

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

November 17, 2016

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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.

ANA



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 – initiation 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](https://www.regulations.gov)
 - [RegInfo.gov](https://www.reginfo.gov)
 - [Federal Register](https://www.federalregister.gov)

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 through [Regulations.gov](https://www.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.

FDA



Tobacco Regulation in the US: FDA Authorities



CENTER FOR
TOBACCO
PRODUCTS

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Products

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

CENTER FOR TOBACCO PRODUCTS (CTP) - VISION

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.

<http://www.fda.gov/downloads/TobaccoProducts/AboutCTP/UCM453547.pdf>

TOBACCO CONTROL GENERALLY NOT IN FDA AUTHORITY

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

CARRYING OUT THE TOBACCO CONTROL ACT

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>

PROTECTING AMERICANS THROUGH NEW REGULATION

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

From the Proposed Rule: Docket No. FDA-2015-N-2002

COMPONENTS AND PARTS

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”



CTP OVERVIEW

Director

Mitchell R. Zeller, J.D.

Deputy Director

Richard Turman, M.P.P.

Office of Management (OM)

Director
Janelle Barth,
M.S., M.B.A.

Office of Regulations (OR)

Director
Beverly Chernaik,
J.D.

Office of Science (OS)

Director
RADM (retired)
David L. Ashley
Ph.D.

Office of Health Communication and Education (OHCE)

Director
Kathleen Crosby

Office of Compliance and Enforcement (OCE)

Director
Ann Simoneau,
J.D.

<http://www.fda.gov/AboutFDA/CentersOffices/OrganizationCharts/ucm351997.htm>

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

<http://www.fda.gov/downloads/TobaccoProducts/Labeling/RulesRegulationsGuidance/UCM401556.pdf>

NURSES COMMENT ON GUIDANCE & RULEMAKING

Submit logical, scientific, personalized comments and data to open dockets of interest, found at [regulations.gov](https://www.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

OFFICE OF SCIENCE: MILESTONE HIGHLIGHTS

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

OFFICE OF SCIENCE: MILESTONE HIGHLIGHTS (CONT.)



<https://pathstudyinfo.nih.gov/UI/HomeMobile.aspx>

- 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

OFFICE OF SCIENCE: MILESTONE HIGHLIGHTS (CONT.)

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

Safety Reporting Portal

ABOUT THE PORTAL SAFETY REPORT DIRECTORY FAQS RELATED LINKS CONTACT US

The Safety Reporting Portal

The Safety Reporting Portal (SRP) streamlines the process of reporting product safety issues to the Food & Drug Administration (FDA) and the National Institutes of Health (NIH).

Whatever your role, (manufacturer, health care professional, researcher, public health official, or concerned citizen), when you submit a safety report through this Portal, you make a vital contribution to the safety of America's food supply, medicines, and other products that touch us all.

Begin Reporting Here

1. Login

EMAIL

PASSWORD

Forgot your password?

☐ Remember me

2. Report As Guest

Not ready to create an account but would like to submit a report?

You can do that here.

Account Benefits

- Save a draft
- Easier follow up
- View submissions
- Faster data entry

Who Should Submit a Safety Report?

Organizations and people in certain professional roles, such as the following, may be required by law to submit safety reports under some circumstances.

- Food Manufacturers, Processors, Packers, and Holders
- Researchers
- An applicant of an approved drug product or a manufacturer, distributor or packer listed on the label of any drug product
- Drug Manufacturers
- Dietary supplement manufacturers, packers, and distributors

Others, including health care providers, public health officials, and other professionals, as well as consumers and concerned citizens, may voluntarily submit reports if they encounter safety issues with a product and/or unanticipated harmful effects that they believe are related to a product.

[Learn more about mandatory and voluntary reporting.](#)

Reports You Can Submit Through this Portal

FDA safety issues involving:

- Marketed human drug and therapeutic biologics
- Human or animal reportable foods
- Animal drugs
- Animal foods
- Tobacco products
- Dietary supplements

NIH safety issues involving:

- NIH gene-transfer research

For other issues, [find out where to submit your report.](#)

DEPARTMENT OF HEALTH & HUMAN SERVICES
USA.gov
FDA U.S. Food and Drug Administration
NATIONAL INSTITUTES OF HEALTH

NURSES ADVANCE KNOWLEDGE

- **Conduct tobacco regulatory research**
 - 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>
- **Read and utilize research knowledge generated**
- **Report tobacco-product related adverse experiences**

