

# ISSUE BRIEF

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## Rethinking Tobacco Policy: The Federal Government Should Stop Blocking Alternatives to Smoking

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Cigarette smokers who are trying to quit smoking have many new and innovative options to help them break the habit. At least they do as of now. E-cigarettes, as well as even newer products which heat but do not burn tobacco, allow those who are unable or unwilling to quit using nicotine to dramatically reduce their exposure to the deadliest components of cigarettes, the products of combustion in the smoke.

However, the federal government is about to prevent individuals who desperately want to stop smoking from having access to these options.

This is a critical moment in determining how the federal government is going to deal with alternative products to smoking: The federal government can either allow people to make free choices that might help save their lives or be co-opted by misguided public health extremists who aim to eradicate tobacco and even nicotine altogether, regardless of the potential damage to millions of Americans who want to stop smoking.

Congress and the Trump Administration should move the government out of the business of blocking access to products that may help individuals reduce their cigarette smoking. One answer is to embrace “tobacco harm reduction,” a strategy that recognizes that reducing the harm from the delivery of nicotine is not an all-or-nothing proposition.

### **Markets Are Providing Solutions to Help Smokers**

As a result of private innovation in the marketplace, important alternatives to smoking can reduce the risks associated with the delivery of nicotine. These alternative products, created through private-sector innovation, appear to be doing what non-stop government spending, costly litigation, addictive excise taxes, warning labels, and punitive regulations have been unable to do for far too many: help cigarette smokers quit.

### **The Federal Government Is Blocking Solutions**

Instead of allowing smokers to have access to these alternatives, the federal government is pushing these products off the market. One of the biggest obstacles for e-cigarettes is an unintended consequence of the Tobacco Control Act of 2009<sup>1</sup>—at least as it is being implemented currently by the Food and Drug Administration (FDA).

On May 10, 2016, the FDA published a final rule<sup>2</sup> that will ban nearly every e-cigarette currently on the market. This is due to a requirement that products not on the market by February 2007 will have to submit a costly and burdensome pre-market tobacco product application.<sup>3</sup>

This requirement is problematic because today’s e-cigarettes that smokers are using as an alternative to cigarettes were not on the market as of this date and will therefore have to go through this application process. There are no assurances that any applications will be accepted. Even if a few are permitted, the vast, diverse, and growing choice of alternatives to cigarettes will be severely curtailed.<sup>4</sup>

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This paper, in its entirety, can be found at <http://report.heritage.org/ib4657>

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Many companies that sell these alternatives to cigarettes are small businesses,<sup>5</sup> and will likely not be able to afford the risk of going through the costly process. Ironically, these lower risk products will have to overcome the outrageously burdensome process, but existing cigarettes are exempt from it.

### Consumers Should Be Free to Choose

Consumers should be able to decide for themselves whether they would like to smoke, purchase alternatives to smoking that could reduce harmful health effects, or not use cigarettes or these alternatives at all. When it comes to the alternatives to smoking, the federal government is blocking products and much-needed innovation that could help save the lives of Americans.

In the most comprehensive government report<sup>6</sup> of its kind, Public Health England described e-cigarettes in 2015 as “95% less harmful than tobacco cigarettes, and maintains they aren’t leading kids to smoke.”<sup>7</sup>

In fact, consumers around the world are switching to e-cigarettes. London’s *City A.M.* reported that Brits are leading the way, thanks in part to relatively rational regulations and science-based advice.<sup>8</sup> This reasonable approach to e-cigarettes is already having a very positive effect. As the *City A.M.* article explained, “Since 2013, one person has switched from traditional smoking to so-called vaping every four minutes in the UK, according to new research from EY [formerly Ernst & Young].”<sup>9</sup>

Critics of e-cigarettes have expressed concern that the products might serve as a gateway for non-smokers to start smoking. The data do not back this claim. The 2014 National Health Interview Survey (NHIS) shows that for people who have never smoked, only 3.2 percent tried e-cigarettes and only 0.4 percent are current vapers.<sup>10</sup> As for the impact of these products on youth, the gateway argument is also weak, but it is exacerbated by the anti-tobacco mentality that permeates the federal government.<sup>11</sup>

