

## Overview

In the second piece of our four-part Harm Reduction series, we explore alternatives to cigarettes, including e-cigarettes and heated tobacco products. According to the Food and Drug Administration (FDA), tobacco use is the leading preventable cause of disease and death in the United States, contributing to nearly half a million premature deaths each year and \$170 billion spent on medical care to treat smoking-related illness. Given the known harms of smoking combustible cigarettes, it is no surprise noncombustible alternatives such as heated tobacco products (HTPs) and e-cigarettes have emerged to provide options for adult cigarette smokers interested in switching to a potentially reduced risk product.

As we consider these products, we ask a few questions: Are they safer than cigarettes? Where does the evidence currently stand? Where do regulations stand? What does the future of tobacco harm reduction look like? Should we encourage *current* smokers to use these products instead?

## What is Harm Reduction?

Under the *Family Smoking Prevention and Tobacco Control Act of 2009*, a product is considered to be *harm reducing* if it benefits the population as a whole taking into account users and non-users of the product. Methods of tobacco harm reduction vary for individuals but can include actions such as using potentially reduced-exposure products (PREPs), reducing or eliminating consumption, switching to long-term nicotine replacement therapy (NRT), and/or switching to noncombustible tobacco products (i.e. e-cigarettes, heated tobacco products, smokeless tobacco).

## What are E-cigarettes?

According to the Centers for Disease Control and Prevention (CDC), e-cigarettes come in various shapes and sizes, and usually involve a battery, a heating element and a place to hold a liquid. The liquid, containing differing levels of nicotine and flavors, is heated to produce an aerosol for users to inhale. Some products are made to look like traditional tobacco products, while others resemble pens and other everyday items. Using an e-cigarette is often called “vaping.” According to the National Institutes of Health (NIH), there are currently 460 e-cigarettes on the market in the U.S.

## Current Evidence

There has been much discussion about e-cigarettes as an alternative to cigarettes, but with the products being so new compared to cigarettes, evidence into the long-term effects is limited and research is ongoing. Here is what we know:

Commissioned by the FDA, the National Academies of Sciences, Engineering, and Medicine published a comprehensive report this year by a panel of experts who evaluated 800 peer-reviewed studies addressing the health impact of e-cigarettes. The 600-page report draws numerous conclusions, but the report says, “There is conclusive evidence that completely substituting e-cigarettes for combustible

## Center Forward Basics

Center Forward brings together members of Congress, not-for-profits, academic experts, trade associations, corporations and unions to find common ground. Our mission: to give centrist allies the information they need to craft common sense solutions, and provide those allies the support they need to turn those ideas into results.

In order to meet our challenges we need to put aside the partisan bickering that has gridlocked Washington and come together to find common sense solutions.

For more information, please visit [www.center-forward.org](http://www.center-forward.org)

## Definitions

- **Electronic nicotine delivery systems (ENDS):** vapes, vaporizers, vape pens, hookah pens, electronic cigarettes (e-cigarettes or e-cigs), and e-pipes are some of the many terms used to describe electronic nicotine delivery systems (ENDS). They are **noncombustible** tobacco products.
- **Combustible products:** ignitable products such as traditional cigarettes, cigars, and hookah. According to the World Health Organization (WHO), traditional cigarettes burn at about 600 degrees Celsius, or 1112 degrees Fahrenheit.

tobacco cigarettes reduces users' exposure to numerous toxicants and carcinogens present in combustible tobacco cigarettes," and there is "substantial evidence that completely switching from regular use of combustible tobacco cigarettes to e-cigarettes results in reduced short-term adverse health outcomes in several organ systems."

However, when it comes to whether e-cigarette use can help smokers quit traditional smoking, the evidence is less clear. On this the experts found there is "insufficient evidence" that vaping can help people quit smoking. The CDC has put out similar guidance saying e-cigarettes can potentially benefit adult smokers who are not pregnant if used as a complete substitute for cigarettes and other smoked tobacco products, but do not recommend starting the use of these products to begin with.

The report was not conclusive on the overall public health impacts of e-cigarettes because of the lack of long-term data available. The question of how these products will affect public health will ultimately be determined by whether cigarette smokers can be convinced to make the switch to these potentially less harmful alternatives over time. The full National Academies of Sciences, Engineering, and Medicine report can be found [HERE](#). The American Cancer Society also released guidance this year which can be found [HERE](#).

## FDA Regulation

FDA finalized a rule, effective August 2016, to extend its regulatory authority to all tobacco products that did not previously fall under FDA's authority, including e-cigarettes, cigars, hookahs, pipe tobaccos, and nicotine gel. Because of the rule, manufacturers of newly regulated tobacco products that were not on the market as of February 15, 2007 have to show their products meet the applicable public health standard set by the *Family Smoking Prevention and Tobacco Control Act*. The deadline to submit products for review has been delayed until 2022 to allow the industry and the agency more time to prepare and to clarify the process.

In 2017, the FDA released their comprehensive plan to shift the trajectory of tobacco-related disease and death, primarily focusing on use in children and young adults. The FDA's multi-year initiative focuses on nicotine at its center and acknowledges that, to truly protect the public, FDA must account for the continuum of risk for nicotine-containing products. The FDA's full announcement can be found [HERE](#).

According to the Truth Initiative, a nonprofit dedicated to making cigarette smoking a thing of the past, preventable disease and death has overwhelmingly been related to combusted tobacco smoking, not to nicotine itself. Nicotine itself is not the the primary cause of harm as much as it is the toxic delivery method of smoking. The Truth Initiative's full report on this can be found [HERE](#).

