Comments to FTC on Hearing, Health and Technology-Workshop, Project No. P171200

Consumers, hearing care professionals and others appreciate the opportunity to provide comments to the Federal Trade Commission (FTC) on the accessibility, affordability and adoption of hearing aids and other technology. Please consider the following:

Comments on Accessibility and Affordability:

There are currently various options for persons with hearing loss to obtain amplification, some of them low cost. The majority of consumers obtain prescriptive fitting of hearing aids through audiologists, ENT offices, big box stores (such as Costco and Sam's Club) and hearing aid dealers. Hearing aids are also available through internet sites, typically without much professional consultation. Digital, state-of-the-art technology, from these practice settings, range from $500 to about $3000 with professional services, depending on the level of digital technology and accessories. Some hearing aids are less costly than the newest iphone that is outdated in three years. It is estimated that one-third to one-half of the above cost is due to the device and one-half to two- thirds is due to multiple services from a hearing healthcare professional. The consumer typically uses the hearing aid(s) for 4-7 years. If the consumer decides on a mid-technology hearing aid for $2000 per ear (inclusive of professional services and appropriate rehabilitation) the cost over five years would be approximately $67 per month. The cost of an entry level digital hearing aid of $800 per ear would be $27 per month over the five year period, while a $500 hearing aid cost is $17 per month. There are affordable options through the current hearing aid dispensing process, which involves important diagnostic evaluation, counseling, needs assessment, rehabilitation and follow-up. Medicaid, in some states, covers the cost for low income people and some insurance plan offer a fixed benefit every few years to their subscribers. In addition, there are agencies that donate hearing aids or recondition used hearing aids.

The consumer usually understands that healthcare professionals need to be paid for services. For instance, the orthodontist's large fee for metal braces ($5,000-$6000) includes the bundled cost of the professional's expertise, a multitude of professional visits and long-term follow-up. The costs of dental implants are extensive largely due to the cost of professional expertise and services. Cost is not the only factor for the low hearing aid adoption rate in the US, since denial, vanity, lack of public awareness, low physician referral and lack of medical insurance coverage are major factors. If the consumer pays an average cost of $2400 per hearing aid, as cited in the announcement to The Over-the-Counter Hearing Aid Act of 2017, it is because that consumer opted for enhanced technology and professional services. There are certainly prescribed hearing aids that have a much lower cost than this quoted average.[1]

The cost of an OTC device has typically been below $250 US dollars in other countries such as China and Japan, without any professional services. Other options are PSAPs and Hearables, which are not regulated by the FDA like the Class I or Class II hearing aids. Although these options are not intended to treat the medical condition of hearing loss, consumers do try these with limited success to amplify soft sounds. Typically, the OTC hearing aids that have been available in Asia are low frequency emphasis, linear hearing aids that do not always help the intended population with presbycusis; namely, older consumers. In addition, studies from Asia have found little innovation and improvement in the

technology of OTC hearing aids for over a decade.[2] Satisfaction with OTC hearing aids in Japan has been found to be very poor compared to those in countries with no OTC option.

Hearing aid technology has improved dramatically over the past decade and allows the hearing impaired user to process speech in many complex listening environments. Current prescribed hearing aids are not like simple OTC reading glasses for presbyopia which allows the consumer to read small print. Hearing aids needs to process speech and music in very complex, variable listening environments and reduce the effects of reverberation, noise, and distance on the speech coming from a communication partner or from a group of people. It is not accurate and, in fact, misleading to report that hearing aid technology has not been innovative over the past decade. [3] The current hearing aid technology is more advanced than even three years ago. The low cost digital aids provide a higher level of features and enhancements than in past so that consumers can be successful in a variety of listening situations.

Professional services in the hearing aid fitting process are essential. Safe and effective amplification is achieved when the proper diagnosis of the type and extent of the hearing loss is made. Each hearing impaired individual is different and the same audiogram can produce very different audiological profiles, even in mild hearing loss. Professional services are needed to determine the listening and cognitive demands of the individual, determine the type of amplification needed along with other assistive devices, program the hearing aid according to well-established prescriptive methods, fine tune programs, evaluate outcomes of benefit according to best practices, counsel the consumer and significant others, provide education and aural rehabilitation and provide follow-up for the duration of use (generally 4 to 7 years). A prescribed amplification system with professional services are key to success, as research shows [4], and consumers should want to use an amplification system that lasts for several years and can be reprogrammed over time as the hearing loss progresses. In the newest MarkeTrak9 (MT9) study[5], consumers give their hearing care professionals substantially higher ratings than the devices they dispense. In MT9, a remarkable 95% of hearing aid owners and 87% of non-owners said they were satisfied with the professionals they had seen in the past 5 years. Japan, where OTC devices are commonplace, had the poorest satisfaction rate; there only 36% said they were satisfied.[6] OTC devices are cheap but are used short-term due to the low success rate. Widespread, easy access does not equate to good or acceptable health outcomes. Without professional services, the OTC device may be inadequate and discouraging for many.

Hearing loss with aging develops slowing over many years and the hearing impaired person tends to deny or minimize the problem. Those who self-diagnose a "mild hearing loss" may in fact have a greater than mild loss, normal hearing, or a sloping, high frequency hearing loss. The loss may also progress over three or four years making the OTC device unusable. The risk of under treatment or failed treatment may lead to the opinion that hearing aids are not helpful, preventing persons from seeking professional help and further delaying appropriate treatment. An unsafe aspect of using an OTC device in a person with normal hearing is the possibility of harm to high sound pressure levels, unless certain output limits are clearly established. In addition, appropriate intervention of accompanied tinnitus or balance conditions will go unaddressed without proper evaluation. The concept of treating a chronic, complicated health condition of hearing loss with an OTC, “do-it-yourself” solution is at odds with the provision of quality health care.

