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Sent: Saturday, September 30, 2000 2:14 PM

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Cameron A. Gillespie, MD
The Gillespie Clinic
427 Main Street
South Boston,
VA 24592

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

Dear Secretary of Health and Human Services, the Honorable Donna E. Shalala,

The Food and Drug Administration may shortly propose cahnges in the ways hearing aids are sold that could put me out of business and impede access to hearing care services for millions of our nation's seniors.

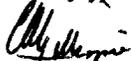
I am a board-eligible, state licensed hearing instrument specialist and a board certified otolaryngologist (medical doctor specializing in disorders of the ear, nose, and throat). For over 25 years I have provided health care services to hundreds of the Navy's and our state's (rural) hearing impaired. Presently, all three members of the health care delivery team (hearing aid specialists, audiologist, and physicians) are recognized as qualified entry points into the health care delivery system. The rule FDA is advocating would allow audiologists--without any justification--to install themselves as the sole entry point into health care by allowing states to require tests that only audiologists conduct prior to the purchase of a hearing aid.

Allowing audiologists an exclusive role in the hearing aid delivery system, without unqualified medical data evidencing that such role is necessary for public health reasons, would severely undermine public health and safety and would increase costs and **greatly limit accessibility** to provision of aids to the hearing impaired, particularly the elderly and disabled who cannot travel easily to urban centers for dispensing or more importantly and frequently, for essential after-care.

Please, as Secretary of Health and Human Services, I urge that this FDA proposed hearing aid rule be withdrawn.

I look forward to your response and would appreciate a copy of any letter you send on my behalf.

Sincerely yours,



Cameron A. Gillespie, MD, BC Otolaryngologist
Virginia State Hearing Instrument Specialist
Assistant Consulting Professor of Surgery, Duke University Hospital

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Secretary Donna Shalala
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