Comments of the

Center for Regulatory Effectiveness

on

FDA-2021-N-0555

Establishing Over-the-Counter Hearing Aids

VIOLATION OF THE INFORMATION QUALITY ACT, THE ADMINISTRATIVE PROCEDURE ACT, EXECUTIVE ORDER 12866 AND THE NATIONAL TECHNOLOGY TRANSFER AND ADVANCEMENT ACT

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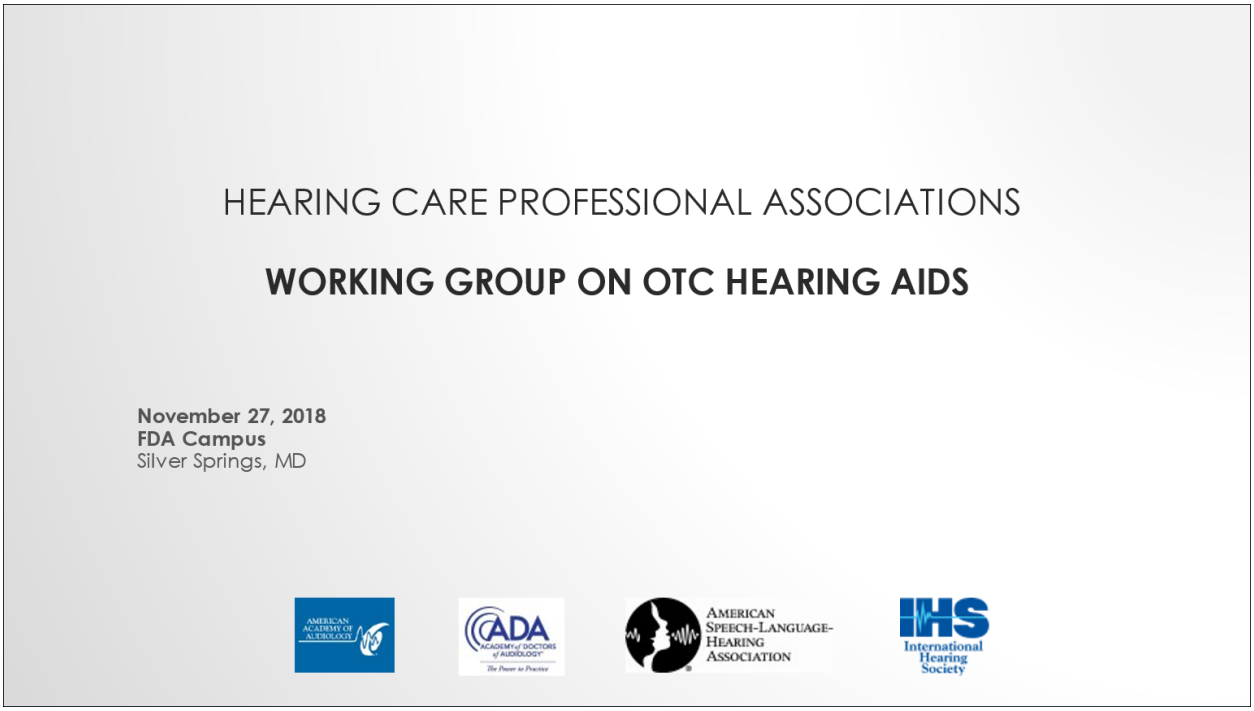
Exhibit 1: A Repository of Information Detailing the FDA Refusal to Allow the Public to Comment on a Duly Sanctioned Voluntary Consensus Standard for OTC Hearing Aids

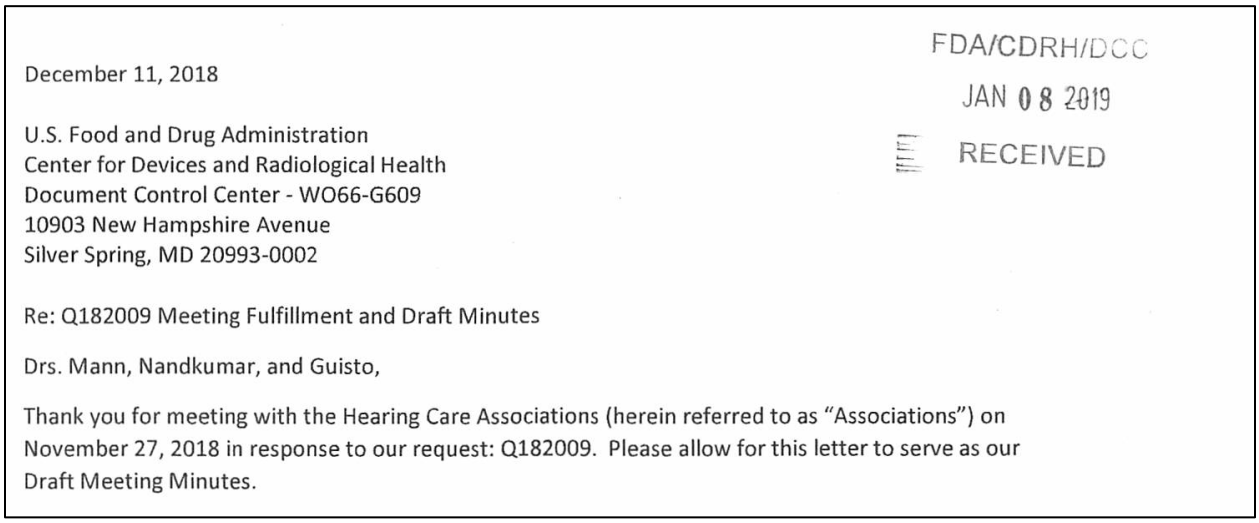
Some three years ago, on November 27, 2018 to be exact, the Hearing Care Work Group (hereinafter referred to as the "Work Group), representing the American Academy of Audiology, Academy of Doctors of Audiology, American Speech Language and Hearing Association, and International Hearing Society, submitted a proposed Voluntary Consensus Standard to the FDA to meet is statutory requirement to establish a regulatory regime for over-the counter (OTC) hearing aids. It was again submitted to both the FDA and OMB on September 28, 2021. The submission to OMB is of particular significance because OMB's Circular A-119 gives a specific mandate to the FDA to the incorporate voluntary consensus standards into federal rulemaking.

