OTC Hearing Aids

Prickly Pear or Fruit Ripe for the Picking?

NCSB

September 27, 2019

Financial Disclosure

- El Paso Hearing Aid & Audiology Center
  - Professional
  - President
  - Practice Audiology including hearing aid dispensing
  - Receive a salary
- Texas Academy of Audiology
  - Professional
  - Board Member – Governmental Liaison
  - Receive travel reimbursement
- NCSB
  - Professional
  - Travel Reimbursement

Topics

- Medical Device Amendment
- Current FDA Guidance on OTC Hearing Aids
- What is a hearing aid?
- MarkeTrak data on OTC Hearing Aids
- Discussion of Relevance to State regulation

OTC Hearing Aid

(A) IN GENERAL.—In this subsection, the term 'over- the-counter hearing aid' means a device that—

(i) uses the same fundamental scientific technology as air conduction hearing aids (as defined in section 874.3300 of title 21, Code of Federal Regulations) (or any successor regulation) or wireless air conduction hearing aids (as defined in section 874.3305 of title 21, Code of Federal Regulations) (or any successor regulation);

(ii) is intended to be used by adults age 18 and older to compensate for perceived mild to moderate hearing impairment;

(iii) through tools, tests, or software, allows the user to control the over-the-counter hearing aid and customize it to the user's hearing needs;

(iv) may—

use wireless technology; or

include tests for self-assessment of hearing loss; and

(v) is available over-the-counter, without the supervision, prescription, or other order, involvement, or intervention of a licensed person, to consumers through in-person transactions, by mail, or online.

(2017 FDARA)

MDA (Medical Device Amendment)

- **Federal Law Applicable To Hearing Aids Sales**
  - In 1976, Congress passed the Medical Device Regulation Act, commonly referred to as the Medical Device Amendments (the MDA).
  - The MDA established comprehensive conditions for premarket and post-market regulation of medical devices
  - Contains an express preemption provision that prohibits states from enacting laws:
    - that are **different from, or in addition to**, any requirement applicable to a device under the MDA, and
    - that relate to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under the MDA (21 USC 360k).

MDA

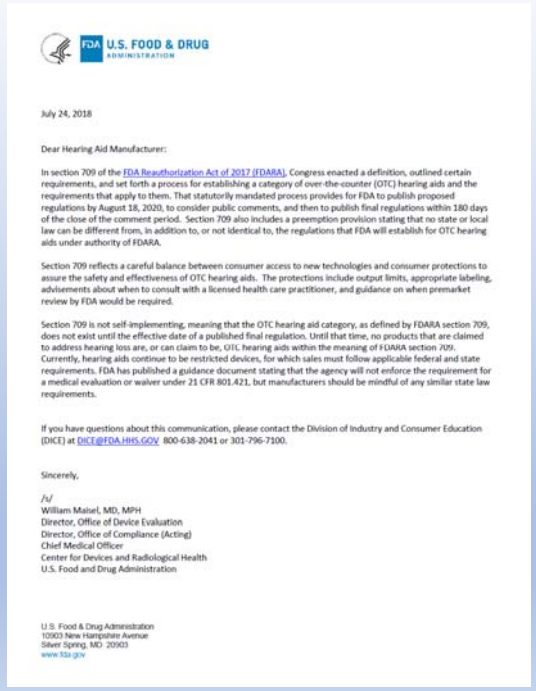
- The MDA, and the subsequent FDA regulations promulgated thereunder, affected hearing aids in three ways:
  - Defined "hearing aid" and who can sell hearing aids;
  - Created two specific regulatory areas of "federal supremacy" with respect to the regulation of hearing aid sales
    - Labeling (21 CFR 801.420)
    - Condition of sale (21 CFR 801.421)
  - Set forth an express preemption test to be utilized to determine whether state laws regulating hearing aids are preempted by federal law, while establishing a state's explicit right to license and regulate those who fit and dispense hearing aids.

FDA

- **July 24, 2018 – Status on Over the Counter (OTC) Hearing Aids**
  - In the FDA Reauthorization Act of 2017 (FDARA),
    - Congress outlined certain requirements to establish a category of over-the-counter (OTC) hearing aids
    - The requirements that apply to them.
  - This statutorily mandated process requires FDA to:
    - Publish proposed regulations for public comment, and then to
    - Publish final regulations.

