International Hearing Society
Position Statement on Personal Sound Amplifiers

The International Hearing Society believes that there is the potential for confusion by the public about the appropriate use of hearing aids and personal sound amplifiers. While the differences between the two devices have been delineated by the Food and Drug Administration (FDA) – hearing aids being meant for hearing-impaired consumers and personal sound amplifying products (PSAPs) for normal hearing consumers – consumers need to be aware of the risk of utilizing a personal sound amplifier when hearing loss exists.

Hearing loss is a medical condition that can be caused by a variety of medical, genetic, and/or environmental factors. The FDA has determined that hearing aids are medical devices, and prior to purchasing a hearing aid, consumers are advised to seek a hearing aid evaluation and obtain medical clearance to ensure no medical and/or treatable conditions exist and that the hearing aid will be of benefit to the end user. Personal sound amplifiers, which are not meant to compensate for impaired hearing, are not regulated by the FDA, and therefore do not carry the same consumer protection and medical evaluation requirements as a hearing aid. The FDA's October 2009 publication, "Hearing Aids and Personal Sound Amplifiers: Know the Difference," states, "Choosing a PSAP as a substitute for a hearing aid can lead to more damage to your hearing." In the same publication, Deputy Director Eric Mann, MD, PhD, goes on to say, "It can cause a delay in diagnosis of a potentially treatable condition. And that delay can allow the condition to get worse and lead to other complications."[1]

IHS cautions prospective users to be wary of personal sound amplification devices that claim to address hearing loss issues. According to the FDA, "promotional materials that make claims or suggest the use of a PSAP for hearing impaired consumers, establish an intended use that causes the product to be a [hearing aid] device and therefore subject to the regulatory requirements for a hearing aid device."[2]

For these reasons, IHS advises those who suspect hearing loss to seek evaluation by a hearing healthcare professional – a hearing aid specialist, audiologist, or otolaryngologist – to determine whether hearing loss exists, and determine whether a hearing aid is appropriate or further medical evaluation is warranted. Additionally, IHS recommends consumers contact the FDA if they have concerns about devices that may be inappropriately being marketed as personal sound amplifiers.

Approved by the Board of Governors on April 21, 2012.

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[1] *Hearing Aids and Personal Sound Amplifiers: Know the Difference,* FDA Consumer Health Information / U.S. Food and Drug Administration, October 2009.

[2] *Guidance for Industry and FDA Staff: Regulatory Requirements for Hearing Aid Devices and Personal Sound Amplification Products*, February 25, 2009.