Notwithstanding these repeated submissions, the FDA has not even acknowledged the existence of the standard proposed by the aforementioned Hearing Care Work Group thereby prohibiting the public from commenting on it. This omission is particularly troublesome in that the National Technology Transfer and Advancement Act of 1995 requires agencies to adopt voluntary consensus standards unless they are impracticable. Therefore, by refusing to mention the standard recommended by the Hearing Care Work Group in the NPRM the FDA has prevented it from utilizing a duly enacted statute to ensure the safety and effectiveness of Over-the-Counter Hearing Aids.

The aforementioned omission must be rectified either by issuing an amended NPRM or incorporating and addressing the said voluntary consensus standard into the final rule.

In order to establish a definitive record regarding the multi-year attempt by the Hearing Care Work Group to have its recommended standard to, at a minimum, at least be presented to the public for their comment, in the text that follows we have gone to extraordinary lengths to document events of the past three years.





December 11, 2018

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JAN 08 2019
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U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center - WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Re: Q182009 Meeting Fulfillment and Draft Minutes

Drs. Mann, Nandkumar, and Guisto,

Thank you for meeting with the Hearing Care Associations (herein referred to as "Associations") on November 27, 2018 in response to our request: Q182009. Please allow for this letter to serve as our Draft Meeting Minutes.

The fact that the FDA would not even recognize a study directly related to the subject matter of the NPRM when the agency was advised of its existence several times over a three-year period is puzzling, if not appalling. The apparent biases of the FDA are accentuated when one understands that the agency also failed to:

(1) recognize a key publication of another federal agency which has a direct bearing on the outcome of this proceeding and

(2) recognize a study conducted by the United Nations which specifically addresses the subject of the Notice of Proposed Rulemaking.

Notwithstanding the fact that the above documents were prepared by governmental organizations and that they specifically address the subject matter in the OTC Notice of Proposed Rulemaking, it is puzzling why the FDA would summarily dismiss these documents by not even mentioning them for public comment in the NPRM and instead devote their complete attention to a standard developed by a trade association whose standard was incorporated into the NPRM to exclusion of other more appropriate standards as discussed below.

The above excursions from the most elemental of accepted rulemaking procedures suggest that it is mandatory that the FDA repropose the NPRM after the above deficiencies are corrected or incorporate the standard proposed by Working Group into the final rule.

This section will demonstrate that:

(1) OMB Circular A-119, which includes actions to be taken to address the implementation of the National Technology Transfer and Advancement Act, requires the FDA adoption of a voluntary consensus standard or, in its absence, a consortia standard unless there is a compelling reason not to do so. In the event an agency does not adopt a voluntary consensus standard it must so inform the National Institute of Standards and Technology (NIST).

(2) The record includes two alternative standards, one advocated by the Consumer Technology Association (CTA) and the other by the Hearing Care Working Group.

(3) The Information Quality Act (IQA aka Data Quality) Act legislated a fundamental change in the regulatory process. More specifically it requires agencies verify the accuracy of the information contained in a regulation before it is disseminated to the public, a process named a pre-dissemination review.

(4) The federal agencies instituted a pacesetting program which was implemented government-wide after an in-depth public comment period. Since its passage in 2000 it has gained bipartisan support and has been the subject of in-depth media inquiries.

(5) The CTA Standard must be disqualified from consideration because it also fails to comply with both FDA's pre-dissemination review requirements, as set forth in the Information Quality Act, and the compelling need requirement which is set forth in Executive Order 12866.

Background

The National Technology Transfer and Advancement Act

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In general, the National Technology Transfer and Advancement Act (NTTAA) states that federal agencies and departments shall:

- use technical standards developed or adopted by voluntary consensus standards bodies if compliance would not be inconsistent with applicable law or otherwise impracticable; and
- consult with voluntary, private sector, consensus standards bodies and shall, when such participation is in the public interest and compatible with agency and departmental missions, authorities, priorities, and budget resources, participate in the development of technical standards.

It should be noted, pursuant to the NTTAA, that the governing principle is that federal agencies are directed to invoke a rebuttable presumption in favor of the adoption of voluntary consensus standards developed or adopted by voluntary consensus standards bodies.

What is ANSI's Role?

- ANSI states that:
    - ❖ ANSI administers and coordinates the private voluntary standards system in the US. ANSI has a Memorandum of Understanding (MOU) with the National Institute of Standards and Technology system. Under the MOU, ANSI has several responsibilities including accrediting Standards Developing Organizations (SDOs) to develop and publish American National Standards and approving proposed consensus standards as American National Standards.
    - ❖ ANSI has been administering the voluntary standards system in the US long before the MOU with NIST and nothing in the signed agreement undermines ANSI's status and authority as an independent, private organization. Although consensus standards in the US may be developed through different mechanisms, the most common development process is through ANSI-accredited SDOs.
    - ❖ The ANSI accreditation, as delineated in ANSI's Procedures for the Development and Coordination of American National Standards, indicates that the internal procedures of SDOs must provide for openness, due process (including an appeals process), a balance of interests, and development of consensus. The ANSI accreditation also signifies that the SDO cooperates with ANSI in standards planning and coordination activities and meets the other requirements for accreditation specified by ANSI. The American National Standards designation for proposed standards are distinct from accreditation for the NIST/ANSI requirements.
- ANSI does not set standards; it administers the voluntary consensus standards process. The development of a voluntary consensus standard requires considerable time and

resources. ANSI places particular emphasis on a balance among the organizations establishing a specific standard. By balance, we mean the participating organizations in the establishment of a standard must represent a wide range of views.

