

March 2, 2000

Jane Henney, M.D. Commissioner
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

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Dear Dr. Henney:

It has come to my attention that the FDA is being asked to take away the rights of a consumer to sign a medical waiver before the purchase of a hearing aid. I wish to retain my rights to purchase a hearing aid without a medical examination or a hearing test.

I am a senior citizen and have been wearing a hearing aid for the past ten years. My hearing condition is presbycusis which is, as you know, a condition of aging. I had a hearing test years ago and since then have purchased hearing aids through the mail. I am entirely satisfied with my purchases and the supporting services I have received, particularly through Excel Hearing Solutions, a firm in DeKalb, Illinois.

The price markup in hearing aids is considerable. I am wearing one that cost \$299 and one comparable to those costing in the thousands if purchased through a dealer or dispenser. When I need a replacement, I wish to be able to buy it at the lowest possible cost, without additional costs of evaluations of my hearing which I already know.

A hearing aid is a rather simple appliance with no more medical implications than a cane, crutch or wheelchair. Hearing aids should be made available to consumers without restrictions beyond the existing medical waiver (with which I agree since the waiver is a responsible alert to the possibility of ear pathology and medical intervention).

As a citizen, I have increasing concern that the medical profession and others in allied health, and in this matter, audiologists, are seeking to pad their incomes at needless expense to the public. The FDA, in prior rulings, found no abuses by firms selling hearing aids via the mails. In my dealings with Excel Hearing Solutions, I have a trial period and a money back guarantee, a wonderfully low price of a quality instrument, and prompt service when needed.

I trust that you will guide your agency as an advocate for the consumer in this matter.

Sincerely,



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