



# **Deeming Tobacco Products to be Subject to the Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Regulations Restricting the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Product Packages and Advertisements**

## **Docket ID: FDA-2014-N-0189**

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### **INTRODUCTION**

The Regulatory Studies Program of the Mercatus Center at George Mason University is dedicated to advancing knowledge about the effects of regulation on society. As part of its mission, the program conducts careful and independent analyses that employ contemporary economic scholarship to assess rulemaking proposals and their effects on the economic opportunities and the social well-being available to all members of American society.

This comment addresses the efficiency and efficacy of this proposed reconsideration from an economic point of view. Specifically, it examines how the relevant rule may be improved by more closely examining the societal goals the rule intends to achieve and whether this reconsideration will successfully achieve those goals. In many instances, regulations can be substantially improved by choosing more effective regulatory options or more carefully assessing the actual societal problem.

### **SUMMARY**

The proposed rule expands FDA regulatory authority over tobacco products to include regulation of cigars, pipe tobacco, hookah tobacco, electronic cigarettes, and other novel tobacco products, such as dissolvable products and gels. Cigars are the most commonly used among this group, though use of

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electronic cigarettes, or e-cigarettes, is rapidly expanding. Under the proposed rule, Federal Food, Drug, and Cosmetic Act (FD&C Act) requirements would apply to these products that include establishment registration and product listing, ingredient listing, submissions prior to the introduction of new products, labeling requirements, and prohibition of free samples.<sup>1</sup> Additional provisions include minimum age and identification requirements, vending machine restrictions, and required warning statements for packages and advertisements.

The proposed rule consists of two co-proposals. Option 1 deems all products meeting the statutory definition of “tobacco product” except accessories of a proposed deemed tobacco product to be subject to chapter IX of the FD&C Act. Option 2 is the same as option 1 except it exempts premium cigars.<sup>2</sup>

The proposed rule is an enabling regulation that allows the FDA to issue in the future public health regulations related to newly deemed products. The FDA is also authorized to collect ingredient and health information on these products. The FDA does not estimate benefits but anticipates that the largest benefit of the proposed provisions would be improvements in health and life expectancy resulting from reductions in the use of combustible tobacco products deemed under this proposed rule. The FDA also states that public health will improve when it is granted authority to take action against new products that pose greater health risks than those already on the market.

This public interest comment argues that the FDA has failed to develop an appropriate benefit-cost analysis of the proposed rule. The FDA claims its failure to quantify benefits is justified by the uncertainty surrounding them, even as the FDA “anticipates” substantial benefits from reducing harm by regulating newly deemed products. However, promises of anticipated benefits require quite a “leap of faith” given the FDA’s acknowledgment that they have no reasonable means of quantifying how much harm the proposed rule will reduce in the future.

The FDA has also failed to adequately assess costs that appear likely from the proposed rule’s suppression of the e-cigarette market. The FDA has mostly ignored the evolving literature on e-cigarettes that strongly suggests they help smokers quit smoking. The proposed rule pushes e-cigarette manufacturers to focus efforts toward developing new flavors, packaging, and other attributes unrelated to improved public health. The proposed rule might also promote combustible tobacco use because manufacturers will be unable to market e-cigarettes as safer alternatives or even state that they don’t contain tobacco. It is likely that fewer smokers will quit or reduce cigarette consumption. Public health will worsen to the extent that e-cigarettes are a safer alternative to tobacco cigarettes.

This public interest comment estimates the range of annual benefits (costs avoided) associated with e-cigarette use as \$15.6 billion to \$49.2 billion and that 2.4 million to 6.4 million smokers may potentially become ex-smokers by using e-cigarettes. Estimates are based on a range of quit rates from the current literature and assume all smokers interested in quitting use e-cigarettes. Even a fraction of estimated benefits (costs saved) are substantial. These estimates indicate the FDA is jeopardizing public health by not estimating benefits associated with e-cigarettes using data from readily available studies on their efficacy as harm-reduction tools.

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1. Existing regulations prohibit the distribution of free samples of any tobacco product except for smokeless tobacco samples distributed in a qualified adult-only facility. This provision would automatically apply to proposed deemed tobacco products.

