Tobacco Regulation in the United States: ANA’s Policy Work and FDA Authorities

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Disclosures to Participants

Disclosures to Participants were delivered electronically upon registration for this program. Please contact Holly Carpenter at holly.carpenter@ana.org if you need an additional copy.
Objectives

• Describe ANA’s policy work in regard to tobacco product use and regulations.
• Discuss FDA’s regulatory authorities over tobacco products.
• Identify how to access and use appropriate reporting pathways for adverse experiences involving tobacco products.
• Explain FDA’s online repository for voluntary reports of health and product problems related to tobacco products.
American Nurses Association
When Nurses are Healthy...

They are more likely to counsel patients about healthy behaviors.

They are viewed as more credible by patients.
ANA Tobacco Cessation Website

• A part of ANA’s Healthy Nurse, Healthy Nation initiative
• Recent HRA data shows
• Website includes
  • Getting started
  • Acquiring better habits
  • Overcoming addiction
  • Getting support
  • Resources
  • Assisting patients to quit

http://www.nursingworld.org/MainMenuCategories/WorkplaceSafety/Healthy-Nurse/Tobacco-Cessation
ANA Policy Work

- Articles
- Social media and list serve postings
- Position statement *Promoting Tobacco Cessation in Pharmacies*
- Nurse nominees for relevant committees
Commenting on Agency Rulemaking – initiations of the process

• Why initiate regulations? Examples include the following:
  • Congressional mandate
  • Recommendations from Congressional committees or federal advisory committees
  • Litigation and petitions from the public
  • Concerns or recommendations from agency staff

Content from the Federal Register’s Guide to the Rulemaking Process
Agencies must following the requirements of the Administrative Procedures Act (APA)

• The APA emphasizes an open public process

• Agencies publish a “Regulatory Plan” in the Fall and an “Agenda of Regulatory and Deregulatory Actions” in the Spring and Fall to update the public

• Publically available at:
  • Regulations.gov
  • RegInfo.gov
  • Federal Register
Agency Development of Proposed Rules

• Structured:
  • Advanced Notice of Proposed Rulemaking
  • Request for Information or Comments
  • Input from federal advisory committees

• Negotiated Rulemaking
  • Agency invites interested parties to participate in meetings to reach consensus
  • Ideas may be used as a basis for proposed rule
Agency Development of Proposed Rules - continued

• Publication in the Federal Register
  • Proposed Rule
    • Summary
    • Comment period (30-60 days; occasionally longer); the period can be reopened if necessary
    • Supplementary information
    • Text of proposed rule
  • Final Rule
    • Summary
    • Effective dates
    • Supplementary information (including response to comments)
    • Text of final rule
Agency Development of Proposed Rules - continued

• Public comments are submitted:
  
  • Electronically though Regulations.gov
  • By regular mail, express or overnight mail, or via courier
  • Occasionally through public hearings
Agency Development of Proposed Rules - continued

• Coordination of agency rules takes place through the Office of Management and Budget and the Office of Information and Regulatory Affairs, which reviews proposed and final rules

• Congressional Review
  • Congressional Review Act
  • Resolution of disapproval
Example – ANA submission on tobacco issue

• ANA submitted a comment letter on proposed rule from the Department of Housing and Urban Development entitled “Instituting Smoke-Free Public Housing”
  • Expressed support for the proposed rule and agreed that it would improve the public housing residents’ health, increase their indoor air quality, and decrease the risk of house fires
  • Noted barriers to implementation and potential impact on children and others at risk for eviction
  • Noted the need to provide support and accessible resources to impacted individuals
Example – ANA submission on tobacco issue – continued

• The comment period closed on January 19, 2016, with more than one thousand public comments received.

• The OMB Dashboard indicates that HUD submitted the Final Rule to OMB on August 22nd.
Tobacco Regulation in the US: FDA Authorities

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Disclaimer: This information is not a formal dissemination of information by the FDA and does not represent Agency position or policy.

