

REGULATING A LESS UNHEALTHY CIGARETTE

The FDA's treatment of e-cigarettes jeopardizes public health.

BY MICHAEL L. MARLOW

The U.S. Food and Drug Administration has recently proposed expanding its regulatory authority over tobacco products to include the regulation of cigars, pipe tobacco, hookah tobacco, electronic cigarettes (e-cigarettes), and other novel tobacco products such as dissolvable products and gels. Cigars are the most commonly used among this group, though e-cigarette use is rapidly expanding. If Federal Food, Drug, and Cosmetic Act requirements were to be applied to those products, they would mandate establishment registration and product listing, ingredient listing, submissions prior to the introduction of new products, labeling requirements, and prohibition of free samples. Additional provisions would include minimum age and identification requirements, vending machine restrictions, and required warning statements for packages and advertisements.

This article argues that the FDA jeopardizes public health by not developing an appropriate benefit-cost analysis of the proposed rule. The FDA “anticipates,” without quantifying, substantial benefits from reducing harm by regulating e-cigarettes and non-cigarette tobacco products. The FDA also does not adequately assess costs that appear likely from its suppression of the e-cigarette market. The evolving literature on e-cigarettes strongly suggests they help smokers to quit smoking. The proposed rule endangers public health by pushing e-cigarette manufacturers to focus efforts toward developing attributes unrelated to improved public health, thereby promoting combustible tobacco use and reducing the number of smokers who would use e-cigarettes to quit or reduce cigarette consumption. Public health would worsen

because e-cigarettes are a safer alternative to tobacco cigarettes.

HARM REDUCTION THEORY

The FDA implicitly assumes that consumption of all tobacco products should be reduced to 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.

The FDA simply states that current tobacco policies are suboptimal and does not consider the possibilities that tobacco products are not equally risky or that all tobacco products are equally controllable through regulation. In claiming this, the FDA dismisses the essence of what is known as “harm reduction theory.” Harm reduction theory asserts that minimizing damage from some risky behavior may promote public health more effectively than simply attempting to eliminate the behavior. Applied to tobacco use, placing highest priority on reducing risks from combustible tobacco products is a reasonable strategy that the FDA should at least discuss.

Such a model is in line with estimates that up to 98 percent of tobacco-related deaths are attributable to combustible products such as cigarettes, pipes, and cigars. The FDA downplays the possibility that noncombustible products (e.g., nicotine-replacement therapies, smokeless tobacco, e-cigarettes) are substantially less dangerous than combustible tobacco products by claiming there is too little information available to make such judgments.

The American Medical Association published a *JAMA Patient Page* last January that lists the following potential benefits of e-cigarettes:

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- 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.
- Smokers may switch to e-cigarettes simply because they are less harmful than tobacco cigarettes.

The *JAMA Patient Page* also outlines various concerns regarding the safety of noncombustible products. These include a 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.

The FDA expresses concern that e-cigarettes might lead youth to use the product and become addicted to nicotine or else lead to use of tobacco products. Evidence so far is limited on these issues. The FDA cites a Centers for Disease Control and Prevention report that found that e-cigarette experimentation and recent use doubled among U.S. middle and high school students from 2011 to 2012, resulting in an estimated 1.78 million students having used e-cigarettes as of 2012. In 2012, about 9 percent of those students had never used tobacco cigarettes. Those estimates

indicate valid concerns regarding risks for nicotine addiction and initiation of tobacco products, but the FDA should consider those concerns within a more sophisticated theory of harm reduction.

E-CIGARETTES AS HARM REDUCTION TOOLS

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. Rapid market 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 estimated that e-cigarette sales in the United States topped \$1.7 billion last year. 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.

The FDA errs on the side of assuming e-cigarettes pose more of a health risk than an opportunity to improve the public’s 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 nicotine replacement therapy (NRT), e-cigarettes deliver nicotine with a device that mimics smoking.

Summary results of relevant recent studies are described below. Evidence is imperfect but nonetheless strongly suggests e-cigarettes are effective harm reduction tools that help some smokers reduce or quit smoking. None of these results are discussed by the FDA:

- Riccardo Polosa et al. (2011) conclude e-cigarettes help smokers remain abstinent or reduce their cigarette con-

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sumption. 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 of the participants (55 percent), with an overall 88 percent fall in cigarettes consumed per day.

- J. Foulds et al. (2011) found that a large majority of e-cigarette users had repeatedly attempted to quit smoking, with most having previously failed despite using NRT therapies. Data were collected from a face-to-face survey of 104 experienced e-cigarette users. Some 78 percent had not smoked in the prior 30 days but averaged 25 cigarettes per day previously; the average quit attempts were nine 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 to quit.
- Pasquale Caponnetto et al. (2013) determined that nearly 1 in 10 Italians quit smoking after trying e-cigarettes. 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 were not smoking cigarettes after one year. Quit rates were 4 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 4 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.
- Christopher Bullen et al. (2013) 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 e-cigarettes, 295 participants patches, and 73 participants placebo e-cigarettes. 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 (3 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 nicotine patches. The authors reported they had insufficient statistical power to conclude superiority of nicotine e-cigarettes to patches or to placebo e-cigarettes.
- Konstantinos Farsalinos et al. (2014) analyzed a worldwide survey of 19,414 dedicated e-cigarette users. 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 secondhand 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.