2. Premium cigars are defined as those that are wrapped in whole tobacco leaf; contain a 100 percent leaf tobacco binder; contain primarily long-filler tobacco; are made by manually combining the wrapper, filler, and binder; have no filter, tip, or non-tobacco mouthpiece and are capped by hand; do not have a characterizing flavor other than tobacco; weigh more than six pounds per thousand units; and sell for \$10 or more per cigar.

## Need a More Comprehensive Model of Reducing Harm

The FDA implicitly assumes that consumption of all tobacco products it seeks to regulate should be decreased toward a goal of zero. While tobacco use is known to be risky, economic theory demonstrates that few to no activities are optimally provided at zero quantity. This applies to consumption of risky products as well as efforts aimed at decreasing their use. There are costs and benefits to improving public health and “perfection”—the elimination of all risks—is not an optimal public health strategy in a world with scarce resources.

OMB Circular A-4 requires agencies to consider risk tradeoffs.<sup>3</sup> Specifically, it states that when benefit and cost estimates are uncertain, agencies should report benefit and cost estimates that include benefits of risk reductions. It states, “If fundamental scientific disagreement or lack of knowledge prevents construction of a scientifically defensible probability distribution, you should describe benefits or costs under plausible scenarios and characterize the evidence and assumptions underlying each alternative scenario.” The FDA needs to directly consider the available evidence on whether all products regulated under this rule pose equal harm and whether e-cigarettes are beneficial to public health.

The FDA argues that current tobacco policies are suboptimal while failing to determine what optimal regulation would look like. A sophisticated model would consider the possibilities that tobacco products are not equally risky or that all are equally controllable through regulation. Such a model is in line with estimates that up to 98 percent of tobacco-related deaths are attributable to combustible products (cigarette, pipe, and cigar smoking).<sup>4</sup> The FDA downplays the possibility that noncombustible products are substantially less dangerous than combustible tobacco products, though this does not mean any are entirely safe. Noncombustible forms include nicotine-replacement therapies (NRTs) as well as smokeless tobacco (e.g., snus) and e-cigarettes.

The FDA does not take a stand on e-cigarette risks and benefits because they believe there is too little information available.<sup>5</sup> However, the American Medical Association published a “JAMA Patient Page” in January 2014 that listed the following potential benefits of e-cigarettes.<sup>6</sup>

- Tobacco is what makes regular cigarettes so harmful to health, but e-cigarettes do not contain tobacco.
- Tobacco products are addictive because of the nicotine they contain and nicotine is not healthy. But nicotine probably does not contribute nearly as much to smoking-related diseases as tobacco.
- “Clean nicotine” has been used as a safe way to help people quit smoking for nearly three decades. Such products include patches, lozenges, gum, orally inhaled products, and nasal spray.
- Although e-cigarettes may contribute nicotine vapor to the air, the vapor is much less toxic than secondhand tobacco smoke.
- People may start using e-cigarettes simply because they are less harmful than tobacco cigarettes.

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3. US Office of Management and Budget, *Memorandum for the Heads of Executive Departments and Agencies*, OMB Memoranda 01-23 (Improving Regulatory Impact Analyses) (Washington, DC, June 19, 2001), [http://www.whitehouse.gov/omb/memoranda\\_m01-23/](http://www.whitehouse.gov/omb/memoranda_m01-23/).

4. Michael C. Fiore, Steven A. Schroeder, and Timothy B. Baker, “Smoke, the Chief Killer — Strategies for Targeting Combustible Tobacco Use,” *New England Journal of Medicine* 370 (January 23, 2014).

5. The FDA does not quantify benefits due to insufficient evidence to estimate within acceptable levels of certainty how consumers will respond to the proposed rule. The FDA argues that estimating effects of the proposed rule on users of these products would require extrapolating from experience of other products and warning labels. The FDA states that the combined uncertainties of inferring changes in behavior based on different products, different warnings, different baseline practices, and different risk profiles create too wide a band of uncertainty to allow it to quantitatively estimate effects of the proposed rule.

6. Deborah Tolmach Sugerman, “e-cigarettes,” *Journal of the American Medical Association* 311, no. 2 (January 8, 2014).

This “JAMA Patient Page” also outlines various concerns regarding safety. These include lack of standardization and quality control among the more than 250 brands. The unclear nature of whether there is a “safe” level of toxins in the vapor and whether e-cigarettes may increase the social acceptability of smoking are also mentioned.

