

# Good Regulatory Practices: A Regulator's Perspective

FDA Office of Global Policy and Strategy (OGPS),  
Office of Trade and Global Partnerships (OTGP)

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# Good Regulatory Practices (GRPs)

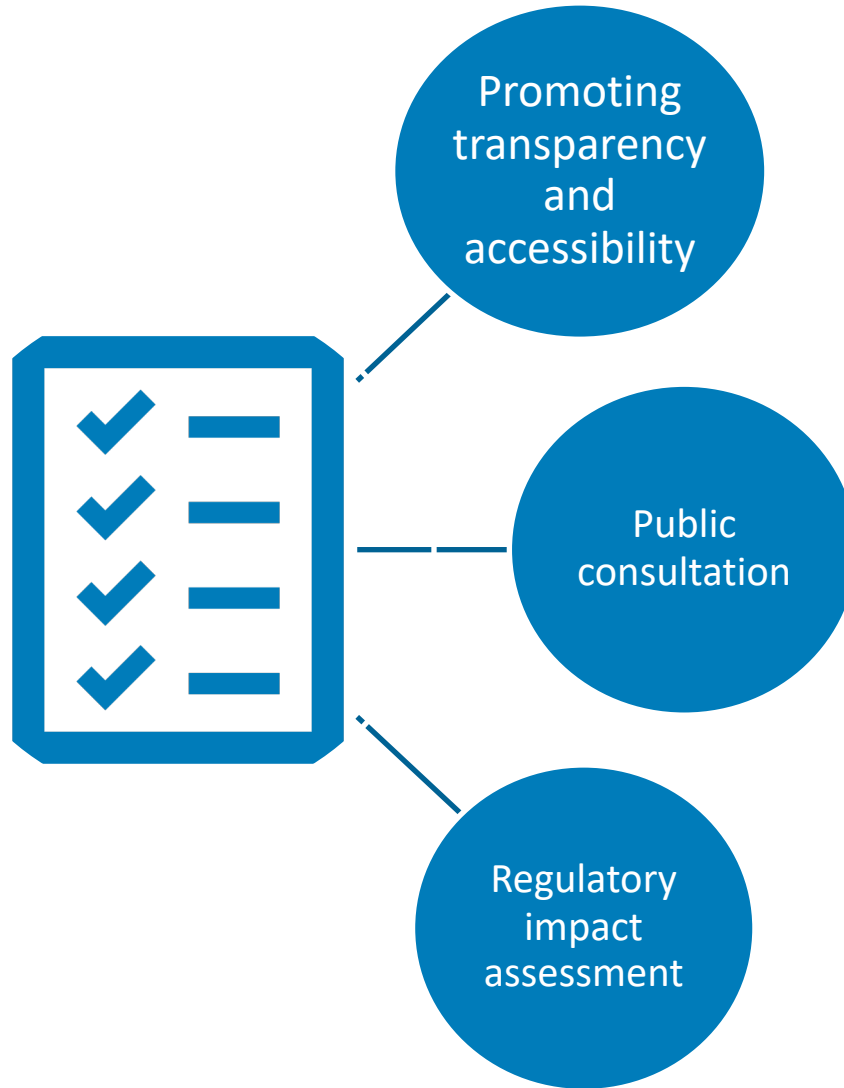
Internationally-recognized processes and procedures that improve the quality and cost-effectiveness of domestic regulations

GRPs guide regulatory authorities in:

