

**Active Hearing and Balance Center**  
**Fall Prevention Center**

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November 20, 2003

Division of Dockets Management  
Food and Drug Administration  
5630 Fishers Lane, Room 1061  
HFA 305  
Rockville, MD 20852

RE: Over the Counter Hearing Aids

Dear Sir or Madam:

As an audiologist and hearing aid user, I wish to speak against the petition to allow over-the-counter hearing aid sales. I do not believe that such sales are in the best interest of the consumer and may, in fact, pose a potential hazard.

In contrast to the petitioner's suggestion that over-the-counter hearing aids would parallel the over-the-counter purchase of reading glasses, I submit that they are not the same. Whereas reading glasses may be tried on before purchase, over-the-counter hearing aids would not allow such a trial. Once the customer has inserted the hearing aid into his ear, it is now contaminated with whatever bacteria, fungus, cerumen or debris that lies in the ear canal. In addition, the mere act of inserting the over-the-counter hearing aid into the ear can create a problem for a consumer who may have a significant accumulation of cerumen in the ear canal. I recently saw a patient who had purchased two different mail order hearing aids which did not perform satisfactorily. Upon inspection of her ear canals, I determined that both ears were plugged with earwax. In all probability, the insertion of the mail order hearing aid pushed the wax deeper into the ear canal until it impacted against the eardrum. Removal of the earwax was made more difficult because of the depth of the impaction but, once removed, her hearing improved greatly.

Even if the ear is not impacted with cerumen, purchases of hearing aids without professional consultation is not in the consumer's best interest. The most potent example is the patient who has an acoustic neuroma that requires medical attention may delay such attention if they purchase an over-the-counter hearing aid to self treat the hearing loss. Such delays can lead to further deterioration in hearing as well as facial palsy and dizziness. Early identification and treatment by a medical professional would allow removal of the tumor with minimal complications. Delays in treatment would increase the risk and complications to the patient.

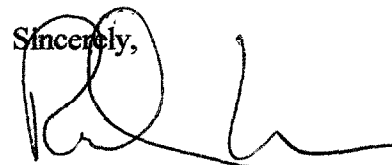
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Furthermore, the insertion of generic over-the-counter hearing aids which do not properly fit the ear canal can abrade the sensitive skin in the ear canal and create an otitis externa. This opens the ear canal abrasion to opportunistic infections in sensitive patients especially those who may have an autoimmune disease.

The petitioner's raise the issue of cost as a major reason that 80% of the hearing impaired do not purchase hearing aids. After 32 years of serving the hearing impaired, I believe the issue is much more complicated than that. In major surveys of the hearing impaired, cost was not listed in the first 5 or 6 reasons why people do not buy hearing aids. The perception that hearing aids are not effective and cosmetically unacceptable were more common reasons. Neither of these reasons would be alleviated by over-the-counter devices. Since over-the-counter hearing aids do not specifically address the sounds that are impaired in the ear, they will not be effective in resolving the consumer's hearing loss. Since over-the-counter hearing aids do not fit the ear properly, they will not be cosmetically superior to custom fit hearing aids.

For these reasons, I encourage the Administration to deny the petition and continue to require professional consultation prior to hearing aid purchases.

Sincerely,  
  
Richard Navarro, Ph.D.  
Audiologist, CCC-A, FAAA

*specializing in SOLVING hearing and balance problems  
for children and adults*