It is problematic that the FDA mostly ignores available evidence that suggests not all nicotine-containing products pose equal harm. The FDA does not explicitly state that e-cigarettes are as harmful as cigarettes, but their model in effect dismisses the essence of “harm-reduction theory.”<sup>7</sup> Harm-reduction theory indicates that minimizing damage from risky behavior may promote public health more effectively than simply attempting to eliminate behavior, even if some people who quit combustibles begin using noncombustible products. Placing highest priority on reducing combustible tobacco products is a reasonable strategy that the FDA should at least discuss.

It is also troubling that the FDA has expended so little effort reviewing the growing evidence that e-cigarettes help some smokers quit tobacco cigarettes. This literature is reviewed below. The literature indicates rapid growth of these products can be partially explained by smokers seeking help in their efforts at quitting. Data are scarce, but one top tobacco analyst predicted e-cigarette sales in the United States to more than double in 2013, hitting \$1.7 billion.<sup>8</sup> This evidence suggests that consumers are interested in using e-cigarettes as harm-reduction tools, though it remains unclear the degree to which smokers will switch to e-cigarettes.

In sum, the FDA should devote time and energy to developing a model in line with conventional benefit-cost analysis that typically concludes that zero use of all risky products is not optimal. Optimal policy focuses more effort on reducing riskier products rather than treating all products as equal threats to public health.

### Ignores Emerging Literature on E-Cigarettes

E-cigarettes are electronic nicotine delivery systems that are battery powered and simulate tobacco smoking by producing a vapor that resembles smoke. A heating element is used to vaporize liquid solutions that contain a mixture of propylene glycol, glycerin, nicotine, and flavorings. The FDA understands that e-cigarette use has expanded rapidly and that their effects on health depend on whether c-cigarettes are substitutes, complements, or unrelated to other risky products.

- If substitutes, the FDA states that fewer cigarettes and cigars are consumed as the market for e-cigarettes grows. If e-cigarettes are safer, the FDA states that substituting them for cigarettes and cigars increases health; if less safe, substitution decreases health.
- If complements, growth in e-cigarettes expands consumption of cigarettes and cigars and thus reduces health according to the FDA.
- If unrelated, growth in e-cigarettes does not influence consumption of other tobacco products. If e-cigarettes are safer, then the FDA expects that health effects depend on their safety compared to substitute products, such as degree of addictiveness. If e-cigarettes pose risks similar to cigars and cigarettes, the FDA expects health effects to be negative.

The FDA expresses concerns that e-cigarettes might lead youth to take up e-cigarettes and become addicted to nicotine or lead to initiation of other tobacco products. Evidence so far is quite limited on these issues.

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7. See, for example, Brad Rodu and William T. Godshall, “Tobacco Harm Reduction: An Alternative Cessation Strategy for Inveterate Smokers,” *Harm Reduction Journal* 3, no. 37 (2006).

8. Dan Mangan, “E-Cigarette Sales Are Smoking Hot, Set to Hit \$1.7 Billion,” *CNBC*, August 28, 2013, <http://www.cnbc.com/id/100991511>.

The FDA cites a Centers for Disease Control and Prevention (CDC) report that found that e-cigarette experimentation and recent use doubled among US middle and high school students from 2011 to 2012, resulting in an estimated 1.78 million students having ever used e-cigarettes as of 2012.<sup>9</sup> In 2012, roughly nine percent of those had never used tobacco cigarettes. These estimates indicate valid concerns regarding risks for nicotine addiction and initiation of other tobacco products. But the FDA should consider them within a more sophisticated model of harm, as previously discussed.

The FDA errs on the side of assuming e-cigarettes pose more of a health risk than an opportunity to promote public health. Studies are readily available that suggest e-cigarettes help some smokers reduce or quit smoking. Their effectiveness appears to be related to the fact that, unlike NRT, e-cigarettes deliver nicotine with a device that mimics smoking.

Summary results of relevant recent studies are below. None of these is discussed by the FDA.

