



February 8, 2022

Janet Woodcock, M.D.
Acting Commissioner
Food and Drug Administration
10903 New Hampshire Ave,
Silver Spring, MD 20993

Dear Acting Commissioner Woodcock,

Thank you for your hard work and leadership on issues related to healthcare equality and access to care for Americans during today's turbulent times.

The Healthcare Equality Network is comprised of leading civil rights organizations and individuals who are devoted to raising awareness about the disparities in healthcare within our country. We are passionate about working alongside lawmakers and regulators to close these gaps and provide better access to healthcare resources to historically underserved communities, particularly Black Americans.

History has shown us that Black Americans have experienced a persistent disparity in our access to and quality of healthcare options and products. According to the [Harvard T. H. Chan School of Public Health](#), black children are 5 times more likely to die from asthma compared to their white peers. On average, Black Americans have to wait [about 20 minutes longer](#) for medical attention than their white counterparts, and in critical care situations, every minute counts. The list goes on and on, which is why our coalition is committed to our mission of healthcare equality.

We are grateful for the Biden administration's effort in attempting to make hearing aids more accessible and affordable to Americans suffering from hearing loss through your proposed rule on over-the-counter (OTC) hearing aids. Hearing loss is one of the most [underreported and prevalent health conditions](#) for older Black Americans who would benefit from better access to hearing aids. However, as the proposed rule currently stands, we are concerned that it may exacerbate the historical trend of Black communities getting access to only lower quality and potentially unsafe health products.

In its current form, the proposed regulations need to be strengthened on a couple of key components. First and foremost, the FDA proposes an output limit of 120 dB and a gain limit of 25 dB. Similar to other organizations and stakeholders who have [commented](#) on this matter, we are gravely concerned that these proposed volume levels are harmful for any user with mild-to-moderate hearing loss, who are the target consumers of these devices. For Black Americans who experience [inadequate access to hearing intervention services](#), including audiologists who properly diagnose these issues, the current volume limits pose a serious threat to further damaging their hearing.

In addition to the functions of the hearing aid itself, the FDA's proposed rule is unclear as to whether these products need to feature the appropriate package labeling to avoid misleading consumers and patients. Specifically, the rule does not clearly require product labeling that indicates users should obtain a hearing test to confirm the presence and degree of their hearing loss. This is a crucial component in determining if someone could benefit from an OTC hearing aid, or if they need professional assistance. Furthermore, it does not feature adequate language to prevent individuals under the age of 18 from purchasing and misusing these devices to their own detriment. With all the new bells and whistles, a clear distinction between these medical devices and consumer electronics products is crucial.

Despite the improvements that still need to be made, [some Members of Congress](#) are trying to push this regulation through too quickly without taking the time to bolster safety standards for Americans who will be using these devices. We are concerned that some of our legislators are prioritizing the needs of [consumer electronic companies](#) over the well-being of vulnerable American consumers. As a leading advocate for healthcare equality for Black Americans, we believe that finalizing the rule without addressing these ambiguities will have disproportionate consequences for our underserved communities.

The COVID-19 pandemic has exposed the systematic faults and flaws in our healthcare system that the Biden administration has promised to tackle, and we are appreciative of your efforts to address these challenging issues. By improving these key aspects of regulating OTC hearing devices for the safety of American consumers and patients, the FDA can take another step in the right direction to make healthcare in this country more accessible and safer for all.

Thank you for your thoughtful consideration.

Sincerely,

Congressman Ed Towns

Southern Christian Leadership Conference

The Healthcare Equality Network

Dr. Benjamin F. Chavis, Jr.

The Frederick Douglass Foundation

Dr. Julianne Malveaux

CC: *Congressional Black Caucus*

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