Tier I Issues

The crux of this rulemaking centers around two esoteric statutes: The National Technology Transfer and Advancement Act (NTTA) and the Information Quality Act . Upon reading the record developed for the OTC Hearing Aid NPRM, both of the aforementioned statutes are foreign in large part to the present incumbents of key managerial positions in the Executive Branch since neither are even mentioned, let alone used, in the formulation of the NPRM.

An acknowledgement of the requirements in the NTTA would have required that the FDA announce to the public the availability of a standard proposed by four professional associations which is not mentioned in the NPRM notwithstanding it was submitted to the FDA several times over a three year period. Recognition of the NTTA, in conjunction with the APA, would have also required the FDA to compare the merits of the standard proposed by four professional associations with that proposed by a trade association representing consumer electronics companies.

An acknowledgement of the requirements of the Information Quality Act would have required the FDA to subject the technical information in the NPRM to a pre-publication test of its statistical integrity. Failure to comply with this fundamental requirement of the Information Quality Act, pre-dissemination review, also shielded the authors of the NPRM from the need to recognize the existence of a standard issued by a technical component of the United Nations as well as an equally relevant pacesetting analysis published by another federal agency.

CRE has established an Interactive Public Docket for this proceeding which allows the public to provide data to the regulators. Wikipedia states:

“The IPD was first developed by the Center for Regulatory Effectiveness and its origins have been discussed on National Public Radio.”

It should be noted that the issues presented herein are those that will determine the outcome of this regulatory proceeding; in essence, they are the Tier I issues.

The Tier I issues include:

(1) Why did the FDA refuse to acknowledge receipt of the voluntary consensus standard developed by four hearing care professional associations in its Notice of Proposed Rulemaking, in that it was submitted to the FDA some three years ago?

(2) Since the FDA decided to base its recommended standard on a PSAP standard developed by a trade association why did it not base it on a PSAP standard developed by the United Nations?

(3) Another federal agency, the Department of Veteran Affairs, addressed the substance of the FDA rulemaking, and developed a standard with a different output level, why did the FDA refuse to address this standard in its NPRM?

(4) The Information Quality Act requires FDA to perform an accuracy check on the data it uses to develop a proposed rule, why did the FDA fail to comply with its own guidelines requiring compliance with the said Act?

(5) The National Technology Transfer and Advancement Act requires the FDA to give deference to standards developed by non-federal entities. Why did the FDA refuse to allow the standard recommended by the Hearing Care Working Group to be a beneficiary of this Act?.

<u>A Tier 2 Issue</u>

Our definition of a Tier 2 issue is one that comes into play only after the Tier 1 issues are addressed.

In preparing its comments on this NPRM CRE did not rely on the views of only one scientist; instead, its recommendations are based on the findings of four scientists, two from governmental bodies, one from a quasi-governmental body and one from the private sector, see page 21 in the attachment below.

A specific Tier 2 issue is one raised by some private sector scientists who disagree with all four of the aforementioned scientists. More specifically they wish to adopt a strategy of "*maximum market penetration*".

The " *maximum market penetration"* strategy poses an irretrievable threat to public health and should not be given more weight (as currently the case) than the importance of ensuring consumers benefit from a regulatory framework that is more appropriately tailored to avoid placing consumers with mild to moderate hearing loss at an increased risk of harm.

It should be noted that the effectiveness of a hearing aid is not dependent solely on the device's specific amplification limits; many other factors determine the effectiveness of a hearing aid, including signal processing, frequency response and noise reduction.

Lastly, in that the FDA has received upwards to a thousand comments and since Regullaion.gov does not have a search engine, CRE has published a webpage titled "Note to Federal Regulators: Expository Submissions on OTC Hearing Aids". The said page contains links to some of the most cogent submissions and is available at https://thecre.com/forum19/ .