

# Tobacco Product Adverse Event Reporting & Surveillance



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## Issues

Tobacco product use is known to cause serious health consequences and novel tobacco products (TPs) are emerging. **CTP works to identify the risk profiles of novel TPs and to prevent or mitigate health consequences associated with the use of TPs.**

## CTP Activity

Soon after its debut on 6/22/2009, CTP established a **tobacco product surveillance program** to track complaints and detect potential safety signals. In January 2014, CTP launched the **Safety Reporting Portal (SRP)**, a web-based reporting system featuring tobacco product-specific queries. Through this portal, consumers, healthcare professionals and others can report tobacco product concerns directly to CTP. FDA evaluates each report and, if appropriate, takes steps to address the issue.

## Your Part!

Report problems you observe or experience with any tobacco products. The FDA is especially interested in reports associated with new types of tobacco products. **Spread the word!**



## What to Report

**Tobacco products that are:**

- Damaged, defective or malfunctioning
- Contaminated (for example, look, smell or taste wrong)

**Unexpected health or safety problems:**

- Fire, burns or other injuries
- Accidental exposures
- Allergic or toxic reactions
- Unusual reaction in a long-time user

## Overview of the SRP

<https://www.safetyreporting.hhs.gov>



Screen # & Title	Concepts Assessed
1: Begin Reporting Here	Sign in as Guest vs. Account Holder*
2: Report	Select Type of Report* (new vs. follow-up) Select Tobacco Product Report as consumer vs. health care provider* (HCP)
3: Introduction	User-created name for report* Type of report* [Adverse Event (AE), Product Problem, or Both]
4: Contact Information	Reporter contact information: Anonymous vs. Address, phone, e-mail HCP role & affiliation Reporting for self vs. other
5: Problem Summary	Demographics of affected person Comorbidities Problem description & Main symptoms* (pre-selects) Free-text Field* Duration, seriousness, and uniqueness
6: Tobacco Product	Product type* Brand name & source of product Product use details Relatedness of use and reaction
7: Other Products Used	Dual use Alcohol use Free text field Medications (Rx and OTC) Vitamins and supplements
8: Attachments	Up to 5 (10MB each)

\* Required Field

## SRP Features

- Anonymous reporting option
- Only 8 required fields
- Mean completion time is 36 min.
- Automated acknowledgement
- 508 compliant
- Webmaster: [support.srp@jbsinternational.com](mailto:support.srp@jbsinternational.com)

## Current Limitations

- Not mobile-device optimized
- No foreign language versions
- No manufacturer version
- No investigator version

## Other Ways to Report

E-mail: [AskCTP@FDA.hhs.gov](mailto:AskCTP@FDA.hhs.gov)

Tel: 1-877-CTP-1373

Mail: Food and Drug Administration  
 Center for Tobacco Products  
 Document Control Center  
 Attn: OS / Tobacco Product Surveillance Team  
 Building 71, Room G335  
 10903 New Hampshire Avenue  
 Silver Spring, MD 20993-0002

## SRP Findings:

**JAN – JUN, 2014 (n=61)**

### Reporters

- Consumers/concerned citizens (n=57)
- Health care providers (n=4)
- From 22 states (n=50 reporting); highest regional reporting from the South and West. Nineteen reports were from 9 tobacco-growing states.
- The majority were aged 25-64 years, White, non-Hispanic; similar proportion of males and females
- Two reports pertained to children < 5 years old.

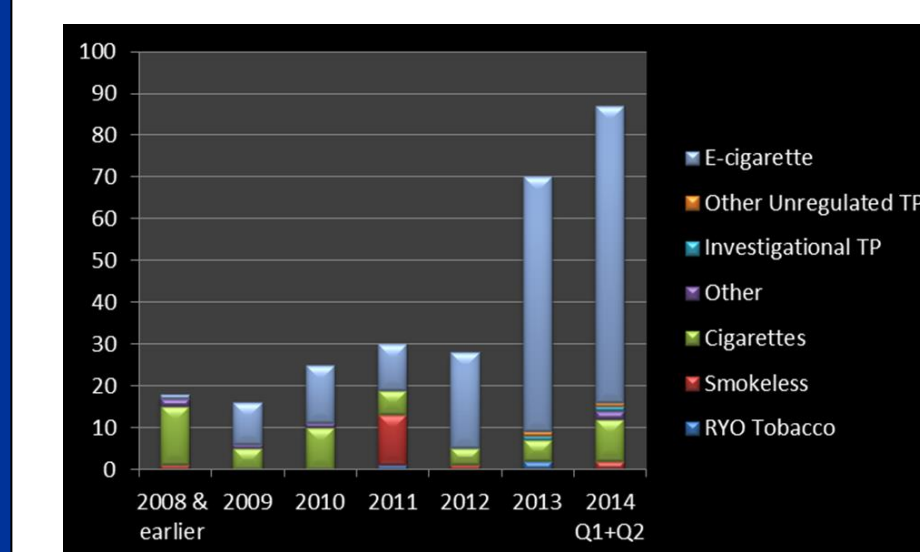
### Report content

- Adverse health effects (n=43; 70%)
- Not serious (n=53; 87%), serious (n=8; 13%)
- About unregulated products\* (n=50; 82%)
- Most reported product = e-cigarettes (n=47; 77%)

\*FDA CTP currently has jurisdiction over cigarettes, roll your own tobacco and smokeless tobacco.