FDA

- **July 24, 2018 – Status on Over the Counter (OTC) Hearing Aids**
  - At this time, there are ***no products*** that can claim to address hearing loss that are or can claim to be OTC hearing aids within the meaning of section 520(q) of the FD&C Act as amended by FDARA.
  - Currently, hearing aids continue to be restricted devices, for which sales must follow applicable federal and state requirements.
  - FDA has published a letter to clarify the status of these products.



U.S. FOOD & DRUG ADMINISTRATION

July 24, 2018

Dear Hearing Aid Manufacturer:

In section 709 of the FDA Reauthorization Act of 2017 (FDARA), Congress enacted a definition, outlined certain requirements, and set forth a process for establishing a category of over-the-counter (OTC) hearing aids and the requirements that apply to them. That statutorily mandated process provides for FDA to publish proposed regulations by August 18, 2020, to consider public comments, and then to publish final regulations within 180 days of the close of the comment period. Section 709 also includes a preemption provision stating that no state or local law can be different from, in addition to, or not identical to, the regulations that FDA will establish for OTC hearing aids under authority of FDARA.

Section 709 reflects a careful balance between consumer access to new technologies and consumer protections to assure the safety and effectiveness of OTC hearing aids. The protections include output limits, appropriate labeling, advisements about when to consult with a licensed health care practitioner, and guidance on when premarket review by FDA would be required.

Section 709 is not self-implementing, meaning that the OTC hearing aid category, as defined by FDARA section 709, does not exist until the effective date of a published final regulation. Until that time, no products that are claimed to address hearing loss are, or can claim to be, OTC hearing aids within the meaning of FDARA section 709. Currently, hearing aids continue to be restricted devices, for which sales must follow applicable federal and state requirements. FDA has published a guidance document stating that the agency will not enforce the requirement for a medical evaluation or waiver under 21 CFR 801.421, but manufacturers should be mindful of any similar state law requirements.

If you have questions about this communication, please contact the Division of Industry and Consumer Education (DICE) at DICE@FDA.HHS.GOV 800-638-2041 or 301-796-7100.

Sincerely,

/s/
William Maisel, MD, MPH
Director, Office of Device Evaluation
Director, Office of Compliance (Acting)
Chief Medical Officer
Center for Devices and Radiological Health
U.S. Food and Drug Administration

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

Contains Nonbinding Recommendations

Immediately in Effect Guidance Document: Conditions for Sale for Air-Conduction Hearing Aids

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Guidance for Industry and Food and Drug Administration Staff

- ***This guidance represents the current thinking of the Food and Drug Administration (FDA or Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff or Office responsible for this guidance as listed on the title page.***

Current FDA thinking

- **Approach to Conditions for Sale**
  - Recent expert reports and recommendations:
    - PCAST – President's Council of Advisors on Science and Technology
    - NAS – National Academy of Sciences
  - Public comments to the dockets for the guidance
  - "Regulatory Requirements for Hearing Aid Devices and Personal Sound Amplification Products - Draft Guidance for Industry and Food and Drug Administration Staff"
  - Provided FDA with new information and perspective on the current regulatory scheme for hearing aids.

Current FDA thinking

- **Approach to Conditions for Sale**
  - The PCAST and NAS reports each reach a similar conclusion
    - Medical examination and waiver requirements are providing little public benefit for users 18 years of age and older
    - Pose barriers to access for consumers that would benefit from the use of a hearing aid

Current FDA thinking

- **Approach to Conditions for Sale**
  - On the basis of these viewpoints, and in light of the fact that the majority of consumers today are opting to waive the requirement for a medical examination, FDA intends to reexamine and propose to modify the corresponding "conditions for sale" regulation (21 CFR 801.421).

