thus, billing models will likely vary from practice to practice, but will need to be evaluated from a variety of stakeholders' viewpoints, especially as we enter into a new era of over-the-counter (OTC) devices and direct-to-consumer (DTC) models for hearing devices. Currently, audiologists have the freedom to select the billing model that is most appropriate for their respective practices. It is also important for audiologists to consider which structure will promote those persons with MSNHL to seek early treatment for their losses.

### Measuring the Cost-Effectiveness of Hearing Health Care and Hearing Aids

Assessment of the economic-effectiveness of HHC services and HAs is central to coverage determinations and reimbursement rates from third-party payers. A common type of health economics assessment is cost-utility analysis, whereby costs are estimated in relation to improvements in measures involving HRQoL. Health utilities are cardinal measures of HRQoL that can be compared across health care conditions and interventions to inform health care policy. For example, cost-utility analysis uses measures composed of units of cost (e.g., U.S. dollars) per quality-adjusted life-years (QALYs) added. Historically, these types of analyses have been used to drive health care coverage provided by third-party payers to include procedures and associated services for cochlear implantation and for HAs.<sup>22</sup> For example, Abrams et al<sup>23</sup> found a reduction in the cost per QALY from \$60.00/QALY for HAs alone to \$31.91/QALY when auditory rehabilitative services were provided as part of HA treatment. However, it should be noted that few generic measures of HRQoL include items that pertain to the social, emotional, and functional consequences of hearing loss. For example, Chisolm and colleagues found smaller effect sizes for HRQoL benefits of amplification for generic versus disease-specific HRQoL outcome measures.<sup>24</sup> A paucity of generic HRQoL measures on the effects of and treatments for SNHL makes it difficult to demonstrate the effectiveness of such treatments when compared to interventions for other health care conditions. As such, Bess called for the development of a multidimensional functional health status measure that includes items that are sensitive to the consequences of hearing impairment.<sup>25</sup> Additional randomized, controlled trials are needed to demonstrate the HRQoL benefits and cost-effectiveness of advanced digital technology (ADT) HAs, specifically those dispensed within individualized, evidence-based auditory rehabilitation programs.

### Insurance Coverage and Reimbursement

Lack of insurance coverage for HHC is a significant barrier to timely diagnosis of and

treatment for SNHL. In the 1960s, the Centers for Medicare and Medicaid Services (CMS) failed to include HAs in coverage determinations and deemed them to be “routine” and “low in cost.”<sup>26</sup> Despite drastic changes in insurance and health care during the past 60 years, this has not been revisited and has set an odious precedent for American HHC going forward. Unfortunately, CMS, the largest insurer of seniors in the United States, has “no provision in the law for Medicare to pay audiologists for therapeutic services” including HAs or associated rehabilitative services to determine the status and clinical management of communication difficulties.<sup>27</sup>

Presently, Medicare only pays audiologists for one hearing test in a person’s lifetime, unless a physician requests evaluations for medical issues (e.g., specific symptoms, change in hearing, etc.). Medicare’s limited coverage for hearing evaluations and lack of coverage for HAs and rehabilitative services continue to serve as challenges and disruptors to the nation’s quest to provide accessible and affordable HHC services and HAs to persons with hearing loss. This leaves many older adults with a void in coverage and impeded access to HHC, possibly saddling them with the financial responsibility, or worse, causing them to go without HAs and auditory rehabilitative services altogether. Similarly, young to middle-aged adults with MSNHL may not seek help due to a lack of insurance coverage for HHC services. A change in billing models and insurance coverage is one way to meet the goals of increasing the accessibility to and affordability of HHC services and HAs for persons with SNHL.

## **OVER-THE-COUNTER HEARING AIDS AND DIRECT-TO-CONSUMER DELIVERY MODELS FOR PERSONS WITH MILD SENSORINEURAL HEARING LOSS**

### **A Historical Perspective**

Untreated hearing loss has been and continues to be a problem throughout the world. The World Health Organization (WHO) composed a guideline that identified the following as obstacles to HHC for persons with SNHL in

developing countries: (1) poor infrastructure for screening and diagnostic assessment, (2) lack of physical resources to identify and manage hearing disorders, and (3) a dearth of trained professionals to meet the growing need for HHC services.<sup>28</sup> The U.S. Department of Health and Human Services (DHHS) released a list of health care objectives for Healthy People 2020, which identified hearing loss as a public health priority, and set a goal of a 10% increase in timely and appropriate access to screening and diagnostic assessments as well as uptake and usage rates of HAs.<sup>29</sup>