- "ANSI facilitates the development of American National Standards (ANS) by accrediting the procedures of standards developing organizations (SDOs) and approving their documents as American National Standards (ANS). This process serves and protects the public interest since standards developers accredited by ANSI – and the ANS they develop – must meet the Institute's requirements for openness, balance, consensus, and due process and adhere to ANSI's neutral oversight, assuring that all interested parties have an opportunity to participate in a standard's development."

- ANSI Accredited Standards Developers:

  - 238 ANSI-accredited standards developers (ASD).
  - Only ASDs may submit standards for approval as ANSI.
  - Accreditation by ANSI is a precondition for submitting a standard for approval.
  - Approximately 13,000 American National Standards.

What are the Differences Between Consensus Standards and Non-Consensus Standards?

- Voluntary Consensus Standards (OMB Circular A-119) states:

  - For purposes of this policy, "voluntary consensus standards" are standards developed or adopted by voluntary consensus standards bodies, both domestic and international. These standards include provisions requiring that owners of relevant intellectual property has agreed to make that intellectual property available on a non-discriminatory, royalty-free, or reasonable royalty basis to all interested parties.

  - For purposes of this Circular, "technical standards that are developed or adopted by voluntary consensus standard bodies" is an equivalent term.

  - "Voluntary consensus standards bodies" are domestic or international organizations which plan, develop, establish, or coordinate voluntary consensus standards using agreed-upon procedures.

  - For purposes of this Circular, "voluntary, private sector, consensus standards bodies," as cited in Act, is an equivalent term. The Act and the Circular encourage the participation of federal representatives in these bodies to increase the likelihood that the standards they develop will meet both public and private sector needs. A voluntary consensus standards body is defined by the following

attributes: (i) openness, (ii)balance of interest, (iii) due process, and (iv) an appeals process.

- What is the Policy for Federal Use of Voluntary Consensus Standards? (OMB A-119)

  - ❖ All federal agencies must use voluntary consensus standards in lieu of government-unique standards in their procurement and regulatory activities, except where inconsistent with law or otherwise impractical. In these circumstances, agencies must submit a report describing the reason(s) for their use of government-unique standards in lieu of voluntary consensus standards to the Office of Management and Budget (OMB) through the National Institute of Standards and Technology (NIST).

The Evolution of Consortia Standards

- As a result of the need by technology-based industries for a timely standards development process, an alternative has emerged which is titled consortia standards. The consortia are associations of organizations which develop technical standards without necessarily adhering to ANSI requirements for openness and consensus. Thus, the consortia are not recognized by ANSI, although the non-consensus development groups may include ANSI members and ANSI-accredited SDOs. Even though a standard is not developed through a consensus process, ANSI procedures may still allow for certification of the standard as an American National Standard, provided that ANSI puts the proposed standard through an open consensus process. In essence, ANSI accredits the procedures of SDOs and can certify one or more of their standards.

- Non-Consensus standards (consortia standards) are standards that have been developed through a streamlined, non-consensus process that usually includes representation from only a limited range of interests. Non-consensus standards can be developed more quickly than consensus standards. Federal policy, as enunciated in OMB Circular A-119, does recognize consortia standards for use by federal agencies.

- Moreover, OMB Circular A-119 also recognizes that some standards development processes do not neatly fit within a consensus/non-consensus dichotomy. The consortia which produce standards are usually alliances "of firms and organizations, financed by membership fees, formed for the purpose of coordinating technology development and/or implementation activities." Their outcomes are publicly available, multi-party industry specifications or standards. Usually their members are large companies, which indicates that the resulting standards are likely to be very relevant to a particular market. Irrespective of market relevance, consortia standards can be of interest to government and academia as well as industry.

The Domineering Role of OMB Circular A- 119

- The record in this proceeding contains two alternative standards: (1) The Hearing Care Working Group standard and (2) the standard developed by a trade association. Nowhere in the NPRM does the FDA provide a rationale for choosing the trade association consensus standard in lieu of the one advocated by the Hearing Care Working Group. It should be noted that the FDA was provided with a copy of the Hearing Care Working Group's consensus standard several times prior to the release of NPRM.

- OMB Circular A-119 states:

    - ❖ (Background) CRE

    - ❖ (Background) OMB

    - ❖ Maintains a strong preference for using voluntary consensus standards over government-unique standards in federal regulation and procurement.

    - ❖ In those circumstances where an agency elects to use or develop a government-unique standard in lieu of using a voluntary consensus standard, Section 12(d) of the NTTAA requires the agency to submit a report describing the reason(s) to OMB. Under the Circular, this report is submitted to OMB through the National Institute of Standards and Technology.

    - ❖ In cases where no suitable voluntary consensus standards exist, an agency may use suitable standards that are not developed by voluntary consensus bodies.

    - ❖ This policy does not establish a preference among standards developed in the private sector. For example, this policy allows agencies to select a non-consensus standard developed in the private sector as a means of establishing testing methods in a regulation and to choose among commercial off-the-shelf products, regardless of whether the underlying standards are developed by voluntary consensus standards bodies or not.

    - ❖ The Circular does not preclude the use of standards other than voluntary consensus standards in rulemaking, procurement, or other program activities in cases where: Voluntary consensus standards do not exist or where use of existing voluntary consensus standards would be inconsistent with law or otherwise impractical, including where use of a voluntary consensus standard would not be as effective at meeting the agency's regulatory, procurement, or program needs. The Circular also recommends that the agency consider allowing the use of other standards as alternative means for complying with agency regulatory, procurement, or program requirements based on voluntary consensus standards

where such other standards are also found to be suitable under the agency's analysis.

