The FDA & Regulation

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Important notice (continued)

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Agenda

1. TOBACCO REGULATION BACKGROUND
2. DEEMING REGULATION OVERVIEW
3. COMPREHENSIVE APPROACH TO NICOTINE AND TOBACCO
4. CLOSING REMARKS


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FDA regulation history

1938

Food, Drug, and Cosmetic Act signed into law by Franklin D. Roosevelt

1938

1996

FDA asserted jurisdiction to regulate tobacco products

March 21, 2000

The Supreme Court struck down FDA's attempts to regulate tobacco products

May 16, 2000

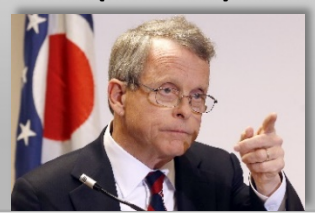
Senator Ted Kennedy introduced the Youth Smoking Prevention and Public Health Protection Act

2002

Senator Kennedy again introduced the Youth Smoking Prevention and Public Health Protection Act

2004

Senator Mike DeWine introduced the Family Smoking Prevention and Tobacco Control Act (FSPTCA)



2005

Senator DeWine again introduced the FSPTCA

February 15, 2007

Representative Waxman introduced the FSPTCA

June 22, 2009

FSPTCA was signed into law

2010

FDA's regulation of tobacco products

FDA Center for Tobacco Products

- Will maximise its statutory reach and enforcement discretion until it decides how to regulate
- Can not ban any tobacco product category
- Can not reduce nicotine levels to zero

Different from other Centers within FDA

- Funded 100% by user fees
- Does not "approve" products
- Appropriate for public health (population health standard) vs. safe and effective
- Variety of enforcement tools

Submission types

		Estimated Timing
Exemption Requests (EX)	"Minor" modifications (tobacco additives only)	60 Days
Product Quantity Change SE (PQCSE)	Changes to product quantity	90 Days
Substantial Equivalence (SE)	Products either have the same characteristics as those marketed on/before February 15, 2007 or have different characteristics but do not raise different questions of public health	90 Days (Regular SE)
Pre-Market Tobacco Application (PMTA)	Products that do not meet criteria for either SE or SE Exemption	180 Days
Modified Risk Tobacco Product Application (MRTPA)	Authorisation to market as reduced harm or reduced risk	360 Days

FDA Product Submissions

Examples of some of our NGP Product Submissions

	Camel – Snus	Eclipse	glo		Other products
PROCESS	PMTA/MRTPA	SE	SE	MRTPA	PMTA/MRTPA
SUBMISSION	2017	2017	2018	2020	2020 - 2022

Taking glo into the U.S. Market

- All regulatory pathways (SE, PMTA, MRTPA) are open for introducing glo into the U.S.
- Only company with a grandfathered HNB (Eclipse) that could be a predicate product for the SE pathway
- Plan to file an SE for glo in 2018
- Will also pursue MRTPA to enable claims that reflect glo's risk profile relative to cigarettes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Deeming regulation

FDA exercised jurisdiction over additional categories of tobacco products

Published May 10, 2016
(effective August 8, 2016)

Vapor

Cigars

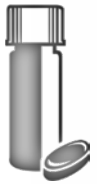
Pipe Tobacco

Dissolvables

Water Pipes

Hookah

Gels



Deeming regulation

Similar Compliance Workstreams

- Product Listing
- Facility Listing
- Ingredients Reporting
- Health Documents Submission
- HPHC Reporting
- Product Submissions (PMTAs)
- Health Warnings

ENDS (Vapor)

What is not prohibited:

- Flavors
- Open systems
- Online sales (with age verification)
- Marketing (TV, print, etc.)
- Branded apparel
- Vape shops

Prepared for compliance

- Experience with all submission pathways
- Continuously engaging with the FDA
  - Face-to-face meetings
  - Conference calls, webinars, industry seminars
  - Invited on-site manufacturing and laboratory tours
  - Facility inspections – every two years
- Enhance IT systems and processes
- Innovative culture driving agility


FDA
COMPREHENSIVE APPROACH TO NICOTINE AND TOBACCO
JULY 28, 2017
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Scott Gottlieb – FDA Commissioner

"In just the last few years, we've seen the advent and adoption of new product categories that may be ***able to deliver nicotine without having to burn tobacco****" –Scott Gottlieb*

On July 28, 2017 – Announced FDA's Comprehensive Approach to Nicotine and Tobacco

Sworn in as FDA Commissioner on May 11, 2017

Physician

FDA announcement – Recognition of the Risk Continuum

"…we must acknowledge that there's a continuum of risk for nicotine delivery. That continuum ranges from combustible cigarettes at one end, to medicinal nicotine products at the other."