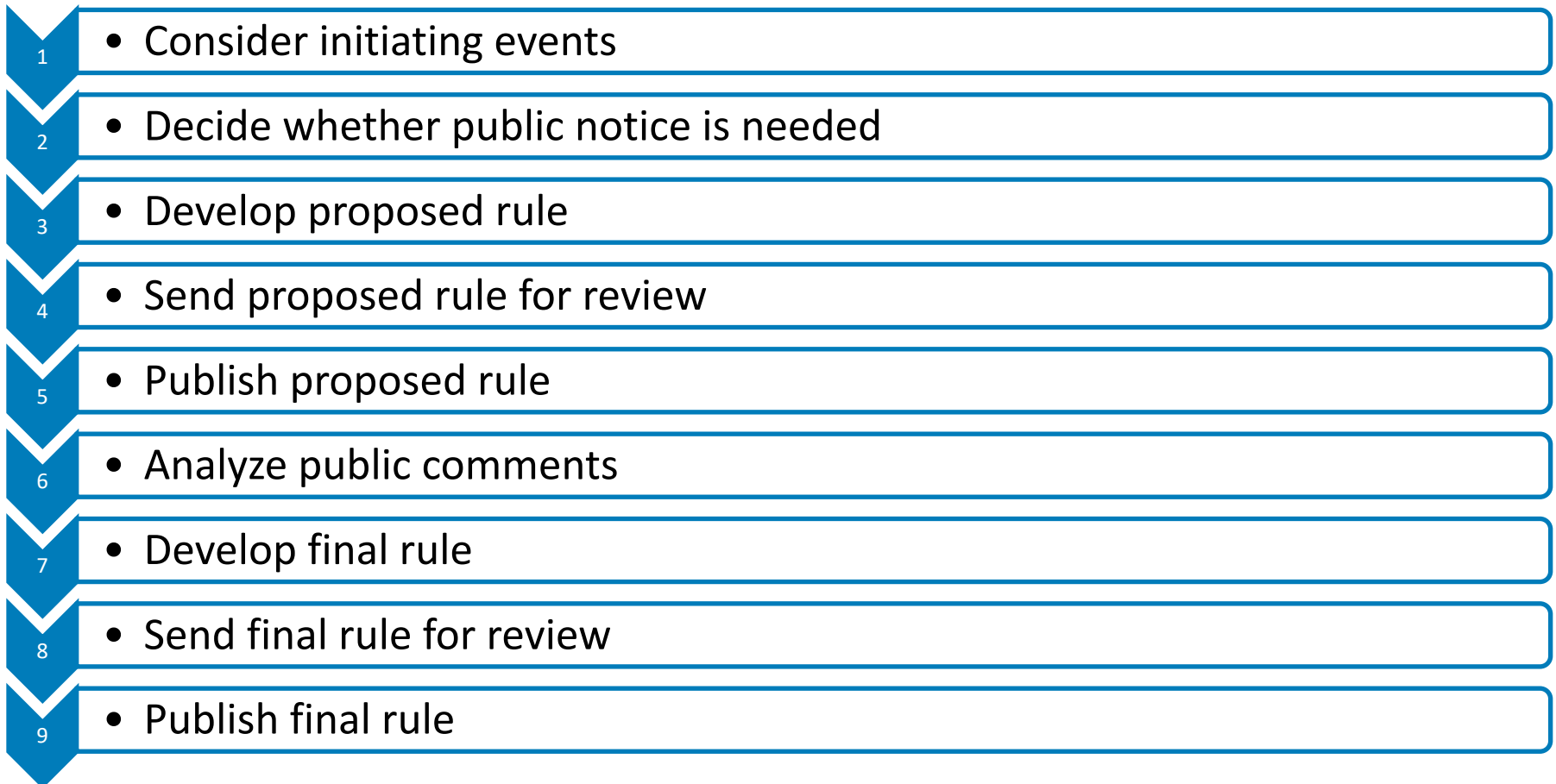
- Setting appropriate regulatory requirements
- Formulating decisions that are clear, transparent, consistent, timely, and based on sound science

# GRPs at FDA

Three general principles for the use of GRPs in the rulemaking process include the following:



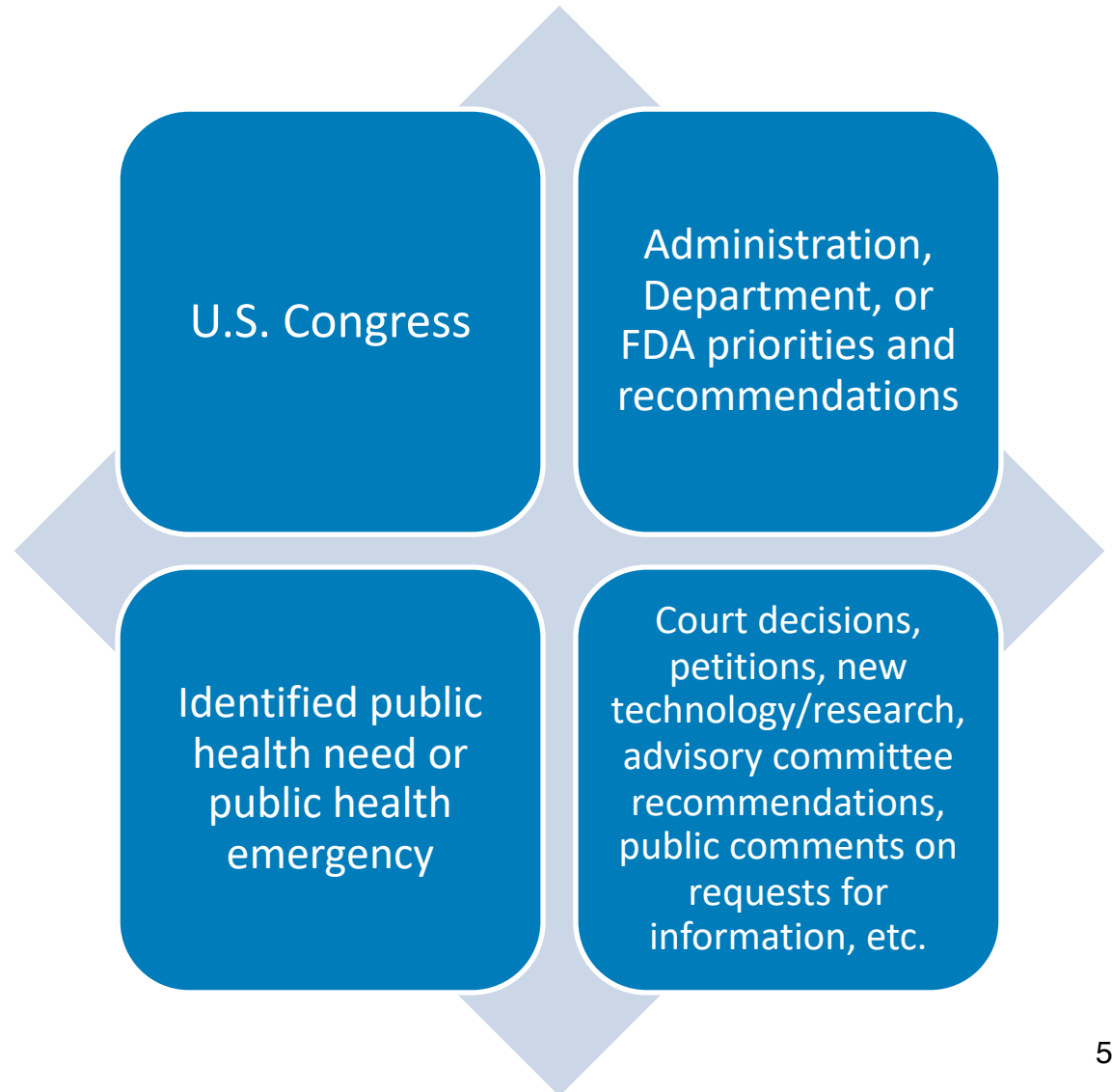
# Rulemaking Process



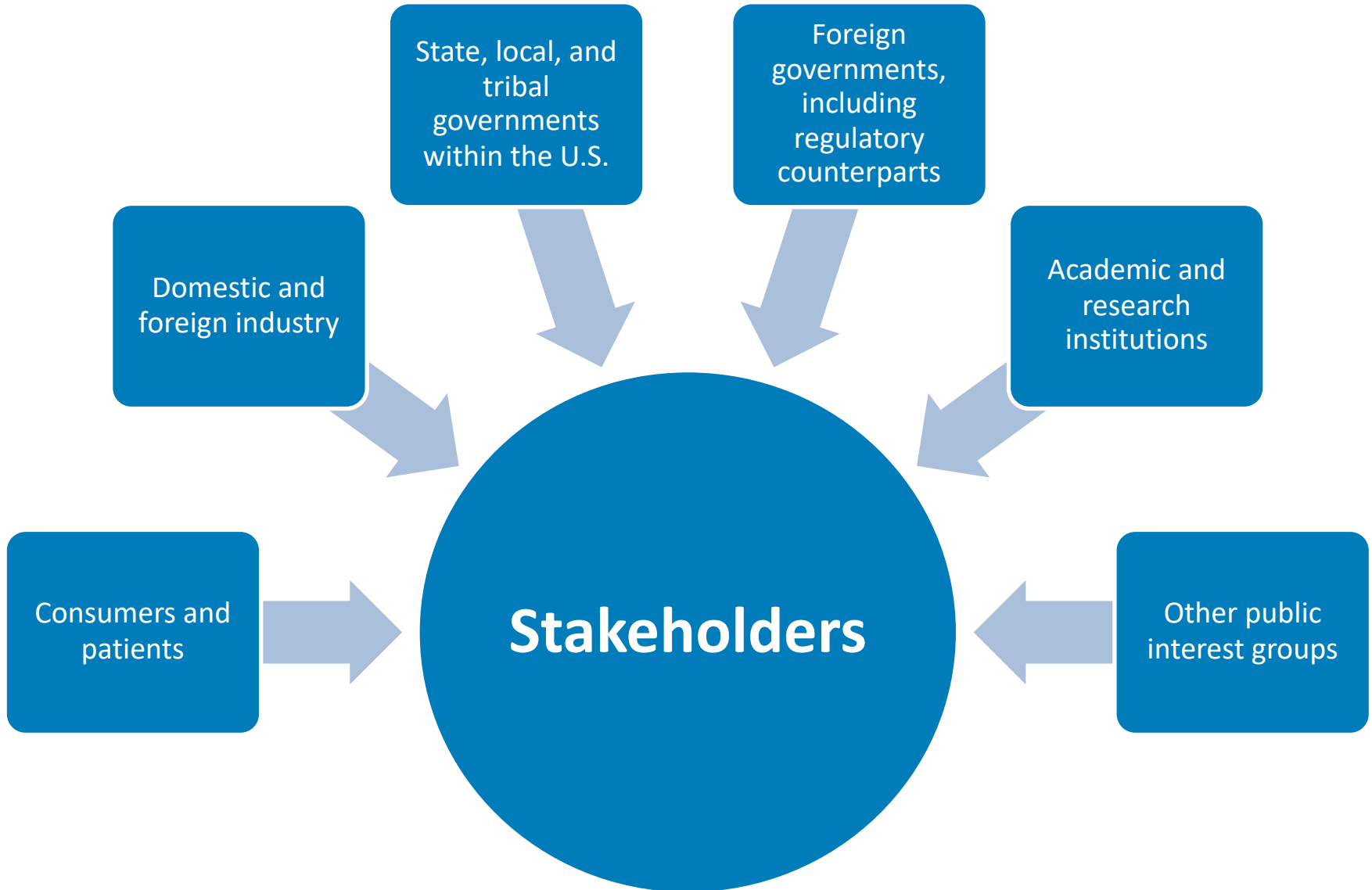
# Identifying Regulatory Priorities



New rules can arise from multiple sources, including:



# Who are stakeholders?



# Why seek input?

Regulators benefit from public participation in important ways.