- ❖ There was also significant support among the commenters for providing federal agencies the flexibility to choose among standards developed in the private sector, particularly standards developed for emerging technologies that may or may not follow the traditional voluntary consensus standards development process precisely. As such, and for agencies to choose the best standards for their needs, this policy maintains flexibility for agencies to use standards developed in the private sector that best meet agencies' regulatory, procurement, or program needs, whether those standards are developed by voluntary consensus standards bodies or not. To assist agencies in deciding which standards to use, the Circular identifies factors to consider including, among others, the effectiveness and suitability of the standard for meeting agency regulatory, procurement, or program needs, the extent to which a standard meets the definition of a "voluntary consensus standard," and whether the standard is reasonably available.

<u>Two Alternative Standards</u>

- The record in this proceeding indicates that there are two standards in play:
  - ❖ The CTA Standard
    - ➢ The CTA Standard was developed by the Consumer Technology Association (CTA).

      CTA is a standards and trade organization for the consumer electronics industry. It is headquartered in Arlington, Virginia and has a conglomerate of 2,200 companies.
  - ❖ Hearing Care Work Group Standard
    - ❖ This standard is the product of the work of four hearing care associations:

      1. The American Academy of Audiology
      2. The Academy of Doctors of Audiology
      3. American Speech Language Hearing Association
      4. International Hearing Society

- Collectively, the four aforementioned organizations represent and address a very wide cross section of the hearing aid community, ranging from audiologists, hearing educators, hearing aid specialists, and clinical practitioners to personnel trained in making referrals to other health care professionals.

Violation 1: The FDA Denied the Right of the Hearing Care Consensus Working Group to Seek Federal Adoption of its Standard Pursuant to:

(1) The National Technology Transfer and Advancement Act
(2) OMB Circular A-119
(3) The Administrative Procedure Act
(4) The Information Quality Act

As noted above, the FDA:

- Never even mentioned the Consensus Standard developed by the Hearing Care Working Group in its NPRM even though it was presented to the FDA several times over the three-year period preceding the issuance of the NPRM.

- Prohibited the Hearing Care Working Group from exercising its duly recognized rights under the aforementioned statutes and Circulars

- Abused its discretion by arbitrarily adopting a standard recommended by a trade association in lieu of a choice based on compliance with the National Technology Transfer and Advancement Act.

Violation 2: Failure to Perform a Pre-Dissemination Review for the Two Standards Under Consideration

The Pre-Dissemination Requirement in the Information Quality Act Governs the Outcome of this Rulemaking.

- The record contains two standards, the standard advanced by the Hearing Care Work Group which fulfills the pre-dissemination review requirement set forth in the Information Quality Act and the standard advanced in the NPRM, the CTA Standard, which does not fulfill the pre-dissemination review requirement.

- The HHS has issued a document which describes the Information Quality Guidelines for each of its components, including those for FDA, whose guidelines are set forth in Section F of the said document.

- The Information Quality Act vests overall authority for the implementation of the Act with OMB. Agencies were directed to tailor their IQA regulations around those issued by OMB, recognizing the unique challenges confronting a particular agency.

OMB states:

- ''Dissemination'' means agency initiated or sponsored distribution of information to the public (see 5 CFR 1320.3(d) (definition of ''Conduct or Sponsor'')). Dissemination does not include distribution limited to government employees or agency contractors or grantees; intra- or interagency use or sharing of government information; and responses to requests for agency records under the Freedom of Information Act, the Privacy Act, the Federal Advisory Committee Act or other similar law.

- When we use the term Pre-Dissemination Review it is anchored in this directive in OMB's regulation:

> As a matter of good and effective agency information resources management, agencies shall develop a process for reviewing the quality (including the objectivity, utility, and integrity) of information before it is disseminated. Agencies shall treat information quality as integral to every step of an agency's development of information, including creation, collection, maintenance, and dissemination. This process shall enable the agency to substantiate the quality of the information it has disseminated through documentation or other means appropriate to the information.

In the context of the PRA, the Pre-Dissemination Review Requirement has a significance second only to the requirement that new forms and recordkeeping mandates be approved by OMB. This unique provision is associated with two critical events: (1) on occasion it is ignored, as is the case in the current NPRM, and (2) when it is implemented it has yielded some of the most dramatic changes in an NPRM.

- A review of the record-to-date reveals the following consequences pertinent to point (2) above:

- Background

  - When the IQA was first framed the reaction of the statistical agencies, dominated by mathematical statisticians, was that the proposal was nothing new; of course, they would only disseminate data that was objective, unbiased and reproducible. To the contrary, the reactions of federal regulators was, in large part, a dramatic opposition to the proposed legislation. The regulators, dominated by attorneys, argued that the statute would initiate a program which would permit the outside parties to initiate actions which would stymie the regulatory process.

  - Notwithstanding many controversial discussions in the executive branch, the career employees within federal agencies worked feverously to initiate a regulatory process, led by John Graham, the Administrator of OIRA, which was unprecedented in its timeliness and content.

  - At the onset, most attention was centered on the filing of a Request for Correction, a mechanism used to challenge information disseminated by a federal agency. It is important to note that, heretofore, one could challenge the content of a rule but not a standalone report. The IQA made standalone agency reports subject to a challenge, thereby thwarting those agency actions which attempt to regulate by information in lieu of resorting to rulemaking.

  - A very substantial number of agencies have instituted very comprehensive programs for pre-dissemination review. We will now describe those programs in order to provide a basis for demonstrating that the NPRM chose an alternative that violated the Information Quality Act.

National Oceanic and Atmospheric Administration (NOAA)

- NOAA is fundamentally a science-based agency with a rulemaking component. Here is a representative work product of NOAA actions to comply with the IQA; see the following post which reproduces the aforementioned page in part.

