



4157 '00 NOV 16 P3:08

October 20, 2000

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

Dear Secretary Shalala:

As a small business owner and hearing health care provider, 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 (FDA) 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 consider the impact that this proposed rule will 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 don't let the FDA put forth their proposed rule that would impede access to needed hearing health care services for millions of Americans.*

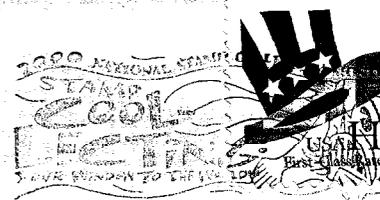
Very truly yours,

Jay K. Nicklas BC-HIS
Board Certified-Hearing Instrument Specialist
10950 N La Canada Dr #22202
Tucson AZ 85737

SN 0372

C4899

Nicklas BC-HIS
Certified-Hearing Instrument Specialist
N La Canada Dr #22202
n AZ 85737



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

hhhhhhhhhhhhhhhh