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ACDHH Position Paper

Issue: FDA Medical Evaluation

Background:

Since the 1970's, in order to protect the public health, the FDA has required that a person 18 years of age or older who wishes to purchase a hearing aid must either receive a medical evaluation or sign a medical waiver prior to the purchase of a hearing aid¹. Recently, the FDA announced it would no longer enforce this requirement, ostensibly to remove a barrier to hearing aid acquisition², however, research shows that a majority of adult hearing aid purchasers sign a medical waiver³ and thus the FDA Medical Evaluation requirement has not, in fact, been a barrier.

Discussion:

There is no evidence locally or nationally that the requirement to see a physician or sign a medical waiver has prevented anyone from purchasing hearing aids. A recent national multiphase pilot study by Tedeschi/Kihm revealed 13% of study participants with suspected hearing loss were unable to self-identify an FDA 'red flag' condition that required immediate physician attention⁴. In the 17 years that ACDHH has had a Hard of Hearing Specialist on staff, no consumer has ever stated that they were deterred from getting a hearing aid due to the FDA requirement. There is local anecdotal evidence that seeing a physician prior to receiving hearing aids has helped to diagnose ear-related conditions needing medical treatment.

ACDHH Position:

To protect consumer health, the FDA should reinstate enforcement of the Medical Evaluation requirement. Increasing the accessibility and affordability of hearing aids in America should not potentially jeopardize the health of consumers. The FDA Medical Evaluation requirement serves as a vital preventive component and reinforces that hearing is an important medical issue. Critically, the removal of consumer health protection by the FDA without the safety and efficacy of this action being evaluated before implementation is ill advised. We strongly encourage efforts to find safe, effective and affordable methods of accessing hearing aids using only evidence-based practices in healthcare.

Citations:

¹ <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcr/CFRSearch.cfm?fr=801.421>

² <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm532005.htm>

³ https://obamawhitehouse.archives.gov/sites/default/files/microsites/ostp/PCAST/pcast_hearing_tech_letterreport_final.pdf

⁴ <http://www.hearingreview.com/2016/12/implications-counter-approach-hearing-healthcare-consumer-study/>

This position paper was unanimously adopted by the ACDHH Board of Commissioners as ACDHH's formal opinion on this issue at the Board of Commissioners meeting on Thursday, February 23rd, 2017.