May 12, 2017

As an audiologist in the United State, I see the stakeholders and the situation of Over-The-Counter (OTC) hearing aids through a professional lens. As my business is the business of audiology (I am a consultant who specializes in billing, reimbursement, and pricing), I have seen this industry disruption coming for over a decade now. I gave my first unbundling/itemization presentation in 2007 and my first disruption talk in 2011. I have tried to stay on the forefront of this movement and tried, many times in vain, to get stakeholders to be proactive rather than reactive. There were many steps along the way where changes and decisions could have been made to alleviate the situation consumers currently find themselves in.

First, I must address the questions specifically posed by the Federal Trade Commission (FTC).

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

   *In my opinion, there is currently no comprehensive, completely **unbiased** consumer site, especially one which focuses on the entire hearing healthcare journey. There are also not many (websites?) which are optimized for use on cell phones and tablets. Many sites are hosted and funded by the six major hearing aid manufacturers, industry (Better Hearing Institute), or for-profit business entities which rely on ad revenue from industry manufacturers. These sites inherent goals appear to be to drive hearing aid sales rather than educate the public on hearing loss, listening and communication, and the journey required to enhance audition. There are also other independent entities (Consumer Reports, Centers for Disease Control (CDC), National Institute of Deafness and Other Communication Disorders (NICDC), Hearing Loss Association of America (HLAA)) but they also have, to date, focused primarily on the statistics or the device rather than one the comprehensive journey (evaluation, fitting, verification, and rehabilitation) to improved hearing, listening, and communication.*

   I would be remiss to comment on a consumer's perception of these sites as I too have an inherent bias (from my 26 years in the industry). I will defer to consumer groups to address the latter part of this question.

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

   Providers purchase the vast majority of the hearing aids they dispense from the six hearing aid manufacturers. The providers' costs range significantly from provider to provider but typically range from $300-$2000 per device, for the device only. This price is, unfortunately, not always based upon volume, or a volume discount. The cost paid by providers is approximately three to four times more than what Costco pays for the exact same product. Despite statements from the Hearing Industries Association (HIA), in my consulting work I note that the cost of goods of the hearing aid makes up about 50-60% of the total bundled hearing aid cost. Hearing aid manufacturers do not give providers much control or leeway in the price they pay for a specific hearing aid. Audiologists have little control over warranties (repair and loss and damage), marketing materials, sales and training, etc. that the manufacturers provide. In other words, independent providers, unlike the Veteran's Administration and Costco purchases, are forced into a bundled purchase from the hearing aid manufacturer, even if they do not want or need those services.

   Hearing aids have been distributed by hearing aid dispensers (since 1950s) and audiologists (since 1977) via a federal and state regulated system. The majority (approximately 70%) of hearing aids sold in the United States are dispensed in a bundled manner. In other words, the hearing aid, the hearing aid examination and selection, the fitting and orientation, the long-term care, and, many times, even

the hearing assessment, are presented and provided, as a single, non-negotiable price, with non-negotiable service and care. Many of these hearing aids are delivered by entities where the devices are proprietarily locked. In other words, the devices cannot be adjusted, modified or programmed by any licensed provider. They can only be adjusted, modified, or programmed by providers within the same franchise system, management group, or business entity.

There are alternative delivery and payment models available, but they have not been heavily adopted to date. Providers can itemize the charges (so the consumer can see the service and product separately). Unfortunately, in this model, long-term service is still non-negotiable. Unbundled pricing means that the consumer pays separately for the hearing assessment, hearing aid examination and selection, the hearing aid, fitting and orientation, verification, and aural rehabilitation. In one unbundled model, the purchaser pays for service on an as-needed basis. In another model, the consumer may pre-purchase, all-inclusive, long-term care for fixed periods of time (six months, one year, three years, five years, etc.). In the latter model, the provider is re-bundling services.

True provider unbundling, where pre-payment of long-term service is optional, decreases the upfront, out-of-pocket costs of amplification. Unfortunately, since there have been very few new entrants into the provider-driven hearing aid industry, the costs providers pay for products has continued to climb. There are very few value based products (under $200) available to providers. Also, current over-the-counter hearing aid manufacturing entities have been reticent, to date, to distribute their products through provider-driven channels. In other words, these new entrants do not offer wholesale provider pricing. Providers are stuck with what six companies offer them at the price they are afforded.

