HHP California

Over the Counter Hearing Aids:

A deeper dive into the OTC Hearing Aid Act of 2017

Michael Scholl

Director of Government and Community Relations

Hear better. Live better.

Director of Government and Community Relations

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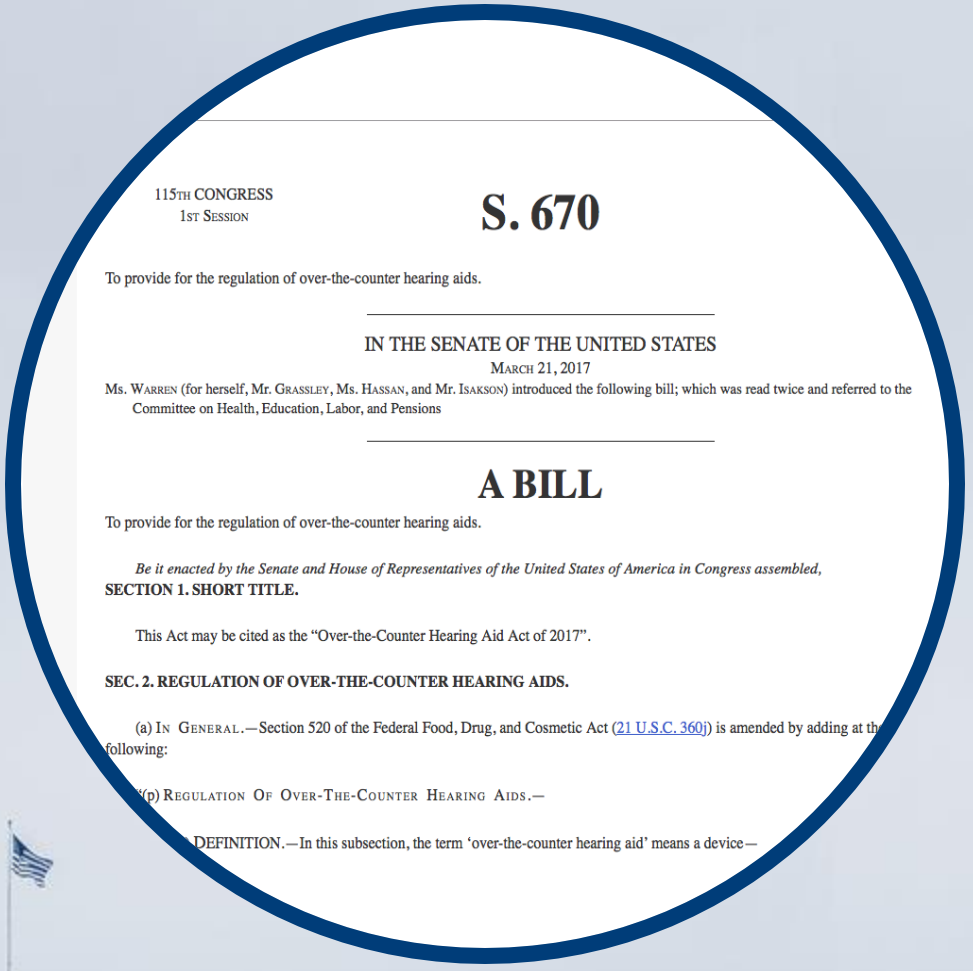
OTC Legislation

2009 – NIH Workgroup to identify research needs for increased accessibility and affordability.
2015 – PCAST Study
2016 – NASEM meeting to discuss strategies to address accessibility and affordability.



115TH CONGRESS
1ST SESSION

S. 670

To provide for the regulation of over-the-counter hearing aids.

IN THE SENATE OF THE UNITED STATES
MARCH 21, 2017

Ms. WARREN (for herself, Mr. GRASSLEY, Ms. HASSAN, and Mr. ISAKSON) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

A BILL

To provide for the regulation of over-the-counter hearing aids.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the "Over-the-Counter Hearing Aid Act of 2017".

SEC. 2. REGULATION OF OVER-THE-COUNTER HEARING AIDS.