In 2009, the National Institute on Deafness and Other Communication Disorders of the National Institute of Health (NIDCD-NIH) assembled a working group to develop a research agenda focused on increasing the accessibility to and affordability of HHC for adults having mild to moderate hearing loss within a context of changing demographics, socioeconomics, technologies, and service-delivery paradigms.<sup>15</sup> Research recommendations were made for the following areas: access, screening, assessment, innovative technologies and outcomes, patient variables and outcomes, aftercare, delivery systems, workforce training of HHC providers, medical evaluation/regulatory issues, and overarching topics. One of the priorities was for research aimed at the development of a self-testing, self-fitting DTC HA for those with mild to moderate levels of hearing impairment.<sup>15</sup> Many in the HHC industry believed that these future devices would be akin to personal sound amplification devices or PSAPs, which are intended to amplify environmental sounds in specific situations (e.g., bird watching) for individuals without hearing loss. In 2009, the Food and Drug Administration (FDA) released their “Regulatory Requirements for Hearing Aid Devices and Personal Sound Amplification Products,” which stated that PSAPs should be appropriately labeled to alert consumers that these devices are not intended for the treatment for hearing loss or other related communication problems (e.g., speech understanding in noise).<sup>30</sup> Indeed, that document differentiated PSAPs from ADT HAs, which are FDA-regulated Class I or II medical devices.<sup>30</sup>

In October 2015, the President's Council of Advisors on Science and Technology (PCAST) released action-based recommendations to address the public health concern for hearing loss among the growing demographic of aging adults.<sup>31</sup> One recommendation was for the FDA to create a separate class of OTC HAs that would be available for purchase in a DTC model, without the consultation of an HHC professional for the treatment of bilateral, mild to moderate, age-related hearing loss (ARHL). It was further recommended that these devices be exempt from quality system regulation, in contrast to air-conduction HAs that are classified as Class I or II medical devices, and that they would be used by consumers with ARHL. Additionally, transparency and transferability also were identified as significant barriers to HHC. Under that recommendation, it was suggested that the Federal Trade Commission (FTC) increase and empower consumer choice by requiring audiologists (like optometrists) to provide patients with a copy of their health-related data (e.g., audiogram, programming profile, and prescription) at the conclusion of the appointment for use at a retailer of their choice. Many audiologists would not see the former as either a challenge or disruptor to the way they routinely practice as many already provide patients with hearing test results. Most audiologists, however, would be hard pressed to define what the authors meant by "programming profile and prescription." Would this be output targets for soft, moderate, and loud inputs across frequencies with the targets having been derived from the hearing thresholds converted to sound pressure level (SPL) thresholds using the individual's real-ear-to-coupler values? Or is this just the audiogram with the expectation that whoever would fit the HA would use an evidence-based method that would include real-ear-to-coupler difference (RECD) and then matching output to targets derived from accurate threshold SPL values (accurate because RECD was applied)? It is important to note here the distinction between HHC delivery models. We view the traditional professional model as distinct because audiologists indeed provide an array of HHC services to their patients. Similarly, audiologists typically view the people who come

to them for services as *patients*, whereas people who purchase OTC HAs via the DTC service-model are viewed as *consumers*.

While the PCAST statement focused mainly on consumer choice and possible barriers to access, a report released by the National Academies of Sciences, Engineering, and Medicine (NASEM) in 2016 provided recommendations on how to address discrepancies in HHC.<sup>32</sup> The NASEM's recommendations were many, but included:

- Establishing population-based data on hearing loss and HHC.
- Lifting of FDA requirements for medical evaluation or waiver prior to HA fitting.
- Creating a new, OTC class of HAs targeted at mild to moderate ARHL.
- Increasing:
  - Consumer choice through transparency and transferability.
  - Accessibility to and affordability of devices.
  - The amount and presence of information on HHC to the public, communities, and individuals.

In response to these recommendations, the FDA opted for nonenforcement of the 1977 statute for medical evaluation or waiver in December 2016.<sup>33</sup> This means that the statute still exists, but is not enforced, which gives the FDA a grace period to conduct research to see if it should be enforced or lifted at a later date.<sup>33</sup> Shortly thereafter, the FDA Reauthorization Act of 2017 passed the 115th Congress in August, which included the Over-the-Counter Hearing Aid Act of 2017.<sup>34</sup> This legislation directed the FDA to create and regulate a new class of OTC HAs. The FDA was given a maximum of 3 years to explore and determine regulations for labeling, technical specifications, and manufacturer protections of OTC HAs.

