



DEPARTMENT OF HEALTH & HUMAN SERVICES

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Food and Drug Administration
Rockville MD 20857

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December 26, 2000

Mr. James E. Doyle
Attorney General
Department of Justice
P.O. Box 7857
Madison, Wisconsin 53707-7857

Dear Mr. Doyle:

This is in response to your letter to Secretary Donna Shalala about a pending proposed rule to change federal hearing aid regulations.

In 1993, the Food and Drug Administration published an Advanced Notice of Proposed Rulemaking in the *Federal Register* to revise its regulations. One concern was the number of hearing aid purchasers who waived the current requirement for a hearing aid evaluation. Manufacturers, medical professionals, consumers, and hearing aid dispensers have commented on the rulemaking notice in writing and in meetings, but FDA has yet to publish a proposal.

Your letter has been added to docket #93N0372, which was set up to receive written comments on the 1993 notice. According to rulemaking procedures, neither FDA nor the Department of Health and Human Service can comment on what the proposal may or may not contain until after it publishes.

Sincerely,

Linda Gangloff
Policy Analyst
Executive Secretariat

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DEPARTMENT OF JUSTICE

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December 6, 2000

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

Dear Secretary Shalala:

I understand that the Department of Health and Human Services is considering a proposal from the Food and Drug Administration that would change federal regulations covering hearing aid sales. As you continue to gather information for the proposed rules, I would hope that you give great weight to consumer access and competitive fairness in the development of these proposed regulations.

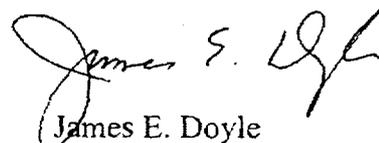
If changes are to be made to federal regulations, it is important that access to hearing health care be a top priority. Wisconsin's model of cooperation among the various hearing professionals has given Wisconsin's hearing impaired citizens the ability to obtain needed services with the highest degree of consumer confidence. Federal rules based on protecting one professional over another should not be the driving force behind proposed changes.

Wisconsin's hearing impaired have been well served by a model of regulation and licensing that historically has involved the Wisconsin Department of Justice, the Department of Regulation and Licensing and the Hearing and Speech Examining Board. To their credit, state licensed hearing instrument specialists and state licensed audiologists have worked well together within Wisconsin's current regulatory system.

I believe that future federal regulations can reflect cooperation among health professionals, protections for consumers and, most importantly, access to this valuable health care. I urge you to keep these items in balance as you continue with your regulatory process.

Thank you for your consideration.

Sincerely,


James E. Doyle
Attorney General