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January 18, 2004

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

Re: 03P-0362 Over-the-Counter Hearing Aids

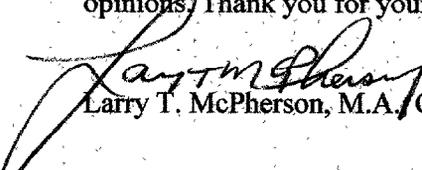
Sirs,

I have read the petition and I am writing to express my opposition to this Citizen Petition to amend the current FDA Hearing Aid Standards and allow a form of Over-the-counter Hearing Aids to be available to the consumer. I am both an Audiologist and a Hearing Aid Dispenser. I have over 30 years of experience in the evaluation hearing loss and I estimate that I have fit over 7500 hearing aids in my career. I have seen the benefit of current FDA standards in reducing the failure rate in hearing aid fittings and strongly feel that the proposed change will result only in increased failure of the consumer to get benefit and help for their hearing health care needs.

I find this proposal to change FDA policy to be unfair to consumers needing hearing health care based on a very important but simple point. There is nothing in the research literature or in my professional experience that will show that this change in FDA policy will result in consumer benefit. The assertions in this petition are not backed up by either quality research nor by the experience I have had with consumers who have tried to fill their needs with a low-cost one-size-fits-all device. There have been simple one-size-fits-all "OTC" like devices available and in my experience with this type of product I have found that the successful obtaining of quality hearing health care is poor.

The several arguments presented by the petitioner are spurious unless the proposal is based on proven success with this type of product. The success for consumers with an OTC hearing aid must revealed by quality research and demonstrable success prior to any changing of FDA policy. Arguments concerning eyeglasses are raised, (an area that I am not familiar with for I am an Audiologist), but eyeglasses are not hearing aids and correcting for an aging lense is not the same as a deteriorating cochlea. The petition is dealing with a hypothesis for a hearing health care system and not something shown to be a successful delivery system for quality hearing health care. This petition's weakness is that something justifying this change must be proven and not just asserted.

Ultimately, I do not believe that improvement in providing quality hearing health care for the consumer lies in removing the caregiver from the equation. If this is not true, let research prove me wrong. The arguments contained in the petition must be backed up by facts, not opinions. Thank you for your kind attention to my letter.

  
Larry T. McPherson, M.A. CCC-A, FAAA

2003P-0362

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