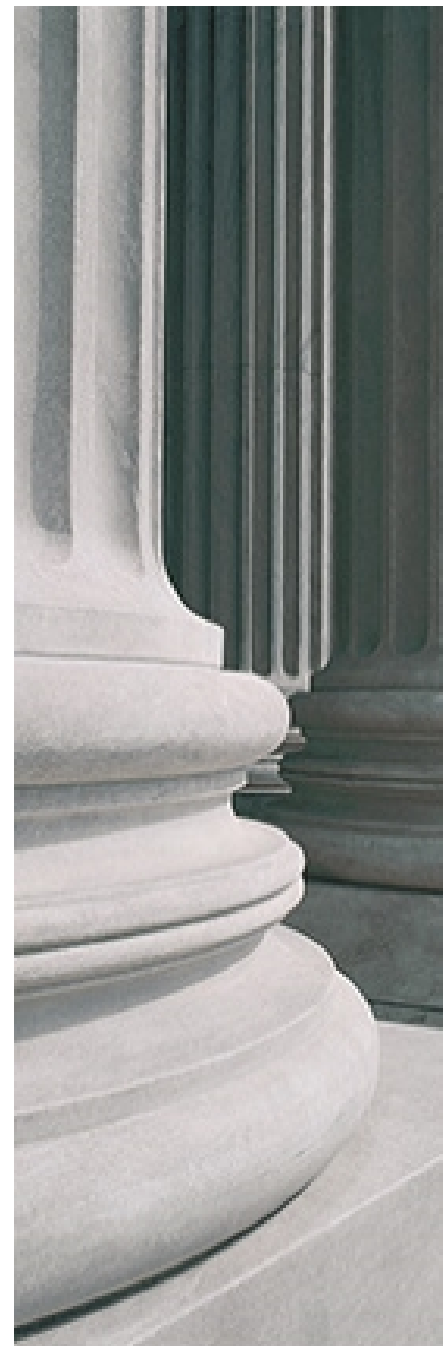


# UNITED STATES REGULATION OF TOBACCO PRODUCTS



*Presented by  
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# OVERVIEW OF TODAY'S PRESENTATION

- Highlights of the Deeming Final Rule
- Looking at Nicotine Differently in a Post-Deeming World



# TOBACCO PRODUCTS DEEMED TO BE SUBJECT TO THE FEDERAL FOOD, DRUG, & COSMETIC ACT



# CARRYING OUT HISTORIC LEGISLATION

Since 2009, CTP had authority to regulate tobacco products intended for human consumption to reduce harm across the population

- Regulate the manufacture, marketing, and distribution of cigarettes, cigarette tobacco, roll-your-own, and smokeless



# PROTECTING AMERICANS THROUGH NEW REGULATION

- On May 5 FDA finalized a rule that “deems” all products meeting the statutory definition of tobacco product, including components or parts (but excluding accessories), to be subject to FDA’s tobacco product authorities, including:
  - ✓ ENDS (e-cigarettes, e-cigars, vape pens, etc)
  - ✓ All cigars
  - ✓ Pipe tobacco
  - ✓ Nicotine gels
  - ✓ Waterpipe (hookah)
  - ✓ Dissolvables not already under the FDA’s authority
  - ✓ Future tobacco products



# DEFINING AUTOMATIC PROVISIONS AND APPLICABLE REGULATIONS

Provisions in the FD&C Act that generally apply to “tobacco products” now automatically apply to these newly-regulated products

- Registering manufacturing establishments and providing product listings to FDA
- Reporting ingredients and harmful and potentially harmful constituents
- Requiring premarket review and market authorization of new tobacco products
- Placing health warnings on product packages and advertisements
- Not selling tobacco products that make modified risk tobacco claims (including “light,” “low,” or “mild”) unless authorized by FDA
- Not allowing distribution of free samples

# ADDING ADDITIONAL RESTRICTIONS TO PREVENT YOUTH ACCESS

Additional restrictions are added to prevent underage access

- Not allowing products to be sold to persons under the age of 18 (both in person and online)
- Requiring age verification by photo ID for anyone under 27
- Not allowing the sale in vending machines (unless in adult-only facility)



