

PHI

Precision Hearing Instruments, Inc.

1020 W. Lackawanna Ave.
Scranton, PA 18504
Phone 717-343-1414
Fax 717-347-2257
1-800-367-2804



Miracle-Ear®

October 23, 2000

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

5253 00 NOV 16 3:08 PM '00

Dear Secretary Shalala:

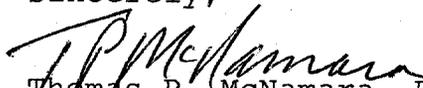
As a small business owner and hearing health provider for more than 32 years, I am very concerned with the report that the FDA has reportedly sent to you. The FDA is advocating that audiologists, without any justification, be the only entry point into the hearing health care system, which would require states to mandate tests that only they could conduct prior to the purchase of a hearing aid. By allowing this to happen without unqualified medical data would greatly reduce their access to follow-up services.

My first 17 years as a hearing health consultant, was with a license for the States of Maryland, Virginia, Pennsylvania and the District of Columbia. The last 15 years has been as a partner in a small business operation. My business partner is an Audiologist and will soon be receiving his Doctorate in Audiology. We have a staff of 37 employees consisting of licensed hearing aid consultants, service consultants, administrative staff and support staff. If this rule is passed, not only would this affect my company, but hundreds of thousands of other hearing aid providers would be put out of business. I have many patients that have become life-long friends of mine and we have thousands of satisfied customers. Many of our customers are unable to come to our offices, therefore, we provide them, if needed, free in-home service and care. That definitely would not take place by the people the FDA is saying should be the gatekeepers.

Hearing impairment is a major health care concern. Please don't allow the FDA to put forth this proposed rule that would impede access to millions of Americans.

Thanking you in advance for your help.

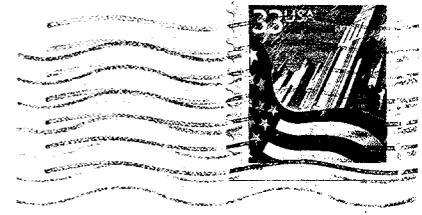
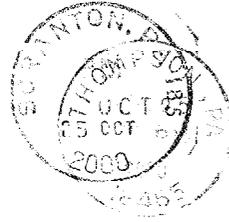
Sincerely,


Thomas P. McNamara, BC/HIS
President-PHI, Inc./Miracle Ear

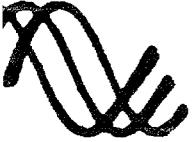
93N 0372

C 4879

ision Hearing Instruments, Inc.
7. LACKAWANNA AVENUE
ITON, PA 18504



The Honorable Donna Shalala
Secretary of Health & Human Service
200 Independence Avenue, S.S.
Room 615F
Washington, DC 20201



Miracle-Ear®

