



DEPARTMENT OF HEALTH & HUMAN SERVICES

HFZ-1

Food and Drug Administration
Rockville MD 20857

9 7 7 4 '00 DEC -6 P2 :01

November 29, 2000

The Honorable Fred Belardi
House of Representatives
Commonwealth of Pennsylvania
Harrisburg, Pennsylvania 17120-2020

Dear Mr. Belardi:

This is in response to your letter to Donna Shalala, Secretary of Health and Human Services, on behalf of Thomas McNamara, 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

93N-0372

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/ AAS



HOUSE OF REPRESENTATIVES
COMMONWEALTH OF PENNSYLVANIA
HARRISBURG

October 30, 2000

The Honorable Donna E. Shalala
Secretary
Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Secretary Shalala:

Enclosed please find a letter I have received from Thomas P. McNamara, President of Precision Hearing Instruments, Inc. in Scranton regarding an FDA report to HHS on the hearing health care system.

Mr. McNamara is concerned about the FDA's advocating exclusive jurisdiction for audiologists with respect to testing and subsequent purchase of hearing aids. If the FDA proposal is adopted, Mr. McNamara contends many current hearing aid providers would be forced out of business.

I would respectfully request your Department's consideration of Mr. McNamara's comments as part of the review process on this issue.

As always, your attention to this important matter on behalf of my constituent will be greatly appreciated.

Sincerely,

A handwritten signature in cursive script that reads "Fred Belardi".

Fred Belardi
State Representative

FB:tm
Enclosure

PHI

*** RECEIVED ***
Nov 06,2000 10:37:33 WS# 03
OFFICE OF THE SECRETARY
CORRESPONDENCE
CONTROL CENTER

Precision Hearing Instruments, Inc.

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



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OCT 26 2000

October 23, 2000

State Representative Fred Belardi
507 Cedar Avenue
Scranton, PA 18505

Dear Representative Belardi:

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 the Secretary of Health and Human Services. 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 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.

Fred, I am asking for your help in writing to the Secretary of Health and Human Services and urge that this FDA proposed hearing aid rule be withdrawn.

I'm thanking you in advance for any help you can afford us.

Sincerely,

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