# REQUIRING HEALTH WARNINGS

- By May of 2018, health warnings are required to be displayed on cigarette tobacco, roll-your-own tobacco, and all newly-deemed covered tobacco products, including on the:
  - Text warnings on product packages covering 30% of principal display panels
    - For packages that are too small for the warning, it may appear on the outer container or be placed on a tag permanently affixed to the product package
  - For cigars sold individually without packaging, all warnings will be placed on a placard near register
  - Advertisements for the products
    - Warning must appear in the upper portion of the area of the ad and occupy at least 20% of the of the area of the ad



# REQUIRING HEALTH WARNINGS



- The addiction warning statement reads:

**“WARNING:** This product contains nicotine.  
Nicotine is an addictive chemical.”

- The final rule includes a self-certification option for covered tobacco products that do not contain nicotine. For these products, the required statement reads:

**“This product is made from tobacco.”**

# REQUIRING SIX WARNINGS FOR ALL CIGARS



There are six warning statements for cigars, and cigar packages and advertisements must bear **one** of the following in accordance with an FDA-approved warning plan:

1. **“WARNING:** Cigar smoking can cause cancers of the mouth and throat, even if you do not inhale.”
  2. **“WARNING:** Cigar smoking can cause lung cancer and heart disease.”
  3. **“WARNING:** Cigars are not a safe alternative to cigarettes.”
  4. **“WARNING:** Tobacco smoke increases the risk of lung cancer and heart disease, even in nonsmokers.”
  5. **“WARNING:** Cigar use while pregnant can harm you and your baby.”
- or**
6. **“SURGEON GENERAL’S WARNING:** Tobacco Use Increases the Risk of Infertility, Stillbirth and Low Birth Weight.”
  6. **“WARNING:** This product contains nicotine. Nicotine is an addictive chemical.”

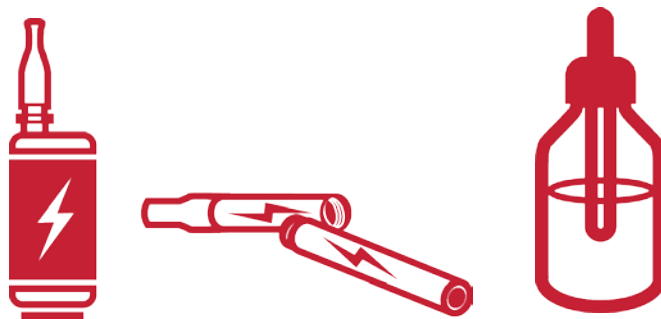
# LOOKING CLOSER AT KEY ISSUES: PREMIUM CIGARS

- All cigars, including premium cigars, are deemed under the final rule
- No appropriate public health justification to exclude premium cigars
  - Available evidence does not provide a basis to conclude that the patterns of premium cigar use sufficiently reduce the health risks to warrant exclusion
- All cigars pose serious negative health risks
- Premium cigars are used by youth and young adults
- All cigars contain harmful and potentially harmful constituents, and all cigars contain nicotine, an addictive chemical



# LOOKING CLOSER AT KEY ISSUES: COMPONENTS AND PARTS

- Final rule includes components and parts of newly-regulated tobacco products
- Defines “component or part” as: any software or assembly of materials intended or reasonably expected:
  - 1) to alter or affect the tobacco product’s performance, composition, constituents, or characteristics; or
  - 2) to be used with or for the human consumption of a tobacco product.  
Component or part excludes anything that is an accessory of a tobacco product



# LOOKING CLOSER AT KEY ISSUES: PREMARKET REVIEW OF NEWLY-REGULATED PRODUCTS

- Newly-regulated tobacco products are now subject to premarket review requirements unless they were commercially marketed as of 2/15/2007
- These products are grandfathered and would not need premarket review unless the product has been modified



# LOOKING CLOSER AT KEY ISSUES: PREMARKET REVIEW OF NEWLY-REGULATED PRODUCTS

- For newly-regulated products on the market as of the effective date, manufacturers will submit applications under staggered timelines specific to each pathway:

Pathway	Time to Submit Application	Time to Continue Selling Product
Exemption from SE	12 months	+12 months = 24 months
SE	18 months	+12 months = 30 months
PMTA	24 months	+12 months = 36 months

# LOOKING CLOSER AT KEY ISSUES: PREMARKET REVIEW OF NEWLY-REGULATED PRODUCTS

- Unless FDA issues an order denying or refusing to accept the submissions, manufacturers who meet these deadlines will continue to be able to sell their products during the continued compliance period
- The product will face enforcement unless it has a marketing order in place at the end of the continued compliance period

# LOOKING CLOSER AT KEY ISSUES: VAPE SHOPS

- Establishments that mix and/or prepare combinations of e-liquids or create or modify aerosolizing apparatus for direct sale to consumers for use in ENDS are tobacco product manufacturers
- The combinations vape shops mix and/or prepare and the new or modified aerosolizing apparatuses are new tobacco products
- Vape shops that are manufacturers are subject to all of the statutory and regulatory requirements that apply to manufacturers, including the requirements to register their establishments, list their products, and obtain premarket authorization





# LOOKING CLOSER AT KEY ISSUES: FREE SAMPLE BAN

- Distribution of free samples of newly-regulated tobacco products is prohibited
- Prospective adult buyers may smell or handle one of the newly-regulated products as long as:
  - the free product is not actually consumed, in whole or in part, in the retail facility and
  - the prospective buyer does not leave the facility with a free tobacco product



# LOOKING CLOSER AT KEY ISSUES: SMALL-SCALE TOBACCO MANUFACTURERS

- Targeted relief for small-scale tobacco product manufacturers
  - Small-scale = Manufacturer of any regulated tobacco product employing 150 or fewer full-time equivalent employees and has annual total revenues of \$5,000,000 or less
- One-time allowance of an additional six months for initial ingredient reporting
  - One-time allowance of an additional six months for submission of health information
  - For the first 30 months following effective date, FDA intends to grant extensions to small-scale tobacco product manufacturers for SE reports that need additional time to respond to SE deficiency letters



# EFFECTIVE DATES

- Generally: The rule is effective on the final rule publication date plus 90 days = **August 8**
- Applies to “deeming” provision and associated automatic provisions, age restriction, free sample ban, and prohibition on vending machine sales
- Compliance periods, during which FDA does not intend to initiate enforcement action for certain automatic provisions to give firms additional time to comply, are included in preamble



# ADDITIONAL REGULATORY DOCUMENTS PUBLISHED

- PMTA Draft Guidance for Electronic Nicotine Delivery Systems (ENDS)
- Tobacco Product Master File (TPMF) Guidance
- User Fee Final Rule
  - Small Entity Compliance Guide for User Fees
- Small Entity Compliance Guide for Deeming



# AVAILABLE RESOURCES AT [FDA.GOV/TOBACCO](https://www.fda.gov/tobacco)

- Deeming Landing Page with links to all relevant documents and webpages, including:
  - Office of Small Business Assistance
  - Retailer Information and Materials
- Webinar series to help industry comply with regulations is live on our website – topics include:
  - The Final “Deeming Rule” – All Tobacco Products Subject to the FD&C
  - New Regulatory Requirements for Tobacco Retailers
  - New Regulatory Requirement for Vape Shops
  - Retail Compliance Check Inspections: An Overview for Tobacco Retailers
  - New Regulatory Requirements for Tobacco Manufacturers and Importers
  - Premarket Tobacco Product Applications for Electronic Nicotine Delivery Systems



# LOOKING AT NICOTINE DIFFERENTLY IN A POST-DEEMING WORLD

# LOOKING AT TOBACCO, DRUGS AND DEVICES DIFFERENTLY

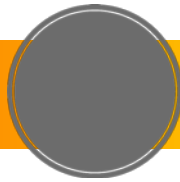
- Establish an integrated, FDA-wide policy on nicotine-containing products that is public health-based
- Understand implications for tobacco, drug, and device regulatory policy



# LOOKING AT NICOTINE DIFFERENTLY

- Recognize there is a continuum of nicotine-containing products
- Understand people smoke for the nicotine but die from the tar
- Acknowledge public health opportunity