(a) IN GENERAL.—Section 520 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j) is amended by adding at th following:

"(p) REGULATION OF OVER-THE-COUNTER HEARING AIDS.—

DEFINITION.—In this subsection, the term 'over-the-counter hearing aid' means a device—

OTC Legislation

July 12, 2017
Passed the House of Representatives

Aug. 3, 2017
Passed the Senate

Aug. 18, 2017
Signed into law by the president

Definition of OTC Hearing aid

"Over-the-counter hearing aid" - a device that:

- Uses same technology as air conduction or wireless air conduction hearing aids;
- Is intended to be used by adults over the age of 18 to compensate for perceived **mild to moderate** hearing impairment;
- 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;
- May use wireless technology;
- May include tests for **self-assessment** of hearing loss; and
- Is available over-the-counter, without the supervision, prescription, or other order, involvement, or intervention of a licensed person to consumer through in-person transactions by mail or online.

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Concessions from congress

- Stronger labeling requirements to include information on how consumers may report adverse events, or symptoms of medically treatable causes of hearing loss
- Requirements that the FDA should consult with relevant stakeholders, including hearing aid manufacturers, licensed hearing professionals, patients, and others, during the rulemaking process
- No later than two years after the FDA regulations are finalized, a report issued by the Secretary of Health and Human Services analyzing the impact of over-the-counter hearing aids

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Regulations of OTC Hearing Aids

- 3 years to promulgate proposed regulations
- Public comment period (generally 60 days)
- 180 days after public comment period, issue final regulations
- April 19, 2021

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Regulations by the FDA

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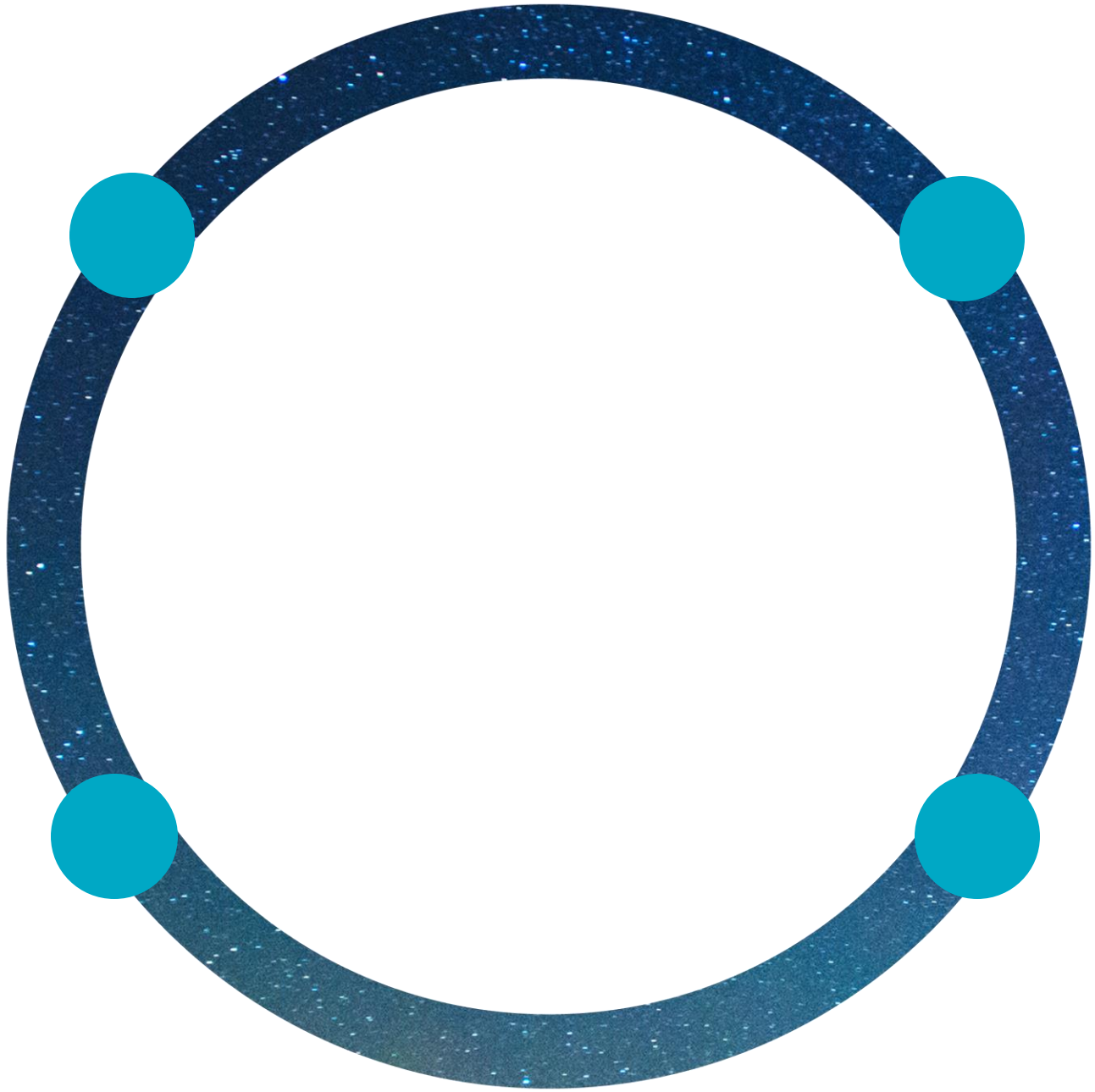
Requirements for Sale