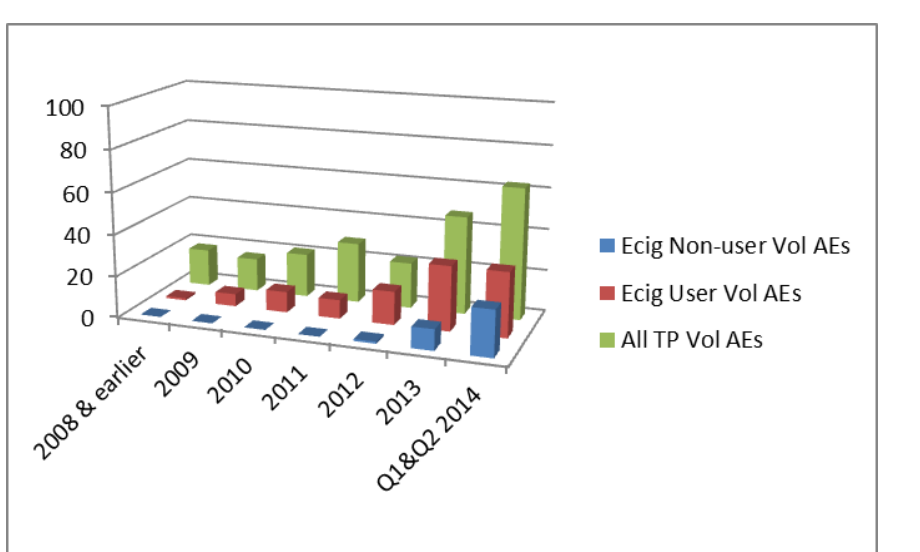
## Cumulative Data through 6/30/2014: Early Trends to Follow

Figure 1: Voluntary Reports per Year



The number of reports is increasing. Reports about unregulated products have predominated since CTP's inception.

Figure 2: E-Cigarette: All TP Reports



Reports of e-cigarette AEs affecting non-users are increasing.

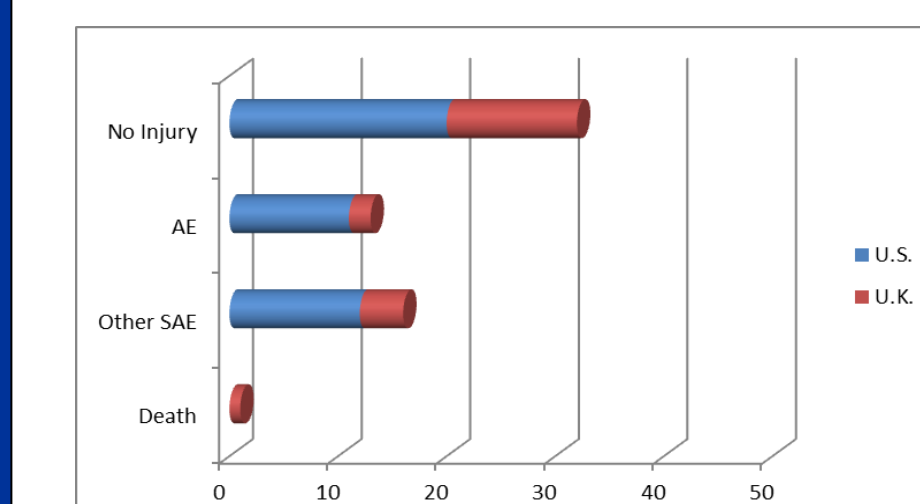


Figure 3 (Left): Media & Voluntary Reports of AEs associated with E-Cigarette Overheating, Explosions or Fires (n=65)

- Explosions have
- injured users and nonusers
  - involved disposable and reusable devices
  - occurred before and during use, and while charging
  - occurred in hospitals, near oxygen, in multiunit housing, and while driving

**LIMITATIONS:** Voluntary reports likely underrepresent the true number and types of AEs associated with TPs and may not have a causal relationship to TP use. The data cannot be used to calculate incidence or to estimate risk. Report content may be influenced by the SRP's structured reporting. Increased reporting rates may reflect SRP launch outreach efforts.