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1. Family Smoking Prevention and Tobacco Act, Public Law 111-31, 111th Cong., 1st Sess., June 22, 2009, <https://www.congress.gov/111/plaws/publ31/PLAW-111publ31.pdf> (accessed February 21, 2017).
  2. *Federal Register*, Vol. 81, No. 90 (May 10, 2016), pp. 28973-29106.
  3. *Ibid.*
  4. Surveys show that a range of nicotine levels, from high to low to none, as well as a range of flavors, is essential in the path from smoking to vaping. See Action on Smoking and Health, “Use of Electronic Cigarettes (Vapourisers) Among Adults in Great Britain,” *Fact Sheet*, May 16, 2016, <http://ash.org.uk/information-and-resources/fact-sheets/use-of-electronic-cigarettes-vapourisers-among-adults-in-great-britain/> (accessed February 21, 2017). Note: Action on Smoking and Health is a major U.K. anti-smoking charity.
  5. News release, “Vapor Technology Association on Proposed FDA Regulations.” Vapor Technology Association, [http://vaportechnology.org/wp-content/uploads/2016/08/4.14.16\\_VAPOR-TECHNOLOGY-ASSOCIATION-ON-PROPOSED-FDA-REGULATIONS.pdf](http://vaportechnology.org/wp-content/uploads/2016/08/4.14.16_VAPOR-TECHNOLOGY-ASSOCIATION-ON-PROPOSED-FDA-REGULATIONS.pdf) (accessed February 21, 2017). See also, Smoke Free Alternatives Trade Association, “About SFATA,” <http://sfata.org/about-sfata/> (accessed February 21, 2017).
  6. News release, “E-cigarettes Around 95% Less Harmful Than Tobacco Estimates Landmark Review,” Public Health England, <https://www.gov.uk/government/news/e-cigarettes-around-95-less-harmful-than-tobacco-estimates-landmark-review> (accessed February 21, 2017).
  7. *Ibid.* See also Maciej Lukasz Goniewicz, Jakub Knysak, Michal Gawron, Leon Kosmider, Andrzej Sobczak, Jolanta Kurek, Adam Prokopowicz, Magdalena Jablonska-Czapla, Czeslawa Rosik-Dulewska, Christopher Havel, Jacob Peyton III, and Neal Benowitz, “Levels of Selected Carcinogens and Toxicants in Vapour from Electronic Cigarettes,” *Tobacco Control*, [https://www.heartland.org/\\_template-assets/documents/publications/goniewicz-tobaccocontrol-2013.pdf](https://www.heartland.org/_template-assets/documents/publications/goniewicz-tobaccocontrol-2013.pdf) (accessed February 21, 2017). In this article, the authors conclude: “We found that the e-cigarette vapours contained some toxic substances. The levels of the toxicants were 9–450 times lower than in cigarette smoke and were, in many cases, comparable with trace amounts found in the reference product.”
  8. Mark Sands, “British Smokers Are Switching to E-Cigarettes Faster than Anyone,” *City A.M.*, February 6, 2017, <http://www.cityam.com/258441/british-smokers-switching-e-cigarettes-faster-than-anyone> (accessed February 21, 2017).
  9. *Ibid.*
  10. Centers for Disease Control and Prevention, “Electronic Cigarette Use Among Adults: United States 2014,” *NCHS Data Brief* No. 217, October 2015, <https://www.cdc.gov/nchs/data/databriefs/db217.htm> (accessed February 21, 2017). See also Melissa Vonder Haar, “Five Positive E-Cigs Facts From CDC’s Health Survey,” *CSP Daily News*, <http://www.cspsdailynews.com/category-news/tobacco/articles/five-positive-e-cigs-facts-cdc-s-health-survey> (accessed February 21, 2017).
  11. For example, the Centers for Disease Control and Prevention play statistical tricks on e-cigarette use data, highlighting occasional youth experimentation (once in 30 days). See, for example, Centers for Disease Control and Prevention, “Youth and Tobacco Use Facts Sheet,” [https://www.cdc.gov/tobacco/data\\_statistics/fact\\_sheets/youth\\_data/tobacco\\_use/](https://www.cdc.gov/tobacco/data_statistics/fact_sheets/youth_data/tobacco_use/) (accessed February 21, 2017). A recent Surgeon General report completely ignored the benefits of e-cigarettes. U.S. Department of Health and Human Services, Surgeon General, “Know the Risks,” <https://e-cigarettes.surgeongeneral.gov/resources.html> (accessed February 21, 2017).

