Introduction to Essential Principles: Good Regulatory Practices

Kristan Callahan
Senior Public Health Advisor
Office of Trade and Global Partnerships

September 11, 2024

Internationally recognized processes and procedures that improve the quality and cost-effectiveness of domestic regulations

In the United States, GRPs include principles and procedures that address:

- Intragovernmental coordination of rulemaking activity
- Impact assessment
- Regulatory transparency
- Stakeholder outreach and engagement
- Accountability

Benefits of Good Regulatory Practices

- Support transparency, accountability, confidence, and trust in the rulemaking process
- Produce a better regulation by allowing those affected to provide input to improve clarity of regulatory requirements and avoid unintended consequences
- Provide regulators with data and information to inform rulemaking
- Promote an understanding of how regulatory actions can have impacts beyond a country's borders

Rulemaking Process and Public Consultation

Rulemaking Process

1. Consider initiating events
2. Decide whether public notice is needed
3. Develop proposed rule
4. Send proposed rule for review
5. Publish proposed rule
6. Analyze public comments
7. Develop final rule
8. Send final rule for review
9. Publish final rule

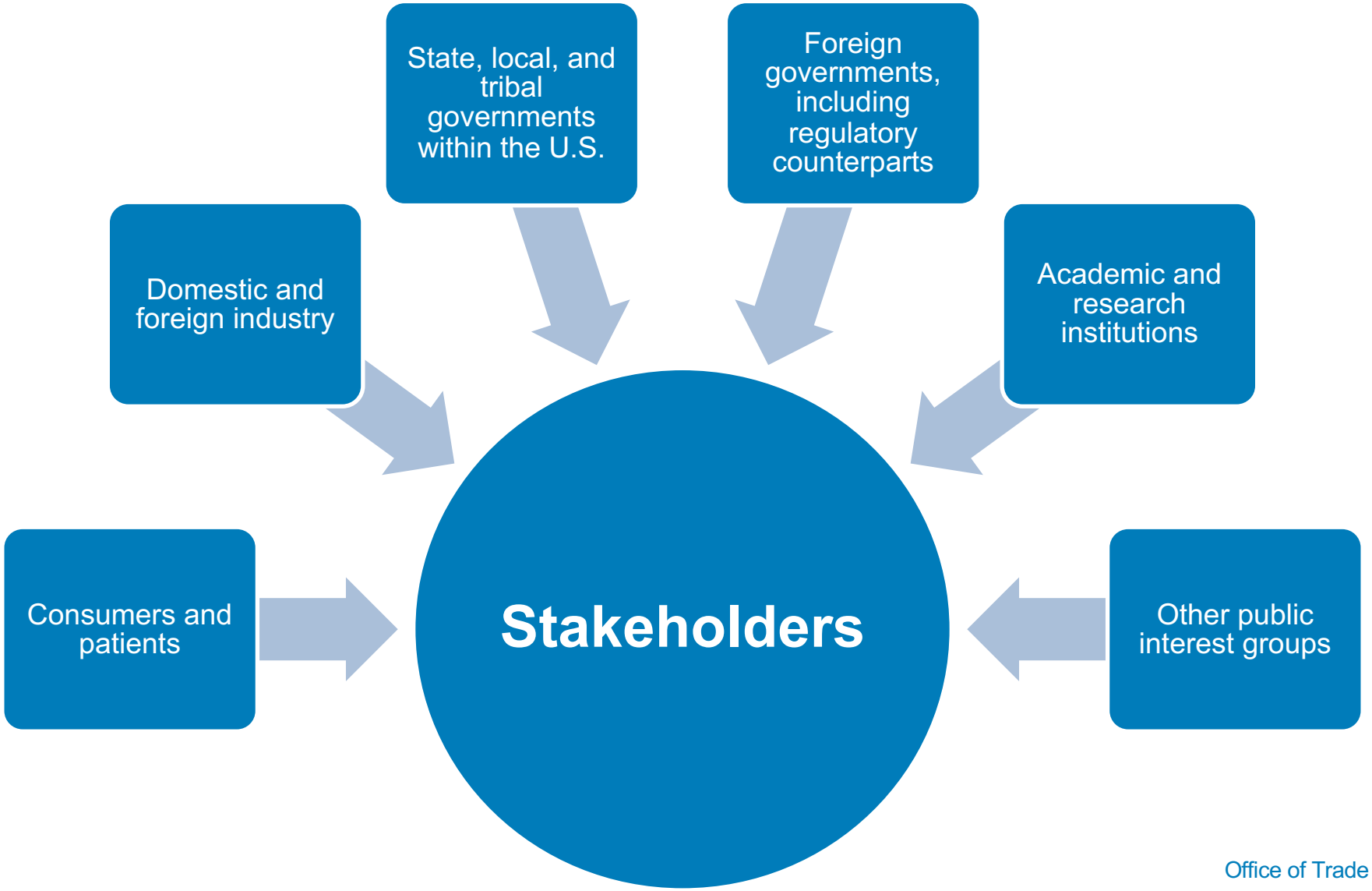
https://www.reginfo.gov/public/reginfo/Regmap/REG_MAP_2020.pdf