"…a world where less harmful alternative forms, efficiently delivering satisfying levels of nicotine, are available for those adults who need or want them…"

–Scott Gottlieb July 28, 2017

Key Takeaway

- Very encouraging
- First FDA Commissioner to **recognise** the **risk continuum**
- CDC changes stance

FDA announcement – Extend submission compliance date for ENDS

"I'm directing CTP to reconsider the various compliance policies … policies relating to the compliance periods for premarket submissions…"

"…part of CTP's task is to reconsider aspects of the implementation of the final deeming rule with an eye towards fostering innovation where innovation could truly make a public health difference…"

–Scott Gottlieb July 28, 2017

Key Takeaway

- Very encouraging
- ENDS product submissions **extended** – August 8, 2022

FDA announcement – Rules on submissions

"We will advance rules that will lay out what needs to be in applications for Substantial Equivalence, Modified Risk Tobacco Product, and Pre-Market Tobacco Product applications."

"We'll also be working to put in place a more comprehensive, transparent, and vigorous regulatory framework that will make our regulatory efforts more sustainable."

–Scott Gottlieb July 28, 2017

Key Takeaway

- Very encouraging
- Achieve **transparency** and **predictability**

FDA announcement – Product standards for Nicotine and Flavors

"…we will develop an Advance Notice of Proposed Rulemaking … to regulate nicotine in combustible cigarettes and render them minimally or non-addictive."

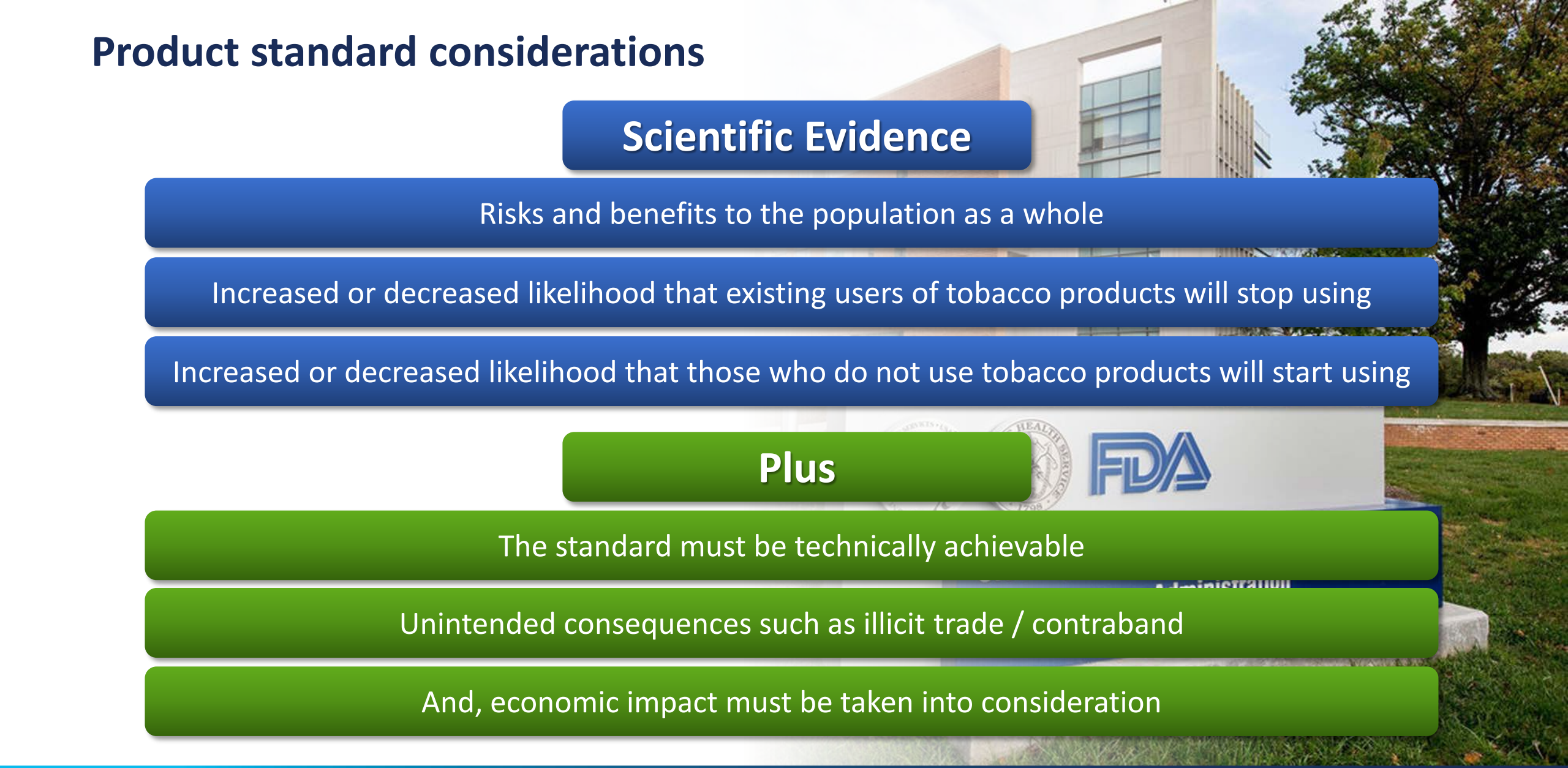
"…we will advance rules that will lay out … how to possibly regulate kid-appealing flavors in products like Electronic Nicotine Delivery Systems … and whether we should ban menthol in cigarettes and flavors in cigarillos … "