### Consumer versus Patient

As noted above, OTC HAs are envisioned to be dispensed via a DTC model, which represents a paradigm shift for HHC providers. The traditional HHC model relies on licensed providers

who are trained in the identification, diagnosis, and management of SNHL through the selection, evaluation, and fitting of HAs and other assistive listening devices as well as the provision of individualized auditory rehabilitation. Alternatively, under the DTC model, persons with hearing loss will self-diagnose and manage their own HHC with OTC HAs.

Again, it is important to note that the traditional HHC model views persons with hearing loss as *patients* of HHC providers. Alternatively, when individuals with hearing loss choose to purchase OTC HAs, they are *consumers* to the retailers and manufacturers of these instruments. It is possible for these roles to become blurred when consumers who purchased OTC HAs seek the services of HHC providers. Should these individuals be referred to as “consumers” who have purchased OTC HAs or are they now “patients”? The answer is that they become *patients* and are protected by the ethical standards to which audiologists and other providers must adhere. For example, the American Academy of Audiology (AAA) Code of Ethics states that “Members shall provide professional services [...] with honesty and compassion, and shall respect the dignity, worth, and rights of those served.”<sup>35</sup> The AAA code also requires that “Individuals shall not limit the delivery of professional services on any basis that is unjustifiable or irrelevant to the need for the potential benefit from such services.”<sup>35</sup> The American Speech-Language-Hearing Association’s Code of Ethics states that “Individuals shall honor their responsibility to hold paramount the welfare of persons they serve professionally [...]”<sup>36</sup> According to this language, membership in either of these organizations thus precludes refusal to provide service to those who opt for OTC HAs. Of course, once these consumers of OTC HAs become patients of HHC providers, they should be given all the same considerations as other patients. A problem may arise, however, if the OTC HAs selected contain proprietary circuitry that will not allow the HHC provider to reprogram the devices. Further, some providers may be reluctant to service a product with which they are not familiar, which could be a challenge and a disruptor to the traditional professional model. However, it is hoped that

these OTC devices will work as a segue into traditional ADT HAs with which the provider is familiar, but it is apparent that HHC providers will need to find ways to accommodate patients with previously purchased OTC HAs who desire to keep those devices.

### Implications for Auditory Rehabilitative Service Provision

It is difficult to determine the future roles of HHC providers with regard to providing services to persons who purchase OTC HAs. If patients present to audiology practices with previously purchased OTC HAs, then the effectiveness and appropriateness of the devices will need to be assessed according to best practices. Because these devices are not yet available, it is difficult to speculate about whether audiologists or consumers will be able to verify or make adjustments to the fittings. Currently, some audiologists already dispense PSAPs to patients, which may likely be the case for those individuals with MSNHL or for those who may not be able to afford ADT HAs. Ideally, audiologists should be able to provide professional guidance to those patients about lower cost OTC options and stress the importance of returning for verification and follow-up services. It is conceivable that some HHC providers will embrace OTC HAs and dispense them as low-end devices via their traditional model. This could potentially be a positive solution rather than a disruptor and help advance the goal of providing accessible and affordable hearing help for persons with hearing loss.

In developing protocols for managing patients with OTC HAs, audiologists should adhere to evidenced-based professional documents such as the AAA Guidelines for the Audiologic Management of Adults with Hearing Impairment, which has three distinct areas for HA treatment: (1) assessment and goal setting; (2) technical aspects of treatment; and (3) orientation, follow-up, and counseling.<sup>37</sup> Assessment and goal setting is based on diagnosis of hearing loss by a licensed audiologist, but in an OTC DTC model, consumers will self-diagnose their hearing losses and likely will not have the benefit of consultation with an audiologist regarding their specific

communication needs. Some consumers-turned-patients may be reluctant to have an audiologic evaluation, which seems counter-intuitive under the assumption that OTC HAs are indicated for mild to moderate degrees of ARHL. However, if these consumers do later become patients, then an audiologic evaluation is warranted to rule out ear disease and to identify functional deficits that would inform treatment recommendations such as speech-in-noise testing and self-assessment questionnaires. Unfortunately, many consumers obtaining OTC HAs via the DTC model will not receive an audiologic evaluation or auditory needs assessment unless they seek consultation with a licensed HHC provider. Auditory needs assessment should include exploration of communication and performance needs, as well as goal setting for treatment, while non-auditory needs assessment should include areas such as expectations with amplification, manual dexterity, near-field visual acuity, cognitive status (e.g., attention, learning, working memory, and executive function), and involvement of a support system during treatment. Indeed, older adults who opt for OTC HAs may have comorbidities and would benefit from nonauditory needs assessment to determine auditory rehabilitative treatment status.