Youth smoking rates have come down sharply at the same time that e-cigarettes have come on the market (and the rate of decline has not slowed down).<sup>12</sup> Significant additional evidence, including from Public Health England, shows that e-cigarettes are not a gateway to smoking for youth.<sup>13</sup> A 2014 study in the *American Journal of Preventive Medicine* found that “[n]on-smoking high school students are highly unlikely to use e-cigarettes; among those who do, most used them only on 1–2 of the past 30 days.”<sup>14</sup> A study in the peer-reviewed journal *Tobacco Control* found that even among students who have vaped, most simply vaped flavoring, not nicotine.<sup>15</sup>

In any case, if one is concerned about minors using e-cigarettes, the FDA (and almost every state) has already banned their sale to minors.<sup>16</sup> The focus for the FDA should be on enforcing its ban, without impeding potentially life-saving alternatives reaching adult smokers who face risks from continued smoking.

## Recommendations

Both Congress and the Trump Administration should make major changes to allow consumers to have access to e-cigarettes, and as a result, enable them to have this option and others that could improve their health:

- **Congress should reform the Tobacco Control Act of 2009.** Congress has been considering changing the arbitrary 2007 “grandfather” date that has led to the absurd situation where

many e-cigarettes could effectively be banned.<sup>17</sup> However, this is just a Band-Aid because the innovation-stifling approval process will live on. For innovation to flourish, the entire tobacco-control regulatory regime must be completely re-envisioned, including eliminating pre-market tobacco product application requirements and ensuring that the FDA does not continue taking an overly expansive view of what constitutes a “tobacco product” (i.e., just because a product has nicotine, which may be derived from tobacco, should not mean it is a tobacco product).

- **Federal agencies should correct misleading information and provide proper information to the public.** The Centers for Disease Control and Prevention and other agencies that work on tobacco policy should correct misleading information and, to the extent that they are still providing information to the public, they should redirect resources toward providing accurate information to smokers so that they may make more informed choices.
- **Congress and the Administration should make tobacco harm reduction the policy norm throughout the federal government.** The goal across the federal government should be to allow adult smokers to make informed decisions and leave the market alone so it can continue to provide a robust choice of lower risk, yet appealing, alternatives to cigarettes.

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12. Centers for Disease Control and Prevention, “National Youth Tobacco Survey,” [https://www.cdc.gov/tobacco/data\\_statistics/surveys/nyts/](https://www.cdc.gov/tobacco/data_statistics/surveys/nyts/) (accessed February 21, 2017). See also Jacob Sullum, “Why is the CDC Lying About E-cigarettes?” *Forbes*, April 23, 2015, <http://www.forbes.com/sites/jacobsullum/2015/04/23/why-is-the-cdc-lying-about-e-cigarettes/#a6b4ac52dbdc> (accessed February 21, 2017).

13. “E-cigarettes Around 95% Less Harmful Than Tobacco Estimates Landmark Review,” Public Health England.

14. Kenneth Warner, “Frequency of E-Cigarette Use and Cigarette Smoking by American Students in 2014,” *American Journal of Preventive Medicine*, Vol. 51, No. 2 (August 2016), pp. 179–184, <http://www.ajpmonline.org/article/S0749-3797%2815%2900782-5/abstract> (accessed February 21, 2017).

15. Richard Miech, Megan E. Patrick, Patrick M. O’Malley, and Lloyd D. Johnston, “What Are Kids Vaping? Results from a National Survey of US Adolescents,” *Tobacco Control*, <http://tobaccocontrol.bmj.com/content/early/2016/07/21/tobaccocontrol-2016-053014> (accessed February 21, 2017). See also Jacob Sullum, “More Evidence That Vaping Is Not a Gateway to Smoking,” Reason Foundation, September 19, 2016, <http://reason.com/archives/2016/09/19/more-reasons-to-doubt-that-vaping-is-a-g> (accessed February 21, 2017).

16. *Federal Register*, Vol. 81, No. 90 (May 10, 2016), pp. 28973–29106. See also “Alternative Nicotine Products: Electronic Cigarettes,” National Conference of State Legislatures, May 5, 2016, <http://www.ncsl.org/research/health/alternative-nicotine-products-e-cigarettes.aspx> (accessed February 21, 2017).

17. See, for example, FDA Deeming Authority Clarification Act of 2017, H.R. 1136, 115th Cong., 1st Sess., <https://www.congress.gov/bill/115th-congress/house-bill/1136/all-info?r=4> (accessed February 21, 2017).

## Conclusion

Congress and the Trump Administration can both help smokers move away from smoking and lower regulatory burdens by embracing tobacco harm reduction as a preferred strategy. This requires no government interventionist policies. Instead, the federal government simply needs to step aside and allow the market to make it possible for smokers to have access to innovative products that can help them stop smoking.

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