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

   Over-the-counter (online, mail order, retail) hearing aids, personal sound amplification product (PSAPs), assistive listening devices (ALDs), wearables/hearables, and mobile applications offer the consumer additional, more accessible and affordable choices for amplification beyond traditional provider-sold hearing aids. The issue is that the introduction of these types of products, some of which have performance and capabilities similar to that of a provider-delivered hearing aid, into this low information, poorly regulated marketplace, has led to confusion amongst consumers.

   Again, I am going to defer to those with more knowledge on the manufacturing aspects of the industry to address the latter aspect of this question. I will close by stating that the technologic line between a wearable/hearable wireless earphone and a traditional hearing aid is closing rapidly.

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

   Unfortunately, this industry has many products (provider-delivered hearing aids, over-the-counter hearing aids, PSAPs, and hearables and many of them, regardless of their classification, are proprietarily locked. In other words, the device cannot be adjusted, modified, or programmed by any licensed provider or by the consumer. Also, many of the devices are not equipped with telecoils, a hardware feature that allow consumers to have direct auditory connections to large space loop systems, or Bluetooth, which allow the consumer to have direct auditory connections to their cell phones and tablets.

Again, I am going to defer to those with greater knowledge on the technologic and manufacturing aspects of the industry to address the latter aspect of this question.

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

This question is a great foray into the second aspect of my comments. I will address this question throughout my comments below.

Here is my view of the role of the stakeholders (i.e. industry manufacturers) from the "cheap seats." It is not meant to be an inclusive list, but rather a glimpse into the role providers have played. My comments are to first point out that no single entity or stakeholder bears the responsibility for these statistics, that "among adults aged 70 and older with hearing loss who could benefit from hearing aids, fewer than one in three (30 percent) has ever used them. Even fewer adults aged 20 to 69 (approximately 16 percent) who could benefit from wearing hearing aids have ever used them." Changing this statistic is the goal of behind the focus on the industry.

In my opinion, these are some changes that need to be addressed across all stakeholders to improve adoption rates of amplification and make communication more accessible, affordable, and approachable.

- Medical community
    - Physicians have a general lack of understanding and education on hearing, communication difficulties, disorders, and their role in long-term patient medical outcomes and in a patient's ability to age independently.
        - The majority of physicians do not screen patients for hearing or communication difficulties, nor do they ask about these concerns and refer when appropriate.
        - **SOLUTIONS:**
            - **Encourage the Centers for Disease Control (CDC) to classify hearing loss a chronic medical condition.**
            - **Encourage Medicare to require that a comprehensive hearing evaluation, by a licensed audiologist or physician, is required in the Welcome to Medicare physical.**
            - **Encourage physicians to screen (using a paper inventory) for communication issues for all patients over the age of 50 and refer when positive.**
            - **Cease opposition of any Federal legislation that increases patient access, without increases in provider scope of practice. Physician groups consistently oppose Medicare legislation, whose only purpose is to make Medicare Part B coverage and benefits consistent with state licensure and coverage and benefits of every other payer, including Medicare Part C (Advantage).**
    - Fighting, through their national professional organizations, any attempt to improve patient access, no matter how irrational, despite assurances that it does not affect the scope of the non-physician healthcare professional.
        - The Food and Drug Administration (FDA) indicated, on December 7, 2016, that they would no longer enforce the medical clearance or medical waiver requirements to purchase amplification. At the same time, a consumer needs a physician order in order for Medicare to cover a comprehensive hearing evaluation by a licensed Audiologist.

The latter makes no sense in light of the FDA action and the fact that direct access to audiologic care and coverage of treatment services provided by audiologists is allowed by Medicare Part C (Advantage), Medicaid, and the vast majority of commercial insurers without physician oversight.

- **SOLUTION:**
  - **Congress should pass legislation, such as US House bill 2276, that allows for better access to care to audiologic evaluation and treatment to traditional Medicare beneficiaries though direct access to licensed audiologists for medically reasonable and necessary audiologic and vestibular evaluations and treatment, without a need for a physician order or certifications of a treatment plan.**

- Some physicians and medical facilities are incentivized, through their ownership of dispensing interests, to maintain the status quo.