November 17, 2016
LEARNER OBJECTIVES

1. Discuss FDA’s regulatory authorities over tobacco products
2. Identify how to access and use appropriate reporting pathways for adverse experiences involving tobacco products
3. Explain FDA’s online repository for voluntary reports of health and product problems related to tobacco products
FDA’S REGULATORY AUTHORITY OVER TOBACCO PRODUCTS
To make tobacco-related death and disease part of America’s past, not America’s future and, by doing so, ensure a healthier life for every family.

Examples are:
• Tobacco product tax measures
• Clean air – where tobacco products cannot be used
• Growing and harvesting of tobacco plants
• Child labor in tobacco agriculture
Created in 2009, CTP has authority to:

• **Regulate** the *manufacture, marketing, and distribution* of:
  1) cigarettes
  2) cigarette tobacco
  3) roll-your-own
  4) smokeless

• **Deem other** products to be subject to FDA’s tobacco authority through regulation.

http://www.fda.gov/TobaccoProducts/Labeling/RulesRegulationsGuidance/ucm246129.htm
May 10, 2016* 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

* Effective 8/8/2016
**REGULATORY DEFINITION OF A TOBACCO PRODUCT**

**Definition of Tobacco Products.** Section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321) is amended by adding at the end the following:

- "(rr) The term 'tobacco product' means any product made or derived from tobacco that is intended for human consumption, including any component, part, or accessory of a tobacco product (except for raw materials other than tobacco used in manufacturing a component, part, or accessory of a tobacco product).
- The term 'tobacco product' does not mean an article that is a drug under subsection (g)(1), a device under subsection (h), or a combination product described in section 503(g)…”
EXAMPLES OF DRUG/DEVICE CLAIMS

- Reduce withdrawal symptoms, including nicotine craving, associated with quitting smoking
- Curing or treating nicotine addiction and its symptoms
- “Stop smoking aid”
- Treating tobacco dependence
- Relapse prevention

The “deeming” rule deems components and parts of tobacco products to be subject to FDA authority.

A component or part:

- Is 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
- Excludes anything that is an accessory of a newly deemed tobacco product
EMPLOYING A PUBLIC HEALTH STANDARD

• Pursue a “public health” standard since tobacco cannot be regulated using FDA’s traditional “safe and effective” standard

• Take into account the effects on both users and non-users of tobacco products

• Assess the population-level health impacts of tobacco products

• Issue “marketing authorization” – **NOT** “approval”
INTEROFFICE REVIEW OF INDUSTRY SUBMISSIONS

Examples of Submission Types:
- Substantial Equivalence (SE)
- Premarket tobacco product applications (PMTA)
- Modified risk tobacco product applications (MRTPA)

FDA review is:
- Multidisciplinary
- Based on the best available science
- Based on CTP’s authorities under the Tobacco Control Act
CTP OFFICE OF REGULATIONS (OR)
OFFICE OF REGULATIONS: ACTIVITIES AND MILESTONES

• Issuing Guidance
  • Guidance represents current Agency thinking on regulatory issues
  • Not legally binding

• Promulgating Regulations (or Rules)
  • To implement additional authorities under the Tobacco Control Act
  • Legally binding

Submit logical, scientific, personalized comments and data to open dockets of interest, found at regulations.gov

“The comment process is not a vote. One well-supported comment is often more influential than a thousand form letters.”

https://www.regulations.gov/docs/Tips_For_Submitting_Effective_Comments.pdf
CTP OFFICE OF SCIENCE (OS)
OFFICE OF SCIENCE: ACTIVITY HIGHLIGHTS

• Conduct and fund research to inform regulation

• Knowledge Development in priority areas
  • Product diversity
  • Addiction
  • Toxicity and carcinogenicity
  • Health consequences
  • Communication
  • Marketing
  • Economics and policy
2013 - Tobacco Regulatory Science Program (TRSP) established
NIH/Office of Disease Prevention coordinates the trans-NIH collaborative research effort with FDA/CTP

https://prevention.nih.gov/tobacco-regulatory-science-program

2013 - $53 Million awarded for Tobacco Centers of Regulatory Science (TCORS) (n=14)

