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Perspectives for Clinicians on Regulation of Electronic Cigarettes

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Since their launch in the United States in 2007, electronic cigarettes (e-cigarettes) have generated much debate, which recent events continue to fuel. In April 2016, the Royal College of Physicians (RCP) reaffirmed its position that e-cigarettes should be promoted as harm-reducing substitutes for combustible tobacco. By May, the U.S. Food and Drug Administration (FDA) deemed e-cigarettes to be under its regulatory authority. We briefly review the major RCP and FDA points and practical issues for clinicians to consider.

THE RCP'S POSITION ON E-CIGARETTES

The RCP report (1) is based on expert opinion, current evidence, and harm-reduction principles. It acknowledges that, although e-cigarettes may have some long-term health effects and are probably more risky than nicotine replacement therapy, their hazard is unlikely to exceed 5% of the harm from cigarette smoking in terms of risks to users (including product-related mortality and morbidity) and to others (for example, injury or economic costs). Furthermore, it notes that e-cigarette uptake by persons who have never used tobacco (including youth) should be monitored as a potential negative population-level consequence, but that data so far in the United Kingdom and elsewhere show that this outcome is relatively rare. In addition, although the report states that more research is needed, selected observational studies and 2 limited clinical trials suggest that e-cigarettes could hold promise as an aid to quitting smoking.

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The RCP also supports regulation of e-cigarettes, (albeit less stringent than that proposed by the FDA), which it argues should take a balanced approach to ensure safety without inhibiting e-cigarettes' harm-reduction potential. Of note, the RCP recommends that health professionals and organizations promote not only e-cigarettes but also nicotine replacement therapy, other pharmacologic treatments, and behavioral support (in general and potentially combined with e-cigarettes).

FDA REGULATION OF E-CIGARETTES

Although the rate of cigarette smoking has decreased in the United States, the use of other tobacco products, including e-cigarettes, cigars, and hookah, has increased. Moreover, e-cigarette use among young persons is increasingly common, with 16% of high school students in 2015 reporting current use (2). In response to these trends, the new deeming rule extends the FDA's authority over cigarettes and roll-your-own and smokeless tobacco to all other tobacco products not previously covered, including those previously mentioned (3). For these newly deemed products, the rule will establish a minimum age of sale of 18 years, ban free samples and vending machine sales, and require a warning label about nicotine addiction and disclosure to the FDA of ingredients and manufacturing processes. In addition, e-cigarettes currently on the market and any new ones planned will require FDA review. Products in existence before February 2007 are grandfathered in to remain on the market. Some of the deeming requirements, such as disclosure of constituents and manufacturing processes, combined with the FDA's powers to set product standards, may make these products as safe as possible. Nevertheless, some organizations, including the RCP, have argued that burdensome regulation of e-cigarettes and manufacturer requirements—particularly the premarket approval process—will stifle innovation and product availability and benefit the more harmful combustible cigarette market. These are valid concerns, although e-cigarette companies will have up to 2 years to submit premarket applications. Current lawsuits and legislative actions may also affect the final form and enforcement of the rule.

UNIFYING THEMES FOR TOBACCO REGULATION

Despite concerns, some commonsense themes for tobacco control policy and regulation could bring concordance. No one wants young persons to use tobacco or nicotine products. In addition, consumers have a right to know about potential risks and should have access to the safest possible versions of these products. Claims of cessation effectiveness should be evidence-based. Finally, both the FDA and RCP seem to recognize that combustible tobacco products are associated with the most harm.

CLINICAL PRACTICE IMPLICATIONS

Because physicians are viewed as credible sources of health information, providers should be aware of the public health issues surrounding e-cigarette regulations. Questions and concerns still exist about e-cigarettes, including potential health effects, whether they may act as a gateway into smoking combustible cigarettes for youth (4, 5), and whether they can

help smokers quit using cigarettes rather than facilitate dual use. The answers are on the horizon as research in these important areas continues.

So far, evidence suggests that e-cigarettes may not be completely safe, but they deliver no carbon monoxide and fewer toxins and potentially less nicotine than combustible tobacco products (1, 6). Although anecdotal evidence and data from convenience samples of e-cigarette users suggest that e-cigarettes are effective cessation tools, rigorous research on this topic is still limited. Observational population-level studies have provided mixed results on the cessation-related outcomes of e-cigarettes but were not designed to study these outcomes and thus provide limited data (7). Only 2 randomized clinical trials have been published (each with several design limitations); however, 1 of these found that e-cigarettes were as effective as nicotine patches (8).