- Regulatory bodies
  - The failure of Medicare to provide coverage for hearing screenings or routine evaluations or treatment provided by an audiologist ensure that some hearing and communication difficulties are missed and that hearing aids are the only path to improving hearing and communication. The evidence undeniably suggests that aural rehabilitation can play a significant role in the performance and satisfaction of a hearing-impaired individual.
  - The failure of the FDA and Federal Trade Commission (FTC) to create regulations that have kept pace with technology and the industry.
    - **SOLUTIONS:**
      - **The FTC should require that the current class (Class I) of air conduction hearing aids (for use with a greater than moderate hearing loss) REQUIRE an audiologic evaluation, whether it is purchased online, via mail order, or from a licensed provider to determine type, degree, and slope of hearing loss, as well as lifestyle, dexterity, communicative, and listening needs and demands.**
        - **In a perfect world, this entire class of hearing aid would require provider delivery and online and mail order sales would be prohibited, although there is no evidence that consumers are happier with provider-driven purchases (http://www.hearingreview.com/2014/01/a-comparison-of-consumer-satisfaction-subjective-benefit-and-quality-of-life-changes-associated-with-traditional-and-direct-mail-hearing-aid-use), unless evidence-based practice is provided.**
        - **The consumer should be provided with a copy of their audiometric test results and plan of care and should pay for these services, even if they do not proceed with amplification.**
          - **If provider-driven delivery is REQUIRED for the current class of hearing aid (prohibition of mail order and online hearing aid sales for devices intended for use for those with greater than a mild impairment), then evidence-based care should be required, including hearing handicap inventories, speech-in-noise testing, and real-ear measurement.**
        - **The consumer should receive an itemized price estimate for treatment options and prices should be transparent, where the service and the product is separately reflected.**

        - **The consumer should be informed in writing, prior to purchase, if the device is proprietarily locked. In an ideal world, no device would be proprietarily locked, allowing patients to access the best provider.**
    - **The FDA would strengthen the regulations on air conduction hearing aids designed for a greater than mild hearing loss or hearing handicap. These regulations should include and address ALL air conduction products, including those currently sold via providers, online, or mail order entities.**
        - **This class should have updated, strict technologic and manufacturing specifications, and output limitations.**
        - **New and existing manufacturers in this market should have to adhere to these requirements.**
        - **This class of hearing aids should have clear "intent of use" guidance.**
        - **This class of hearing aids should have clear warning labels.**
    - **The FDA should create a class of hearing aids for over-the-counter use and this class would not require an audiologic evaluation prior to purchase.**
        - **This class of hearing aids should have self-limiting technologic and manufacturing specifications and limitations (gain and output limits) and should follow the Consumer Electronics Guidance. I do not believe it should be classified by degree of hearing loss. Ideally, in my opinion, I would recommend:**
            - **High-frequency full-on gain of less than 20dB SPL.**
            - **Output levels of less than 115dB SPL.**
            - **Noise suppression technology.**
            - **Feedback management technology.**
            - **Telecoil.**
            - **Battery life, without recharging or battery replacement, of 16 hours or more per day.**
        - **These devices should be created on a one, singular platform and not proprietarily locked. All licensed providers should have access to this platform.**
        - **This class should have clear "intent of use" guidance.**
        - **This class should have clear warning labels.**
    - **The FDA should create specifications for personal sound amplification products (PSAPs).**
        - **These devices should have self-limiting technologic and manufacturing specifications and limitations (gain and output limits).**
        - **This class should have clear "intent of use" guidance (for normal hearing individuals only).**
        - **This class should have clear warning labels.**

- Insurance industry
    - Insurance companies puts very little focus into hearing healthcare coverage and, when they do, they focus the coverage solely on the product and not on the evaluation and treatment required to select, fit, and manage that product, although evidenced-based services are proven to increase patient outcomes and performance.
        - **SOLUTION:**

