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Dockets Management Branch
Food and Drug Administration,
Department of Health and Human Services, Rm 1-23
12420 Parklawn Dr.
Rockville, MD 20857

CITIZEN PETITION

A. Action requested

The Commissioner is asked to create a new OTC (over-the-counter) hearing aid classification that grants over-the-counter sales, distribution and use status to one-size-fits-most hearing-aid-type devices that meet safety and efficacy requirements established by rule.

B. Statement of grounds

Explanation of need

Although the analogy between hearing aids and eyeglasses is often overworked, there is one dramatic distinction between the two: It costs a consumer with a mild hearing loss $1500 to $6000 or more to purchase a binaural pair of hearing aids, while the same consumer with a mild visual impairment can purchase binocular reading glasses for about $10-20 at a variety of retail outlets. The difference in cost is largely a result of differences in FDA policy regarding the two prosthetic devices.

Persons with beginning presbyopia are at little risk in choosing their own glasses except for the loss of money if they make a bad choice. Anyone who needs one to three diopters of correction in order to read clearly can choose reading glasses with the appropriate magnification and purchase them without professional assistance. Virtually no one is prevented from reading clearly because they don't want to see a professional, or because they are unable to afford prescription reading glasses.

Those who suffer the worst effect of the present FDA hearing aid policy are seniors on a fixed income, those with no supplemental insurance benefits, and low-income persons for whom the cost of a professionally dispensed hearing aid is out of the question. In practice, the present FDA hearing aid policy is discriminatory against the low-income population.

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At present, the FDA strictly regulates hearing aids. By rule, the FDA requires that anyone needing even a small amount of hearing help must see a medical professional or sign a waiver. FDA regulations further determine what comprises a hearing aid, and most states require that anyone selling such devices must be a professional who is licensed by the State. In most states, therefore, someone wanting hearing assistance is required to see two professionals (or sign a waiver for one) before obtaining any help. Professional fees often put hearing aids out of the reach of the indigent.

Unnecessary restriction

Approximately two-thirds of the retail price of a hearing aid is the cost of professional fees, most of them "bundled" into the hearing aid price. Under the FDA hearing aid rule, people cannot decide for themselves whether or not to see a professional to purchase hearing aids. A comparable policy would be to deny everyone the right to decide for themselves between taking a couple of aspirin and seeing a professional when something hurts. The former choice is allowed, even though pain is sometimes an indication of a life-threatening medical condition, because experience has taught us that the majority of people can make intelligent decisions with regard to aspirin. If they make a mistake they can correct it if the pain persists.

The operative principle that separates over-the-counter drugs or devices from those that require prescription by a physician is whether misuse of that drug or device can cause harm to the user. The wrong prescription drug may be dangerous to a particular patient. The potential harm from the direct purchase of a hearing aid without medical evaluation or professional dispensing is negligible.

It has been estimated that 80% of hearing-impaired persons who need hearing aids have not purchased them. The majority of those non-users do not have ear pathology that requires medical intervention. Going without hearing aids, however, creates a new pathology: Without hearing aids, these persons gradually withdraw from active society, or, less dramatically, make mistakes in the workplace or in social and family situations. At the least, they annoy their companions, who must always raise their voices when speaking to them.

Safety considerations

The main purpose for an FDA rule about hearing aids is to protect consumer safety and ensure efficacy of the products provided.

Possibly for the first time in history, we now have the technology to deliver safe and effective hearing aids at a fraction of the cost of a professionally dispensed custom product. In those cases in which such devices prove ineffective, they can easily be discarded.

Arguments against over-the-counter hearing aids

1. A one-size-fits-most eartip might cause an allergic reaction, ear canal irritation, abrasion or a bleeding ear canal.

2. The sound pressure level (SPL) output of the hearing aid might be too high, which could cause permanent hearing damage or tinnitus.

3. Not seeing a hearing professional could mean missing a medical condition (e.g., draining ear, sudden hearing loss, etc.) that, untreated could cause permanent damage to the ear.