Professional services from a licensed hearing healthcare professional are essential for the majority of hearing impaired consumers, especially for older consumers. Hearing loss is a medical condition and should be view within the medical model of healthcare. A hearing aid is a medical device not a simple electronic appliance or simple eye len. The analogy between OTC hearing aids and OTC reading glasses is seriously flawed. [7] Greater satisfaction of hearing aid use is correlated with professional services. Although the penetration rate is fairly low in the US (approximately 30%), satisfaction rates have risen over the last few decade to about 80% (MT9 study), largely due to the continued availability of services from a hearing healthcare professional and the improvement in technology.

Comments on Adoption Rate in the U.S.:

The Over-the-Counter (OTC) Hearing Aid Act is designed to increase the adoption rate of hearing aids. The fact is that the availability of OTC devices does not translate into an increase in adoption rate. In Japan where OTC hearing aids are readily available in drug stores, appliance stores and other stores, the adoption rate is only 13.5%. Some researchers have reported that the poor quality of cheap, OTC hearing aids and poor success rate contribute to the low adoption rate. In countries where there are no OTC options, adoption rates range from 30% (France, US) to 41% in the UK (studies). Despite little to no coverage for prescriptive hearing aids in the US, adoption rates are not that much lower than in the UK where hearing aids are covered through the national health plan. Studies on elderly Chinese, who have access to OTC hearing aids, show the most common reason for non-adoption of a hearing aid was not always cost. Very often participants did not consider their hearing impairment severe enough to warrant a hearing aid or that it is a normal part of aging and acceptable. [8] Access and affordability alone does not result in high adoption rates but the addition of professional services does. [9]

Further comments:

As an audiologist, researcher and educator who worked with thousands of hearing impaired patients in all practice settings (hospital, otology office, VA, industry, private practice), I am in favor of increasing competition and adoption so that hearing aids are more affordable. However, I am not in favor of the current OTC proposal that would risk reducing an important and critical piece of hearing healthcare; namely, proper evaluation, support, counseling, aural rehabilitation and continued follow-up. By short-circuiting the quality process with a “do-it-yourself” solution, we are doing a disservice to our hearing impaired patients and offering an OTC, cheap solution to a complex and chronic health issue.

Recommendations:

1. Encourage hearing screening programs by physicians and other healthcare professionals.

2. Conduct educational programs to increase awareness of hearing loss and the need for intervention based on studies that highlight the detrimental affects of hearing loss on cognition, memory, and physical and emotional well-being.

3. A Hearing Aid Tax Credit or insurance benefit should be supported in the legislature, even $1000 per four-five years.

4. Create incentives for third party payers to offer hearing care components and fixed hearing aid benefits to their coverage.

5. Establish direct access to audiologists for Medicare recipients for audiological evaluation and rehabiliation.

If the OTC hearing aid bill is passed, then the following should be done:

1. Require a hearing evaluation from a licensed professional, such as an audiologist, physician or from a licensed hearing aid dispenser for the purchase of OTC device. The copy of the audiogram will be given to the patient.

2. Limit gain and output requirements of the OTC device to insure hearing safety.

3. Restrict the use to only mild hearing loss and not allow hearing loss to exceed 40 dB.

4. Protections to insure that children under the age of 18 are not users of the OTC hearing aids.

5. Requirement for the FDA to collect data on the adverse events and contraindications of OTC use.

6. Require manufacturers to adhere to the same quality guidelines as other hearing aids. Distinction should be made between OTC hearing aids and PSAPs or Hearables.

7. Labels should be used to warn about potential health issues that require medical intervention such as a draining ear, tinnitus, vertigo, sudden hearing loss and asymmetrical hearing loss.

8. Label the requirements for consumers to report adverse events using the devices.

Thank you for the opportunity to comment and provide my expertise in the area of hearing healthcare and rehabilitation.

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[1] ConsumerReports.org. Hearing aid buying guide, 2015.

[2] Z.Chan, B. McPherson, Over-the-Counter Hearing Aids: A lost decade for change. BioMed Research International, 2015, Vol.827463, p. 1-15.

[3] Hearing Industries Association, letter to the FTC re: Hearing, Health and Technology-Workshop Project no.P171200, March 31, 2017.

[4] Sergei, Kochkin et al, MarkeTrak VIII: The impact of the hearing healthcare professional on Hearing aid user success, 17 (4), Hearing Review, 12 (2010).

[5] Abrams,HB, Kihm,J. An Introduction to MarkeTrak IX: a new baseline for the hearing aid market. The Hearing Review, 2015:22(6): 16.

[6] S. Hougaard, S. et al, Euro-Trak and JapanTrak, 2012, Societal and Personal Benefits of Hearing Rehabilitation with hearing aids, The Hearing Review, 2013.

[7] Chasin, M., Facts vs. Values: Faulty Analogies in the Rationale for OTC Devices," Hearing Review, March, 2017.

[8] PWY Wong, B.McPherson, Reasons for non-adoption of a hearing aid among elderly Chinese. Asian J. Gerontol Geriatrics, 2010; 5: 62-8.

[9] Sergei, Kochkin et al, MarkeTrak VIII: The impact of the hearing healthcare professional on Hearing aid user success, 17 (4), Hearing Review, 12 (2010).