

Coalition Applauds FDA Decision to Finalize Rule Enabling Access to Over-the-Counter Hearing Aids

Washington, D.C. – August 17, 2022 – On Tuesday, the U.S. Food and Drug Administration finalized a proposal allowing access to hearing aids without a medical exam, prescription, or fitting by a specialist, improving access to hearing devices for millions of Americans experiencing mild- to moderate hearing loss. The decision follows a recent Executive Order by President Biden which directed the FDA to allow hearing aids to be sold over-the-counter. The announcement marks a significant victory to address social isolation and loneliness in the U.S.

“We know that uncorrected hearing loss is associated with increased risk of dementia, falls, and depression and is a significant contributing factor to social isolation and loneliness according to [AARP](#). Over-the-counter hearing aids hold the promise of improving social interactions and community engagement for millions of people with hearing impairments,” said Andrew MacPherson, Founder and Chairman of the Coalition to End Social Isolation and Loneliness. “We stand ready to work closely with the Administration and diverse national stakeholders to ensure the successful implementation of the rule.”

Individuals 18 years of age or older with perceived mild to moderate hearing impairment will be able to purchase hearing aids directly from stores or online retailers as early as mid-October, enabling more people to stay socially connected with their family, friends, and community. The Coalition is pleased that the FDA agreed with our recommendation to lower the maximum sound output from 120 decibels (dB) to 111 dB as a consumer protection measure. The Coalition also voiced its support for the requirement that all over-the-counter hearing aids have a user-adjusted volume control in order to ensure the devices are safe and effective.

The Coalition to End Social Isolation & Loneliness (CESIL) brings together a diverse set of national organizations including consumer groups, health plans, health care providers, technology innovators, patient advocates and more to develop and advocate for federal policy solutions to address the crisis of social isolation and loneliness. For more information, please visit: www.endsocialisolation.org.