- The following text demonstrates the serious attention given to compliance with the pre-dissemination requirements of the IQA by NOAA,

Southwest Region
National Marine Fisheries Service
National Oceanic and Atmospheric Administration

SECTION 515 PRE-DISSEMINATION REVIEW & DOCUMENTATION FORM[1]

AUTHOR/RESPONSIBLE OFFICE: Garwin Yip; Sacramento Area Office

TITLE/DESCRIPTION: Biological and Conference Opinion on the Long-Term Operations of the Central Valley Project and State Water Project (CVP/SWP operations); Endangered Species Act (ESA) section 7 formal consultation

PRESENTATION/RELEASE DATE: June 4, 2009

MEDIUM: Posting on the Southwest Region website

PRE-DISSEMINATION REVIEW:
Name and Title of Reviewing Official: Russell M. Strach, Assistant Regional Administrator, Protected Resources Division
(Must be at least one level above person generating the information product)

- Please note that a management official must certify that the Pre-Dissemination Review is complete and is answerable to OMB, Congressional Committees and the Courts.
- Review the complete pre-dissemination review.

Department of Transportation

- The Department of Transportation has an extremely detailed pre-dissemination program. It states:

  Prior to dissemination, all influential information produced by the DOT shall be peer reviewed by subject matter experts (may be either internal or external to DOT, or both) that have not participated in the preparation of the influential information being reviewed. When using scientific information, including third-party data or models, to support their policies, DOT will comply with the requirements of OMB's Information Quality Bulletin for Peer Review. DOT will ensure reviewers are asked to evaluate the objectivity of the underlying data and the sensitivity of conclusions to analytic assumptions. Furthermore, when influential information that has been peer-reviewed changes significantly, DOT will conduct a second peer review. Peer review will also apply to influential information in economically significant regulations under Executive Order 12866.

Environmental Protection Agency

- What are the Administrative Mechanisms for Pre-dissemination Reviews?

EPA states:

- ❖ Each EPA Program Office and Region will incorporate the information quality principles outlined in section 6 of these Guidelines into their existing pre-dissemination review procedures as appropriate. Offices and Regions may develop unique and new procedures, as needed, to provide additional assurance that the information disseminated by or on behalf of their organizations is consistent with these Guidelines. EPA intends to facilitate implementation of consistent cross-Agency pre-dissemination reviews by establishing a model of minimum review standards based on existing policies. Such a model for pre-dissemination review would still provide that responsibility for the reviews remains in the appropriate EPA Office or Region. For the purposes of the Guidelines, EPA recognizes that pre-dissemination review procedures may include peer reviews and quality reviews that may occur at many steps in development of information, not only at the point immediately prior to the dissemination of the information.

Food and Drug Administration

- FDA is governed by three sets of IQA guidelines:

(1) OMB

(2) HHS

(1) FDA (Section F)

- All three documents have explicit statements on the central role that pre-dissemination review has in meeting the statutory requirements of the Information Quality Act.

- OMB states:

  - ❖ As a matter of good and effective agency information resources management, agencies shall develop a process for reviewing the quality (including the objectivity, utility, and integrity) of information before it is disseminated. Agencies shall treat information quality as integral to every step of an agency's development of information, including creation, collection, maintenance, and dissemination. This process shall enable the agency to substantiate the quality of the information it has disseminated through documentation or other means appropriate to the information.

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- HHS states:

  - ❖ Research and scientific studies disseminated by HHS are subject to an external, objective peer review process at both the inception stage and the pre-dissemination stage as a part of the publication process in peer reviewed journals. In addition, the quality of all of the intramural research programs of HHS agencies is continually reviewed and monitored by advisory committees and boards of scientific advisors. In accordance with widely accepted scientific research practice in the U.S., research reports disseminated by HHS agencies describe the methods, data sources, analytical techniques, measures, assumptions and limitations of the research, so that the study could be substantially reproduced. If original data are employed, it is the policy of HHS to make every effort to make the data available to the public in de-identified form consistent with confidentiality requirements, proprietary restrictions and resource availability.

- FDA states:

  - ❖ . . . [W]e use a number of mechanisms to ensure the quality of the information we disseminate. FDA reviews the quality (including the objectivity, utility, and integrity) of information before it is disseminated and treats information quality as integral to every step of the development of information, including its creation, collection, maintenance, and dissemination. Quality, as defined in the OMB Guidelines, encompasses (1) utility, the usefulness of the information to its intended users, including the public; (2) objectivity, whether information is being presented in an accurate, clear, complete, and unbiased manner; and (3) integrity, the information is protected from unauthorized access or revision.

Consult this library of agency pre-dissemination programs.

Unlike the CTA Standard, the Hearing Care Work Group Standard has been subjected to an Excruciating Peer Review Which Is Equivalent to the Contents of a Pre-dissemination Review**.**

- Subsequent to the release of The Hearing Care Work Group Standard, it was augmented by the publication of a peer reviewed document titled *Real World Evidence on Gain and Output Settings for Individuals with Mild-to-Moderate Hearing Loss*. This publication is equivalent to conducting a pre-dissemination review and concludes:

- Conclusions in the document include audiograms of over 28,000 adults. This study shows that commercially available hearing aids, programmed according to parameters typical of those used for individuals with mild-to-moderate hearing loss, yield output and gain

levels that are well within the recommended limits (110 dB SPL output and 25 dB gain) specified by a recent Consensus Paper issued by the four national professional organizations representing hearing healthcare providers.

- The goal of the aforementioned article is to derive hearing aid gain and output settings appropriate for individuals with mild-to-moderate hearing loss by taking a more practical approach. Specifically, by assessing the electroacoustic response of a current, commercially available hearing aid (device) that has been used in over 1,000,000 fittings around the world. The gain and output of this device were measured using the two most common prescriptive gain approaches available in this device.

- "Based on an examination of objective outcomes, we conclude that commercially available hearing aids, programmed according to parameters typical of those used for individuals with mild-to-moderate hearing loss, yield output and gain levels that are within the recommended limits specified in the Associations' Consensus Paper. It was also noted that, in fact, the recommended limits proposed in the Consensus Paper are higher than the levels prescribed in professionally fitted devices for long-term hearing aid users with mild and moderate hearing loss."