The second section of the AAA guidelines pertains to the technical aspects of treatment, including HA selection, verification, and candidacy/recommendations for hearing assistive technology. Recall that the PCAST and the NASEM recommended increased transparency through provision of audiograms to patients for use in the selection of OTC HAs. Most audiologists would agree that a pure-tone audiogram alone is not sufficient to inform recommendations for a complete auditory rehabilitation plan that includes selection of an appropriate style of HAs, occlusion/coupling methods, monaural or binaural fittings, gain characteristics (linear vs. nonlinear), frequency response and shaping, maximum power output, digital noise reduction, omnidirectional and/or directional microphones, specialty arrangements or processing (e.g., BAHA, CROS, or frequency lowering), and the need for hearing assistive technology. Unfortunately, the options for OTC HAs may

be quite limited and simply not appropriate for patients according to best practices. Again, it is difficult to speculate about the sophistication of the OTC HAs that will be developed over the next 3 years, but some feature options may include volume controls, multiple memories, direct audio input, telecoil, and/or wireless connectivity.

Lastly, orientation, follow-up, counseling, and outcomes measurement are crucial components for achieving successful rehabilitative outcomes for patients. Unfortunately, with OTC HAs obtained via the DTC model, consumers are on their own in selecting their own coupling, fitting, use, and maintenance of the instruments. Some of the most difficult tasks in the self-fitting process will include the initial choice of appropriate tubing and dome size and the ability to insert the devices.<sup>38,39</sup> Consumers must self-orient to the OTC HAs via written instructions in users' manuals, which are (even for ADT HAs) notorious for being poorly written and difficult to read, and significantly more so for the 20% of the elderly population with dual sensory impairment.<sup>40-42</sup> Alternatively, some instruction may be offered via Internet Web sites with video instruction. Health literacy may be an issue for the segment of the population with hearing loss who may opt for lower cost OTC HAs. Even patients with MSNHL who were fit with ADT HAs within a private practice setting that uses an extensive auditory rehabilitation follow-up program were lacking in confidence in advanced handling skills with their devices.<sup>43</sup> If patients have reduced self-efficacy with extensive follow-up from HHC providers, then it is hard to imagine that patients with no HHC assistance will exude high confidence levels in handling OTC HAs obtained in a DTC model. The issues raised in this article will become clearer over the next 3 years. Until then, audiologists must do what they can to provide best practices for all patients, and consumers of OTC HAs will need to be aware of the challenges inherent in self-diagnosing and treating their hearing losses with DTC purchases. Whether the challenges and disruptors discussed in these articles ultimately advance the goal of universal HHC or whether DTC OTC HAs end up not being the panacea



and further discourage persons from pursuing professional help for their hearing losses remains to be seen.

## CONCLUSIONS

This article has discussed professional issues related to increasing the accessibility to and affordability of HHC and HAs, particularly for persons with mild hearing losses. With the passage of the Over-the-Counter Hearing Aid Act, OTC HAs and DTC models will continue to be investigated during the FDA's 3-year consideration period. The HHC industry has a great opportunity to help inform these processes through research and development. In the interim, audiologists should consider current ethical issues and utilize evidence-based practice guidelines to inform clinical practice that addresses the needs of a rapidly growing population with hearing impairment.

Part I of this two-part discussion has raised issues that may be seen as challenges and/or disruptors to the traditional professional model of HHC. Because DTC OTC HAs will likely play a major role in the attempt to provide greater accessibility and affordability to HHC for larger segments of the population with hearing loss, a logical next step is to review the literature to determine if there is evidence to support them in this effort. Therefore, Part II of this discussion will summarize the results of that review and recommendations for including DTC OTC HAs into the HHC system for those with MSNHL.

## CONFLICT OF INTEREST

Anna M. Jilla, Au.D.: University of Oklahoma Health Sciences Center (employment).

Carole E. Johnson, Ph.D., Au.D.: University of Oklahoma Health Sciences Center (university employment).

Jeffrey L. Danhauer, Ph.D.: University of California Santa Barbara (emeritus professor); Hearing Consultants of California (private practice owner).

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