- Polosa et al. conclude e-cigarettes help smokers remain abstinent or reduce their cigarette consumption.<sup>10</sup> This study monitored smoking habit changes of 40 regular smokers (unwilling to quit) experimenting with e-cigarettes. Study participants were monitored during intervals of up to 24 weeks on product use, number of cigarettes smoked, and exhaled carbon monoxide levels. The study found a sustained reduction in numbers of cigarettes, with a sustained 50 percent reduction and smoking abstinence shown in 22 out of 40 (55 percent of) participants, with an overall 88 percent fall in cigarettes per day.
- Foulds et al. found that a large majority of e-cigarette users had repeatedly attempted to quit smoking with most having previously failed with NRT therapies.<sup>11</sup> Data were collected from a face-to-face survey of 104 experienced e-cigarette users. Seventy-eight percent hadn't smoked in the prior 30 days but averaged 25 cigarettes per day previously; the average quit attempts were nine attempts prior to using e-cigarettes with two-thirds having used NRT. Three-fourths used e-cigarettes as another attempt at quitting smoking with most stating it helped them quit smoking.
- Caponnetto et al. determined that nearly 1 in 10 Italians quit smoking after trying e-cigarettes.<sup>12</sup> A clinical trial of e-cigarettes tracked 300 smokers who agreed to try e-cigarettes between 2010 and 2012 and concluded that 8.7 percent weren't smoking cigarettes after one year. Quit rates were four percent for those given e-cigarettes without nicotine, but 13 percent for those given e-cigarettes with the highest dose of nicotine. This study is noteworthy because study participants said they had no intention of quitting smoking when they entered the trial. Moreover, the four percent quit rate for those given e-cigarettes without nicotine is consistent with the view that e-cigarettes help smokers quit by mimicking the act of smoking. The study also reported that 73 percent of smokers who discontinued smoking cigarettes after one year had also quit using e-cigarettes.
- Bullen et al. conducted a randomized-controlled superiority trial of 657 adult smokers in New Zealand between September 6, 2011 and July 5, 2013. The study gave 289 participants nicotine

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9. "Notes from the Field: Electronic Cigarette Use Among Middle and High School Students — United States, 2011–2012," *Morbidity and Mortality Weekly Report* 62, no. 35 (September 6, 2013): 729–30.

10. Polosa et al., "Effect of an Electronic Nicotine Delivery Device (e-Cigarette) on Smoking Reduction and Cessation: A Prospective 6-Month Pilot Study," *BMC Public Health* 11 (2011): 786.

11. J. Foulds, S. Veldheer, and A. Berg, "Electronic Cigarettes (e-cigs): Views of Aficionados and Clinical/Public Health Perspectives," *International Journal of Clinical Practice* 65, no. 10 (October 2011): 1037–42.

12. Pasquale Caponnetto et al., "Efficiency and Safety of an Electronic Cigarette (ECLAT) as Tobacco Cigarettes Substitute: A Prospective 12-Month Randomized Control Design Study," *PLoS One* (June 24, 2013), doi: 10.1371/journal.pone.0066317.



e-cigarettes, 295 participants patches, and 73 participants placebo e-cigarettes.<sup>13</sup> At six months, verified abstinence was 7.3 percent (21 of 289) with nicotine e-cigarettes, 5.8 percent (17 of 295) with patches, and 4.1 percent (three of 73) with placebo e-cigarettes. The study concluded that e-cigarettes, with or without nicotine, were modestly effective at helping smokers to quit, with similar achievement of abstinence as with nicotine patches. The authors reported they had insufficient statistical power to conclude superiority of nicotine e-cigarettes to patches or to placebo e-cigarettes.

- Farsalinos et al. analyzed a worldwide survey of 19,414 dedicated e-cigarette users.<sup>14</sup> Participants were divided according to their smoking status: former smokers and current smokers. Eighty-eight participants reported they were not smokers when they initiated e-cigarette use. The most important reasons for initiating e-cigarette use for both subgroups were to reduce the harm associated with smoking and to reduce exposure of family members to second-hand smoking. The authors concluded that e-cigarettes can be effective even in highly dependent smokers. Complete substitution of smoking was reported by 81 percent of participants (former smokers) while current smokers had reduced smoking from 20 to four cigarettes per day.
- Brown et al. interviewed 5,963 smokers in England who had attempted to quit smoking without the aid of counseling from a health professional.<sup>15</sup> Smokers were much more likely to succeed if they used electronic cigarettes than over-the-counter NRT.<sup>16</sup> While about a tenth of those using over-the-counter therapies had quit smoking at the time of the survey, about a fifth of those using e-cigarettes were successful. That is, e-cigarette users were twice as likely to successfully quit as those using NRT without counseling.