- The Federal regulatory process should encourage the regulated industry to conduct the equivalent of a pre-dissemination review and not penalize it by the proposed adoption of a standard which (1) is not supported by peer reviewed information, and (2) is applicable to a device that services individuals with no hearing loss as opposed to those individuals which is the focus of this rulemaking: individuals with mild-to-moderate hearing loss.

Violation 3: Failure to Assess the Relative Merits of Two Alternative Non-Consensus Standards

- The lack of a documented rationale for choosing one standard over another demonstrates that FDA acted in an arbitrary and capricious manner. Surprisingly, FDA did not attempt to give the slightest effort to justify its decision to adopt the CTA trade association standard in lieu of the Hearing Care Working Group Standard. The absence of such an action on the part of the FDA places it in a particularly precarious position.

- The complete dismissal of the Hearing Care Working Group Standard, without any explanation, is not justified because FDA was supplied with a copy of the proposed standard prepared by the Working Group several years ago and by CRE well before the issuance of the NPRM. CRE also presented the standard proposed by the Working Group to FDA during the course of an interagency meeting on the OTC rulemaking before the NPRM was issued.

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- It should be noted that at the aforementioned meeting CRE presented a paper which emphasized the controlling role that OMB Circular 1-119 has on this proceeding, namely regulators must adopt a voluntary consensus or consortia standard unless it is impracticable to do so. Pursuant to OMB guidelines the FDA and OMB must examine the relative merits of both the Hearing Care Working Group Standard and the CTA Standard.

- Pursuant to 5 U.S.C. § 553(c), an agency must consider ". . .the relevant matter presented." The courts have recognized that an agency is not required to respond to every comment it receives but only to those which the courts designate as "significant" comments. One court described "significant comments" as ". . .those which raise relevant points and which, if adopted, would require a change in the agency's proposed rule." Am. Mining Cong. v. EPA, 965 F.2d 759, 771 (9th Cir. 1992).

- By any stretch of the imagination, when a commentor identifies a requirement set forth in an OMB Circular which mandates an action to be taken by both a regulator and a reviewing authority located within the confines of the Executive Office of the President of the United States, then the said requirement most certainly rises to a "significant comment" as noted in the aforementioned judicial decision.

- As explained in Exhibit 1 the Hearing Care Consensus Standards were also furnished to the FDA by its authors some three years ago and in September 2021.

- A fundamental principle mandated in Executive Order is the concept of a compelling need. Where is the compelling need for federal agency to resort to the unilateral adoption of a standard developed by a trade association without giving any recognition whatsover to a standard proposed over a three year period which is commensurate with the findings of another federal agency?

- For the above reasons, if serious attention is to be accorded to the CTA Standard, it is incumbent on FDA to (1) assess the relative merits of the CTA Standard and the Hearing Care Working Group Standard,

- and (2) provide the rationale for choosing one standard over the other.

Violation # 4: The Failure to Limit Output to 110 dB SPL and gain to 25 dB

- When one encounters a rulemaking dealing with public health, there is usually a diversity in views among the affected stakeholders, which includes a wide range of health care providers, academicians, and consumers.

- In that the author of this post is a veteran, he often reviews the studies of the Veterans Administration when dealing with health-related issues because the VA's constituency is the immediate receptors of a federal regulatory action. Furthermore, since the VA is a federal agency it must abide by the conditions set forth in the Information Quality Act, which prescribes the quality dimensions of information disseminated by all federal agencies.

- To this end, Dr. Earl E. Johnson, with the James H. Quillen VA Medical Center, Mountain Home, TN, USA and the Department of Audiology and Speech-Language Pathology, East Tennessee State University, Johnson City, recently wrote a journal article which addresses head-on the issue presently before us, the article is titled "*Safety limit warning levels for the avoidance of excessive sound amplification to protect against further hearing loss".*

- With excruciating detail Dr. Johnson explains his reasoning behind recommending a standard of 111 dB. In that Dr. Johnson is a federal employee his recommendations should demand, at a minimum, the same attention accorded to a recommendation made by a trade association. Unfortunately, the FDA does not share our views.

Why Did the FDA Favor the CTA Standard Over One Adopted by the United Nations?

- First, and prior to examining the work of Dr. Johnson, the rationale used by the FDA to adopt a standard used to protect users of electronic products who have no deficiency in their hearing as the basis for protecting a segment of the public with a mild to moderate hearing loss is puzzling.

- Even if one were to accept the aforementioned misguided operating paradigm proposed by the FDA, the FDA got the numbers wrong.

- We introduce the International Telecommunication Union (ITU) which is a specialized agency of the United Nations responsible for all matters related to information and communication technologies. CRE approached the UN because of its well-known presence in scientific forums throughout the world.

Two years ago, some two years after the CTA Standard was published, the ITU published a report titled H.871: Safe listening guidelines for personal sound amplifiers. We note that nowhere in the document is there a reference to the CTA Standard.

- Therefore, the first question which comes to mind is why did the FDA, in its NPRM, accept unilaterally a standard developed by a trade association in lieu of one developed by one of the most significant governmental organizations on the world stage?

- The import of the aforementioned question is magnified further when one recognizes that the attendant regulatory regime to be developed will implement a new regulatory program which is governed, in part, by an Executive Order of the President.

We have reproduced several governing statements in the ITU report below:

- This Recommendation describes safety requirements for personal sound amplifiers (PSAs), including both personal sound amplification products (PSAPs) and personal sound amplification apps (PSAAs), to protect people from further hearing loss.

    - ❖ Currently, there is no international standard for PSAPs. An international standard is needed to ensure that these devices, which are freely available to anyone, are safe for users and do not further damage users' hearing.

    - ❖ Personal sound amplifiers are non-medical devices which amplify sounds picked up by a microphone. This device is intended for people with normal hearing.