CTP OFFICE OF HEALTH COMMUNICATION AND EDUCATION (OHCE)

OHCE: ACTIVITY HIGHLIGHTS

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>

OHCE: EDUCATIONAL CAMPAIGN MILESTONES

Public Education Campaign	Launch	Target Audience
<u>The Real Cost</u>	2014	Youth (12-17 years) who are open to smoking or already experimenting
	2016	Rural males (12-17 years) who are at risk for smokeless tobacco use
<u>Fresh Empire</u>	2015	Multicultural youth (12-17 years) who identify with the hip-hop peer crowd
<u>This Free Life</u>	2016	Lesbian, Gay, Bisexual and Transgender young adult (18-24 years) occasional tobacco users

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

OFFICE OF COMPLIANCE: ACTIVITY HIGHLIGHTS (CONT.)

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>

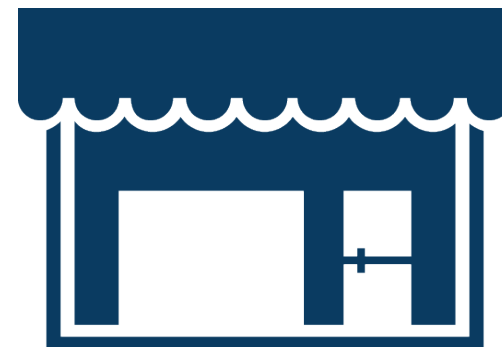
OFFICE OF COMPLIANCE: MILESTONE HIGHLIGHTS

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:

- Fill out the [Potential Tobacco Product Violations Reporting Form](https://www.accessdata.fda.gov/scripts/ptvr/index.cfm),
<https://www.accessdata.fda.gov/scripts/ptvr/index.cfm>
- 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 SAFETY REPORTING PORTAL (SRP)

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>



The screenshot displays the homepage of the Safety Reporting Portal (SRP). At the top, a banner features images of medical supplies and a smiling child with a dog. The title "Safety Reporting Portal" is prominently displayed. Below the banner, a navigation bar includes links for "ABOUT THE PORTAL", "SAFETY REPORT DIRECTORY", "FAQS", "RELATED LINKS", and "CONTACT US".

The main content area is divided into several sections:

- The Safety Reporting Portal:** A paragraph explaining that the SRP streamlines the process of reporting product safety issues to the Food & Drug Administration (FDA) and the National Institutes of Health (NIH).
- Begin Reporting Here:** A section with three columns:
 - 1. Login:** Includes fields for "EMAIL" and "PASSWORD", a "Forgot your password?" link, a "Remember me" checkbox, and a "Log In" button.
 - 2. Report As Guest:** Includes a "Report as Guest" button and a note: "Not ready to create an account but would like to submit a report? You can do that here."
 - Account Benefits:** Lists benefits such as "Save a draft", "Easier follow up", "View submissions", and "Faster data entry", with a "Create Account" button.
- Who Should Submit a Safety Report?:** A section titled "Who Should Submit a Safety Report?" that lists organizations and people required to submit reports (e.g., Food Manufacturers, Researchers, Drug Manufacturers) and others who may voluntarily submit reports (e.g., health care providers, consumers). It includes a link to "Learn more about mandatory and voluntary reporting."
- Reports You Can Submit Through this Portal:** A section titled "Reports You Can Submit Through this Portal" that lists FDA safety issues (e.g., Marketed human drug, Animal drugs, Tobacco products) and NIH safety issues (e.g., NIH gene-transfer research). It includes a link to "find out where to submit your report."

At the bottom of the page, there are logos for the Department of Health & Human Services, USA.gov, the FDA (U.S. Food and Drug Administration), and the National Institutes of Health.

REPORT TOBACCO PRODUCT PROBLEMS IN USERS & NONUSERS

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

Reporting Pathway based on Role	Guest Reporter (Anonymous or Identified)	Individual Registered Reporter (Identified)	Group Account Registered Reporter (Identified)
Consumer/ Concerned Citizen	X	X	X
Healthcare Professional	X	X	X
Manufacturer		X	X
Researcher		X	X

TOBACCO SAFETY REPORTERS WITH MULTIPLE ROLES

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

Questionnaire Sections	Consumers or Healthcare Professionals	Manufacturer	Researcher
Introduction	X	X	X
Problem Summary	X	X	X
Research Summary			X
Tobacco Products	X	+ Manufacturer Investigation	"Study Tobacco Products" and Investigation
Other Tobacco Products Used	X	X	X
Additional Information	X	X	X
Attachments	X	X	X