–Scott Gottlieb July 28, 2017

Key Takeaway

- This is ***not*** **a surprise**
- The Act grants FDA the authority to issue product standards
- We are **well prepared** and will be actively engaged in the science based process

Product standard considerations



Scientific Evidence

- Risks and benefits to the population as a whole
- Increased or decreased likelihood that existing users of tobacco products will stop using
- Increased or decreased likelihood that those who do not use tobacco products will start using

Plus

- The standard must be technically achievable
- Unintended consequences such as illicit trade / contraband
- And, economic impact must be taken into consideration

Rulemaking process

Step One	Step Two	Step Three	Step Four	Step Five	Step Six	Step Seven	Step Eight	Step Nine
Initiating Event	Determination Whether a Rule is Needed	Preparation of Proposed Rule	OMB Review of Proposed Rule	Publication of Proposed Rule	Public Comments	Preparation of Final, Interim, or Direct Rule	OMB Review of Final, Interim, or Direct Rule	Publication of Final, Interim, or Direct Rule
Agency Initiatives **Required Reviews** **Statutory Mandates** **Recommendations from Other Groups** **Lawsuits** **Petitions** **OMB Prompt Letters**	Agencies are required to publish in the Federal Register substantive rules, rules of procedure, and interpretive rules	**Proposed Rule** **Optional Procedures to Help Prepare a Proposed Rule:** ▪ Advance Notice of Proposed Rulemaking ▪ Negotiated Rulemaking Rules may be established only after rulemaking procedures (steps three through six) have been followed, unless an exemption applies	**OMB Review** OMB reviews only those rulemaking actions determined "significant"	Proposed rules must be published in the Federal Register	An agency must provide the public the opportunity to submit comments for consideration 60 days is the standard for a comment period A public hearing is discretionary unless required by statute or agency policy	**Final Rule** **Special Types of Final Rules:** ▪ Interim Final Rule ▪ Direct Final Rule	**OMB Review** OMB reviews only those rulemaking actions determined "significant"	An agency must submit most final, interim, and direct final rules to both houses of Congress and General Accounting Office before they can take effect Agencies are required to publish final rules in the Federal Register

