Factual Considerations Re: OTC Hearing Aid Rulemaking

Non-Compliance With Procedural and Substantive Statutes and Executive Orders

- Adoption of the standard proposed by the trade association, the Consumer Technology Association, for OTC hearing aids is not supported by *neither* prevailing statues and Executive Orders nor internationally recognized institutions.

Summary

(1) The NPRM containing the proposed CTA standard is a *gross violation* (See CRE Initial Filing) of both the National Technology Transfer and Advancement Act and OMB Circular A-119 because the NPRM did not even recognize an alternative standard proposed by the Hearing Care Associations that was submitted a number of times during the three year period preceding the issuance of the NPRM. The decision to ignore the Hearing Care Associations submission, but to accept an alternative proposal, not only denied the rights of an affected party to participate in the rulemaking but also suggests that the public would benefit from being informed of the communication channel that works for contacting the FDA prior to the release of a NPRM.

(2) If one were to compare, pursuant to Executive Order 12866 and the Information Quality Act, the merits of the proposed CTA standard for OTCs with the OTC standard developed by the Hearing Care Associations, which is in sync with the Safe Listening Standard developed by the World Health Organization, the standard proposed by the Hearing Care Association would prevail because three internationally recognized organizations have either opposed the CTA standard or recommended a standard not supportive of the CTA standard:

- Cleveland Clinic
- Department of Veterans Affairs

- The United Nation's International Telecommunication Union

Non-Compliance with Procedural Statutes

- We will now discuss the aforementioned topics beginning with the National Technology Transfer and Advancement Act and OMB Circular A-119.

- National Technology Transfer and Advancement Act

  - Enacted 1996

  - The primary objective was to decrease the time needed to bring new technology to the market.

  - Congressional review of the issue resulted in the finding that the processes in place to license new technologies were not keeping up with the development of emerging technologies.

  - The solution was to pass a statute which made it easier to license new technologies by enacting the concept of voluntary consensus standards.

  - Key Components of the National Technology Transfer and Advancement Act:

    - (1) All Federal agencies and departments shall use technical standards that are developed or adopted by voluntary consensus standards bodies, using such technical standards as a means to carry out policy objectives or activities determined by the agencies and departments.

    - EXCEPTION.—If compliance with paragraph (1) of this subsection is inconsistent with applicable law or otherwise impractical, a Federal agency or department may elect to use technical standards that are not developed or adopted by voluntary consensus standards bodies if the head of each such agency or

department transmits to the Office of Management and Budget an explanation of the reasons for using such standards. Each year, beginning with fiscal year 1997, the Office of Management and Budget shall transmit to Congress and its committees a report summarizing all explanations received in the preceding year under this paragraph.

- OMB Circular A-119

  - Circular A-119 not only reinforces the National Technology Transfer and Advancement Act but strengthens and expands the coverage of the Act to include non-consensus standards. The first three of the following statements are direct quotations from OMB Circular A-119.

  - This Circular directs agencies to use voluntary consensus standards in lieu of government-unique standards except where inconsistent with law or otherwise impractical.

  - This Circular applies to all agencies and agency employees who use standards and participate in voluntary consensus standards activities, domestic and international, except for activities carried out pursuant to treaties.

  - This policy does not establish a preference among standards developed in the private sector. Specifically, agencies that promulgate regulations referencing non-consensus standards developed in the private sector are not required to report on these actions, and agencies that procure products or services based on non-consensus standards are not required to report on such procurements.

  - ANSI does not develop standards. Rather, it helps to facilitate the development of standards by establishing the guidelines for consensus, due process and openness.

  - The OTC NPRM contains a number of substantive violations of the National Technology Transfer and Advancement Act and Circular A-119 and most specifically because it failed to address the voluntary

standard proposed by the Hearing Care Associations; hopefully the conclusions set drawn from the submission of three internationally recognized experts, set forth on pages 4 and 5, which were not available at the time of the issuance of the NPRM will steer the ultimate rule in direct of safe and efficient regulation

- More specifically the FDA:
  - Denied the right of the Hearing Care Associations to seek federal adoption of its standard pursuant to federal statutes and an Executive Order.
  - Failed to perform a pre-dissemination review for either of the two standards under consideration.
  - Failed to assess the relative merits of two alternative standards.

- Collectively the aforementioned shortcomings jeopardize the ultimate survival of a final rule if it is not modified as noted.

Non-Compliance with Substantive Statutes and Executive Orders

- Collectively the Information Quality Act and Executive Order 12866 require that data used in the formulation of rules be the best available data which are objective, unbiased and reproducible. Data presented in support of the CTA standard fail to fulfill any of these requirements.
  - Cleveland Clinic
    - OTC devices must be able to amplify up to moderate loss while safely managing more mild loss. The proposed rule suggests output limits that substantially overcompensate for the intended population and could actually damage the residual hearing of a consumer.

- Department of Veterans Affairs

  - 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. 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.***

  - Dr. Johnson's work supports a standard of 111 dB.

- UN International Telecommunication Union

  - 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".

The UN Safe Listening Standard

- The recent publication of the Safe Listening Standard by the World Health Organization should cast a long shadow over this proceeding.

The Bottom Line

Why should the FDA adopt for OTC hearing aids a standard developed by the consumer technology industry in lieu of adopting an OTC standard developed by the Hearing Care Associations which not only complies with the National Technology Transfer and Advancement Act and OMB Circular A-119 but is also in sync with a related standard developed by the World Health Organization and is in agreement with the views of three internationally credentialed organizations?