Four Key Studies Which Will Facilitate the Review of the FDA Record for the Over-the-Counter Notice of Proposed Rulemaking

A review of the FDA NPRM on OTC Hearing Aids will reveal a wide disparity in the fundamental data in the record. To assist our readers in developing their comments on the NPRM we are providing for easy reference four critical documents three of which have been authored by governmental bodies.

FDA's NPRM gives unilateral recognition to a standard recommended by a trade association and no attention to the research of two governmental bodies (The Veterans Administration; Johnson) and the United Nations.

Johnson

Dr. Johnson's work was authored as part of the Contributor's official duties as an **Employee of the United States Government** and is therefore a work of the United States Government. Dr. Earl E. Johnson is a Coordinator of Research at the *Department of Veterans Affairs* and is the author of *Safety limit warning levels for the avoidance of excessive sound amplification to protect against further hearing loss.* He recommends a standard of 111 dB; CTA recommends 120 dB.

Lalwani

Dr. Anil K. Lalwani is the Vice Chair for Research, Director of Division of Otology, Neurotology & Skull Base Surgery, Co-Director of Columbia Cochlear Implant Program in the Department of Otolaryngology and the Medical Director of Perioperative Services at New York-Presbyterian Hospital/CUIMC. He concludes: "FDA's output limit of 115/120 dB exceeds Johnson's recommended safe output sound pressure levels for such devices used by individuals with mild to moderate hearing loss, which are roughly in the 100-110 dB range."

United Nations

It is puzzling, if not misguided, for the FDA to adopt standards applicable to PSAPs for hearing aids. It should be noticed that a component of the United Nations concluded that: "When these devices [personal sound amplification apps] do not have the capacity to measure weekly sound dose, the maximum output of the device needs to be permanently limited to 95 dBA". Therefore if the FDA is going to use an incorrect basis for a standard they must work to utilize the right numbers for the wrong reason.

The International Telecommunications Union—European Federation of Hard Hearing People

The IFHOH organization is an international non-governmental organization of national associations of and for the hard of hearing and late deafened people. It concludes: ”However, we have concerns about the safety aspects of the current draft proposal, which proposes a limit of 120 dB SPL for an OTC hearing aid that implements input-controlled compression and a user-adjustable device volume control. With only this limit being required, OTC hearing aid users may be exposed to a significantly higher weekly sound dose than the 1.6 Pa^2h (equivalent to 80 dBA exposure for 40 hours), as required in the ITU/WHO H.870 (''Guidelines for safe listening devices/systems'') and ITU H.871 (“Safe listening guidelines for personal sound amplifiers”) standards”.

Summary

Notwithstanding the fact that two of the documents were prepared by governmental organizations and that they specifically address the subject matter in the OTC Notice of Proposed Rulemaking and that the other document was prepared by a leading non-governmental organization, it is puzzling why the FDA would summarily dismiss these documents by not even proposing them for public comment in the NPRM. In that the documents were authored by governmental organizations and have been in existence for a number of years it is even more puzzling that the FDA would unilaterally endorse a standard developed by a trade association without notifying the public of its merits relative to those developed by governmental organizations.