

September 2, 2014

Renee P. Clark, Executive Director
Hearing Aid Dispensing Examiners Committee
124 Halsey Street, 6th Floor
Newark, NJ 07102

Re: Online Hearing Aid Sales

Dear Ms. Clark:

The American Academy of Audiology (the "Academy") appreciates the opportunity to offer our position in response to the New Jersey Hearing Aid Dispensers Examining Committee's investigation regarding the sale of hearing aids by Walmart both online and in their New Jersey stores. The Academy is the world's largest professional organization of, by, and for audiologists, representing over 12,000 members. The Academy promotes quality hearing and balance care by advancing the profession of audiology through leadership, advocacy, education, public awareness, and support of research.

It is the Academy's position that rehabilitative amplification services including the selection, fitting, verification, and maintenance of hearing aids and related devices should always be provided in person, by or under the supervision of a licensed audiologist who is involved in the care of the individual with hearing loss.¹ Hearing aids purchased through direct-to-consumer hearing aid delivery models, including hearing aid devices sold online, often do not adequately meet the needs of an individual with hearing loss. Additionally, hearing loss may be caused by a potentially serious medical condition including acoustic neuroma, which could go undetected, undiagnosed, and untreated if hearing aids are purchased without the involvement of a licensed audiologist or hearing health professional.

Food and Drug Administration (FDA) "Red Flag" Conditions Associated with Hearing Loss

In reviewing the letter (dated May 2, 2014) from Walmart to the Hearing Aid Dispensers Examining Committee, the Academy feels that Walmart does not appropriately address or acknowledge the potential health risks associated with the condition of hearing loss. Walmart

¹http://www.audiology.org/advocacy/publicpolicyresolutions/Documents/MailOrderInternetOrder_HA.pdf

argues that hearing aids have been classified as Class I medical devices by the FDA because they “do not present a potential, unreasonable risk of illness or injury.” Walmart cites other examples in which they feel the FDA has indicated that Class I hearing aids pose few risks to consumers. The Academy believes that this argument provides a limited description of the complete FDA regulations related to the sale of hearing aids, and fails to take into consideration the complex nature of identifying and treating hearing loss.

Though Class I hearing aids in and of themselves may not present a high risk to the consumer, there are still serious health risks associated with hearing loss and the use of hearing aids. The FDA has classified hearing aids as Class I medical devices, but also recognizes that there are certain “red flags” which indicate potentially serious medical conditions, and these “red flags” can only be identified through a comprehensive case history, physical examination, and thorough audiologic examination of the individual with hearing loss.² Omission of a comprehensive hearing evaluation and involvement by a licensed audiologist may lead to the failure to detect an underlying medical cause of hearing loss. In other words, a consumer who is experiencing hearing loss may seek to “treat” this hearing loss by purchasing a hearing aid online. This practice involves treating a condition without a diagnosis, and without a diagnosis, underlying problems requiring medical attention may not be addressed.

Walmart goes on to argue that the FDA has made the policy determination that hearing aids should be readily accessible, and maintains that the FDA has not sought to prohibit mail order hearing aids sales provided that all the requirements of the regulation be met. In response to this statement, it is worth noting that in the past ten years, the FDA has also continually denied requests for over-the-counter hearing aids sales due to serious concerns about missing the potential “red flag” conditions references above. Again, the issue at hand is not that the hearing aids in themselves present a high risk to the consumer, but that the FDA recognizes that serious health conditions may be missed if an examination is not conducted. It is also important to note that all 50 states and the District of Columbia have implemented laws governing the sale and distribution of hearing aids in order to protect individuals with hearing loss.