    - ❖ When these devices 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 ITU is very clear on its recommendation. It recommends an output standard of 95 dBA. The ITU also issued this report on the same subject. NIOSH recommended 85 dBA for an eight-hour workday.

- The ITU report concludes: To avoid the risk of permanent hearing damage, according to the WHO-ITU Safe Listening Standards H870 and H871, one can only be exposed for 15 seconds/week to sound with a loudness level of 120dB, for 4 seconds/week to 125 dB and even less than 2 seconds/week to 130dB**. It is clear, that a personal amplifier is not intended to be only used 15 seconds or less per week.

- The CTA concludes: In the design of any device reproducing live sound there is a required development balance to provide undistorted reproduction of content such as live music while at the same time avoiding sudden peak output SPLs which would be uncomfortable to the listener. To optimize this balance, a maximum output level of 120 dB is recommended.

    - ❖ A 120 dB SPL sound measured in a 2cc coupler is equivalent to a level of approximately 115 dBA for a measured sound field

This ITU article says it all when it concludes:

- ❖ For the availability of hearing protection at work, for personal music players and personal amplifiers the exposure should be less than 1.6 Pa^2h, which corresponds to 80dBA for 40 hours. Although only setting a maximum output level is not

> advisable, since this can result in higher compression in the source music file or in the amplification, for personal sound amplifiers that don't have the capacity to measure weekly dose needs to be permanently limited to 95dBA.

In summary, we are in no way suggesting that a PSAP standard should be applicable to a standard to be imposed for a hearing aid. That said even if we were to adopt this misplaced reasoning as a basis for hearing aids, the FDA simply has the numbers wrong when they reject the views of the United Nations without providing any reasons for doing and accepting instead the views of a trade organization.

It appears that the FDA has ignored the advice (95 dBA) of established international scientific organizations and has adopted the views (115 dBA) of a trade association without one iota of information in support of its choice. We find it difficult to comprehend that the above record would survive a substantive review by either OIRA or the courts.

The Views of a Practitioner at the Veterans Administration

Now returning to the paper written by Dr. Johnson of the Veteran's Administration:

- The paper states:

  - Secondly, there has been a recent push for more availability of electronic sound amplifiers to garner affordable and accessible provision of products in order to meet the needs of a large swath of persons, particularly aging adults, with hearing loss.

  - These electronic sound amplifiers are available as over-the-counter wearable hearing devices or personal sound amplification products [e.g. Food and Drug Administration (FDA), 2009; President's Council of Advisors on Science and Technology (PCAST), 2015].

  - "The 2016 recommendations from the National Academy of Sciences entitled ''Hearing healthcare for adults: Priorities for improving access and affordability'' included as the seventh recommendation *the need for defining safe output SPL for sound amplifiers* as determined in conjunction with national experts in hearing conservation."

  - "Presumably then, the concern for amplitude levels in the ear of a hearing aid wearer is really then the same type of concern that is often expressed for workers exposed to occupational noise hazards, that of too much amplitude level over a period of time (e.g. ISO, 1999, 1990; OSHA, 29 CFR 1910.95; NIOSH, 1996; 1998)."

- Dr. Johnson addresses the actions that must be taken to ensure the public is not injured by unnecessarily high dB levels. Dr. Johnson lists (tables 1&2) for a maximum moderate hearing loss (55dB) the equation formula is 111dB and for the 4-frequency average is also 111dB SPL

- The Hearing Care Consensus Work Group recommends 110 dB

- The CTA recommends 120 dB.

- It is ironical that the FDA would adopt a standard recommended by a trade association without even recognizing the existence of a standard developed by another federal agency. Of course this is to be expected because the United Nations developed a standard for PSAPS and the FDA did not even mention it in the OTC proceeding.

The above posts are summarized in the following section.

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 ITU 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 the documents prepared by governmental organizations by not even proposing them for public comment in the NPRM. In that two of 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.

POINTS OF EMPHASIS

1. The Need to Limit Output to 110 dB SPL and gain to 25 dB.

The FDA Reauthorization Act (FDARA) requires FDA to restrict output, which is the upper limit of amplification measured in sound pressure level (SPL), referenced in decibels (dB). FDARA does not expressly require FDA to establish a limit on gain, but to ensure that OTC hearing aids are effective, it must establish such a limit.[1]

Regarding OTC hearing aids, the four leading hearing health professional associations recommend **output be restricted to 110 dB SPL and that the maximum gain be 25 dB as measured in the 2cc coupler**. These recommendations are based on professional and scientific evidence demonstrating the ability to ensure OTC hearing aids will be safe and effective for the intended population of potential users: consumers with perceived mild-to-moderate hearing loss.[2]

Importantly, real-world data conclusively demonstrates that limiting output to 110 dB SPL and gain to 25 dB will ensure OTC hearing aids are safe and effective.[3] According to a recent study that compared the audiograms of over 28,000 adult patients, ". . .[C]ommercially-available hearing aids programmed according to parameters typical of those used for individuals with mild-to-moderate hearing loss yield output and gain levels that are well within the recommended limits (110 dB SPL output and 25 dB gain)." This study is important because it relied on ASHA's classifications of mild and moderate hearing loss when examining extensive real-world data, effectively showing that the recommended output and gain limits are most appropriate for the OTC hearing aid category. This research provides strong evidence to support FDA's adoption of the output and gain limits consistent with the Consensus Recommendations. Doing so will ensure that OTC hearing aids are used as intended while being safe and effective.

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[1] Gain, the second key aspect of hearing aid performance that needs to be regulated, is the difference between the SPL of the incoming sound and the output. In short, gain helps determine clarity when the sound is amplified. Modern hearing aids perform sophisticated audio processing to maximize the device's effectiveness in a wide range of settings and situations. Controlling gain is a key part of this processing and hearing aids often offer automatic gain control. Advanced hearing aids may provide different levels of gain in different frequency ranges to meet the specific hearing needs of each user. However, if the gain is too high in relation to the output, the amplifier will not be able to properly reproduce the incoming audio signal and the result is distortion.