• ≥ 3 theoretically grounded, strong research projects
• ability to respond quickly to emerging research questions
• career development and training
• 2013 - Began field work in a longitudinal population assessment of tobacco use and its effects on health

• Enrolls ~ 46,000 people (tobacco users and nonusers) ages 12 years & older

• Computer-assisted questionnaires, live interviews, and biospecimen collections assess reasons for and patterns of tobacco product use, as well as related changes in attitudes, behavior and health over time, by gender, age, and ethnicity
2014 - Launched a questionnaire in the DHHS Safety Reporting Portal (SRP) to collect tobacco-product related adverse experiences.  
https://www.safetyreporting.hhs.gov

2016 – Revised and expanded questionnaires
NURSES ADVANCE KNOWLEDGE

- Conduct tobacco regulatory research
  - Resources for Researchers [https://prevention.nih.gov/resources-for-researchers](https://prevention.nih.gov/resources-for-researchers)
  - Backinger, C. L., Meissner, H. I., & Ashley, D. L. (2016). The FDA “Deeming Rule” and Tobacco Regulatory Research. *Tobacco Regulatory Science*. 2(3), 290-293. DOI: [http://dx.doi.org/10.18001/TRS.2.3.8](http://dx.doi.org/10.18001/TRS.2.3.8)

- Read and utilize research knowledge generated

- Report tobacco-product related adverse experiences
CTP OFFICE OF HEALTH COMMUNICATION AND EDUCATION (OHCE)
Conduct public education campaigns and messaging

- Identify problems to address
- Research target audiences and the best way to reach them
- Test messages and materials on the target audience
- Share the messages using a variety of media
- Assess effectiveness of messages

http://www.fda.gov/TobaccoProducts/PublicHealthEducation/PublicEducationCampaigns/default.htm
<table>
<thead>
<tr>
<th>Public Education Campaign</th>
<th>Launch</th>
<th>Target Audience</th>
</tr>
</thead>
<tbody>
<tr>
<td>The Real Cost</td>
<td>2014</td>
<td>Youth (12-17 years) who are open to smoking or already experimenting</td>
</tr>
<tr>
<td></td>
<td>2016</td>
<td>Rural males (12-17 years) who are at risk for smokeless tobacco use</td>
</tr>
<tr>
<td>Fresh Empire</td>
<td>2015</td>
<td>Multicultural youth (12-17 years) who identify with the hip-hop peer crowd</td>
</tr>
<tr>
<td>This Free Life</td>
<td>2016</td>
<td>Lesbian, Gay, Bisexual and Transgender young adult (18-24 years) occasional tobacco users</td>
</tr>
</tbody>
</table>
NURSES CAN AMPLIFY OHCE OUTREACH

- **Share free messages on your websites and social media channels** through CTP's Exchange Lab, a free resource that allows you to digitally publish our tobacco-related content
- **Download, print, and order free materials for youth**
- **Send at-risk youth to The Real Cost campaign website** and social channels: www.facebook.com/KnowTheRealCost
  @TheRealCost on Instagram
  http://knowtherealcost.tumblr.com/
  "The Real Cost" on YouTube
CTP OFFICE OF COMPLIANCE AND ENFORCEMENT (OCE)
OFFICE OF COMPLIANCE: ACTIVITY HIGHLIGHTS

Help the tobacco industry understand the law

Training sessions, presentations and guidance on how to comply with the law

Office of Small Business Assistance

Monitor tobacco industry compliance with the law

Inspect manufacturing facilities and retail establishments

Review industry registrations, and listings

Review print and online advertising

Monitor promotional activities

Handle potential violation complaints from the public
Take Action as appropriate

- Warning letter—encourages voluntary compliance
- Civil money penalty (a fine)
- No tobacco sales order ("NTSO")
- Criminal prosecution
- Seizing tobacco products
- Injunction against distribution or sale of tobacco products

http://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/ucm232109.htm
Retailer inspections: > 646,000, covering 56 states and territories

Warning letters: > 48,100

Civil Money Penalty actions against tobacco retailers: > 8,200

October 2015: Initiated No Tobacco Sales Orders (NTSO) to retailers for repeated violations, including sales to minors

