

Mark L. Oyler, BC-HIS
Board Certified by the
National Board for
Certification In
Hearing Instrument Sciences
&
Corporate President / CEO

Honorable Donna Shalala
Secretary of Health and Human Services

200 Independence Av., Suite S.W. Room 6052 60 '00 OCT 19 P2:09
Washington, D.C. 20201

9/30/00

Dear Secretary Shalala:

I am a small business owner in Springdale Arkansas, providing hearing health care services to the area's hearing impaired. I am very concerned that the Food and Drug Administration (FDA) is reportedly advocating changes to the current hearing aid regulations that would dramatically increase the cost of hearing health care and reduce access to hearing health care providers. Please take the time to consider the impact of this proposed hearing aid rule on the nation's hearing-impaired and on the nation's small business hearing health care providers, as required by the Small Business Regulatory Enforcement Fairness Act (SBREFA).

Hearing health care providers like me have been working with the FDA since 1993 to streamline the current FDA hearing aid regulations. Now, just weeks before the election of a new Administration, FDA is rushing to put forth a proposal that could eliminate hearing aid specialists like me from the marketplace. FDA reportedly favors allowing each state to determine the conditions for dispensing hearing aids. This will create inconsistency and confusion and will launch a 50 state effort by audiologists to install themselves as the sole gatekeepers to hearing health care without any medical or health policy justification.

As you may have seen, the AARP recently published a *Consumer Guide to Hearing Aids* which found that "almost everyone with a hearing loss hears better with a hearing aid, yet only 20 percent of those who need a hearing aid have one." Please don't let the FDA erect unwarranted barriers to this safe and effective medical device.

Please do not let the FDA publish its proposed hearing aid rule.

Sincerely,

Mark L. Oyler

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C4730

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1177 W. Sunset Av., Suite 4
Springdale, AR 72764

Specialized Hearing Instruments, Inc.

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

Dear Secretary Shalala:

As a small business owner and hearing health care provider, I write with respect to hearing aids. As the AARP has confirmed, hearing aids are highly effective but dramatically underutilized medical devices.

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.

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,

Sheree Dylor 9/30/00

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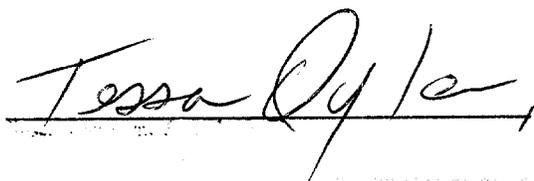
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Very truly yours,

 Tessa Dyle, 9/30/00

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