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February 26, 2021

Dear Mr. President:

RE: FDA Hearing Aid Regulations

I am writing to ask you to support the establishment of the following regulations to complement the FDA's authorization of over-the-counter hearing aids (OTCHA) under the FDA Reauthorization Act of 2017 (FDARA):

1-Mandate generic names for OTCHA features
2-Develop a rating system for the features
3-Require the FDA to test all features regardless of their predecessors' functional equivalent.

BACKGROUND:

Hearing aids (HAs) are critical for people with hearing loss, a growing population that the CDC anticipates will reach 82 million by 2040 as people live longer. Yet HAs have remained unaffordable to many Americans due to monopolistic pricing. OTCHAs will partly resolve this issue.

In 2011, I approached Senator Elizabeth Warren to discuss how she could help break up the HA monopoly as she did with credit cards. In 2017, Senators Warren and Grassley passed FDARA. As a result, people with mild to moderate hearing loss will be able to purchase OTCHA "without the supervision, prescription, or other order, involvement, or intervention of a licensed person, to consumers through in-person transactions, by mail, or online."

However, OTCHA is subject to safety and effectiveness regulations, which the FDA hasn't yet created. Consumers are currently dependent on audiologists/dispensers who prescribe and sell HAs, a conflict of interest. Hearing aid manufacturers (HAM) exacerbate this conflict by incentivizing

sales from audiologists with free equipment and perks, despite the FDA discouraging this practice in the pharmaceutical sector.
The FDA doesn't require HA testing if HAs are their predecessor's functional equivalent. As a result, consumers buy untested equipment, while HAMs limit technology changes to save money.

DISCUSSION:

Section 709(b)(2)(A) of FDARA requires the FDA to provide reasonable assurances of safety and effectiveness of OTCHAs. Testing is the only way to determine whether OTCHAs are effective. In 2009, I filed a petition requesting the FDA to evaluate HAs using the international ANSI standards. The FDA didn't respond.

People assume that audiologists can compare HA brands and models, but they cannot determine whether features like noise reduction are comparable. HAMs trademark proprietary names for various elements, making it impossible to compare them. Consumer Reports' editor told me in 2016 that they could not rate HAs for this very reason.

During my 2016 FDA testimony, I requested that the FDA require generic feature names and test the features using international ANSI standards to determine whether OTCHAs are effective.

STRATEGIC RECOMMENDATIONS:

Consumers have no idea if HAs provide what they claim, and the HAMs will not offer this information without regulations. The FDA should, with the support of the White House:

1 - Mandate generic names for OTCHA features by standardizing features, so consumers understand what they are purchasing.

2 - Develop a rating system for the OTCHA features, so consumers can directly compare HAs and not rely on Audiologists/HAM's assessment, and ensure FDA oversight over OTCHA quality.

3 - Require the FDA to test all features regardless of their predecessors to ensure OTCHAs perform as claimed.

Thanking you in advance,

Janice S. Lintz

2020 WBENC WeTHRIVE Program in Partnership with IBM
2018 Bill and Melinda Goalkeepers Foundations Partnership with TPG Recipient
2016 Aspen Institute Spotlight Health Scholar
2016 Nominated United State of Women Changemaker
2008 People Magazine Hero
Founder and CEO
Hearing Access & Innovations Inc