Evidence is imperfect but nonetheless strongly suggests e-cigarettes are effective harm-reduction tools that help some smokers reduce or quit smoking. It is especially troubling that the FDA fails to discuss the widely-reported Alpert et al. study that casts considerable doubt on the efficacy of FDA-approved NRT treatments, such as patches, gum, and drugs, such as Zyban and Chantix.<sup>17</sup> This study concludes that persons who have quit smoking relapsed at equivalent rates, whether or not they used NRT to help them in their quit attempts. In other words, FDA-approved NRT may not be any more effective in helping smokers quit their smoking habits than going “cold turkey.” The possibility that e-cigarettes represent a market response that attempts to fill the need for harm reduction by smokers is worth pursuing. This is especially true given concerns over the efficacy of NRT.

### Slowing E-Cigarette Market Probably Harms Public Health

The FDA acknowledges that its proposed rule is expected to slow development of the e-cigarette market. The proposed rule prohibits manufacturers from marketing e-cigarettes as safer than cigarettes since the proposed rule expands section 911 of the Family Smoking Prevention and Tobacco Control Act to e-cigarettes. Section 911 bans marketing tobacco products as modified risk products without FDA approval. Moreover, manufacturers are unable to inform consumers their products do not contain tobacco, thus suggesting to some consumers that e-cigarettes are more similar to tobacco cigarettes than is actually the case.

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13. Christopher Bullen et al., “Electronic Cigarettes for Smoking Cessation: a Randomized Controlled Trial,” *The Lancet* 382, no. 9905 (November 2013): 1629–37.

14. Konstantinos E. Farsalinos et al., “Characteristics, Perceived Side Effects and Benefits of Electronic Cigarette Use: A Worldwide Survey of More than 19,000 Consumers,” *International Journal of Environmental Research and Public Health* 11 (2014): 4356–73.

15. Brown et al., “Real-World Effectiveness of E-cigarettes When Used to Aid Smoking Cessation: A Cross-Sectional Population Study,” *Addiction* 109 (early online publication, accessed May 20, 2014), doi: 10.1111/add.12623.

16. Prescribing nicotine replacement therapy in conjunction with professional counseling is the standard treatment. Rates at which smokers were able to quit using e-cigarettes were found to be similar to those receiving this standard treatment

17. Hillel R Alpert, Gregory N Connolly, and Lois Biener, “A Prospective Cohort Study Challenging the Effectiveness of Population-based Medical Intervention for Smoking Cessation,” *Tobacco Control* 22 (2013): 32–37.

The FDA acknowledges that deeming e-cigarettes to be subject to chapter IX of the FD&C Act would raise the cost of premarket applications and therefore would increase the cost of entering and remaining in the market. Warning labeling is also believed to serve as a negative signal to consumers that possibly discourages their use. The FDA acknowledges these requirements would reduce e-cigarette consumption below levels that would be observed without regulation.

While the FDA might grant marketing claims of safer alternatives or allow manufacturers to inform consumers that e-cigarettes do not contain tobacco, such approval would probably require many dollars of research. Many years of continued use by thousands of users would probably be required before the FDA would be willing to make such a revision, going by the FDA's track record with drug approvals: it has been estimated that it takes an average of 12 years for an experimental drug to travel from the laboratory to FDA approval.<sup>18</sup>

The following adverse consequences to public health appear likely from slowing the evolution of the e-cigarette market:

- Suppressing the e-cigarette market can be devastating to product innovation. Manufacturers will be unable to market their products as safer alternatives to cigarettes to smokers who are seeking harm reduction. The proposed rule pushes manufacturers to enlist other marketing angles, such as flavors, price, convenience, and appealing packaging. Public health worsens to the extent that manufacturers steer away from developing new products aimed at helping smokers reduce or quit smoking. In effect, the proposed rule removes much of the profit out of developing safer and more effective harm-reduction products and redirects resources toward other attributes unrelated to improved public health.
- Suppressing the e-cigarette market is likely to promote FDA-approved NRT. This effect might improve public health if NRT is more effective than e-cigarettes in promoting lower consumption and quitting by smokers. However, as discussed above, the efficacy of NRT is debatable. Moreover, the literature suggests that smokers find e-cigarettes helpful. The FDA needs to explain why favoring the NRT industry promotes public health in light of this evidence.
- The e-cigarette industry is likely to become less competitive as costs of bringing products to market and other costs rise. Limiting competition allows e-cigarette manufacturers to gain market power, thus raising prices, curbing consumption and limiting consumer choices. Larger firms carry an unfair advantage due to greater financial and legal resources, thus again limiting competition at the expense of consumers. Raising prices of e-cigarettes for smokers who might be interested in quitting is unlikely to promote public health when e-cigarettes are effective harm-reduction tools.
- Prohibition of health claims might entice nonsmokers—especially youth—to become e-cigarette consumers when they are susceptible to marketing that focuses on flavors, convenience, and other factors unrelated to promoting public health. Fostering e-cigarette use among nonsmokers is unlikely to promote public health.
- The proposed rule may promote traditional tobacco use. The number of cigarette users switching to e-cigarettes is likely to decrease when manufacturers are unable to inform smokers that e-cigarettes are safer alternatives or that they don't even contain tobacco. The proposed rule

