



# Johnson Hearing Aid Service

October 20, 2000

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Honorable Donna Shalala  
Secretary of Health and Human Services  
200 Independence Avenue, S.W. Room 625F  
Washington, D.C. 20201

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We are concerned that the Food and Drug Administration may shortly propose changes to the way that hearing instruments are sold. This could put the Hearing Instrument Dispensers out of business and put the hearing impaired access to receiving the care they may require for their hearing loss.

I am Board Certified, Nebraska state-licensed Hearing Instrument Specialist. Our office services over 33 Care Centers in a 75-mile radius of Lincoln. We go their locations and have the proper equipment that is calibrated each year to ensure that testing of hearing loss is accurate.

We believe that we can be of service without having the clients brought into our office. We believe this is a service that is needed and it does help the hearing impaired and those who care for these clients. We also make home visits to those who are unable to drive or depend on someone else to bring them into an office.

We are recognized as qualified entry points into the hearing health care delivery system. The rule that the FDA is advocating would allow Audiologists – without justification – to install himself as the sole entry point into the hearing health care by allowing states to require testing that only Audiologists conduct prior to the purchase of a hearing instrument.

We believe that allowing this rule to pass would let the Audiologist have the exclusive role in the hearing aid delivery system and could severely undermine the public health and safety of the hearing impaired.

We would appreciate your concern and appropriate action to this FDA proposed hearing aid rule.

Sincerely,

Judith L. Johnson, BC-HIS

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**JOHNSON HEARING AID SERVICE**  
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