Developing a Draft Regulation

FDA may draw on many sources of information and input when developing a regulation, including:

- Scientific literature and data analysis
- Surveys and pilot studies
- Advisory committees
- Requests for Information (RFIs)
- Listening sessions and public meetings
- Participation in international initiatives and dialogue
- Considering scientific and voluntary consensus standards

Who are Stakeholders?



Notice and Comment (Public Consultation)

Use of dockets:

- Dockets available at regulations.gov
- Repository for all public comments received

FDA may also:

- Alert the appropriate U.S. point of contact to notify the corresponding WTO committee
- Extend comment period (case-by-case basis)

Analyzing Public Comments

FDA reviews every comment filed during the comment period by the following:

- Collecting all comments received
- Organizing comments, consolidating form letters and duplicates, and identifying out-of-scope comments
- Identifying substantive issues and categorizing comments by topic
- Preparing high-level summaries of comments (including specific data or recommendations)
- Discussing and preparing detailed responses
- After considering substantive comments, drafting the final rule and clearly referencing any changes within comment response

Establishing Over-the-Counter Hearing Aids

Over-the-Counter (OTC) Hearing Aid Regulation

In 2021, FDA proposed multiple regulatory changes, including proposing requirements for OTC hearing aids.

Steps to initiate an update to the hearing aid regulatory framework included:

- 2015 report by President's Council of Advisors on Science and Technology
- 2016 study, co-sponsored by FDA, on "Hearing Health Care for Adults"
- 2016 public workshop on "Streamlining Regulations for Good Manufacturing Practices for Hearing Aids"

https://www.federalregister.gov/documents/2022/08/17/2022-17230/medical-devices-ear-nose-and-throat-devices-establishing-over-the-counter-hearing-aids

Proposed Regulation	Final Regulation
Labeling warnings referred to “ear specialist”	Revised labeling to refer to “ear-nose-throat doctor” and “ENT”
Maximum output level of 115 decibel (dB) sound pressure level (SPL)	Finalized a lower output limit of 111 dB SPL

https://www.federalregister.gov/documents/2022/08/17/2022-17230/medical-devices-ear-nose-and-throat-devices-establishing-over-the-counter-hearing-aids

Proposed Regulation	Final Regulation
Expected battery life required on labeling inside the package	Maintained requirement because information will help prospective consumers Clarified that we did not propose, and are not requiring, a specific method to estimate battery life
No limit on gain (how much the device amplifies or reduces the input)	Did not propose, and did not finalize, a separate gain limit: Imposing a gain limit may constrain device design and innovation, which could have an undesirable effect on device benefit for intended users. By not requiring a gain limit, the broadest range of intended users will have access to effective devices.

https://www.federalregister.gov/documents/2022/08/17/2022-17230/medical-devices-ear-nose-and-throat-devices-establishing-over-the-counter-hearing-aids

Using Information and Stakeholder Input

- High-quality information early in the regulation development process and through public comments support better regulations.

- Maintaining a consistent approach in addressing public comments can provide certainty to stakeholders as well as contribute to transparency in FDA's decision-making.