## Looking Ahead

So where is this market headed? While the U.S. has been slower than some countries in adopting alternatives to cigarettes, FDA Commissioner Scott Gottlieb has said his agency would work to offer less risky products for smokers who want or need nicotine. In a 2017 article published by the New England Journal of Medicine, Commissioner Gottlieb partnered with the FDA Center for Tobacco Products Director Mitch Zeller to write, "Rendering cigarettes minimally addictive or nonaddictive, within a landscape including other, noncombustible products such as e-cigarettes, represents a promising foundation for a comprehensive approach to tobacco harm reduction." According to the Commissioner, the FDA is committed to striking a balance between protecting public health and fostering

- **Noncombustible products:** non-ignitable products including chew, dip, dissolvables, snuff, and snus. E-cigarettes and heated tobacco products (HTPs) are also noncombustible because they heat tobacco and/or nicotine, but do not burn like traditional cigarettes. According to WHO, heated tobacco products reach temperatures of about 350 degrees Celsius, or 662 degrees Fahrenheit.

## Key Statistics

- Nearly 40 million US adults smoke cigarettes.
- In addition to the nearly half a million Americans who die prematurely of smoking or exposure to secondhand smoke every year, another 16 million live with a serious illness caused by smoking.
- Current smoking has declined from 20.9% (nearly 21 of every 100 adults) in 2005 to 15.5% (more than 15 of every 100 adults) in 2016.
- In 2016, 3.2% of U.S. adults were current e-cigarette users.
- 5.3% of Americans believe that e-cigarettes are "much less harmful" than cigarettes and 37% believe they are the same or worse than smoking.

innovation in a less harmful way to deliver nicotine.

It is clear researchers need more information into the long-term effects, but it is unsurprising that other countries are already regulating and promoting e-cigarettes as a safer alternative to smoking. For example, Public Health England (PHE), an executive agency of the UK Department of Health, included e-cigarettes as part of their yearly “Stoptober” campaign in 2017 as a method to quit smoking. PHE released their own evidence review in 2015 and a second one shortly after the US National Academies of Sciences, Engineering, and Medicine released theirs this year. UK experts drew similar conclusions, even going so far as to say e-cigarettes are 95 percent less harmful than cigarettes. On other alternatives to cigarettes, the report concluded heated tobacco products significantly reduce a user’s exposure to harmful elements and acknowledged that snus, a form of smokeless tobacco, has not been found to increase the risk of serious health problems in adults. PHE’s full evidence review can be found [HERE](#).

Evidence into the long-term effects of e-cigarettes is still evolving; however, what we know for sure is promising compared to what we know about cigarettes. With nearly half a million Americans dying each year from smoking, we should expect to see manufacturers continue to innovate in smoking alternatives and the U.S. continue to follow the UK’s lead in regulating e-cigarettes and heated tobacco products as potentially less harmful alternatives.

## Links to Other Resources

National Academy of Sciences, Institute of Medicine:

<http://www.nationalacademies.org/hmd/~media/Files/Report%20Files/2003/Clearing-the-Smoke-The-Science-Base-for-Tobacco-Harm-Reduction/tobacco8pgfinal2.PDF>

Harm Reduction International:

<https://www.hri.global/contents/692>

CDC Smoking and Tobacco Use:

[https://www.cdc.gov/tobacco/data\\_statistics/index.htm](https://www.cdc.gov/tobacco/data_statistics/index.htm)

National Academies of Sciences, Engineering, and Medicine:

<https://www.nap.edu/catalog/24952/public-health-consequences-of-e-cigarettes>

CDC Electronic Cigarettes:

[https://www.cdc.gov/tobacco/basic\\_information/e-cigarettes/index.htm](https://www.cdc.gov/tobacco/basic_information/e-cigarettes/index.htm)

FDA Family Smoking Prevention and Tobacco Control Act:

<https://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/ucm246129.htm>

FDA Comprehensive Regulatory Plan:

<https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm568923.htm>

FDA Youth Tobacco Prevention Plan:

<https://www.fda.gov/newsevents/newsroom/pressannouncements/ucm605432.htm>

FDA New Tobacco Rule:

<https://www.fda.gov/ForConsumers/ConsumerUpdates/ucm506676.htm>

Public Health England Stoptober:

<https://campaignresources.phe.gov.uk/resources/campaigns/6-stoptober/overview>

Public Health England E-cigarette Evidence Review:

<https://www.gov.uk/government/news/phe-publishes-independent-expert-e-cigarettes-evidence-review>

FDA Electronic Nicotine Delivery Systems (ENDS):

<https://www.fda.gov/tobaccoproducts/labeling/productingredientscomponents/ucm456610.htm>

The BMJ Tobacco Control:

<https://tobaccocontrol.bmj.com/content/25/2/174>

World Health Organization - Heated Tobacco Products:

[http://www.who.int/tobacco/publications/prod\\_regulation/heated-tobacco-products/en/](http://www.who.int/tobacco/publications/prod_regulation/heated-tobacco-products/en/)

Family Smoking Prevention and Tobacco Control Act:

<https://www.gpo.gov/fdsys/pkg/PLAW-111publ31/pdf/PLAW-111publ31.pdf>

American Cancer Society on E-cigarettes:

<https://www.cancer.org/healthy/stay-away-from-tobacco/e-cigarette-position-statement.html>

Public Health England:

<https://www.gov.uk/government/publications/e-cigarettes-and-heated-tobacco-products-evidence-review/evidence-review-of-e-cigarettes-and-heated-tobacco-products-2018-executive-summary>

Annual Review of Public Health:

<https://www.annualreviews.org/doi/pdf/10.1146/annurev-publhealth-040617-013849>

New England Journal of Medicine:

<https://www.nejm.org/doi/full/10.1056/NEJMp1707409>

The Truth Initiative:

<https://truthinitiative.org/sites/default/files/ReThinking-Nicotine.pdf>