PRODUCT TYPE IMAGES AND DESCRIPTIONS IN SRP



Product Type Images and Descriptions

Close Window

Cigarette

Roll-your-own cigarette

Bidis, Cloves, Herbal Cigarettes with tobacco

Electronic Cigarette, Electronic Nicotine or Vaping Product (E-cigarettes, e-cigars, e-hookahs, e-pipes, vape pens, hookah pens, and personal vaporizers; E-liquids, e-juice or vape juice)

Tobacco Heating System (heats tobacco leaf not liquid)

Waterpipe (also known as hookah, nargile, shisha, or goza)

Cigar (premium or large)

Small Cigar, Little Cigar or Cigarello

Pipe or pipe tobacco

Snuff (dry or moist for use in nose or mouth)

Snus (pouches or loose)

Chewing tobacco (loose leaf chew, plug, twist/roll)

Gutka (or Gutkha), Betel Quid with Tobacco

Mixture of tobacco with spices, herbs, nuts, fruit, plant leaves, etc. (used for chewing)

Dissolvable (for example strips, sticks, orbs)

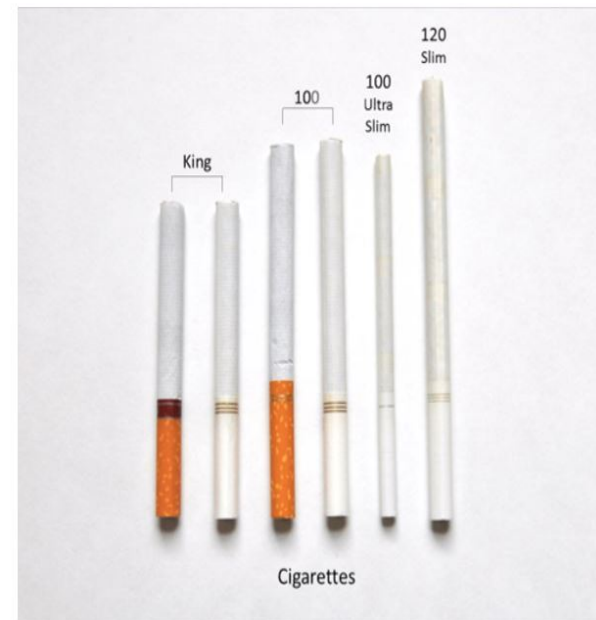
Nicotine Lotions or Gels (applied to the skin)

Tobacco Powder, gel or paste applied to the teeth, gums, or mouth

Other

Cigarette:

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

[f SHARE](#)[TWEET](#)[in LINKEDIN](#)[PIN IT](#)[EMAIL](#)[PRINT](#)

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:

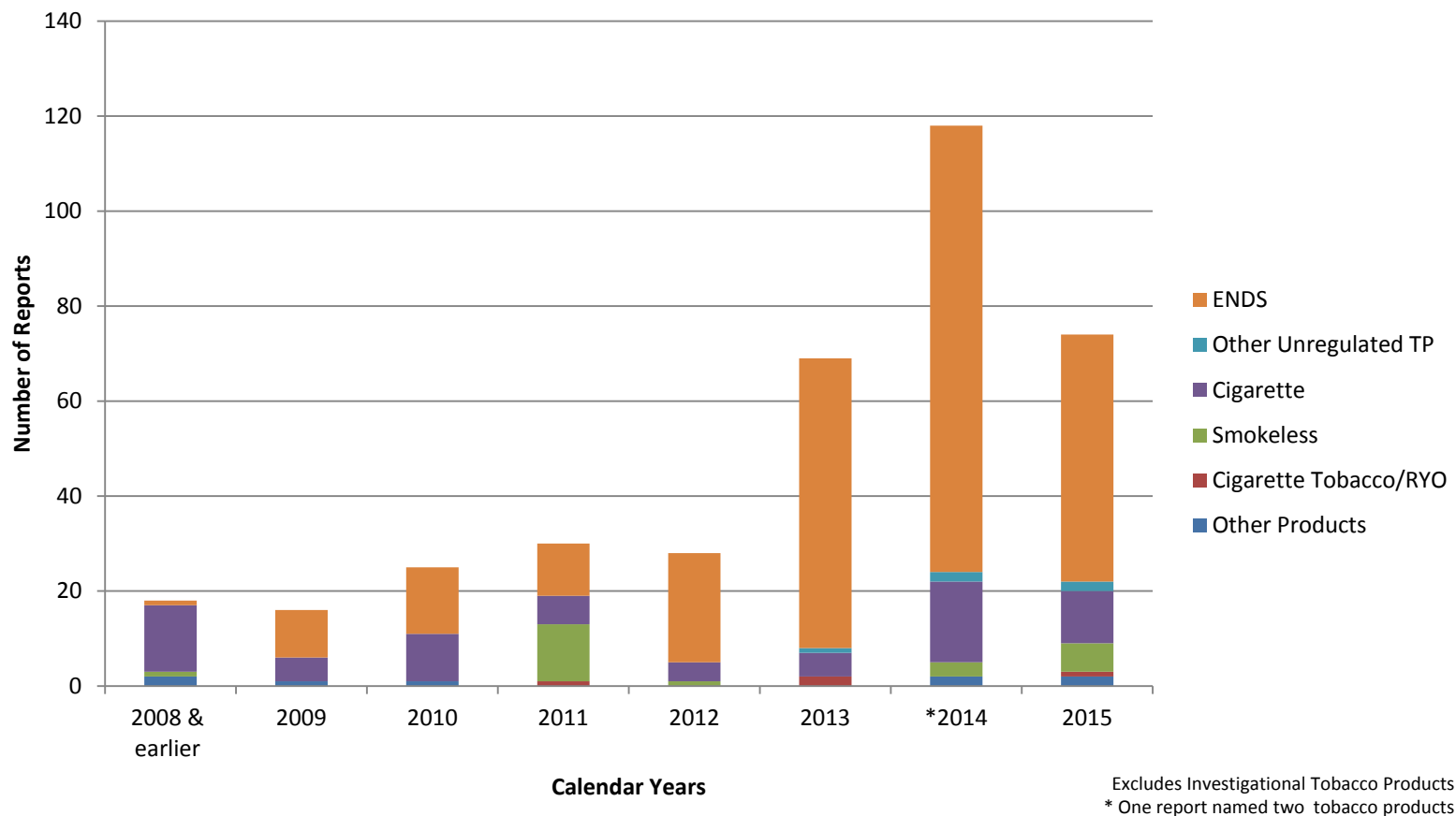
<https://www.safetyreporting.hhs.gov/fpsr/FpsrRoutingPage.aspx>

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**

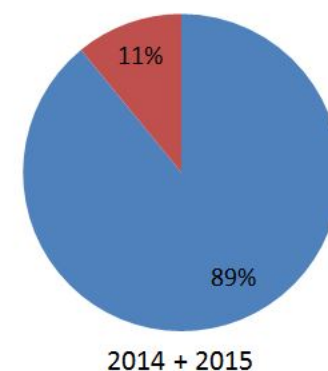
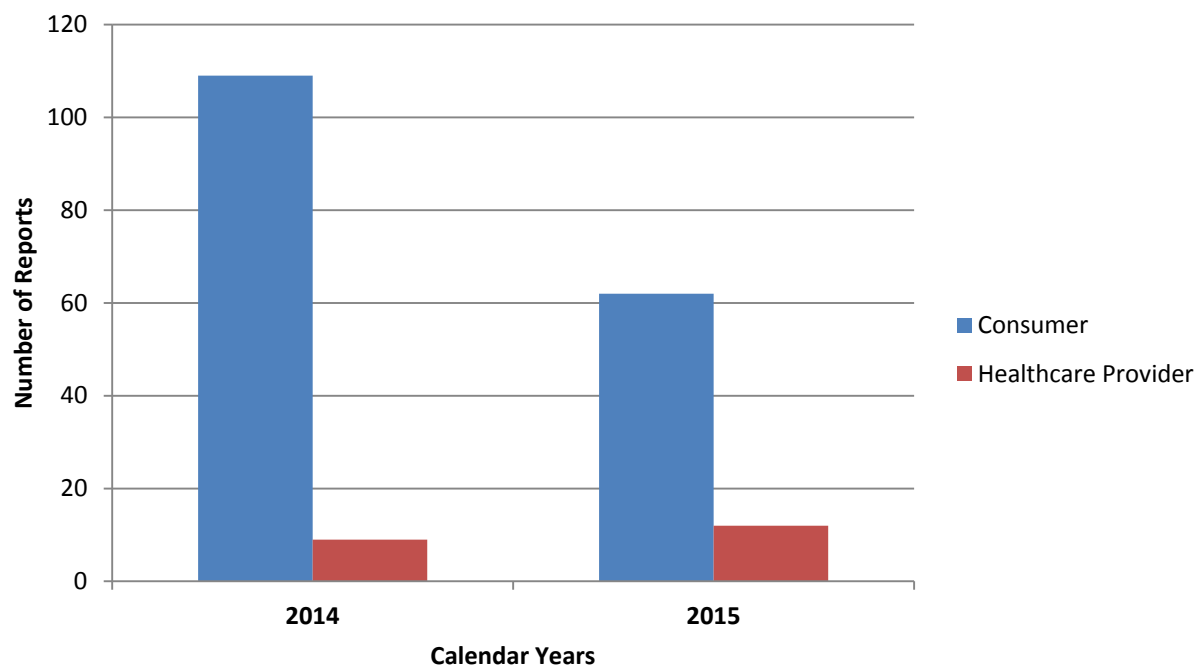
<http://www.fda.gov/Safety/MedWatch/default.htm>

