The World Health Organization Report on Safe Listening

The Catalyst for Regulatory Integration

The Safe Listening Standard

On March 2, 2022 the World Health Organization promulgated a *Global Standard for Safe Listening at Venues and Events,* some seven months subsequent to the FDA publication of its NPRM for OTC hearing aids.

The Report concludes:

- Over 1 billion people aged 12 to 35 years risk losing their hearing due to prolonged and excessive exposure to loud music and other recreational sounds. This can have devastating consequences for their physical and mental health, education, and employment prospects.

- Millions of teenagers and young people are at risk of hearing loss due to the unsafe use of personal audio devices and exposure to damaging sound levels at venues such as nightclubs, bars, concerts and sporting events.

The WHO recommendations include a maximum average sound level of 100 decibels at the aforementioned venues and events.

Implementation

- **Legislation or Regulations:** relevant departments in the government should develop appropriate laws/regulations/policies that address the issue of sound exposure mitigation in venues or events where amplified music is played. (WHO)

Raising awareness among audiences and people working in the music and entertainment industries about the risk of permanent hearing injury following exposure to high sound levels, and the safe listening practices that can help to reduce that risk, is critical to achieving the overarching goal of this Standard: to create an environment in which people are empowered to enjoy amplified music while protecting their ears. (WHO)

It must be acknowledged that many people who attend or work at venues and events do so because they enjoy the feelings and sensations associated with listening to music at high levels. Effective health communication messaging around safe listening must reflect this reality. (WHO)

Where a venue or event has been certified by a competent authority as adequately implementing the features of this Standard, it may identify as a “safe listening venue” or “safe listening event”. This could include the use of these (or similar) phrases on notices, on tickets, and in event listings and other marketing materials, online and in print. (WHO)

The following regulatory actions are those that will enhance the WHO Safe Listening Standards and provide a basis for the initiation of a macro change in the administrative process as set forth in the last section of document.

Regulatory Requirements for Personal Sound Amplification Products

- In October 2021, some seven months prior to the WHO issuance of its Safe Listening Standards, the FDA issued proposed requirements of PSAPs.
- There are scenarios where the utilization of a PSAP could lead to a violation of the WHO Safe Listening Standard.

A Public Comment

- CHPA recommended that FDA revise the Draft Guidance to further clarify when the design or technology of a product may be evidence that the product has such an intended use and is subject to regulation as a hearing aid device. (Consumer Health Products Association)
- CRE believes that the proposed FDA guidance for PSAPs should be revised to incorporate the WHO Sale Listening Standard.

Establishing Over-the-Counter Hearing Aids

- The use of an OTC hearing aid greatly reduces the chances that its users will violate the Safe Listening Standards if the appropriate gain and output limits are adopted
- (CRE) has provided its recommendations on this issue to the FDA. Read the **Center for Regulatory Effectiveness** Submission

Three years ago a group of affected parties submitted a proposed Voluntary Consensus Standard to the FDA to meet its 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. OMB's Circular A-119 gives a well-defined mandate to the FDA that it must consider voluntary consensus standards in federal rulemaking.

Notwithstanding these repeated submissions, the FDA has not even acknowledged the existence of the aforementioned proposed standard in its NPRM. This omission by the FDA 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 even mention the aforementioned standard in the NPRM the FDA has arbitrarily denied the right of the aforementioned affected parties to participate in the rulemaking.

Medical Device Manufacturers Association We write to support the recommendations included in a consensus paper…..which strikes a careful balance between issues of consumer access and affordability while ensuring safety and effectiveness in all hearing aid devices. We urge consideration and adoption of recommendations in the consensus paper, including limiting output to 110 dB and gain to 25 dB for OTC hearing aids, and supporting strong consumer protections.

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.

Now that the record has been established, the continued defiance of (1) the National Technology Transfer and Advancement Act, (2) OMB Circular A-119 and (3) the views of one of the world's most prestigious health institutions is a non-starter.

