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September 25, 2000

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

Dear Secretary Shalala:

Having assisted a board certified, state licensed hearing specialist, I write with respect to hearing aids. As the AARP has confirmed, hearing aids are highly effective but dramatically underutilized medical devices.

I am very concerned with reports that the Food and Drug Administration has reportedly sent to you a proposal for revising the current regulations governing the dispensing of hearing aids in this country that would dramatically increase the cost of hearing health care services and restrict access to hearing health care providers. Please stop and carefully consider the impact that this proposed rule would have on the nation's hearing impaired and on the nation's small business hearing aid specialists. In particular, please ensure that any proposed rule meets the obligations of the Small Business Regulatory Enforcement Fairness Act.

Hearing impairment is a major health care concern. Please do not let the FDA put forth their proposed rule that would impede access to needed hearing health care services for millions.

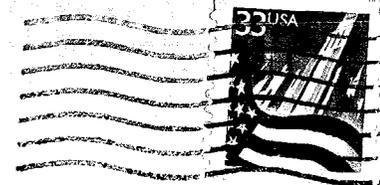
Very truly yours,

Debbie Helmholt  
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