ADVERSE EXPERIENCES REPORTED TO CTP

VOLUNTARY REPORTS BY PRODUCT & CALENDAR YEAR



VOLUNTARY REPORTS BY REPORTER & CALENDAR YEAR



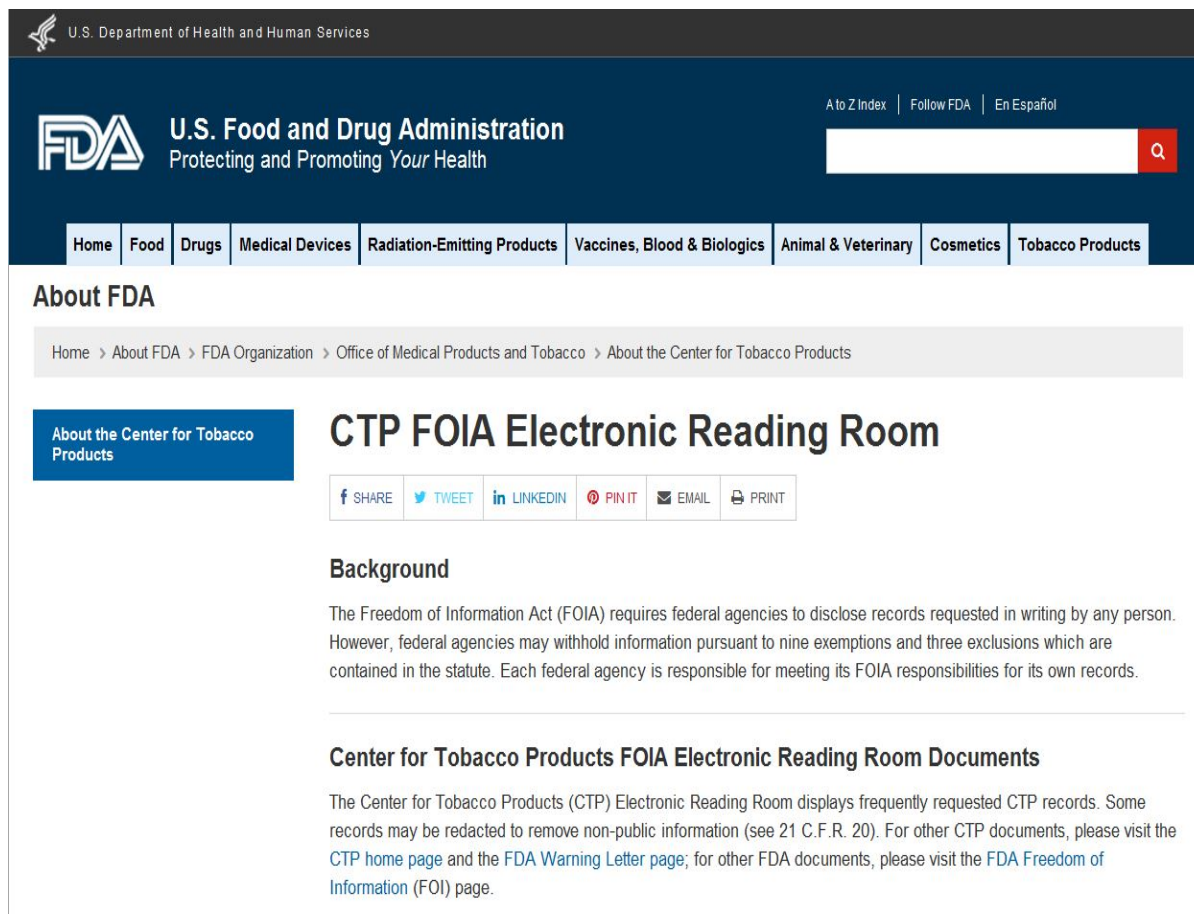
PUBLIC ACCESS TO AE REPORTS: PUBLISHED DATA

<http://www.ncbi.nlm.nih.gov/pubmed/>

- Chen, I. (2013, FEB). Letter: FDA summary of adverse events on electronic cigarettes. *Nicotine & Tobacco Research*, 15, 615-616. doi: [10.1093/ntr/nts145](https://doi.org/10.1093/ntr/nts145)
- Yang, L., Rudy, S. F., Cheng, J. & Durmowicz, E. (2014). Electronic cigarettes: Incorporating human factors engineering into risk assessments. *Tobacco Control*, 23, Suppl 2, ii47-ii53. doi: [10.1136/tobaccocontrol-2013-051479](https://doi.org/10.1136/tobaccocontrol-2013-051479)
- Durmowicz, E. L., Rudy, S. F., Chen, I. (2015, April 23). Research letter - Electronic cigarettes: Analysis of FDA adverse experience reports in non-users. *Tobacco Control*, 23, ii47-53. doi: [10.1136/tobaccocontrol-2015-052235](https://doi.org/10.1136/tobaccocontrol-2015-052235)
- Rudy, S. F., Durmowicz, E. (2016, March 9). ENDS Overheating, Fires and Explosions. *Tobacco Control*. doi: [10.1136/tobaccocontrol-2015-052626](https://doi.org/10.1136/tobaccocontrol-2015-052626)

PUBLIC ACCESS TO AE REPORTS: POSTED REPORTS

<http://www.fda.gov/tobaccoproducts/aboutctp/ucm221165.htm>



The screenshot displays the FDA website's navigation and content for the Center for Tobacco Products (CTP) FOIA Electronic Reading Room. At the top, the U.S. Department of Health and Human Services logo is visible. The FDA logo and name are prominently displayed, along with the tagline "Protecting and Promoting Your Health". A search bar is located on the right side of the header. Below the header, a navigation menu includes links for Home, Food, Drugs, Medical Devices, Radiation-Emitting Products, Vaccines, Blood & Biologics, Animal & Veterinary, Cosmetics, and Tobacco Products. The "About FDA" section is active, showing a breadcrumb trail: Home > About FDA > FDA Organization > Office of Medical Products and Tobacco > About the Center for Tobacco Products. A blue box on the left contains the text "About the Center for Tobacco Products". The main heading is "CTP FOIA Electronic Reading Room", followed by social media sharing options for