

Constance F. Park
345 Mountain Avenue
Springfield, NJ 07081

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

November 9, 2000

Dear Secretary Shalala:

I am employed by a small business owner in Rockaway, who provides hearing health care services to hundreds of hearing-impaired Americans in New Jersey. I am also the mother of a hearing-impaired son. I am outraged to hear that after seven years of inaction, the U.S. Food and Drug Administration is suddenly planning to publish in the last days of the present Administration a totally ill conceived and extremely misdirected proposed rule governing the sale of hearing aids.

I understand that this newly proposed rule will supposedly abdicate Federal FDA authority over hearing aid sales and allow the states to determine who will dispense hearing aids and what tests should be administered before an aid is purchased. Presently, hearing instrument specialists, physicians and audiologists are essential and fully qualified entry points into the hearing health care system. If the FDA defers to the states, audiologists have indicated that they would endeavor to position themselves as the sole entry point into hearing health care. Such gatekeeper status could be achieved by lobbying states to require expensive hearing tests that only audiologists provide. This would not only force hearing instrument specialists such as my employer out of business, but it would greatly increase the costs and impede access to hearing health care services for the nation's hearing impaired, including my son.

Hearing impairment is a major health care concern. Only approximately 20% of the 28 million hearing-impaired Americans who could benefit from a hearing aid actually use one. The proposed rule

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that the FDA is advocating would truly impede access to needed hearing health care services for millions of Americans. Please don't let this happen.

Please carefully weigh the impact on small business and especially on the hearing impaired. Please reject this ill-conceived proposal.

Thank you.

Respectfully yours,

Constance F. Park

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Secretary

Precision Hearing Instruments

Mrs. Constance F. Park
345 Mountain Avenue
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