Safety and Efficacy



Labeling

Output Limits

Requirements for Sale

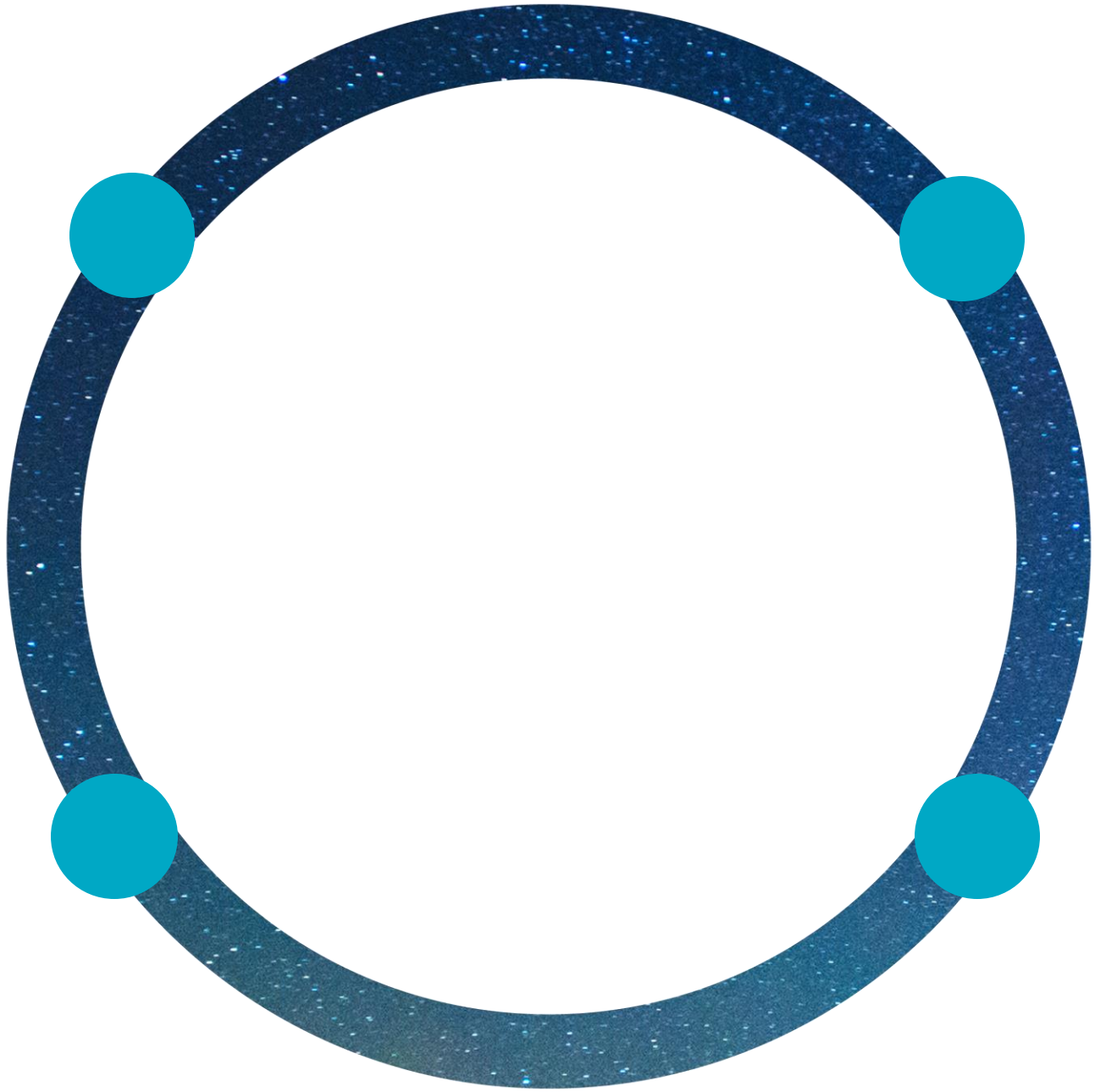
Safety and Efficacy

Labeling

Output Limits