Current FDA thinking

- **Approach to Conditions for Sale**
  - Notice of such a proposal would be provided in the Federal Register.
  - However, for the same reasons prompting FDA to reassess the hearing aid regulations, and until such publication of a final rule or order, FDA does not intend to enforce compliance with the specified "conditions of sale" for certain hearing aids as described in this guidance.

http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm373461.htm) and FDA's workshop on "Streamlining Good Manufacturing Process for Hearing Aids"

(http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/ucm480336.htm),

Hearing aids vs. Everything else

- **Other Products and Devices to Improve Hearing**
  - Assistive Listening Devices
  - Cochlear Implants
  - Implantable Middle Ear Hearing Devices
  - Bone-anchored Hearing Aids
  - Personal Sound Amplification Products

Hearing Aids vs. PSAP

- **Hearing Aids and Personal Sound Amplifiers: Know the Difference**
- **How They Differ (FDA)**
  - In March 2009, FDA issued guidance describing how hearing aids and personal sound amplifying devices differ.
  - The recently issued (2018) guidance defines a hearing aid as a sound-amplifying device intended to compensate for impaired hearing.
  - PSAPs are not intended to make up for impaired hearing. Instead, they are intended for non-hearing-impaired consumers to amplify sounds in the environment for a number of reasons, such as for recreational activities.
  - The difference between PSAPS and hearing aids are among the topics covered in a new Web page created by the FDA.

Contains Nonbinding Recommendations

Immediately in Effect Guidance Document: Conditions for Sale for Air-Conduction Hearing Aids

Guidance for Industry and Food and Drug Administration Staff

Document issued on December 12, 2016.

For questions about this document, contact Eric Mann at (301) 796-5620.

U.S. Department of Health and Human Services

Contains Nonbinding Recommendations

- FDA regulations regarding conditions for sale have also been cited as a potential barrier to availability and accessibility of hearing aids.
- The FDA does not intend to enforce certain conditions for sale of hearing aid devices that are required per FDA regulation. Specifically, FDA does not intend to enforce the medical evaluation (21 CFR 801.421(a)) or recordkeeping (21 CFR 801.421(d)) requirements prior to the dispensing of certain hearing aid devices to individuals 18 years of age and older. However, FDA will continue to enforce 21 CFR 801.421(b) and (c), which require hearing aid dispensers to provide prospective users an opportunity to review and to make available the "User Instructional Brochure," containing specific required labeling, before the sale of a hearing aid.

- Lin FR, Niparko JK, Ferrucci L. *Hearing loss prevalence in the United States*. Archives of Internal Medicine 2011;171(20):1851-1853.2 Dalton DS. *The impact of hearing loss on quality of life in older adults*. The Gerontologist 2005;43(5):661-668. 3
- World Health Organization Deafness and hearing impairment. Fact sheet No. 300. 2006 http://www.who.int/mediacentre/factsheets/fs300/en/index.html. 4 McCormack A, Fortnum H. *Why do people fitted with hearing aids not wear them?* International Journal of Audiology 2013;52(5):360-368. 5
- President's Council of Advisors on Science and Technology (PCAST) Report on *Hearing Aids: Aging America & Hearing Loss: Imperative of Improved Hearing Technologies*, October 2015 available at https://www.whitehouse.gov/sites/default/files/microsites/ostp/PCAST/pcast_hearing_tech_letterreport_final.pdf.6
- National Academies of Sciences, Engineering and Medicine (NAS) Report on *Hearing Health Care for Adults: Priorities for Improving Access and Affordability*. June 2016.

FDA Guidance

- This guidance is being implemented without prior public comment because the Agency has determined that prior public participation is not feasible or appropriate (Section 701(h)(1)(C)(i) of the FD&C Act and 21 CFR 10.115(g)(2)).
- FDA has determined that this guidance document presents a less burdensome policy that is consistent with public health.
- Although this guidance is immediately in effect, FDA will consider all comments received and revise the guidance document as appropriate.

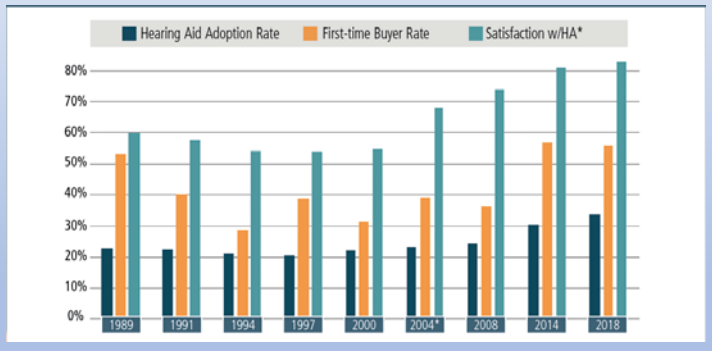
FDA Guidance

- FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities.
- Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited.
- The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