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18. "Drug Approvals - From Invention to Market ... A 12- Year Trip," MedicineNet.com, accessed June 12, 2014, <http://www.medicinenet.com/script/main/art.asp?articlekey=9877>.

thus weakens the creative destruction that the e-cigarette industry might otherwise exert on the tobacco industry.

- The proposed rule fails to protect nonsmokers from secondhand-smoke in the event that e-cigarettes are safer than combustible tobacco products. Public health worsens to the extent that e-cigarettes are a safer alternative.

### Preliminary Analysis of Benefits from E-Cigarettes

In 2010, 43.5 million adults (19.3 percent) in the United States were smokers.<sup>19</sup> The CDC estimates the annual costs attributed to smoking in the United States are between \$289 billion and \$333 billion, including at least \$130 billion for direct medical care of adults, over \$150 billion for lost productivity due to premature death, and more than \$5 billion for lost productivity from premature death due to exposure to secondhand smoke.<sup>20</sup>

A recent Gallup poll finds that 74 percent of US smokers want to quit.<sup>21</sup> These numbers indicate that roughly 32.2 million smokers want to quit out of the entire population of 43.5 million smokers. Smoking costs attributable to those looking to quit can be approximated by multiplying the annual costs of \$289–\$333 billion by 74 percent, the percentage of smokers looking to quit. This calculation yields the \$214–\$246 billion range of annual smoking costs attributable to smokers looking to quit.

Table 1 exhibits estimations of benefits (costs avoided) associated with using e-cigarettes by all smokers interested in quitting. Column 1 displays three quit rates estimated from previously discussed studies of e-cigarettes.

- Bullen et al. concluded that 7.3 percent of adult smokers using nicotine e-cigarettes no longer smoked after six months.<sup>22</sup>
- Caponnetto et al. found that nearly 10 percent quit smoking after trying e-cigarettes.<sup>23</sup>
- Brown et al. reported that roughly 20 percent of smokers who had attempted to quit smoking using e-cigarettes were successful.<sup>24</sup>

Columns 2 and 3 display the \$214–\$246 billion range of annual smoking costs attributable to smokers looking to quit.

Benefits are cost savings from successful quitting as approximated by multiplying quit rates in column 1 by the range of annual costs attributable to smokers looking to quit in columns 2 and 3. Columns 4 and 5 indicate the estimated potential range of annual benefits (costs avoided) stemming from successful quitting by using e-cigarettes: \$15.6 billion to \$49.2 billion.

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19. "Vital Signs: Current Cigarette Smoking Among Adults Aged  $\geq$ 18 Years — United States, 2005–2010," *Morbidity and Mortality Weekly Report* 60, no. 35 (September 9, 2011).

20. US Department of Health and Human Services, *The Health Consequences of Smoking—50 Years of Progress, A Report of the Surgeon General* (Atlanta, GA: US Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, 2014), [http://www.cdc.gov/tobacco/data\\_statistics/sgr/50th-anniversary/index.htm](http://www.cdc.gov/tobacco/data_statistics/sgr/50th-anniversary/index.htm).

21. Frank Newport, "Most US Smokers Want to Quit, Have Tried Multiple Times," *Gallup*, July 31, 2013, <http://www.gallup.com/poll/163763/smokers-quit-tried-multiple-times.aspx>.

