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Otology and Neurology

John R. Emmett, M.D., M.S., F.A.C.S.
Paul F. Shea, M.D., F.A.C.S.

Nasal and Facial Plastic Surgery

J. Gregory Staffel, M.D.



SHEA EAR CLINIC
EAR, NOSE AND THROAT

Audiology
Micci Henry, Au.D., CCC-A
Jessica Rippy, Au.D., CCC-A
David Everitt, M.C.D., CCC-A
Karen R. Fetzer, M.A., CCC-A
Melissa Blakeman, H.I.S.
Carrie Eaton

Anesthesia
Chris Connell, CRNA

Administrator
John R. Gross, FHFMA

May 12, 2017

Commissioner Maureen Ohlhausen
Acting Chair
Commissioner Terrell McSweeney
FTC
Federal Trade Commission
600 Pennsylvania Avenue, NW
Washington, DC 20580

Dear Commissioners Ohlhausen and McSweeney:

I am writing today to commend you for hosting the April 18th Workshop: Now Hear This: Competition, Innovation, and Consumer Protection Issues in Hearing Health Care. Bringing the issues of the hearing-impaired forward in this open session is important for education, awareness and protection.

Understanding that you are collecting comments, through May 18th on this matter, I also want to share the following:

1. **I am opposed to the approval of over-the-counter hearing aids** and believe the creation of an FDA-approved classification of OTC hearing aids should only be considered following a comprehensive actual use study to validate whether individuals can self-diagnose, self-treat and self-manage safely. If they cannot, this study should determine which mechanisms must be put into place to ensure safe and effective care, such as having an in-person hearing evaluation from a licensed provider within six months of purchasing a device over the counter.
2. My personal story in support of this position highlights the importance of understanding the complexity of diagnosing, treating and managing hearing aids patients:

I am a fellowship-trained neuro-otologist (doctor who specializes in the hearing and balance system) and have been in practice for fifteen years at the Shea Ear Clinic in Memphis, TN. I see patients with hearing loss every day, ranging from the mildest losses to those so deaf they can only be helped with a cochlear implant. Hearing loss is an increasingly common problem with our aging population, but it is a problem that should be managed by a health professional, either an ear, nose and throat doctor or an audiologist. There are many causes for hearing loss, ranging from wax in the ears, to infections, to nerve damage, or to a problem with the tiny bones in the middle ear. Patients with hearing loss should have, at a minimum, a proper audiogram (hearing test) performed by an audiologist, and an exam, in order to determine whether a hearing aid is appropriate for them. In some cases, the proper treatment may be antibiotics, ventilation tubes in the eardrums, or even surgery. There is a great deal of dissatisfaction with hearing aids in the general population because many patients have not been properly counseled about hearing aids, or their aids have not been properly fitted or adjusted. Dispensing hearing aids over the counter will only add to this dissatisfaction. The auditory system is exceedingly complex, and problems with it should be managed by an audiologist or physician. Hearing aids should thus be dispensed by licensed and trained practitioners who can determine which patients are appropriate for them, and which need referral to an ear, nose and throat doctor.

Thank you for your careful consideration of this complicated and nuanced matter.

Sincerely,

Paul F. Shea, M.D., FACS
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