



Quality Hearing Systems

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October 5, 2000

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

Dear Secretary Shalala:

I am a small business owner in North County, San Diego providing hearing health care services to the area's hearing impaired. I am a California licensed hearing aid dispenser, am National Board Certified in Hearing Instrument Sciences and served a term as a Governor's appointee on the State Hearing Aid Board.

I am very concerned that the Food and Drug Administration (FDA) is reportedly advocating changes to the current hearing aid dispensing 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).

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.

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% 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 sproposed hearing aid rule.

Sincerely yours,

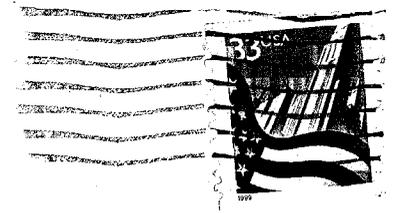
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