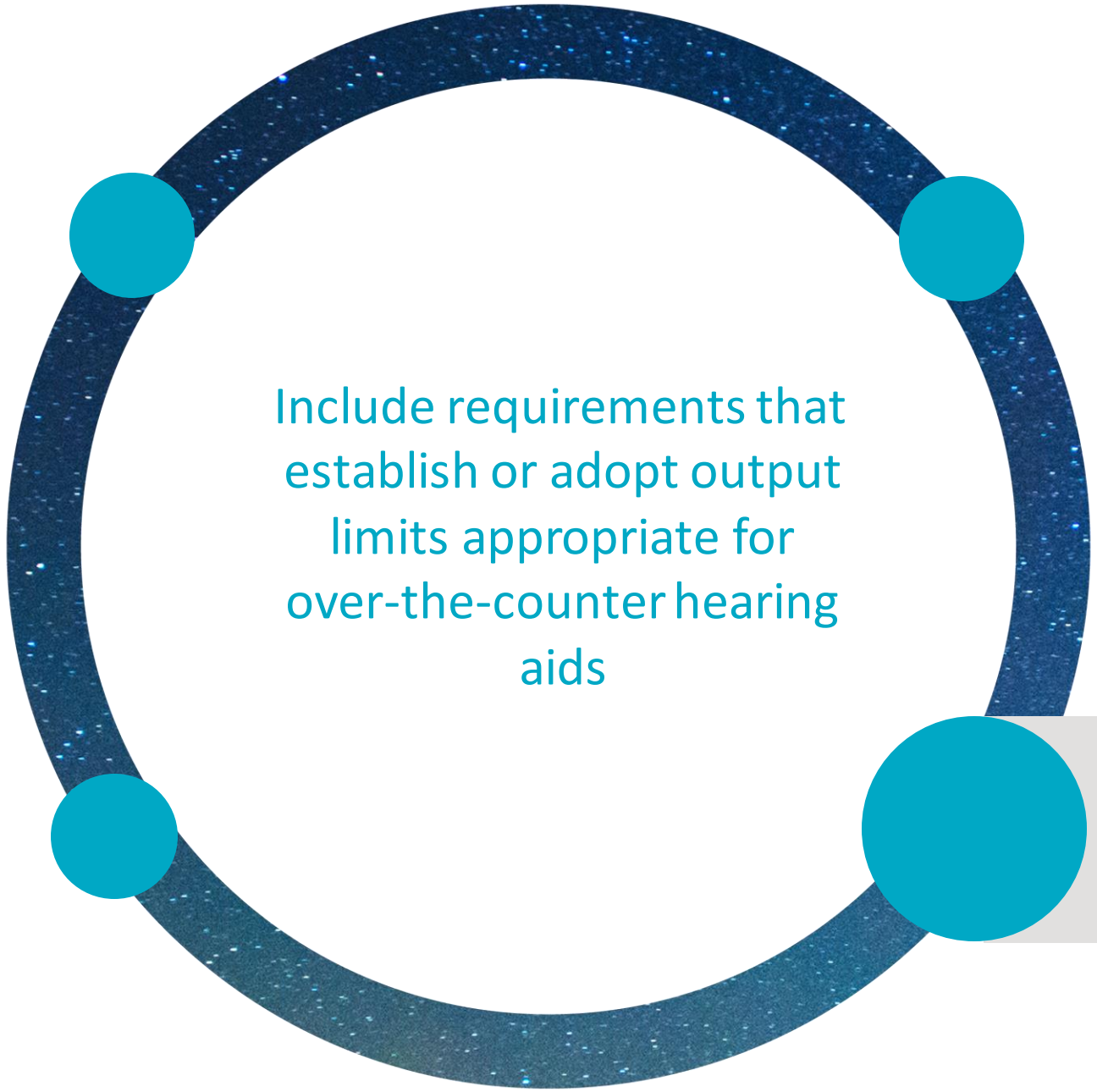
Requirements for Sale

Safety and Efficacy



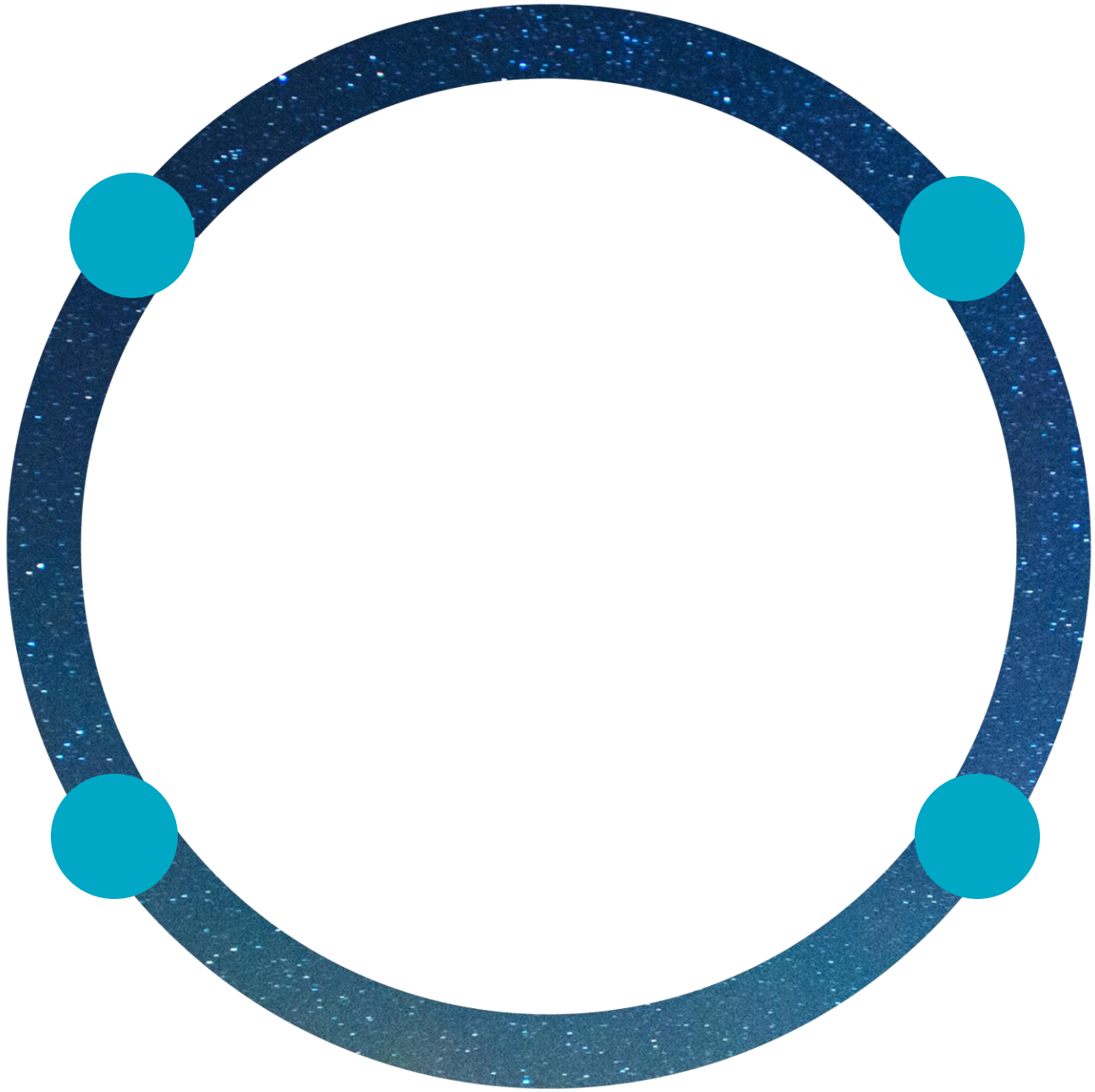
Labeling

Output Limits


Requirements for Sale
Safety and Efficacy
Include requirements that establish or adopt output limits appropriate for over-the-counter hearing aids
Labeling
Output Limits