[2] American Academy of Audiology (AAA), Academy of Doctors of Audiology (ADA), American Speech-Language-Hearing Association (ASHA), International Hearing Society (IHS), Regulatory Recommendations for OTC Hearing Aids: Safety & Effectiveness (Aug. 2018), available at https://www.asha.org/uploadedFiles/Consensus-Paper-From-Hearing-Care-Associations.pdf.

[3] Thomas J. Tedeschi, AuD, Christine Jones, AuD, and Elizabeth Stewart, AuD. *Real World Evidence on Gain and Output Settings for Individuals with Mild-to-Moderate Hearing Loss*, available at https://www.hearingreview.com/inside-hearing/research/real-world-evidence-on-gain-and-output-settings-for-individuals-with-mild-to-moderate-hearing-loss.

Moreover, these recommendations are in line with standards of the Occupational Safety and Health Administration (OSHA), which has long recognized the seriousness of noise-induced hearing loss, which is why it sets legal limits on noise exposure in the workplace. **OSHA's permissible exposure limit (PEL) is 90 dB for an 8-hour day.[4] At 110 dB, OSHA recommends only ½ hour per day exposure to avoid noise-induced hearing loss.** The National Institute for Occupational Safety and Health (NIOSH) recommends that all worker exposures to noise should be controlled below a level equivalent to 85 dBA for eight hours to minimize occupational noise-induced hearing loss. If a consumer with normal hearing were to wear an OTC hearing aid with certain output and gain characteristics, it is conceivable that this person may experience noise-induced hearing loss, which could have been avoided had the person learned of their normal hearing before using an OTC hearing aid.

2. Need for 510(k)s and Strong Enforcement by FDA.

Currently, FDA does not require manufacturers of "traditional hearing aids" to obtain premarket clearance under section 510(k) of the Food, Drug and Cosmetics Act (FDCA) prior to commercialization of new devices. However, FDARA empowers FDA to impose premarket requirements on manufacturers of OTC hearing aids to provide reasonable assurances of safety and effectiveness. CRE recommends that FDA require manufacturers of OTC hearing aids to obtain clearance from FDA under section 510(k) prior to marketing any new devices to consumers.

In 2018, Bose Corporation submitted a De Novo request to FDA to create the "self-fitting air-conduction hearing aid" category. As part of FDA's establishment of the "self-fitting" category, the agency ultimately determined that 510(k) premarket clearance was necessary to provide reasonable assurances of safety and effectiveness, as well as heightened special controls, including clinical data to evaluate the effectiveness of the self-fitting strategy incorporated into any newly commercialized device. Like "self-fitting" hearing aids intended for sale to consumers, without the involvement of a licensed hearing care provider, OTC hearing aids demand heightened regulatory controls to provide reasonable assurances of safety and effectiveness. A 510(k) premarket clearance requirement will help ensure that OTC hearing aids are, at least, as safe and effective as other devices on the market.

Moreover, FDA must closely monitor, and strongly enforce, the new regulatory framework, along with existing hearing aid regulations, to protect consumers from potentially unsafe and ineffective OTC devices sold by companies that fail to comply with the FDA's heightened controls. Presently, the market is flooded with companies selling illegally marketed, improperly listed, and untested hearing aids. Many companies are already advertising "OTC" hearing aids when the category does not yet exist, as well as selling "self-fitting" hearing aids even though these devices have not been properly reviewed by the FDA; let alone properly listed under the correct medical device category. Unfortunately, the FDA is not enforcing its current rules to rein in these improprieties. Without strong enforcement action from the FDA, the market

[4] 21 C.F.R. §1910.95.

will continue to be inundated with illegal hearing aids and potentially ineffective OTC hearing aids that may harm consumers, rather than help them.

FINDINGS

- The CTA Standard:

  - ❖ violates the Information Quality Act if it were incorporated into the NPRM.

    - ➢ There is no information in the record which demonstrates that the FDA prepared a pre-dissemination review for its recommended CTA standard. This inaction is a complete violation of the Information Quality Act, OMB guidelines, HHS guidelines and FDA guidelines as referenced above.

    - ➢ The above finding is beyond question. A pre-dissemination review available for review by the public simply does not exist for the CTA Standard, and its absence prohibits adoption by the FDA.

    - ➢ Conversely, there is an abundance of information readily available for the formulation of the pre-dissemination review for the Hearing Care Work Group Standard and, therefore, is immediately available for adoption by FDA.

    - ➢ The CTA standard Is inconsistent with the standard promulgated by the United Nations.

    - ➢ The CTA standard violates the Administrative Procedure Act because there is no data in the record which demonstrates the advantage of the CTA Standard over the Hearing Care Working Group Standard.

    - ➢ The CTA standard violates the Executive Order 12866 because there is no compelling need for the CTA Standard given the presence of the aforementioned UN Standard.

- FDA's premature adoption of the CTA Standard could result in litigation which would greatly extend the timely implementation of the Over-the-Counter Hearing Aid program and in doing so would jeopardize the timely availability of safe and effective hearing aids to the public.

CONCLUSIONS

(1) Pursuant to the Information Quality Act, the FDA should conclude that the Hearing Care Working Group Standard fulfils the pre-dissemination requirements of the Information Quality Act and the CTA standard does not.

(2) Pursuant to the Administrative Procedure Act, the FDA must assess the relative merits of the CTA Standard and the Hearing Care Working Group Standard.

(3) Pursuant to OMB Circular A-119 and Executive Order 12866, FDA should announce its adoption of the Hearing Care Work Group Standard and not the CTA standard.

(4) Actions should not be taken which would compel the regulated community to resort to litigation to enforce existing statutes such as the Information Quality Act and the National Technology and Transfer Act.