Facebook, Twitter, LinkedIn, Pinterest, Email, and Print. The "Background" section explains the Freedom of Information Act (FOIA) requirements. The "Center for Tobacco Products FOIA Electronic Reading Room Documents" section provides information about the CTP Electronic Reading Room and links to the CTP home page, FDA Warning Letter page, and FDA Freedom of Information (FOI) page.

U.S. Department of Health and Human Services

FDA U.S. Food and Drug Administration
Protecting and Promoting Your Health

A to Z Index | Follow FDA | En Español

Home | Food | Drugs | Medical Devices | Radiation-Emitting Products | Vaccines, Blood & Biologics | Animal & Veterinary | Cosmetics | Tobacco Products

About FDA

Home > About FDA > FDA Organization > Office of Medical Products and Tobacco > About the Center for Tobacco Products

About the Center for Tobacco Products

CTP FOIA Electronic Reading Room

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Background

The Freedom of Information Act (FOIA) requires federal agencies to disclose records requested in writing by any person. However, federal agencies may withhold information pursuant to nine exemptions and three exclusions which are contained in the statute. Each federal agency is responsible for meeting its FOIA responsibilities for its own records.

Center for Tobacco Products FOIA Electronic Reading Room Documents

The Center for Tobacco Products (CTP) Electronic Reading Room displays frequently requested CTP records. Some records may be redacted to remove non-public information (see 21 C.F.R. 20). For other CTP documents, please visit the [CTP home page](#) and the [FDA Warning Letter page](#); for other FDA documents, please visit the [FDA Freedom of Information \(FOI\) page](#).



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 Caller 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](#)

KEY POINTS

- 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

KEY POINTS (CONT.)

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!

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QUESTIONS?

ASKCTP@FDA.HHS.GOV

1-877-287-1373 (9AM-4PM EST)



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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

fdaofficeofhealthandconstituentaffairs@fda.hhs.gov