Rulemaking process

Step One	Step Two	Step Three	Step Four	Step Five	Step Six	Step Seven	Step Eight	Step Nine
Initiating Event	Determination Whether a Rule is Needed	Preparation of Proposed Rule	OMB Review of Proposed	Publication of Proposed	Public	Preparation of Final, Interim, or Direct Rule	OMB Review of Final, Interim, or Direct Rule	Publication of Final, Interim, or Direct Rule
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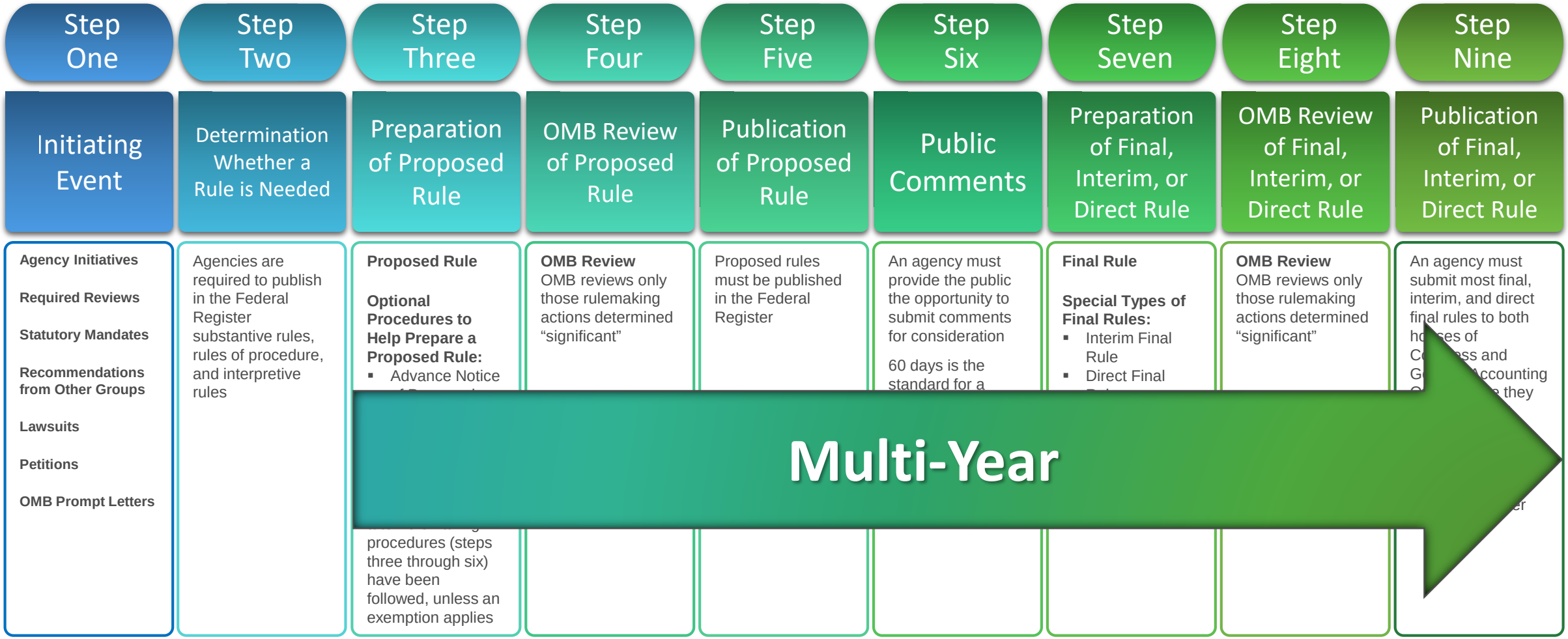
Proposed Rule

<u>Optional Procedures</u> to Help Prepare a Proposed Rule:

- Advance Notice of Proposed Rulemaking (ANPRM)
- Negotiated Rulemaking

Rulemaking process

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Closing remarks

- Science based decisions will prevail
- Continue high level engagement
- Very optimistic with Dr. Gottlieb's balanced approach
- Innovative and scientific horsepower of the BAT and RAI companies expands our agility and ability to compete and thrive

Thank you