- Jamie Brown et al. (2014) interviewed 5,963 smokers in England who had attempted to quit smoking without the aid of counseling from a health professional. Smokers were much more likely to succeed if they used e-cigarettes than over-the-counter NRT. 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 quit as those using NRT without counseling.

It is noteworthy that the FDA fails to discuss a widely reported study by Hillel Alpert et al. (2013) that casts considerable doubt on the efficacy of FDA-approved NRT treatments such as patches, gum, and drugs such as Zyban and Chantix. The 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.

JEOPARDIZING PUBLIC HEALTH

The FDA acknowledges that its proposed rule is expected to slow development of the e-cigarette market and reduce consumption below levels that would be observed without regulation. The proposed rule prohibits manufacturers from marketing e-cigarettes as safer than tobacco cigarettes because the proposed rule expands Section 911 of the Family Smoking Prevention and Tobacco Control Act to cover 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. The FDA states that deeming e-cigarettes to be subject to Chapter IX of the Federal Food, Drug, and Cosmetic Act would raise the cost of premarket applications and therefore would increase the cost of entering and remaining in the market. Warning labels are also believed to serve as a negative signal to consumers that possibly discourage e-cigarettes' use.

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.

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 tobacco cigarettes. 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 from developing safer and more effective harm-reduction products and redirects resources toward other attributes unrelated to improving 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 because of 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 even that they do not contain tobacco. The proposed rule 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.

BENEFITS FROM E-CIGARETTES

In 2010, 43.5 million U.S. adults (19.3 percent) were smokers. 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 from premature death of smokers, and more than \$5 billion for lost productivity from premature death as a result of exposure to secondhand smoke.

A recent Gallup poll finds that 74 percent of U.S. smokers want to quit. That means 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, yielding the \$214–\$246 billion range of annual smoking costs attributable to smokers who want to quit.

Table 1 exhibits estimations of benefits (that is, 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. (2013) concluded that 7.3 percent of adult smokers using nicotine e-cigarettes no longer smoked after six months.
- Caponnetto et al. (2013) found that nearly 10 percent of smokers quit smoking after trying e-cigarettes.
- Brown et al. (2014) reported that roughly 20 percent of smokers who had attempted to quit smoking using e-cigarettes were successful.

TABLE 1
THE BENEFITS OF E-CIGARETTES

Annual benefits (cost savings) associated with e-cigarette use

(1)	(2)	(3)	(4)	(5)	(6)
QUIT RATE	ANNUAL COSTS OF SMOKING		ANNUAL BENEFITS (COSTS SAVED)		NEW EX-SMOKERS
	LOW (\$BILLIONS)	HIGH (\$BILLIONS)	LOW (\$BILLIONS)	HIGH (\$BILLIONS)	(MILLIONS)
0.073	214	246	15.6	18	2.4
0.1	214	246	21.4	24.6	3.2
0.2	214	246	42.8	49.2	6.4

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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 stemming from successful quitting by using e-cigarettes is \$15.6–\$49.2 billion. Column 6 displays the number of e-cigarette users who successfully quit tobacco use, estimated to be between 2.4 million and 6.4 million.

A full-scale analysis is beyond the scope of this article. There are many caveats to Table 1's 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 using tobacco will 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 or transformation of smokers into ex-smokers is achieved, the benefits are substantial:

- One-fourth of estimated annual benefits stemming from successful quitting by using e-cigarettes indicate a range of \$3.9–\$12.3 billion per year.
- One-fourth of the estimated range of individuals who become ex-smokers by using e-cigarettes is 600,000 to 1.6 million individuals per year.

Those 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. A large potential cost of the proposed rule is thus the forgone reduction in costs associated with smoking tobacco. The FDA needs to take them into account.

CONCLUSION

The FDA has failed to make a strong and compelling case that its proposed e-cigarette rule improves public health. It has not determined 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 tobacco use. 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 from 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 keep some nonsmokers (including youth) from purchasing e-cigarettes. On the other hand, the proposed rule might 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 article estimates the range of annual benefits associated with e-cigarette use as \$15.6–\$49.2 billion per year. The estimates also suggest that, each year, 2.4–6.4 million smokers might become ex-smokers. Fractions of those estimates indicate substantial benefits that the FDA has ignored in its analysis.

Finally, this analysis does not conclude that the FDA should not regulate e-cigarettes. Prohibiting sales to youth and requiring a clear description of product ingredients may be 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. R

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