



preferred QUALITY HEARING IS OUR CONCERN  
hearing aid center  
www.comehear.com

September 16, 2000

8458 '00 OCT 19 P2:28

Honorable Donna Shalala  
Secretary of Health and Human Services  
200 Independence Avenue, S.W. Room 615F  
Washington, D.C. 20201

Experience

- Acoustic feedback (whistle) elimination specialists
- Our specialists use hearing instruments
- We listen carefully to our patients' concerns

Dear Secretary Shalala:

I am a small business owner in Hemet, California, providing hearing health care services to the area's hearing impaired. I am very concerned that the Food and Drug Administration (FDA) is reportedly advocating changes to the current hearing aid regulations that would dramatically increase the cost of hearing health care and reduce access to hearing health care providers. Please take the time to consider the impact of this proposed hearing aid rule on the nation's hearing-impaired and on the nation's small business hearing health care providers, as required by the Small Business Regulatory Enforcement Fairness Act (SBREFA).

Technology

- Digital, programmable, and analog hearing instruments
- Real Ear computer fittings
- Video otoscopic (ear) exams

Hearing health care providers like me have been working with the FDA since 1993 to streamline the current FDA hearing aid regulations. Now, just weeks before the election of a new Administration, FDA is rushing to put forth a proposal that could eliminate hearing aid specialists like me from the marketplace. FDA reportedly favors allowing each state to determine the conditions for dispensing hearing aids. This will create inconsistency and confusion and will launch a 50-state effort by audiologists to install themselves as the sole gatekeepers to hearing health care without any medical or health policy justification.

Service

- Pre-determined insurance benefits
- Hearing evaluations and recommendations
- Continuing follow-up care
- All brand repair services with warranty
- Minor repairs on site
- Referrals to physician when warranted

As you may have seen, the AARP recently published a Consumer Guide to Hearing Aids which found that "almost everyone with a hearing loss hears better with a hearing aid, yet only 20 percent of those who need a hearing aid have one." Please don't let the FDA erect unwarranted barriers to this safe and effective medical device.

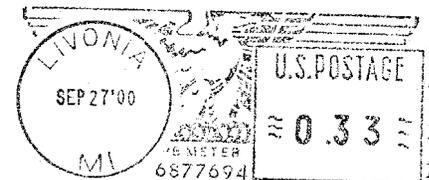
Please don't let the FDA publish its proposed hearing aid rule.

Sincerely,

*Ronald C. Perry*  
Ronald C. Perry, BC-HIS

93N 0372

04627



Honorable Donna E. Shalala  
Secretary of Health and Human Services  
200 Independence Avenue, S.W.  
Room 615F  
Washington, D.C. 20201

