



American Academy of Otolaryngology — Head and Neck Surgery

WORKING FOR THE BEST EAR, NOSE, AND THROAT CARE

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January 14, 2004

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Subject: Comments on Citizen's Petitions to FDA

The American Academy of Otolaryngology-Head and Neck Surgery formally comments and expresses concern regarding the Citizen's Petitions filed with the FDA by Killion and Gudmundsen. Our opposition to the citizen's petitions is based on issues regarding patient safety and health.

The Killion petition [2003P-0362] proposes a new device to amplify sound for the hearing impaired. While the petition proposes to make sound louder for individuals and the device cheaper than current hearing aids, it actually raises patient safety concerns because the device could amplify sound to 115dB Sound Pressure Level – fully 25 decibels above the “safe level” for individual's noise exposure. The paradox presented here is that a device proposed to aid consumers with impaired hearing could damage and diminish the normal or residual hearing of an individual user, leaving them with impaired hearing! In our currently noisy world, the addition of another source of acoustic trauma is neither safe nor healthy.

The Gudmundsen petition [2003P-0363] fails to offer full disclosure to consumers, de-emphasizes (if not underestimates) the medical nature of hearing loss, and potentially delays appropriate medical treatment when indicated.

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Currently, *Code of Federal Regulations, Title 21, Volume 8. Cite: 21CFR801.420 Subpart H - - Special Requirements for Specific Devices, Section 801.420 Hearing aid devices: professional and patient labeling, and Section 801.421 Hearing aid devices: conditions for sale*, sensibly and appropriately requires hearing aid dispensers to obtain a medical waiver from adults who are purchasing a hearing aid. Revocation of *Subpart H Section 801.421* as requested by the petitioner is a threat to patient safety.

The current waiver informs consumers with examples of medical/surgical conditions that represent a threat to citizens' safety and health. The aptly named "red warning flags of ear disease"(draining ears, sudden onset of hearing loss and or dizziness, a "bad" ear versus a normal hearing ear, recent physical trauma, etc. – all readily apparent to the individual or their parents) should be evaluated by a physician, preferably a specialist in ear, nose and throat diseases. Specialized radiographic and clinical laboratory tests may be indicated to diagnose surgically and medically treatable diseases such as cholesteatoma and autoimmune sensorineural hearing loss. Recent advances in the successful medical and surgical treatment of hearing nerve impairments make the option of medical evaluation evermore relevant. Consumers should be offered this opportunity for a medical diagnosis before they chose a prosthetic device and perhaps ignore a potentially life-threatening medical/surgical condition. Thus citizens retain free choice and responsibility for their health but only after being appropriately informed.

Your careful consideration of our concerns is appreciated. A personal contact is offered through the offices of our Executive Vice-President, David R. Nielsen, MD, at 703-519-1559.

Respectfully submitted,

David R. Nielsen MD

David R. Nielsen, MD
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American Academy of Otolaryngology—
Head and Neck Surgery