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

# Developing a Draft Regulation

FDA promotes transparency and facilitates public participation in a variety of ways, as applicable:

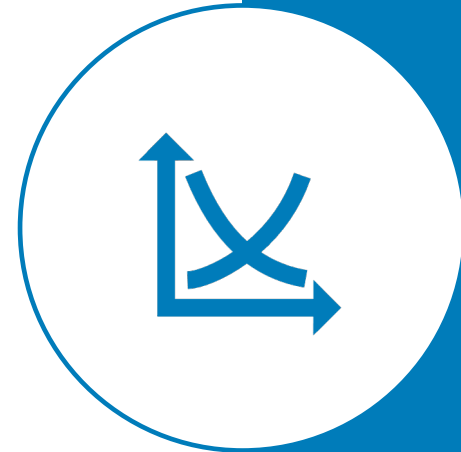
- Holding listening sessions and public meetings or public workshop
- Opening a docket on [regulations.gov](https://www.regulations.gov) for comments on specific topics
- Seeking information, data, or alternatives via an Advanced Notice of Proposed Rulemaking (ANPRM)
- Maintaining an updated agenda of the Agency's upcoming rulemakings ([FDA-TRACK](#))
- Consulting with advisory committees
- Considering scientific and voluntary [consensus standards](#)
- Abiding by the principles of [plain language](#)





# Benefits of Conducting RIA

- To understand the impacts of draft regulations, FDA conducts regulatory impact analyses (RIAs) when applicable.
- The RIA:
  - Provides an objective, unbiased assessment that is an essential component of policy development
  - Considers both qualitative and quantitative impacts
  - Can inform policy decisions



# Why conduct RIAs?

There are important benefits to regulators from well-conducted RIAs, including:



Indicating whether regulation is necessary and justified to achieve a social goal



Identifying the regulatory option that provides the largest net benefits to society



Providing comprehensive consideration of impacts and avoiding unintended consequences

The [OECD has developed best practice principles for RIAs](#), and different countries make different determinations about the use of RIAs in the development of regulations.

# Why conduct RIAs?

## Executive Order (EO) 12866 on Regulatory Planning and Review:

- Regulatory philosophy and principles related to when agencies should promulgate regulations and what agencies should consider in developing regulations.
- An agency must identify the nature and assess the significance of the problem it intends to address as well as possible alternative solutions to address the problem; and, where possible, select approaches that maximize net benefits to society.

# Reviewing a Draft Regulation



Draft regulations are subject to an intensive review process.



The Office of Management and Budget (OMB) coordinates interagency review of significant and economically significant rules.



[Reginfo.gov](https://www.reginfo.gov) provides information on regulatory actions currently under 12866 review.



Stakeholders may request [12866 meetings](#) with OIRA to discuss a rule under review.

# Notice and Comment (Public Consultation)

## After OMB review, FDA will:

- Publish the draft regulation in the Federal Register
- Open a docket at [regulations.gov](https://www.regulations.gov)

## FDA may also:

- Alert the appropriate U.S. point of contact to notify the corresponding WTO committee
- Extend comment period (case-by-case basis)
- Hold listening sessions, public meetings, or public workshops to support commenting process

# Analyzing Public Comments

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

- Gathering comments by unique identifier and commenter
- Consolidating form, duplicate, and out-of-scope comments
- Identifying 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





# Issuing a Final Rule

- FDA responds to comments received during the comment period that are within the scope of the rulemaking.
- OMB reviews significant final regulations and coordinates interagency comments and feedback.
- After internal and external feedback is evaluated and addressed, FDA publishes the final rule in the Federal Register and its effective date.
- FDA will periodically review the effectiveness of the rule.

# GRPs at FDA

These best practices are foundational to developing regulations that protect and promote public health.