More clinical trial research is needed. Meanwhile, it is important to note that e-cigarettes seem to appeal to smokers far more than nicotine replacement therapy products (1, 9). As the RCP report indicates, “among smokers, e-cigarette use is likely to lead to quit attempts that would not otherwise have happened” (1). If a proportion of these attempts lead to successful cessation, e-cigarettes could serve as a transition away from smoking.

It is also important to remember that e-cigarette regulation largely considers population-level public health effects, whereas clinicians seeing patients who smoke should make sensible recommendations for those individuals. Quitting tobacco entirely is the best outcome and should be encouraged; however, moving those who have been unable to quit down the risk continuum to a less harmful product could be a viable approach, as acknowledged in the most recent surgeon general’s report (10).

CLINICIANS SHOULD GET INVOLVED

Finally, clinicians should participate in the U.S. tobacco regulatory process by submitting comments on FDA proposals. Future proposed rules may include restrictions on flavored cigars and menthol cigarettes. The tobacco industry is highly mobilized in voicing its positions to the FDA, and these need to be balanced by strong messages from public health and health care professionals.

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References

1. Royal College of Physicians. Nicotine without smoke: tobacco harm reduction. 28 April 2016. Accessed at www.rcplondon.ac.uk/projects/outputs/nicotine-without-smoke-tobacco-harm-reduction-0 on 3 June 2016.

2. Singh T, Arrazola RA, Corey CG, Husten CG, Neff LJ, Homa DM, et al. Tobacco use among middle and high school students—United States, 2011–2015. *MMWR Morb Mortal Wkly Rep*. 2016;65:361–7. 10.15585/mmwr.mm6514a1 [PubMed: 27077789]
3. Food and Drug Administration, HHS. Deeming tobacco products to be subject to the Federal Food, Drug, and Cosmetic Act, as amended by the Family Smoking Prevention and Tobacco Control Act; restrictions on the sale and distribution of tobacco products and required warning statements for tobacco products. Final rule. *Fed Regist*. 2016;81:28973–9106. [PMID: 27192730] [PubMed: 27192730]
4. Barrington-Trimis JL, Urman R, Berhane K, Unger JB, Cruz TB, Pentz MA, et al. E-cigarettes and future cigarette use. *Pediatrics*. 2016;138 10.1542/peds.2016-0379 [PubMed: 27544347]
5. Niaura RS, Glynn TJ, Abrams DB. Youth experimentation with e-cigarettes: another interpretation of the data. *JAMA*. 2014;312: 641–2. 10.1001/jama.2014.6894 [PubMed: 25117133]
6. Goniewicz ML, Knysak J, Gawron M, Kosmider L, Sobczak A, Kurek J, et al. Levels of selected carcinogens and toxicants in vapour from electronic cigarettes. *Tob Control*. 2014;23:133–9. 10.1136/tobaccocontrol-2012-050859 [PubMed: 23467656]
7. Delnevo CD, Giovenco DP, Steinberg MB, Villanti AC, Pearson JL, Niaura RS, et al. Patterns of electronic cigarette use among adults in the United States. *Nicotine Tob Res*. 2016;18:715–9. 10.1093/ntr/ntv237 [PubMed: 26525063]
8. McRobbie H, Bullen C, Hartmann-Boyce J, Hajek P. Electronic cigarettes for smoking cessation and reduction. *Cochrane Database Syst Rev*. 2014;CD010216. 10.1002/14651858.CD010216.pub2
9. Steinberg MB, Zimmermann MH, Delnevo CD, Lewis MJ, Shukla P, Coups EJ, et al. E-cigarette versus nicotine inhaler: comparing the perceptions and experiences of inhaled nicotine devices. *J Gen Intern Med*. 2014;29:1444–50. 10.1007/s11606-014-2889-7 [PubMed: 24830741]
10. U.S. Department of Health and Human Services. The Health Consequences of Smoking—50 Years of Progress: A Report of the Surgeon General. Atlanta, GA: U.S. 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.