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October 16, 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 Pinellas, Pasco and Hernando Counties, providing hearing health care services to hundreds of hearing-impaired American in Florida. 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 (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 market place. 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 audiologist 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.

It is ironic that we, Hearing Instrument Specialist, really pioneered this industry and now it may get taken away from us by a group who want control of it. We are willing to share out industry, as the main concern should be to help the hearing impaired.

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

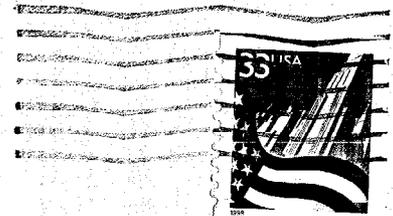
Sincerely,


Robert Smith, BC-HIS

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Robert Smith
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