MarkeTrak 10

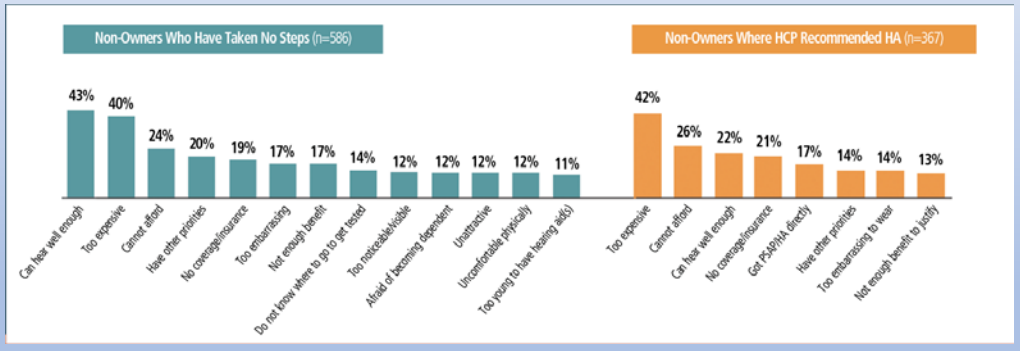
- The hearing aid market is poised for waves of disruption over the next few years. This will come in several forms:
  - New technology from the existing manufacturers;
  - New manufacturers entering into the hearing aid market;
  - New entries into the upcoming OTC (Over-the-Counter) market; and
  - New delivery channels including the expansion of the evolving DTC (direct-to-consumer) market.

Adoption Rates



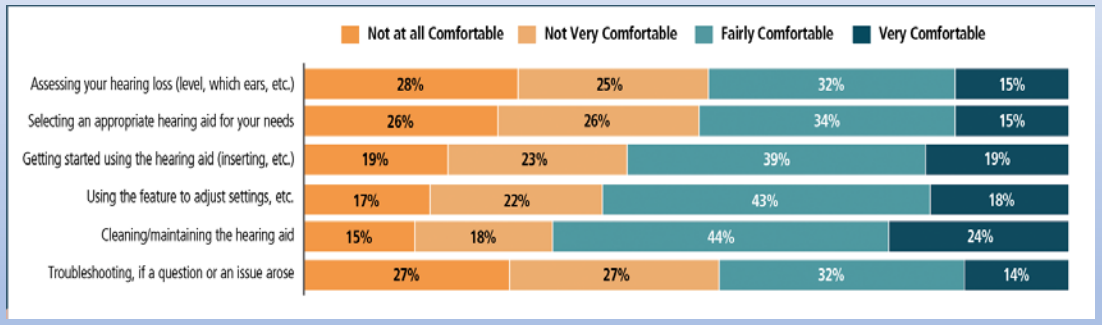
MarkeTrak 10: First-time buyer rate and hearing aid satisfaction rates

