



Miracle-Ear

NOV 16 P3:05

Sears Hearing Center
317 Greece Ridge Center
Rochester, NY 14626
716-723-5366

October 24, 2000

Honorable Donna Shalala
Secretary of Health and Human Services
200 Independence Avenue, S.W.
Room 615F
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 carefully 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,

Sharon Jean Cornuta BC-HIS

SJC/da

C 4957