Florida Academy of Audiology

FDA rule making on OTC: key topics and plan

- AUGUST 3, 2018

Several events shaped the discussion around OTC hearing aids over the past ~3 years

Oct 2015

President's Council of Advisors on Sciences and Technology (PCAST)

Report on "Aging America & Hearing Loss: Imperative of Improved Hearing Technologies"

Apr 2016

Food and Drug Administration (FDA)

Public workshop "Streamlining Regulations for Good Manufacturing Practices (GMPs) for Hearing Aids"

Jun 2016

The National Academies of Sciences (NASEM)

Report on "Accessible and Affordable Hearing Health Care for Adults"

Dec 2016

Sens. Warren and Grassley

Introduced Bill S.09 titled "Over-the-Counter Hearing Aid Act of 2016"

Dec 2016

The National Academies of Sciences (NASEM)

Dissemination Meeting. FDA announces "Conditions for Sale for Air-Conduction Hearing Aids"

Jan 2017

Federal Trade Commission (FTC)

Announced a public workshop to be held on Apr 18, 2017

Mar 2017

Sens. Warren, Hassan, Grassley, Isakson Reps. Kennedy, Blackburn, Carter

Introduced Bill S.670 in the Senate and H.R. 1652, both titled "Over the Counter Hearing Aid Act of 2017"

Eventually attached to FDARA 2017 and signed into law on Aug 03rd, 2017

August 2017

President Donald J. Trump

Signed into law the Food and Drug Administration Reauthorization Act of 2017

Legislation that included the *Over the Counter Hearing Aid Act of 2017*

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1. The FDA is required by law to create a new category for **OTC hearing aids.**
2. Designed to provide greater public accessibility and affordability
3. Designed to enable adults with perceived mild-to-moderate hearing loss to access OTC hearing aids without being seen by a hearing care professional.
4. Set **safety and effectiveness standards** for the devices.
5. Ensure they meet the same high standards for safety, consumer labeling, and manufacturing protection that all other medical devices must meet
6. FDA has 3 years from the passage of the bill (August 2017) to finalize a rule.

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Time Table

1. FDA publishes in the Federal Register twice per year their agenda for the next six months.
2. June 2018 FDA agenda did not list the draft OTC regulation
3. Next published agenda will be late December – early January 2019.
3. FDA will publish a Ruling Proposal and seek comment from all stake holders. There is a 180 day time period required by law for the comment period.
4. FDA would then release the final rule sometime between the end of the 180 day time period or the 3 year date from passage of the legislation which would be August 2020.
5. Earliest date Fall 2019; Latest late 2020

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So, What is Happening

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Build a stronger alliance across the Industry

- September 2017
  - Post-Mortem of what took place demonstrated that the CTA was united in purpose and message
  - The various hearing care associations were all splintered, there was not a unified message from the hearing sector
  - OTC is a reality, we need to work together to develop standards to recommend to the FDA. CTA had already put together their recommendations
- September – October 2017 the Hearing Associations Working Group was formed
  - AAA, ADA, ASHA and IHS leadership selected two individuals from each organization to represent their association. AAO-HNS and HIA were also invited but declined the invitation to participate.
- Working Group Goals
  - Definition of common interests and common position papers
  - for current, potential and desired changes in the regulatory landscape
  - both passively (mitigate risk) and proactively (create opportunity)
  - with an aligned & integrated stakeholder engagement approach
  - and an agreed redline response (if applicable)
  - *(share opportunities, lobby resources, market intelligence related to regulatory activities)*

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Progress

- **November 2017 – First Working Group Meeting**
  - Agreement on specific concerns regarding currently proposed OTC FDA-standards
  - Agreement on modus operandi for the meetings
  - Aggregation of member associations positions
  - Definition of a common position and supporting evidence
  - Agreement on an aligned & integrated stakeholder engagement approach (plan & network)
  - Proposal for an agreed recommendation to the FDA
  - No one walk out of the meeting

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Current Status

- **January 2017 CTA released "*CTA Standard 2015: Personal Sound Amplification Performance Criteria*"**
- **The Working Group has met 4 times formally**
  - The group unitedly established proposed OTC product specifications, standards and labeling requirements
  - Develop and draft a Consensus Paper that would contain the above, which would be evidence based
  - Ensure **Safe and Effective** standards while allowing for **Affordability and Accessibility.**
- **Today – August 3rd**
  - The Consensus Paper is complete and being approved by the boards of AAA, ADA, ASHA, and IHS
  - The Consensus Paper is approximately 30 pages in length
  - We hope to have all board approvals early next week
  - The Consensus Paper will be published first electronically by all associations simultaneously mid-August
  - HIA Board has reviewed the Consensus Paper and has given their unanimous approval

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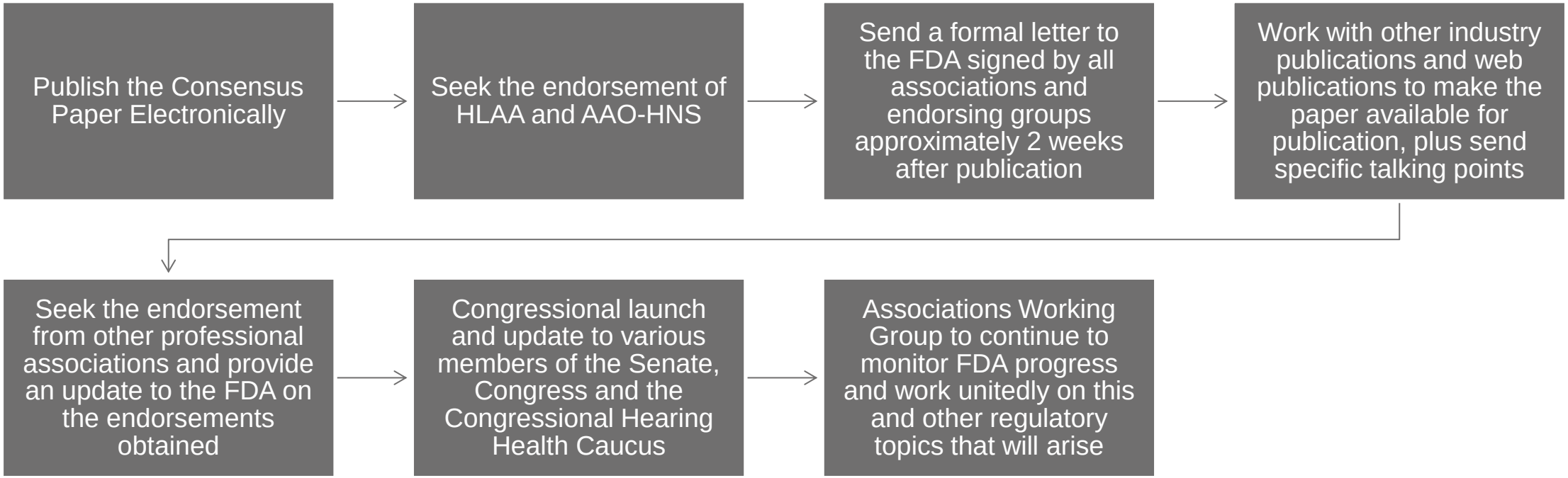
Plan



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Questions