Rationale for OTC hearing aids

1. Eartips: Eartips should pass standard animal tests for allergic reactions, and extensive real-world testing for ear canal safety. An eartip that has an established safety record in a similar application (e.g., one-size-fits-most hearing protectors) may reasonably be accepted on the basis of its history of freedom from allergic reaction, ear canal irritation, abrasion or instances of bleeding ear canal.

2. Unsafe Output: Restricting peak OSPL-90 (maximum output with 90 dB SPL input) to 115 dB SPL or less provides a substantial margin of safety from hearing aid trauma. Decades of evidence indicate that even users of hearing aids having extraordinarily high peak OSPL-90 (130-140 dB SPL) simply turn them down. Documented instances of trauma caused by hearing aids have been extremely rare in the literature (see references 1-10). The time-intensity tradeoff between high-intensity sounds and hearing damage provides even a user with slow reaction time more than enough time to reduce the volume control or remove the hearing aid without risk.

   Example: For a hearing aid with 112 dB maximum output, the user has nearly a full minute of safe exposure in which to turn down the hearing aid (regardless of the initial volume control setting or the intensity at the input). With a 115-dB maximum output, the user still has more than 30 seconds to turn the volume down even if a continuous loud tone is encountered. Note: a single such exposure typically does little damage, although repeated exposures above safe time-intensity limits can cause permanent hearing loss. (The allowable safe exposure times above were arrived at based on the commonly assumed safe exposure of 85dBA for 8 Hours, five times per week, combined with the conservative European rule that allows only a 3dB increase per halving of exposure time, i.e., using what is called the "85 Trade 3" rule. The standard OSHA rules allow 90 dBA for an 8 Hour exposure and a 5dB increase in SPL per halving of time. [Berger et al, ref 11, p175 and pp 679-680] The OSHA rules would predict that 15 minutes of exposure to 115 dB SPL would be safe each day in the absence of other insults to the ear.) By contrast to these exposures, competitive "boom cars" can produce 150-160 dB SPL continuously. Such SPL level capabilities are regularly documented in national contests. The hearing levels of their drivers has not been reported, to the writer's knowledge.

3. Patient health and safety: While it is true that a professional hearing aid dispenser is trained to recognize signs indicating that medical intervention is needed, it is also

true that 80% of those needing (but not buying) hearing aids will not see a hearing professional. Thus, the important question is whether a new risk is introduced for such persons by allowing OTC hearing aids. The opposite may be true: Trying an OTC hearing aid may uncover indications for medical or audiologic consultation.

Efficacy and Quality

Arguments against OTC hearing aids based on effectiveness and quality considerations

1. Inferior-quality over-the-counter hearing aids (such as the former Whisper XL or Whisper 2000) may become available to buyers, but their high distortion levels and severely limited bandwidth provide negligible benefit, causing their unwary buyers to permanently distrust hearing aids.
2. Low-cost over-the-counter hearing aids won't be effective.
3. The availability of low-cost OTC hearing aids will damage hearing aid manufacturers because the latter will find it difficult to maintain their prices.

Rationale for allowing the purchaser to determine the efficacy and quality of OTC hearing aids

1. Inferior-quality merchandise of all sorts is available to the buyer in a free economy. In general, where only the purchaser's wallet and not his or her safety are at risk, it is best to let the buyer beware. Unsatisfactory OTC products can often be returned for a refund.

2. The basic question is: Who should decide whether a hearing aid is effective and has adequate quality? Since major hearing aid manufacturers offer widely different signal processing characteristics in their hearing aids, it is the purchaser who must determine quality even with professional dispensing.

   Note: There is strong evidence that low-cost aids can be highly effective. A recent report from Cambridge University of a study comparing a two-channel programmable analog hearing aid, two of the latest-technology digital aids, and the $40.00 disposable Songbird hearing aid indicated that the Songbird aid compared favorably on every measure with the more expensive aids (Brian E.A.G. Moore et al, 2001, ref 12).