Requirements for Sale

Safety and Efficacy



Labeling

Output Limits

Requirements for Sale

Safety and Efficacy

Labeling

Output Limits

Requirements for Sale

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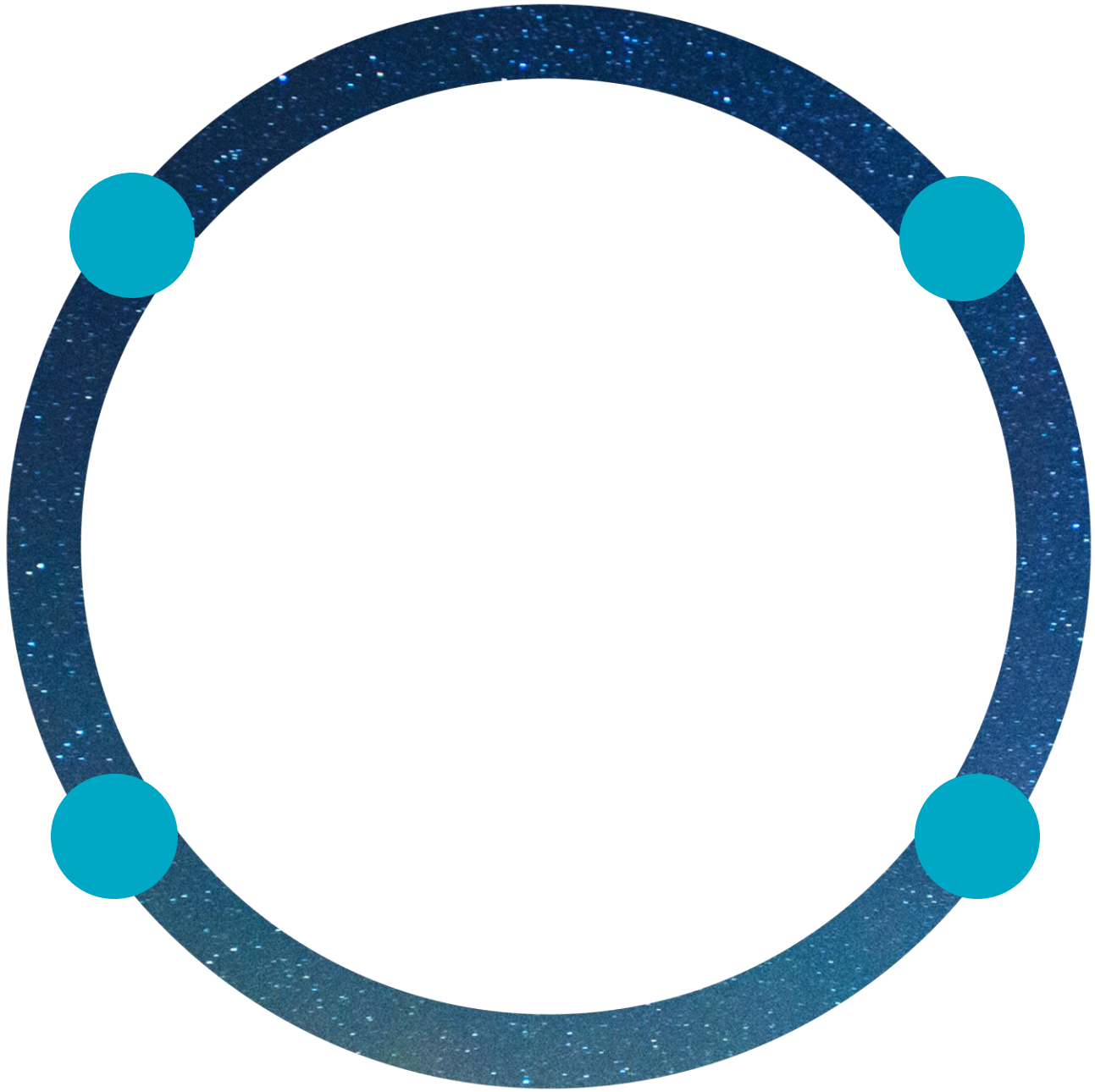
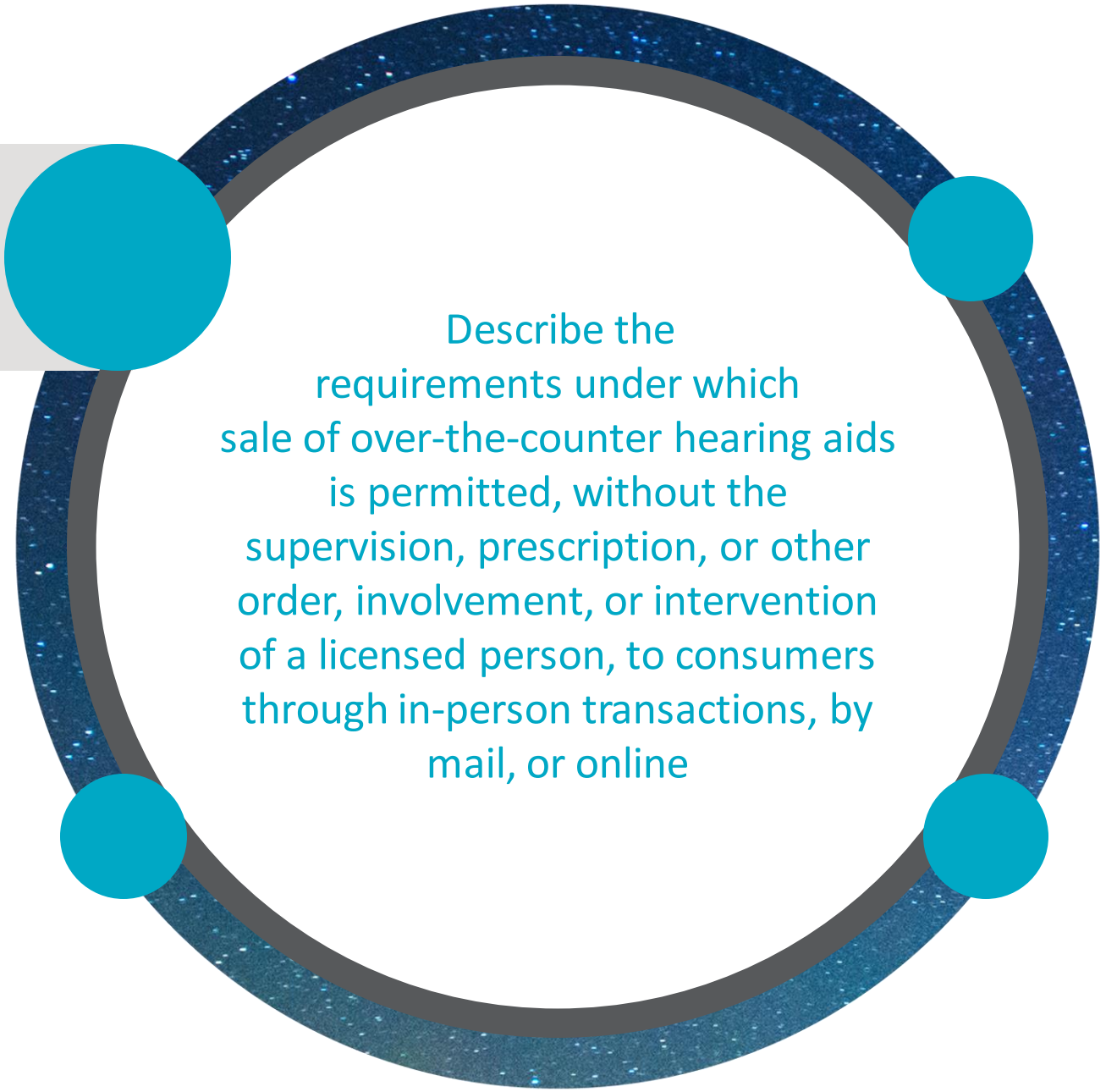


