

# Otolaryngology & Head and Neck Surgery, P.A.



5167 '00 OCT -2 A9:45

**Kent S. Wilson, M.D.** September 15, 2000

**Dennis R. Brady, M.D.**  
**Thomas L. Okner, M.D.**  
**Barbara N. Malone, M.D.**

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

**Robert W. Smith, M.D.** Dear Secretary Shalala:

**Christopher J. Tolan, M.D.** As a hearing aid specialist, I write with respect to hearing aids. As the AARP has confirmed, hearing aids are highly effective but dramatically underutilized medical devices.

**Inell C. Rosario, M.D.**

**V. Stuart Cox, M.D.**

I am very concerned with reports that the Food and Drug Administration (FDA) has reportedly sent to you a proposal for revising the current regulations governing the dispensing of hearing aids in this country that would dramatically increase the cost of hearing health care services and restrict access to hearing health care providers. Please stop and carefully consider the impact that this proposed rule will have on the nation's hearing impaired and on the nation's small business hearing aid specialists. In particular, please ensure that any proposed rule meets the obligations of the Small Business Regulatory Enforcement Fairness Act.

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Hearing impairment is a major health care concern. Please don't let the FDA put forth their proposed rule that would impede access to needed hearing health care services for millions of Americans.

Very truly yours,

Paul Tuveson, BC-HIS  
President

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HEARING AID  
SERVICE**

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5171 '00 OCT -2 A9:46

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September 18, 2000

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

Dear Secretary Shalala:

The Food and Drug Administration may shortly propose changes to the way 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.

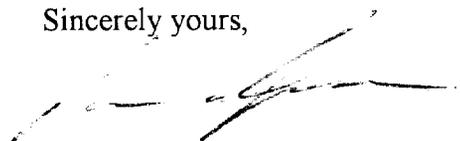
I am a board certified, state-licensed hearing instrument specialist. For over 11 years, I have provided hearing health care services to hundreds of our state's hearing-impaired. Presently, all three members of the hearing health care delivery team (hearing aid specialists, audiologists and physicians) are recognized as qualified entry points into the hearing health care delivery system. The rule FDA is advocating would 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 role is necessary for public health reasons, would severely undermine public health and safety and would increase costs to the hearing impaired.

Please write to the Secretary of Health and 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,



Paul W. Roark, BC-HIS

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Honorable Donna Shalala  
Secretary of Health and Human Services  
200 Independence Avenue, SW Room 615F  
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