3. At present, the cost of obtaining hearing aids is typically $750 to $3000 per aid. By contrast with the potential $40-$300 cost of non-custom OTC hearing aids, the

present high prices represent a substantial impediment to someone who wants to try hearing aids.

4. Even those who can afford hearing aids may find the time-cost of finding good medical and good hearing aid professionals, and making and keeping the minimum of three appointments required to obtain hearing aids, demands too much time. This factor, combined with the ever present tendency to deny that one's hearing loss is great enough to worry about, has resulted in millions of family members who are required to raise their voices on a daily basis.

5. While it can easily be asserted that a bad experience with a $9.95 hearing aid might discourage some consumers, it may also reasonably be assumed that most consumers know that good hearing aids cost more than that. Example: It is possible to buy a screwdriver for $0.79 that bends in the screw slot, or buy a screwdriver for $7.95 that will hold up for years. Perhaps a few consumers would be disillusioned forever on screwdrivers after purchasing one for $0.79, but the majority will understand that a cheap screwdriver may be a low-quality screwdriver.

6. The 15-30% return rate in the U.S. for expensive digital hearing aids indicates that users are capable of deciding when something doesn't work well, even if it is professionally dispensed. In addition, both Kochkin (2000, ref 13) and VanVliet (2003, ref 14) reported that 5% of the hearing aids that are sold end up in dresser drawers within 6-12 months, presumably because the consumer doesn't want to tell the nice professional that they didn't help. By the time five years have passed since the purchase of hearing aids, Kochkin (2000) reported that 20% end up in dresser drawers; for a variety of stated reasons, their purchasers choose not to wear hearing aids.

7. The retail sale of reading glasses may provide some prediction for the hearing aid field. In the vision-care industry, the majority of eyeglasses are dispensed professionally, even though low-cost reading glasses are readily available in retail outlets without prescription.

8. Many professionals may find it beneficial to allow hesitant potential patients to first try inexpensive OTC hearing aids purchased from them, under the assumption that the patient is more likely to come back when greater sophistication in fitting is desired.

Fairness

The analogy with eyeglasses is pertinent. If a purchaser of OTC eyeglasses is not required to see a physician, sign a waiver, or have a professional eye examination to

determine acuity or rule out glaucoma or other disease, it is arguably unnecessary to require a hearing aid purchaser to take a hearing test or see a physician.

Any federal regulation that restricts access of a large segment of the population to a beneficial product or service is unnecessary regulation at best and harmful regulation at worst. More importantly, hearing aids are presently available from sources where little or no regulation is imposed (e.g., Radio Shack personal amplifiers, or hearing-aid-type devices available through magazines, catalogs, newspaper ads, mail order and the Internet). Sporting goods stores and specialty catalogs sell hearing devices that are clearly hearing aids, but the purchasers of these devices are not required to obtain medical clearance, sign a waiver, or go to a licensed dispenser.

It would not be consistent with this petition to argue for vigorous enforcement of present FDA regulations to stop such violations, but the current lack of enforcement allows unfair competition against legitimate manufacturers who voluntarily obey the present regulations.

Possible opposition to FDA approval of OTC hearing aids

Among those who might oppose FDA approval of OTC hearing aids are audiologists and hearing aid dispensers, some of whom may take the position that OTC hearing aids present a danger to the health and safety of prospective consumers who might purchase hearing aids that fit poorly, had poor sound quality, and were ineffective. Such consumers might not seek a professional consultation because of a bad experience. Many hearing professionals believe that a consumer's best interest is always best served when a hearing aid is dispensed by a trained, experienced, licensed hearing care professional.

Additional opposition may come from physicians who feel that hearing loss is a medical condition that can only be diagnosed by a physician (Holt, 2002, ref 15). This group argues that the current FDA requirement of medical evaluation prior to the purchase of a hearing aid ensures that there is no potentially harmful underlying pathology that requires medical or surgical intervention.