Federal Law and the Preemption of State Laws Concerning the Sale of Hearing Aids

Walmart claims that any state law or regulation attempting to regulate the conditions for sale of hearing aids is preempted if it “imposes requirements different from, or in addition to, the federal conditions for sale, and relates to the safety or effectiveness of the devices.” In the case of New Jersey, Walmart asserts that the New Jersey requirement related to the sale of hearing aids “is to assure the safety and effectiveness of hearing aids.” For this reason, Walmart believes that New Jersey laws attempting to regulate the conditions for sale of Class I hearing aids beyond the regulations set forth by the FDA are expressly preempted. This would then allow

² <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?fr=801.420>

Walmart to engage in the “mere sale” of hearing aids without first providing a hearing evaluation. The Academy believes that the requirements and regulations established by the state of New Jersey are to protect the consumer by ensuring that hearing aid devices are accessed and used in a safe manner, rather than to protect consumers from the device themselves. As stated, hearing aids alone do not pose a serious risk to the consumer, it is accessing the hearing aid without a proper examination that does. The Academy understands that there are other examples where a state imposes additional requirements beyond what is required by federal, i.e. the appearance of warning labels on certain devices, requirements dictating who may dispense specific prescriptive devices, etc. In these cases, the state law may not be preempted, as it is not the safety of the device in question, but more so that devices are accessed and used in a manner that is safe for the consumer.

Further, it is the Academy’s understanding that the FDA has primary jurisdiction over the question of whether the state law is preempted by federal law, and that this issue cannot be determined by Walmart or even the state of New Jersey. State law preemption, especially in the area of product liability, has a complex history, and is not as straightforward as Walmart suggests. The only way to appropriately determine if a state law is preempted is to obtain an official opinion from the FDA. If Walmart feels that the state law concerning the conditions for sale of hearing aids is preempted, it should go directly to the FDA to seek an opinion. Until that time, the issue of preemption cannot be properly addressed.

Overall Consumer Protection and Satisfaction

Walmart asserts that they are only engaged in the “mere sale” of hearing aids, and not in the evaluation or measurement of hearing. The practice of simply selling aids without a hearing evaluation and fitting by a licensed audiologist can result in a substandard experience for the consumer. In addition to the potential health risks associated with hearing loss, there are many other considerations for consumers who are looking to purchase a hearing aid.

If a consumer is purchasing a hearing aid online, it is likely that the device will be programmed at a remote location, and mailed to the individual without verification performed to ensure its functioning. As a result, this device may require further modification from its default settings, as the default settings may not provide the correct amount of amplification necessary to make sounds audible and tolerable for the individual with hearing loss. With hearing aids purchased online, there is often no method of providing this necessary onsite ability for modification, maintenance or repair, essential tenets of the hearing aid fitting process. It is also possible that the consumer may purchase a hearing aid unnecessarily, or even purchase a device that is less than ideal for the treatment of their hearing loss.

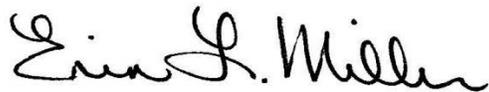
When a consumer purchases a hearing aid online, they also do not receive the support or counseling about other options to improve overall hearing capabilities. This one-on-one counseling regarding additional options to manage hearing loss, as well as verification of the

prescribed hearing aid settings, have been shown to improve outcomes, satisfaction, and usage of hearing aids.

Additionally, there are psychological correlates associated with hearing loss that may also go untreated if the consumer purchases a hearing aid online or without the proper evaluation and continued involvement of a licensed audiologist. Untreated hearing loss can exacerbate conditions such as depression, isolation, and other emotional issues, so it is important that consumers receive complete and comprehensive care for their hearing loss. Walmart may claim to only be involved in the “mere sale” of hearing aids, but the process of diagnosing and treating hearing loss goes far beyond just the sale of hearing aids.

The Academy would like to thank the NJ Hearing Aid Dispensers Examining Committee for the opportunity to share our position regarding online hearing aids sales and the importance of safeguarding consumers during this process. Please contact Kate Thomas, assistant director of state, federal, and political affairs at 202-544-9336 or kthomas@audiology.org if you should need additional information or clarification regarding the Academy’s comments.

Sincerely,

A handwritten signature in black ink that reads "Erin L. Miller". The signature is written in a cursive style with a large initial "E".

Erin L. Miller, AuD
President
American Academy of Audiology