

# Precision Hearing

475 East Tabernacle ~ St. George, Utah 84770

Phone (435) 628-9015 ~ Fax (435) 628-9015

Ralph S. VonCannon, BC-HIS

8 4 3 4 '00 OCT 19 P2:27

September 27, 2000

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

Dear Secretary Shalala:

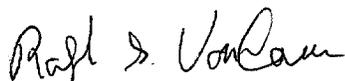
I am a small business owner in St. George, Utah, providing hearing health care services to the areas' hearing impaired. I am very concerned that the Food and Drug Administration is reportedly advocating changes to the current hearing aid regulations that would dramatically increase the cost of hearing 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.

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 aids 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.

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,



Ralph S. VonCannon, BC-HIS  
Board Certified - Hearing Instrument Science

93N 0372

C 4643

"Where Hearing Is Believing"

*Precision Hearing Instruments*

Ralph S. VonCannon, BC-HIS  
475 East Tabernacle  
St. George, Utah 84770

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