COMBUSTIBLES



NRT



# LOOKING AT TOBACCO, DRUGS AND DEVICES DIFFERENTLY

- Related actions include:
  - Develop FDA-wide jurisdiction policy on nicotine-containing products
  - Work with CDER and CDRH to determine how regulation of therapeutic nicotine products (Rx, OTC, drugs, devices) could evolve
  - Explore options at CTP for an expedited premarket review policy based on principle of relative toxicity and risk
  - Implement the Deeming regulation as of August 8, 2016

# ACKNOWLEDGING THE NICOTINE REALITY

## Concerns about the toxic mix of chemicals...

- The nicotine in tobacco products creates and sustains addiction
- But smokers don't ultimately die directly from the nicotine
- So it's more about the toxic chemicals that come along with the nicotine than the drug
- But the drug itself is not benign, and youth and pregnant women, in particular, should not be using nicotine in any form
- Nicotine-containing products should not be packaged and marketed in ways that appeal to youth and encourage trial by kids
- Kids are using flavored e-cigarettes at alarming rates; and citing flavors as the number one reason for usage

# ACKNOWLEDGING THE NICOTINE REALITY

## What about nicotine and people who are addicted?

- Nicotine has been marketed as a “safe and effective” medication for 30 years; so safe that a prescription is not required for gum, patch or lozenge forms
- So it’s not the drug...it’s the delivery mechanism
- The disease and death is primarily due to combustible tobacco
- So if Michael Russell was right 40 years ago, how should we be thinking about nicotine today?

# PROTECTING SMOKERS

## Can e-cigarettes be a solution for smokers who can't or won't quit?

- 40 million adult smokers in the U.S. today
- Almost 70% of smokers want to stop smoking completely
- 53% tried to quit in the last year, yet only 6% remain cigarette-free after 6 months
- 70% of adult e-cigarette users continue to smoke regular cigarettes



# PROTECTING SMOKERS

## We need to know more about...

- The health effects of using e-cigs
- The ingredients, harmful or otherwise, found in the product that are ingested into the lungs
- Some flavors found in e-cigarettes, when inhaled, cause lung toxicity and the respiratory effects of others are unknown
  - Examples: Diacetyl and Cinnamonaldehyde
- Exactly what is in the aerosol plume
- How the products are manufactured and designed from a product safety standpoint

# PROTECTING SMOKERS

## We need to know more about...

- The variations in nicotine levels depending on the device
- The patterns of use; what are the implications of the widespread dual usage of e-cigs with regular cigs
- The impact on cessation; no e-cig has been approved by FDA for smoking cessation
- The U.S. Preventive Services Task Force has concluded the evidence is insufficient to support recommending e-cigs for cessation
- If long-time quitters are relapsing back to nicotine use with e-cigs

# PROTECTING YOUTH

## Concerns about nicotine and teens include...

- Nicotine is never safe for non-users
- E-cigarette use by youth may be a pathway to cigarette use
- Nicotine is a highly addictive chemical that can re-wire a teen's developing brain to crave more nicotine, thereby creating an addiction
- The earlier a teen becomes addicted to nicotine, the harder it will be for them to quit

# DEBATING THE WRONG THING?

- Current debate has been about e-cigarettes
  - Emotional
  - Divisive
  - Value-laden
  - Filled with misperceptions about nicotine safety
- Is the real need for society to grapple with profound questions about nicotine itself?
  - Longer-term use for those who may need it
  - Potential need for a transitional period of dual use; but for how long?
  - Unintended consequences (e.g. youth initiation, dual use, relapse)
  - Revised labeling and indications for medicinal nicotine
- Where does the principle of harm reduction come in?



# THE PUBLIC HEALTH IMPERATIVE TO GET THIS RIGHT

- Progress since the first Surgeon General's Report 50 years ago
- But still the leading cause of preventable disease and death; now over 480,000 annual tobacco-related deaths
  - 17,600,000 avoidable deaths by mid-century
- 90% of all adult smokers started before age of 18
  - Half become addicted before they are old enough to legally buy tobacco
- What will it take to change this trajectory?
- What role can a sensible nicotine regulatory policy play?

THANK YOU

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