Reasons for not proceeding with Recommendation for hearing aids



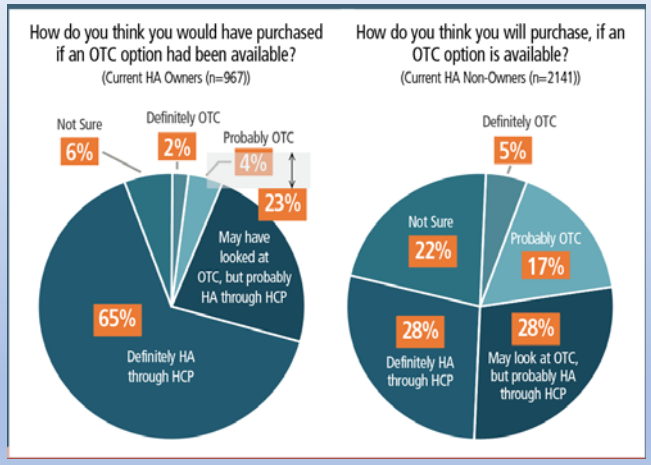
MarkeTrak 10

OTC Comfort Level



MarkeTrak 10

Likelihood of purchasing OTC

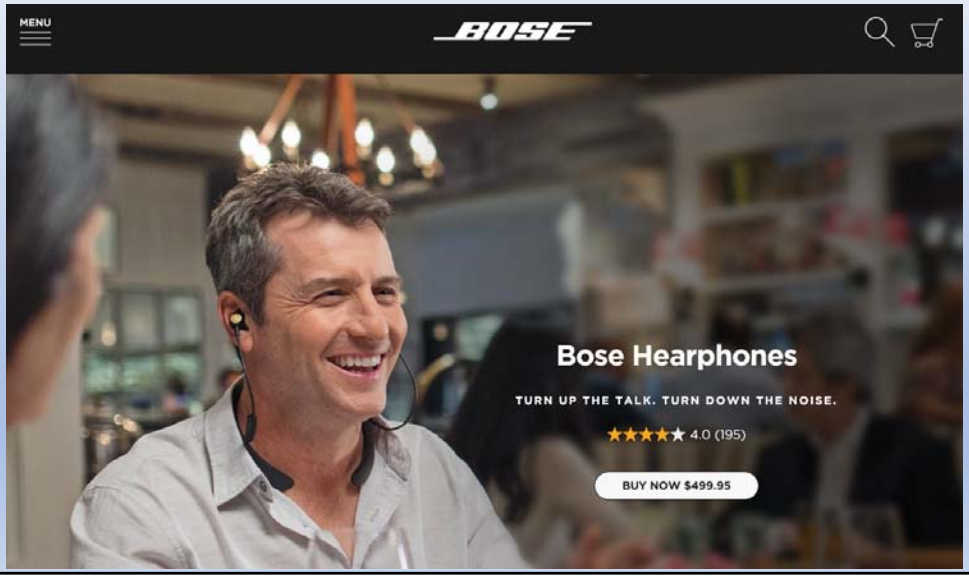


MarkeTrak 10

Bose

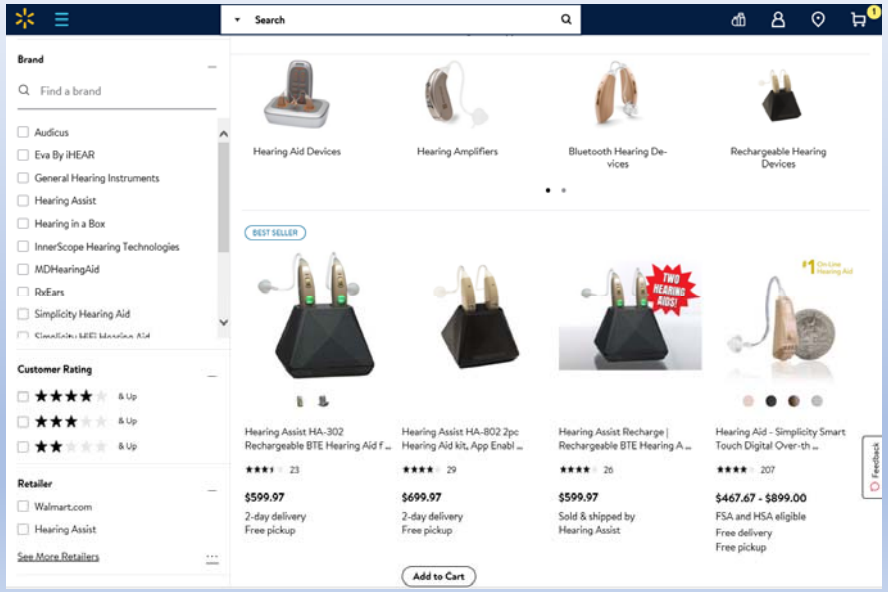
- While the new products aren't supposed to appear until 2020, one company, Massachusetts-based Bose Corp., got special approval from the FDA to sell its aid earlier, using the same process that allows promising and novel medical devices to get to the market quickly.
- Although there's not yet a release date or price, Bose's application gives an idea of what other OTC hearing aids may look like. The company's filing suggests its product may look more like a Bluetooth cellphone headset than a more familiar behind-the-ear or in-air amplifier. It would be similar to a product Bose already sells, called Hearphones, which retail for $499.95 and are marketed as a personal sound amplification product (PSAP), which is not considered a medical device.
- Bose's application shows a product worn around the neck with wires leading to earbuds. It's programmed through a smartphone and can be used to listen to music or talk on the phone. "It's kind of like a pair of reading glasses that hangs around your neck."

