

**Honorable Donna Shalala**

Secretary of Health and Human Services  
Washington, D.C. 20201

4141 '00 NOV 16 P3:07

October 27, 2000

Dear Secretary Shalala:

The Food and Drug Administration may be proposing changes to the way hearing aids are sold that could put me out of business and prevent access to hearing care services for millions of our nation's seniors.

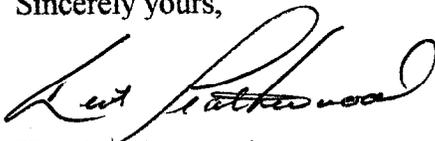
I am a state-licensed hearing instrument specialists. I have been in the hearing health care industry for one year and find it very rewarding to help individuals improve the quality of their lives. I feel that I'm well qualified to help people in this industry. Presently, all three members of the hearing health care delivery team, hearing aid specialist, audiologists, and physicians, are recognized as qualified entry points into the hearing health care delivery system. The rule FDA is advocating would allow audiologists-without any justification - to install themselves as the sole entry point into hearing health care by allowing states to require tests that only audiologists conduct prior to purchase of a hearing aid.

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.

**Please don't let the FDA erect unwarranted barriers to this safe and effective medical device.**

**Please don't let the FDA publish its proposed hearing aid rule.**

Sincerely yours,



Kent Leatherwood  
LHIS

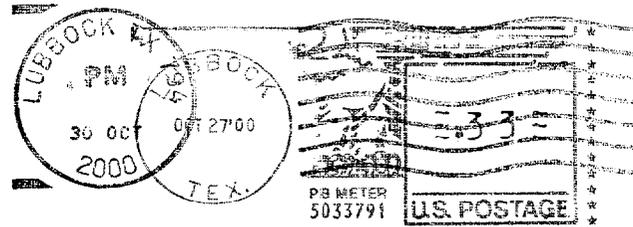
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