Utilizing the Latent Authorities of the FCC and FTC to Implement and Enforce an Effective National Hearing Program

Federal Communications Commission

Read CRE Submission to the FCC

- Personal Sound Amplification Products Which Advertise Their Compliance with FCC Compatibility Requirements Should Be Required to Provide Advertising and Promotional Materials to the FCC

One thrust of this proposal is to use data collected by the FCC for the betterment of the American public through its subsequent use by the FDA. In particular, this initiative is aimed at facilitating the implementation of a statutory directive which the FDA must implement shortly after the FDA proposes a final rule on the implementation of the Over-the-Counter Hearing Aids Act which states:

(c) New Guidance Issued--Not later than the date on which final regulations are issued under subsection (b), the Secretary shall update and finalize the draft guidance of the Department of Health and Human Services entitled ``Regulatory Requirements for Hearing Aid Devices and ***Personal Sound Amplification Products****'', issued on November 7, 2013.*

Given the extremely stringent deadlines for the FDA, as described above, coupled with the fact that the FCC has a well-established system for collecting information from devices which assist consumers interested in sound devices, CRE recommends that the FCC issue a directive requiring the manufacturers of PSAPs who claim in their advertisements that their devices are compatible with a particular handset provide the totality of the copies of their advertising and promotional material to the FCC. Such an action would be in accord with the requirements in the Paperwork Reduction Act which directs federal agencies to share in the responsibility for collecting data. And finally, of particular importance, is the fact that the FCC should collect the aforementioned data before a decision is made to incorporate PSAPs into its benchmark for compatibility.

Federal Trade Commission

The Federal Trade Commission has been most vigilant in assuming a prominent role in promoting the health of our citizenry by taking the needed steps to ensure PSAPs are used as intended, as so described by the U.S. Food and Drug Administration.

Read CRE's Statement on the FTC Enforcement Program

The aforementioned post is provided as an example of the latent authorities the FTC has over PSAPs in particular and hearing programs in general. It is also an example of the massive powers inherent in federal agencies to address issues across differing agency jurisdictions.

A NGO/Private Sector Driven but Federally Sanctioned Hearing Enforcement Program

The aforementioned list of actions cannot and will not be implemented under the existing federal regulatory regime by a single agency for a number of reasons including:

- Limited statutory authority
- Limited financial resources
- Limited number of employees
- Limited priority relative to other statutory mandates

The aforementioned obstacles can be overcome by harnessing the strengths of the NGO and private sector communities. Such an action is endorsed by any number of statutes and Executive Orders. The strategy outlined herein differs from the previous recommendations in that it is envisioned that actions outlined herein would be initiated by the NGO and private sector communities without virtually any involvement by federal agencies at the onset.

More specifically the NGO/private sector communities would:

- serve as regulatory watchdogs and report violations of agency regulations to the relevant federal agencies.
- report repeated violations to the press
- develop case histories on each recommendation and publish them on a community website. If the nation wishes to address the hearing problems facing our citizens we must recognize the existence of constraints which could make such an advancement

impossible. Of particular importance is that in this rapidly changing technology-based economy, a new degree of nimbleness must be introduced into any management scheme.

Take for example the actions that must be taken to implement just one program recommended by the internationally recognized experts in the WHO Safe Listening program.

First, examine the magnitude of the problem:

- Over 1 billion people aged 12 to 35
- Millions of teenagers and young people

Second, examine a partial listing of the vast array of WHO recommended corrective actions:

- Relevant departments in the government should develop appropriate laws/regulations/policies that address the issue of sound exposure mitigation in venues or events where amplified music is played.
- Governments should consider establishing a mechanism to certify venues or events as "safe listening". Due process for certification and regular monitoring is essential to ensure that the label is not misused
- Where there is a requirement for third parties – for example, performers, sound engineers, or talent bookers – to play a role in achieving safe listening conditions, these requirements should be codified in a formal contractual relationship.
- For each venue or event, the responsible party should ensure that a responsible actor is appointed to periodically monitor the sound level.
- The effective control of sound levels at venues and events requires that the sound level be measured accurately and that the results be made visible to the responsible actor in real time,

As noted above, clearly the existing regulatory paradigms must change if the administrative state is to be responsive to its citizenry. There is no better example of the need for such an action than the recently published report of the World Health Organization on Safe Listening particularly when it can be augmented by programs in a number of federal agencies as well as the NGO and private sectors.

Of equal or even greater significance is that the implementation of the regulatory regime provided herein serves as a protype of the ability of the administrative state to address emerging and constantly changing demands in a timely and efficient manner in any number of venues.

The program set forth herein has been developed over a number of years, each component is designed to compliment the others, non-marginal changes in one component could jeopardize the efficacy of the others.