Bose

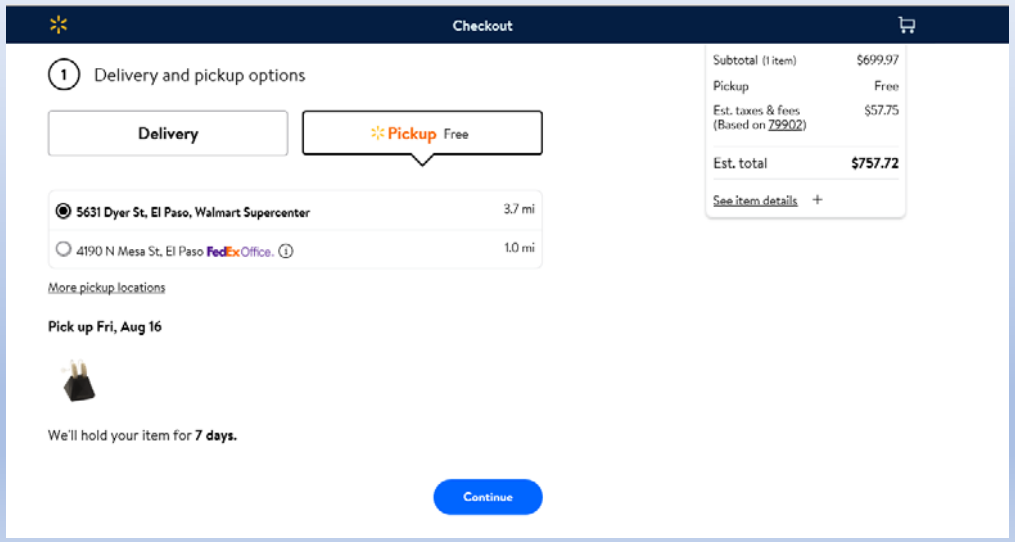


When will the OTC Hearing Aids Arrive?