Labeling

Output Limits


Requirements for Sale
Safety and Efficacy
Describe the requirements under which sale of over-the-counter hearing aids is permitted, without the supervision, prescription, or other order, involvement, or intervention of a licensed person, to consumers through in-person transactions, by mail, or online
Labeling
Output Limits

Other TBD by fda

- Premarket notification
  - Will the FDA make OTC devices 510(k) exempt?

- PSAP Guidance
  - FDA to update and finalize 2013 draft guidance titled, “Regulatory Requirements for Hearing Aid Devices and Personal Sound Amplification Products.”

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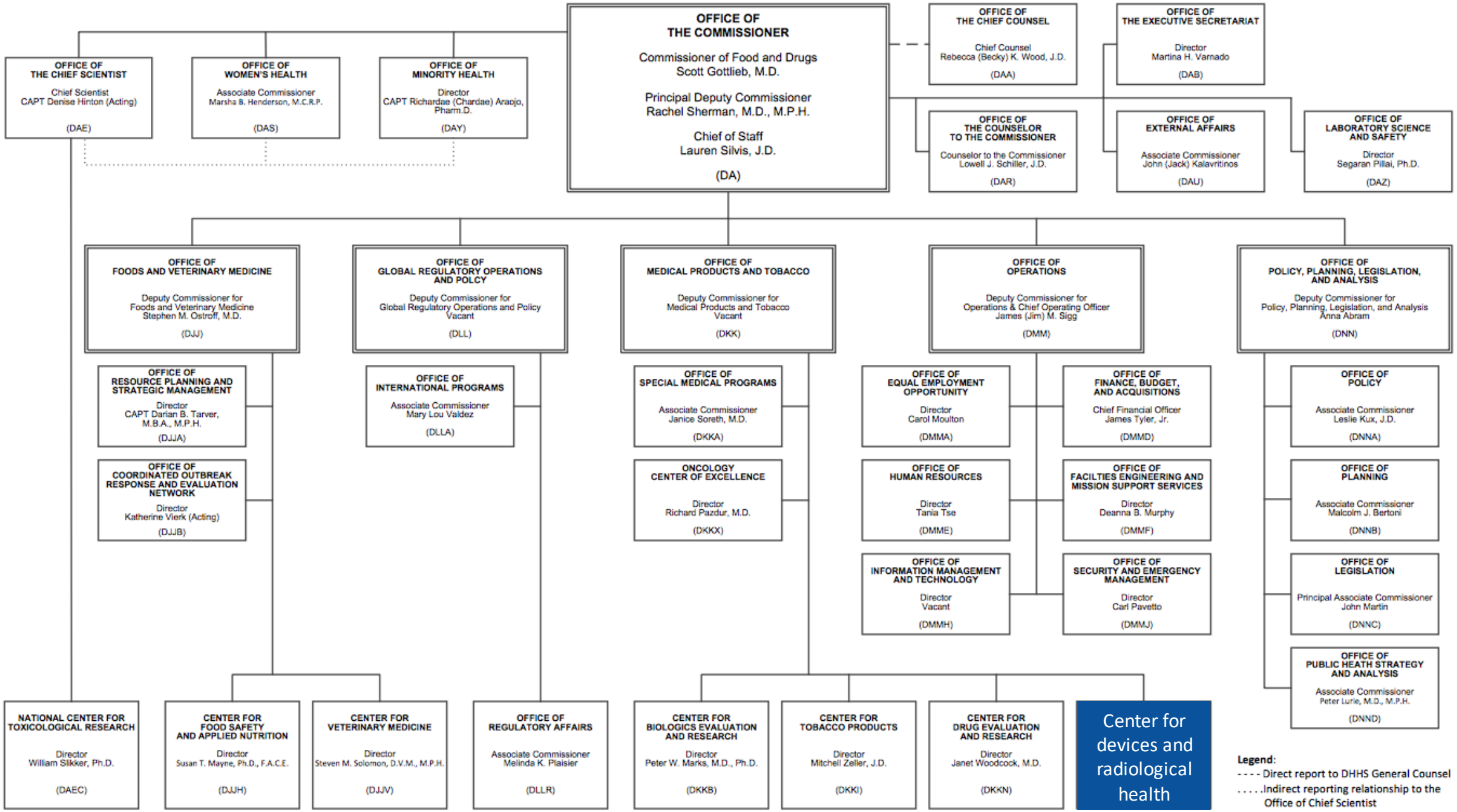
FOOD AND DRUG ADMINISTRATION

Approved by the FDA Reorganization Coordinator & Principal Delegation Control Officer
25 September 2017



The decision makers at the FDA

Jeffery Shuren, Director for Devices and Radiological Health (CDRH)

Dr. Srinivas “Nandu” Nandkumar, Branch Chief for ENT

- How to stay in touch with FDA:
- https://www.fda.gov/RegulatoryInformation/Dockets/Comments/default.htm

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Thank you

Hear better. Live better.

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