22. Bullen et al., "Electronic Cigarettes," 2013.

23. Caponnetto et al., "Efficiency and Safety," 2013.

24. Brown et al., "Real-world Effectiveness," 2014.



TABLE 1. ANNUAL BENEFITS (COST SAVINGS) ASSOCIATED WITH E-CIGARETTE USE

(1)	Annual costs of smoking		Annual benefits (costs saved)		(6)
	(2)	(3)	(4)	(5)	
Quit rate	Low (\$B)	High (\$B)	Low (\$B)	High (\$B)	New ex-smokers
0.073	214	246	15.6	18.0	2.4M
0.10	214	246	21.4	24.6	3.2M
0.20	214	246	42.8	49.2	6.4M

Column 6 displays estimated associated numbers of successful quits (by quit rate): 2.4 million (.073), 3.2 million (0.10), and 6.4 million (0.20) individuals who become ex-smokers by using e-cigarettes. These numbers are approximated by multiplying the various quit rates by 32.2 million smokers (numbers of smokers looking to quit).

A full-scale analysis is beyond the scope of this public interest comment. There are many caveats to this estimation of benefits. The CDC estimates of costs associated with smoking used here may be subject to considerable error. Information on risk, quit rates, youth access, addiction properties, whether e-cigarettes are gateways to riskier products, and other important public health issues require further investigation. Estimates also assume all smokers looking to quit try e-cigarettes in their quit efforts. Benefits are only estimated for one year.

While this analysis is based on some assumptions and has some obvious limitations, if even a small fraction of estimated benefits (costs saved) or transformation of smokers into ex-smokers are achieved, the benefits are substantial.

- One-half of estimated annual benefits (costs avoided) stemming from successful quitting by using e-cigarettes indicates a range of \$7.8 billion to \$24.6 billion.
- One-fourth of estimated annual benefits (costs avoided) stemming from successful quitting by using e-cigarettes indicates a range of \$3.9 billion to \$12.3 billion.
- One-half of the estimated range of individuals who become ex-smokers by using e-cigarettes: 1.2 million to 3.2 million individuals.
- One-fourth of the estimated range of individuals who become ex-smokers by using e-cigarettes: .6 million to 1.6 million individuals.

In sum, the FDA has committed a major error by ignoring potential benefits (costs saved) associated with e-cigarettes. These benefits are expected to be lower under the proposed rule to the extent that the rule slows down innovation and growth in the e-cigarette market. In other words, one large potential cost of the proposed rule is the forgone reduction in costs associated with smoking tobacco. The FDA ignores evidence that suggests e-cigarettes help current smokers reduce and quit smoking, but it should reconsider its model of economic harm to include the possibility that e-cigarettes can improve public health. Rather than ignoring these potential benefits to society, the FDA needs to take them into account.

## CONCLUSION

The FDA has failed to make a strong and compelling case that its proposed rule improves public health. It has not developed what an optimal regulation might look like, failed to quantify benefits, and ignored the evolving literature on e-cigarettes that strongly suggests they help smokers interested in quitting. An

optimal policy is likely to be one that focuses more effort on reducing riskier products rather than treating all products as equal threats to public health.

The FDA has downplayed many adverse consequences to public health that appear likely from its slowing of the e-cigarette market. The proposed rule removes much of the profit out of developing safer and more effective harm-reduction products and redirects resources toward developing new flavors, packaging, and other attributes unrelated to improved public health. Prohibition of health claims regarding e-cigarettes might entice some nonsmokers (including youth) to purchase e-cigarettes. The proposed rule might also promote combustible tobacco use because manufacturers will be unable to market e-cigarettes as safer alternatives to tobacco cigarettes. Rates at which smokers quit or reduce consumption of tobacco products are likely to fall, as well. Public health worsens to the extent that e-cigarettes are a safer alternative that helps smokers in their harm-reduction efforts.

This public interest comment estimates the range of annual benefits (costs avoided) associated with e-cigarette use as \$15.6 billion to \$49.2 billion. These estimates suggest that from 2.4 million to 6.4 million smokers might become ex-smokers. Fractions of these estimates indicate substantial benefits that the FDA has ignored in its analysis.

Finally, this public interest comment does not conclude that the FDA should not regulate e-cigarettes. Prohibiting sales to youth and requiring a clear description of product ingredients appear appropriate. But prohibiting any information regarding potential efficacy in harm-reduction is hard to justify given substantial benefits reported in currently available studies. The FDA needs to develop a regulatory strategy that fully considers the potential benefits that smokers receive from e-cigarettes and the many unintended adverse effects on public health associated with how this proposed regulation slows the evolution of a promising harm-reduction tool.