Summary

While those of good will and good judgment may take opposite sides on the question of how low-cost OTC hearing aids will affect current hearing aid manufacturers and professionals, the petitioner believes that with only 20% market penetration into the class of people who need hearing aids, and a 15-30% percent return rate for professionally dispensed hearing aids, any means of getting people started with hearing aids can be expected to ultimately bring many more users into the market. Thus, the long-term effect of over-the-counter hearing aids is likely to be healthy overall.

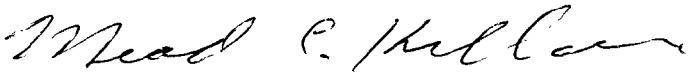
Regardless of whether or not OTC hearing aids ultimately benefit current hearing aid manufacturers and professionals, however, the important question is whether or not they will benefit those who need hearing aids (Sweetow, 2001, ref 16). Once safety and effectiveness issues have been resolved, it is reasonable to allow the U.S. population (high income and low income), access to low-cost, high quality, minimal-risk OTC hearing aids.

C. Environmental impact

No known environmental impact is predicted except an increase of disposed batteries if more people use hearing aids. Recent developments in battery technology and regulation have reduced the mercury content to essentially zero, so the hazard from discarded batteries has been reduced accordingly.

E. Certification

The undersigned certifies that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information that are known to the petitioners and that are unfavorable to the petition.



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References

1. Podoshin, L., Kremer, M., Fradis, M., Feiglin, H. (1984). Effect of hearing aids on hearing. *Laryngoscope, 94(1)*, 113-117.
2. Macrae, J.H. (1991). Permanent threshold shift associated with overamplification by hearing aids. *Journal of Speech and Hearing Research, 34(2)*, 403-414.
3. Melnick, W. (1991) Human temporary threshold shift (TTS) and damage risk. *Journal of the Acoustical Society of America, 90,* 147-154.
4. Humes, L.E., Jesteadt, W. (1991). Modeling the interactions between noise exposure and other variables. *Journal of the Acoustical Society of America, 90,* 182-188.
5. Macrae, J.H. (1991). Prediction of deterioration in hearing due to hearing aid use. *Journal of Speech and Hearing Research, 34(3)*, 661-670.
6. Macrae, J.H. (1994). Prediction of asymptotic threshold shift caused by hearing aid use. *Journal of Speech and Hearing Research, 37(6)*, 1450-1458.
7. Heffernan H.P., Simons, M.R. (1979) Temporary increase in sensorineural hearing loss with hearing aid use. *Ann Otol Rhinol Laryngol, 88*, 86-91.
8. Macrae, J.H. (1995). Temporary and permanent threshold shift caused by hearing aid use. *Journal of Speech and Hearing Research, 38(4)*, 949-959.
9. Macrae, J.H. (1994). An investigation of temporary threshold shift caused by hearing aid use. *Journal of Speech and Hearing Research, 37(1)*, 227-237.
10. Macrae, J.H. (1993) Temporary threshold shift caused by hearing aid use. *Journal of Speech and Hearing Research, 36(2)*, 365-372.
11. Berger E.H., Royster L.H., Royster J.D., Driscoll D.P., and Layne M. (2000), *The Noise Manual, Fifth Edition.* American Industrial Hygiene Association, Fairfax, VA.
12. Moore, B.E.A.G., Stone, M.A., and Alcantara, J.I. (2001). Comparison of the electroacoustic characteristics of five hearing aids. *British Journal of Audiology, 35,* 307-325
13. Kochkin, S. (2000). Marketrak V: Why My Hearing Aids are in the Drawer: A Consumers' Perspective. *H Journal, 53(2),* 34-42.
14. Van Vliet, D. (2003). Self Reported Hearing Aid Outcomes and Patient Demographics, paper PP107 presented at the American Audiology Association convention, April 5, 2003, San Antonio, TX.
15. Holt, G.R. (2002), AAO-HNS leader criticizes article by Fabry. *Hearing Journal, 55(8),* 52.
16. Sweetow, R. (2001). An Analysis of entry-level, disposable, instant fit, and implantable hearing aids. *Hearing Journal, Feb 2001, 54(2),* 28-43.