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October 10, 2000

Honorable Donna Shalala
Secretary of health and Human Svcs
Room 615 F
200 Independence Ave, SW
Washington DC 20201

Dear Madam Secretary,

The Food and Drug Administration is in the process of proposing changes to the way hearing aid are sold that could put me out of business and impede access to hearing care services for millions for our nation's hearing impaired and seniors.

I am an Alabama state licensed Hearing Instrument Specialist. For years I have provided quality health care services to thousands of our state's hearing impaired. Presently, all three members of the hearing health care delivery team, (Hearing Instruments Specialist, Audiologist and Physicians) are recognized as qualified entry points into the hearing health care delivery system. The rule FDA is advocating would allow audiologist, **with any justification**, to instill themselves as the sole entry point into hearing healthcare by allowing states to require expensive and **non essential tests** that only audiologist are qualified to perform.

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 reason, would severely undermine public health and safety and would increase costs to the hearing impaired.

The medical community, specifically the American Academy of Otolaryngologist (Ear, Nose, and Throat) **opposes** this FDA proposal.

Please contact the Secretary of Health and urge that this FDA proposed hearing aid rule be withdrawn.

I look forward to your response.

Cordially,

A handwritten signature in cursive script that reads "Terri Mitchell".

Terri Mitchell, HIS

93N-0372

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Post Office Box 230933 • Montgomery, Alabama 36123-0933 • Phone 334.213.0300 • Fax 334.213.0303

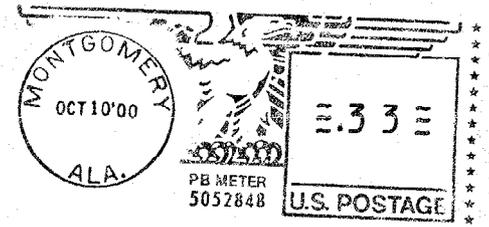
MONTGOMERY 2800 Zelda Road, Suite 200-4 • **SELMA** 2425 North Broad Street



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Post Office Box 230933
Montgomery, Alabama 36123-0933



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ATTN: Honorable Donna Shalala