        - **Third-party hearing aid coverage should mirror the Federal Employee Health Benefit Plan (FEHP) and offer a fixed dollar amount benefit/allowance (in the case of FEHP it is $1250/ear, every three years). This benefit requires the provider to offer the patient amplification within their benefit/allowance amount, with no out-of-pocket cost to the member, while also allowing consumers (who are appropriately notified in writing) who wish to upgrade to a more advanced technology to do so.**
    - Provide coverage and benefits that afford the patient very little control over the products and delivery and often make it financially unviable for a provider to participate.
        - **SOLUTION:**
            - **Like traditional Medicare, Medicaid, and commercial payers (e.g. United Healthcare), third-party payers should be required to make the provider contracted fee schedules and allowable rates available to providers via their website or a specific web portal. Providers should be informed of the available allowances for certain levels of amplification.**

- Academia
    - Medical (M.D.) school academia for failure to teach medical students and residents more about hearing and communication and its importance in overall patient care.
    - Doctor of Audiology (Au.D.) program academia for failure to teach consistently teach ethics, business, and practice management. As a result, they have created students who keep repeating the same delivery and marketing patterns of the generations that existed decades ago.
        - **SOLUTIONS:**
            - **Medical (M.D.) school curriculum should include training on the importance of hearing and communication on the patient care delivery process and include a rotation through not just otolaryngology but audiology during their training.**
            - **Doctor of Audiology (Au.D.) programs should have required coursework (three credit hours or more) specifically related to ethics, business and practice management. This is currently not a requirement for accreditation through the Council of Academic Accreditation.**

- Audiologists, Hearing Aid Dispensers, and Physicians
    - When audiologists entered the hearing aid dispensing arena four decades ago, they began practicing and delivering care like hearing aid dispensers rather than healthcare providers. They adopted the dispensers' bundled pricing structure, despite the fact that Audiologists were fee-for-service prior. Audiologists stopped illustrating the monetary cost and value of their care to insurers, regulators, or patients.
        - **SOLUTION:**
            - **Audiologists, hearing aid dispensers, and dispensing physicians should be required, at a minimum, to itemize their prices for consumers. The provider should separate the costs of the evaluation, fitting, and long-term care from the costs of the devices themselves.**
            - **Consumers should receive an itemized price estimate prior to purchase that outlines costs of the evaluation, fitting, long-term care, and the devices themselves, as well as warranty and return for credit information.**

- Audiologists and hearing aid dispensers are entirely too dependent on hearing aid manufacturers. They rely on them for **everything**, from loans and leases, to travel, to training, to marketing support, and, finally, to business and practice management, including pricing. As a result, the fox is running the henhouse. The financial and business ties run too deep with their vendors. The manufacturers perpetuate this and it is the providers who blindly follow.

    - **SOLUTION:**
        - **In order to shed light on the relationships between providers and industry and create increased, much needed transparency within stakeholders, hearing aid manufacturers, personal sound amplification product manufacturers, audiologists, hearing aid dispensers, and physicians should be subject to the provisions and requirements of the Sunshine Act (https://www.cms.gov/openpayments/), especially since Medicaid and TriCare offer hearing aid coverage and benefits.**
        - **Hearing aid dispensers, audiologists, and dispensing physicians should have to disclose and report manufacturer- or buying/management group-sponsored educational events, where the sponsor is paying for travel, accommodations, food and beverage, and entertainment. These events have led to the increased costs of amplification to the provider, who then pass these costs onto the consumer. This is common practice in the industry, especially for those who do not work in academia or for governmental entities.**
- Providers have failed to consistently provide evidence-based evaluation and treatment services and, as a result, the patient perceives no value of audiologic care in most situations.
- Dispensers have failed to consistently increase their academic credentials and licensure requirements. The International Hearing Society (IHS), the governing body for most hearing aid dispensers in the US, is not a US Department of Education accredited academic institution and hearing healthcare cannot be merely learned through a book and webinar series. It takes more than a distance learning course that you "cram and get it done in a few weeks, or utilize the full year to complete" to practice hearing aid dispensing. Dispensers are attempting, at the state level, to practice audiology, beyond the evaluations of hearing for the purposes of amplification and the fitting of said amplification, without commensurate education. Audiologists need more than a thousand hours of supervised clinical experience and commensurate academic training. Due to the lack of education, hearing aid dispensers' identity and livelihood is tied solely to selling a product.
    - **SOLUTION:**
        - **The FTC and/or state licensure should dictate what constitutes both a hearing aid prescription (audiologic and/or communication needs assessment) and "audio profile," which providers can perform each of these procedures, and set forth minimum standards of care that are supported by peer-reviewed clinical evidence.**