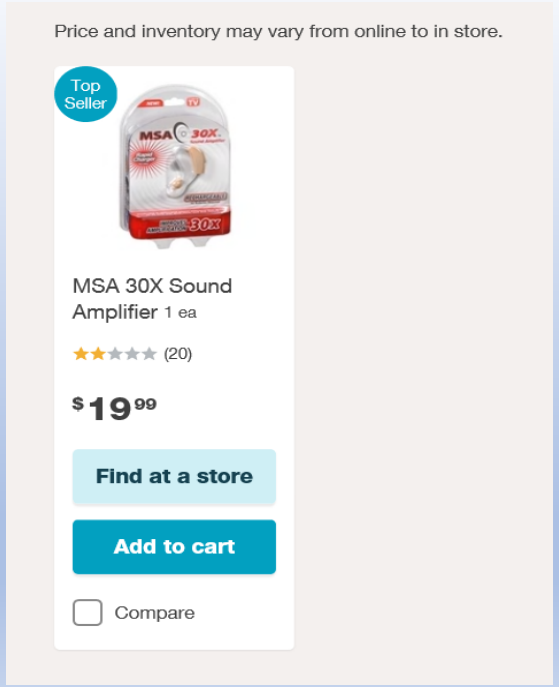
Walmart



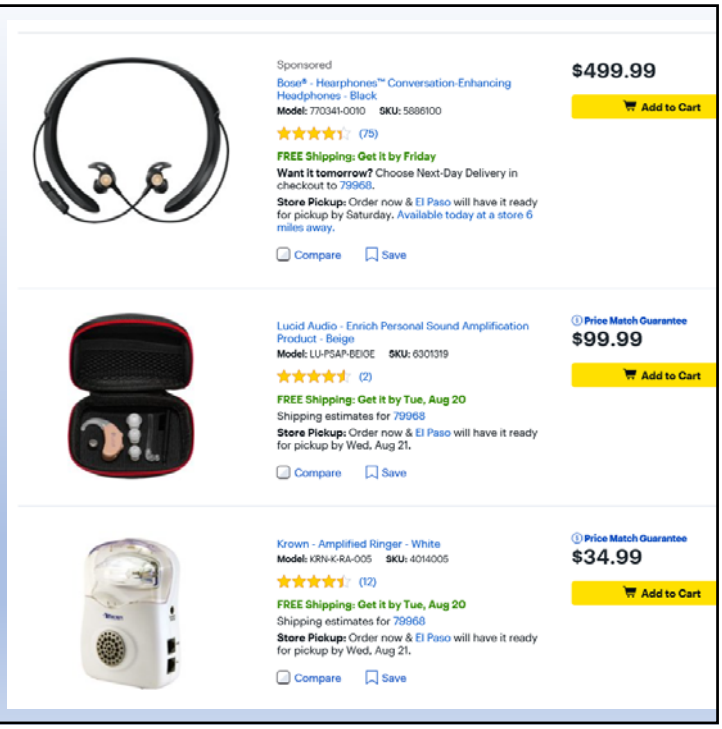
Walmart



Walgreens



Best Buy



Affect on Current Law and Rule

- Medical Waiver
  - Will likely be removed from the MDA.
  - States will need to accommodate this change.
- New Classification of hearing aid
  - Will existing Hearing Aid Dispensers and Audiologist sell these?
  - The sale of these devices will most likely be regulated by the FTC and FDA and not the States.
- Definition of hearing aid vs. labeled as hearing aid
  - Sales tax
  - Regulation of Audiologist and Dispensers

Effect on State Law

- No State or local government shall establish or continue in effect any law, regulation, order, or other requirement specifically related to hearing products that would restrict or interfere with the servicing, marketing, sale, dispensing, use, customer support, or distribution of over- the-counter hearing aids (as defined in section 520(q) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j), as amended by subsection (a)) through in-person transactions, by mail, or online, that is different from, in addition to, or otherwise not identical to, the regulations promulgated under this subsection, including any State or local requirement for the supervision, prescription, or other order, involvement, or intervention of a licensed person for consumers to access over-the-counter hearing aids.
  - (2017 FDARA)

Interesting Court Cases

•MISSOURI BOARD OF EXAMINERS FOR HEARING INSTRUMENT SPECIALISTS v. HEARING HELP EXPRESS INC

MISSOURI BOARD OF EXAMINERS FOR HEARING INSTRUMENT SPECIALISTS v. HEARING HELP EXPRESS INC

United States Court of Appeals, Eighth Circuit.
MISSOURI BOARD OF EXAMINERS FOR HEARING INSTRUMENT SPECIALISTS, Plaintiff-Appellee, v. HEARING HELP EXPRESS, INC., Defendant-Appellant.

No. 05-3313.
Decided: May 11, 2006

Interesting Court Cases

Smith v. Pingree

United States Court of Appeals, Fifth Circuit. Unit B
Jul 27, 1981
651 F.2d 1021 (5th Cir. 1981)

Interesting Court Cases

IN THE UNITED STATES DISTRICT COURT
OF THE EASTERN DISTRICT OF TEXAS
MARSHALL DIVISION

METX, LLC, ET AL.	§	
Plaintiffs	§	
	§	
V.	§	**No. 2:13CV547**
	§	
WAL-MART STORES TEXAS, LLC, ET AL.	§	

Interesting Texas AG Opinion

Tex. Att'y Gen. Op. No. GA-0525 (2007) -- Greg Abbott Administration

ATTORNEY GENERAL OF TEXAS
GREG ABBOTT

March 6, 2007

Mr. Ronald Ensweiler, President
State Committee of Examiners in the Fitting and Dispensing of Hearing Instruments
1100 West 49th Street
Austin, Texas 78756-3183

Opinion No. GA-0525

Re: Constitutionality of provisions of the Occupations Code, which prohibit the fitting and dispensing of hearing instruments ordered by mail by an unlicensed individual and the sale of a hearing instrument by mail (RQ-0524-GA)

The Truth About Preemption

A legal analysis of the federal and state laws governing the sale of hearing instruments in Texas and the effect (or non-effect) of the 2014 Walmart district court decision on these laws

THAA – April 2016

Conclusion:

Under federal law through the MDA and the implementing FDA regulations, any person can "sell" a hearing aid to any member of the consuming public as long as he complies with the labeling and condition of sale provisions in 21 CFR 801.420 and 801.421. These federal regulations neither require that a seller be licensed as a condition for sale nor prohibit an unlicensed person from engaging in the mere sale of a hearing aid.