Data as of 8/2016
NURSES CAN BE EYES AND EARS FOR OCE

Report potential violations of the Tobacco Control Act:

- Call (toll-free): 1-877-CTP-1373
- Email CTPCompliance@fda.hhs.gov
- Send a letter to:
  Center for Tobacco Products, Document Control Center
  Building 71, Room G335, 10903 New Hampshire Avenue
  Silver Spring, MD 20993-0002
REPORTING ADVERSE EXPERIENCES INVOLVING TOBACCO PRODUCTS TO FDA
The SRP is a secure online portal to streamline the process of reporting safety concerns to NIH and FDA.

Begin reporting at https://www.safetyreporting.hhs.gov
Product Problems

- Damaged or defective products
- Products that look, smell or taste wrong or contain foreign objects
- Products that are difficult to use
- Product packaging mix-ups

Unexpected Health Problems or Safety Problems

- Accidental exposures of nonusers such as poisoning, choking or breathing tainted air
- Fires, burns or other injuries
- Allergic or toxic reactions
- Unusual type or severity of reaction in a long-time user
- Pregnancy or fertility problems

**NOTE:** Effects of tobacco products on pets should be reported to FDA’s Center for Veterinary Medicine using [Form FDA 1932a](#).
## SRP REPORTING ROLES & ACCESS TYPES

<table>
<thead>
<tr>
<th>Reporting Pathway based on Role</th>
<th>Guest Reporter (Anonymous or Identified)</th>
<th>Individual Registered Reporter (Identified)</th>
<th>Group Account Registered Reporter (Identified)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Consumer/Concerned Citizen</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Healthcare Professional</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Manufacturer</td>
<td></td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Researcher</td>
<td></td>
<td>X</td>
<td>X</td>
</tr>
</tbody>
</table>
A nurse who lives with a smoker, and practices nursing, and conducts research, and is employed by a tobacco product manufacturer, may report using each of the four tobacco pathways:

1) Personal problem with tobacco → consumer role pathway (as a Guest or Registered Reporter)
2) Manufacturer’s customer complaint → manufacturer’s pathway (Registered)
3) Research participant problem → researcher pathway (Registered)
4) Hospital patient problem → healthcare professional pathway (as a Guest or Registered)

Note: A unique e-mail address is needed for each registered reporter pathway.
## CORE CONTENT OF TOBACCO QUESTIONNAIRES BY ROLE PATHWAY

<table>
<thead>
<tr>
<th>Questionnaire Sections</th>
<th>Consumers or Healthcare Professionals</th>
<th>Manufacturer</th>
<th>Researcher</th>
</tr>
</thead>
<tbody>
<tr>
<td>Introduction</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Problem Summary</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Research Summary</td>
<td>X</td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>Tobacco Products</td>
<td>X</td>
<td>+ Manufacturer Investigation</td>
<td>“Study Tobacco Products” and Investigation</td>
</tr>
<tr>
<td>Other Tobacco Products Used</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Additional Information</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Attachments</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
</tbody>
</table>
PRODUCT TYPE IMAGES AND DESCRIPTIONS IN SRP

Cigarette
- Roll-your-own cigarette
- Cigars, Cigars with tobacco
- Electronic Cigarette, Electronic Nictotine or Vaping Product (e-cigarettes, e-hookahs, e-pipes, vape pens, hookah pens, and personal vaporizers; e-liquids, e-juice or vape juice)
- Waterpipe (also known as hookah, nargile, shisha, or goza)
- Pipe and pipe tobacco
- Snuff (dry or moist for use in nose or mouth)
- Snus (pouches or loose)
- Chewing tobacco (loose leaf chew, plug, snuff)
- Gutka (or Gutthka), Betel Quid with Tobacco
- Mixture of tobacco with spices, herbs, nuts, fruit, plant leaves, etc. (used for chewing)
- Snus (for example strips, sticks, orbs)
- Nicotine Lotions or Gels (applied to the skin)
- Tobacco Powder, gel or paste applied to the tooth, gums, or mouth
- Other

Cigarettes
The basic components of most cigarettes are tobacco, a filter, and paper wrapping. Cigarettes can have various lengths (e.g., King, 100, or 120) and diameters (e.g., slim or ultra-slim) as pictured.

