



# A HEARING SERVICE, INC.

By Duane L. Wass & John W. Pickett

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Duane L. Wass  
A Hearing Service, Inc.  
1523 N. Post Road  
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October 2, 2000

Honorable Donna Shalala  
Secretary of Health and Human Services  
200 Independence Avenue, S.W.  
Washington, D.C. 20201

Secretary Shalala:

In 1979, I earned my B.S. from Ball State University, and in 1981 I obtained my M.S. from the University of Minnesota. I have worked as a licensed hearing aid specialist in Indianapolis for over 18 years. I passed the National Board for Certification in Hearing Instrument Sciences in October of 1993. Please do not allow the FDA to restrict our customers' access to a hearing aid specialist or their right to select a provider of their choice.

I thought you should be very aware of proposed changes by the FDA. The FDA may defer hearing aid dispensing rules back to each state, setting the stage for 50 state fights. Inconsistency between states would confuse a market which only has a 20% penetration rate.

The FDA held a public hearing on hearing aids in Rockville, MD on December 6 and 7 of 1993. Among the proposed regulations by audiology special interest groups were diagnostic hearing tests. At the FDA hearing, all audiology groups testifying stated that all hearing-impaired individuals **must have** a comprehensive audiologic diagnostic hearing assessment performed by an audiologist as their point of entry into the hearing health care system. A comprehensive audiological diagnostic hearing assessment includes: (1) site of lesion assessment to include tone decay, short increment sensitivity index, and alternative binaural (or monaural) loudness balance testing; (2) auditory brainstem response; (3) otoacoustic emissions; (4) tympanometry; and (5) central auditory processing screening or evaluation.

Since the vast majority (over 90%) of people with a hearing problem have a sensori-neural hearing loss, and no underlying medical cause, currently required audiometric and otoscopic examinations already cover their needs. These people do not wish to spend an extra \$200-\$400 for unnecessary tests! The **eight warning flags** currently specified by the FDA indicate those individuals who may need some of the above special tests.

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The 8 warning flags are:

**Visible congenital or traumatic deformity of the ear.**

**Any history of or active drainage from the ear within the previous 90 days?**

**Any history of sudden or rapidly progressive hearing loss within the previous 90 days?**

**Any acute or chronic dizziness?**

**A unilateral hearing loss of sudden or recent onset within the previous 90 days?**

**Any pain or discomfort in the ears?**

**Visible evidence of significant cerumen accumulation or a foreign body in the ear canal?**

**Audiometric air-bone gap equal to or greater than 15 dB at 500Hz, 1000Hz, and 2000Hz?**

If any of the above are noted, the client must be referred to a physician, preferably an ear specialist, for medical clearance prior to hearing aid fitting. I also maintain that any person should have the right to sign a medical waiver as now allowed, for religious or personal reasons.

Allowing audiologists an exclusive role in the hearing aid delivery system, without unqualified medical data evidencing that such role is necessary for public health reasons, would severely undermine public health and safety and would increase costs to the hearing impaired.

**Please call or write to the Secretary of Health and urge that this FDA proposed hearing aid rule be withdrawn.**

I do appreciate your help and concern in making sure that this matter is handled correctly.

Sincerely,

Duane L. Wass, M.S., BC-HIS

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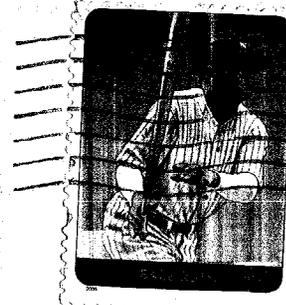
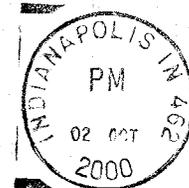
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