



# NATIONAL GRANGE

1616 H ST. NW, WASHINGTON, DC 20006 | PHONE (202) 628-3507 | FAX (202) 347-1091  
WWW.NATIONALGRANGE.ORG | INFO@NATIONALGRANGE.ORG

*American Values. Hometown Roots.*

January 14, 2022

The Honorable Janet Woodcock  
Acting Commissioner  
Food and Drug Administration  
RE: DOCKET NUMBER FDA-2021-N-0555-0001

Dear Commissioner Woodcock:

The National Grange is the oldest general farm and rural life organization in the United States. Now in its 155<sup>th</sup> year of service to its members and their communities, our organization works not only to celebrate and protect this important segment of our American life, but also to voice concerns and address challenges which disproportionately impact rural populations.

As I am certain you know, there are significant barriers to obtaining health care services and products in rural America. Distance to clinics and hospitals, scarcity of providers – particularly specialty care providers, limitations on access to products and services, and the demands of rural life all intervene. Moreover, rural residents have higher incidences of many health conditions, thus making the situation more concerning. This is the case regarding hearing loss. A research study<sup>1</sup> published in *Laryngology* discussed the access and socio-economic barriers that impact rural residents with hearing loss noting that “...like many healthcare disparities, untreated hearing loss is more prevalent in rural areas...” The authors also said that “hearing impairment prevalence is positively correlated with poverty, reduced educational attainment, and manual labor occupations --characteristics more prominent in rural communities.”

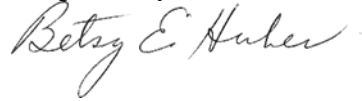
We welcomed the Over-the-Counter Hearing Aid Act which made affordable hearing aids more available; it’s an important access tool for rural adults with hearing loss. We also strongly support the consensus recommendations of the professional hearing care associations regarding their guidelines for effectiveness and safety.

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<sup>1</sup> *Rurality and Determinants of Hearing Healthcare in Adult Hearing Aid Recipients. Laryngoscope, October 2017.*

It would be a double tragedy if adults with impaired hearing were to suffer more damage because safety regulations were not in place. We have real concern that reliance solely upon the hearing aid user to determine whether the volume (output and gain) is at a safe level will not adequately protect them. For many reasons from mobility issues to distractions or situational difficulties that could arise, hearing aid users might be unable to remove devices quickly enough to prevent damage were the volume to be excessive. Please set the output limit for over-the-counter hearing aid at 110 dB and the gain limit at 25 dB.

Respectfully,

A handwritten signature in cursive script that reads "Betsy E. Huber".

Betsy Huber  
President