Pictured from left to right: King (this is the standard length of most conventional cigarettes), 100 (normal diameter and ultra-slim diameter), and 120 (slim diameter).
PRODUCT DESCRIPTIONS, IMAGES AND INFORMATION

Products, Ingredients & Components

Tobacco use is the single largest preventable cause of disease and death in the United States. As part of its goal to improve public health and protect future generations from the risks of tobacco use, the FDA has extended its authority to cover all tobacco products. The fact that FDA regulates these tobacco products does not mean they are safe to use.

In 2016, FDA’s Center for Tobacco Products (CTP) finalized a rule to regulate:

- E-Cigarettes
- Dissolvables
- Pipe Tobacco
- Hookah Tobacco
- Cigars
- Novel and Future Products

Since June 2009, CTP has regulated:

- Cigarettes
- Roll-Your-Own Tobacco
- Smokeless Tobacco

http://www.fda.gov/TobaccoProducts/Labeling/ProductsIngredientsComponents/default.htm
HOW TO REPORT OTHER CONCERNS & PRODUCTS

Find out **where to report concerns about other non-tobacco products** from a link on the SRP home page:


Report serious adverse events, product problems, product use errors, and therapeutic failures for most FDA-regulated products, including smoking cessation products (such as nicotine replacement therapies) to **MedWatch**

http://www.fda.gov/Safety/MedWatch/default.htm
ADVERSE EXPERIENCES REPORTED TO CTP
VOLUNTARY REPORTS BY PRODUCT & CALENDAR YEAR

Number of Reports

Calendar Years


ENDS
Other Unregulated TP
Cigarette
Smokeless
Cigarette Tobacco/RYO
Other Products

Excludes Investigational Tobacco Products
* One report named two tobacco products
VOLUNTARY REPORTS BY REPORTER & CALENDAR YEAR

Excludes Investigational Tobacco Product Reports
PUBLIC ACCESS TO AE REPORTS: PUBLISHED DATA


Special Interest Topics

E-cigarette Adverse Events

- Adverse Events 10/5/13 to 3/12/14
- Adverse Events 6/25/13 to 10/5/13
- Adverse Events 6/22/2009 to 6/25/13

NSE Letters

- NSE letters October 2013
- NSE letters August 2013
- NSE letters June 2013

Other

Lorillard SE applications and reviews SE3730 and SE3731 (Persons using assistive technology may not be able to fully access information in these documents. For assistance, please call the CTP Callor Center at 1-877-287-1373.)

Additional Resources

- FDA Information on Tobacco Products
- Tobacco Products Guidance, Compliance, and Regulatory Information
- FDA Freedom of Information Act Information
- How to Make a FOIA Request
1) FDA is using the full power of the law to protect public health

2) FDA regulation of tobacco products does not mean the products are safe

3) FDA does not “approve” tobacco products but can authorize tobacco product marketing when appropriate for the protection of public health
4) Nurses can assist CTP in its mission to prevent people from initiating tobacco use, to encourage quitting and to reduce the harms caused by tobacco use

- Report health and product problems with tobacco products to the Safety Reporting Portal
- Report potential violations of the Tobacco Control Act to the Office of Compliance and Enforcement
- Submit comments on draft guidances and proposed regulations to regulations.gov
- Distribute public education materials to target audiences
- Use public adverse experience reports and published summaries to educate patients and colleagues
- Conduct or utilize tobacco regulatory research
THANK YOU!

FOLLOW US ON TWITTER: @FDATOBACCO
QUESTIONS?

ASKCTP@FDA.HHS.GOV
1-877-287-1373 (9AM-4PM EST)
Tobacco Regulation in the United States: ANA’s Policy Work and FDA Authorities

Questions?
Presentation Recording

http://www.fda.gov/ForHealthProfessionals/LearningActivities/ucm524662.htm
Contact Us

fdaofficeofhealthandconstituentsaffairs@fda.hhs.gov