- Hearing aid manufacturers
    - Six hearing aid manufacturers control 98% of the world's hearing aid market. In the US, they also control a majority of the delivery channels from full- or partial-practice ownership or franchise arrangements. Additionally, the manufacturers have contracts with the Veteran's Administration and Big Box retail entities where they provide hearing aids to these entities at a fraction of the cost as they offer to private clinics. They have ownership of third-party

insurance administrators that offer funded and unfunded hearing aid coverage and benefits. Big Six manufacturers also have ownership of buying groups and other business management entities that assist practices' in lowering their costs of goods, human resources, marketing and financial management. Finally, hearing aid manufacturers often have an incestuous financial and business relationships with many private dispensing practices, corporate owned entities, third-party administrators and buying and management groups. They have been able to accomplish this with very little oversight or regulatory controls.

- The manufacturers have focused their whole identity on increasing the average selling price (ASP) of products, while failing to offer value-based alternatives to providers. As a result, consumers have no low-cost option available to them.
- Many associations, too, have been lured into submission by the manufacturers and their need for financial support. Associations have failed to meet their membership needs relying solely on manufacturers to be a revenue stream. However, this is not the fault of the manufacturers, it is the fault of those who cannot stand on their own two feet.
- Lack of independent research and subsequent peer-reviewed publication of findings and results. It is difficult to find unbiased, transparent, hearing aid research on performance, outcomes, patient perceptions, and delivery.
    - **SOLUTION:**
        - **I recommend an examination of this industry, its stakeholders, and its business practices from a regulatory, legal standpoint to explore whether evidence exists of anti-competitive trade practices amongst within the industry. This environment has created an uneven playing field for new entrants into the industry, as well as for independent providers.**
        - **Manufacturers should have to offer 'a la carte' pricing to practices who do not wish to have mandatory training, marketing materials, business development funds, extended warranties, no charge accessories, no charge batteries, or loss and damage warranties mandated in the purchase price.**

- Consumers/Patients
    - Healthcare is not free. If consumers want the price of technology itself to decrease, they have to acknowledge and accept that there will be a charge for professional evaluations and treatment. In a bundled model, hearing aid purchasers pay for the evaluation and, often the fitting of non-purchasers. Itemization will require all consumers and/or their third-party payers to pay for the costs of the care they receive.
    - Hearing aid performance, outcomes, and satisfaction is not solely tied to the product. As a result, evidence-based evaluation and treatment consistently produce the greatest patient outcomes. Patients need to better understand this fact and better educate themselves on the differences between provider types and standards of care.
    - Everything, in every situation, cannot be purchased or accomplished online or in a retail storefront. Sometimes, consumers will require or prefer the care of a professional and, when that happens, they need to expect to pay for that care. With increased access, comes increased responsibilities.
        - **SOLUTION:**
            - **Creation and maintenance of unbiased consumer information and education about hearing loss, communication difficulties, the amplification delivery process, costs, pricing, the value of post-fitting rehabilitation and long-term success with amplification.**

In closing, I was taught by my mentor that, when you "put the patient first, the rest will follow." My goal is for more consumers to have more accessible and affordable options so that they can begin their hearing journey, and have access to amplification, when they are younger and more mildly impaired. I also believe that today's consumers have the right to guide their own journey on their own terms and not mine. While, evidence based, audiologic evaluation and treatment are the gold standard and there is significant evidence to illustrate their value to patient performance and satisfaction with amplification, the risks of non-treatment of hearing loss now surpasses the risk of less-than-ideally-treated hearing loss. I would like to see straightforward, consistent, research based regulation on every class of amplification product. I would also like to see, once and for all, enforcement of these regulations to ensure quality, patient safety and a competitive manufacturing environment.

Please let me know if I can be of any further assistance to your Commission.

Respectfully,

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