

November 20, 2003

8656 '03 NOV 26 P1:35

Division of Dockets Management  
Food and Drug Administration  
5630 Fishers Lane, Room 1061  
Rockville, MD 20852

RE: Petitions for Over-The-Counter (OTC) Hearing Aids  
PER: Mead Killion & Gail Gudmundsen

To Whom It May Concern:

In regard to the above-noted petitions, I am writing to voice my opinion. In my experience as an audiologist and hearing aid dispenser in the state of California, it is rather surprising that two top professionals in our field would support, much less propose, petitions for the sale of OTC hearing aids.

As many of us who have worked in the field of Audiology and Hearing Aid Dispensing have come to realize, fitting a hearing aid is entirely different than fitting eyeglasses. When one is properly fit with eyeglasses, the test chart becomes much more clear almost immediately before that person leaves the fitting appointment. Accordingly, the improvement in vision is quickly noticed and virtually undeniable by the person whose vision has been corrected. Conversely, when one is properly fit with a hearing aid, it rarely is the case that the person who has been fit immediately notices a marked improvement in their ability to hear. As a result, the fitting process typically involves numerous follow-up visits during which the hearing aids are fine-tuned as the patient makes the adjustment to speech and other sounds as they appear when amplified by the hearing instruments. Perhaps the reason for this is because sound is electronically manipulated by hearing aids, whereas there is no electronic alteration in the visual signal when one is fit with eyeglasses. That is, with eyeglasses a correction of vision only requires a lens, which essentially alters visual input in the appropriate manner to compensate for the patients vision problems. Hence, the patient whose vision is corrected is not challenged by an entirely new type of stimulus from which the brain must make decisions regarding judgment and character, which is exactly what is required of the brain when one has to adapt to the sounds of a hearing aid—even with the most sophisticated digital instruments.

Because the success of the majority of hearing aid fittings requires extensive follow-up to assist the patient in the adaptation process, an availability of OTC hearing aids very likely could result in situations where patients who otherwise could have benefited from hearing aids give up on them much too early. As a result, instead of receiving the benefits of amplification, they may instead put off the use of amplification for a much greater period of time than may otherwise have occurred.

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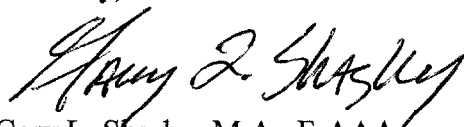
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In addition, considering how strong the issue of denial is when faced with the prospect of having to wear hearing aids in order to improve ones hearing, the access to OTC hearing aids may serve as an easy facilitator for this denial. For example, a hard-of-hearing individual who has been "bothered" by friends and family to do something about their hearing loss could simply buy a set of OTC hearing aids, try them for a little while, and then claim they did not help their hearing. In this way, the person is afforded the perfect excuse that "hearing aids are just not for me." In reality, if the individual had been properly fit and followed by a licensed audiologist and/or hearing aid dispenser, their adjustment to amplification may have been met with much better success, and as a result they would be on the way to a life of better hearing.

Finally, I cannot help but wonder if these petitions have something to do with issues of personal gain concerning the persons who have proposed them. Both of these individuals are nearing the end of their careers, and both are employed by Etymotic Research (Dr. Killion is the President). Etymotic Research is a well-known manufacturing company for hearing aids and hearing aid parts, and most likely would stand to benefit tremendously from the sale of OTC hearing aids. Hence, one might question whether these petitions are really for the benefit of the hard-of-hearing or for the benefit of those in the business of manufacturing hearing instrumentation?

For the record, I personally am opposed to the sale of OTC hearing aids. I hope that in making any decisions pertaining to this matter, the concerns I have mentioned in this letter are duly considered.

Sincerely,

A handwritten signature in black ink, appearing to read "Gary L. Shasky". The signature is written in a cursive, somewhat stylized script.

Gary L. Shasky, M.A., F-AAA  
Clinical Dispensing Audiologist