

MIRACLE EAR

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October 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,

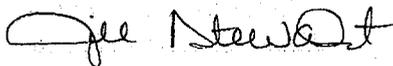
I am a hearing aid specialist in San Angelo, providing hearing health care services to hundreds of hearing-impaired Americans in Texas. The U.S. Food and Drug Administration (FDA) may shortly propose changes to the way hearing aids are sold that could put me, and according to a study commissioned by the International Hearing Society in 1998, 92% of Hearing Instrument Specialists out of the profession we know and love. I am outraged that the FDA, after over seven years of inaction, is planning to publish in the last few months of the Administration a totally ill-conceived and misdirected rule governing the sale of hearing aids.

Presently, all three members of the hearing health care delivery team (hearing aid specialists, audiologists and physicians) are recognized as qualified entry points into the hearing health care delivery system. The rule FDA is advocating would reportedly 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. The rule would allow audiologists, without any justification, to install themselves as the sole entry point into hearing health care.

Allowing audiologists an exclusive role in the hearing aid delivery system, without unqualified medical data evidencing that such a role is necessary for public health reasons, would severely undermine public health and safety and would increase costs to the hearing impaired. This makes no sense at all especially given the fact that hearing aids are a tremendously beneficial yet dramatically underutilized medical device.

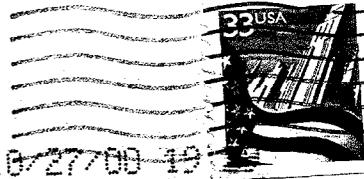
Please don't let the FDA propose this new rule. It's bad for the hearing impaired and bad for small business hearing health care providers.

Respectfully yours,



Jill J. Stewart

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