E-Cigarettes and Harm Reduction: An Artificial Controversy Instead of Evidence and a Well-Framed Decision Context

Jonathan M. Samet, MD, MS, and Jessica Barrington-Trimis, PhD

ABOUT THE AUTHORS

Jonathan M. Samet is with the Colorado School of Public Health, Aurora. Jessica Barrington-Trimis is with the Department of Population and Public Health Sciences, Keck School of Medicine, University of Southern California, Los Angeles.

See also Balfour et al., p. 1661.

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In this issue of *AJPH*, a distinguished group of tobacco control researchers and practitioners call for a more balanced look at e-cigarettes for reducing the enormous and persistent burden of smoking-caused morbidity and premature mortality—a worthy goal. The article is built around the artifice of a controversy between "fervent opponents" of harm reduction who emphasize risk to young people and "enthusiastic supporters" who want to facilitate smoking cessation and reduce harm with e-cigarettes. This "controversy" exists because we lack evidence on the long-term consequences of policies that promote the use of e-cigarettes for harm reduction, both for the smoking adults who switch to them and for the youths who start using them. Of course, we cannot see or model far enough into the future to have credible projections of the impact of regulatory decisions made now, decisions that will undoubtedly have long-term, generational repercussions.

In our comments, we redirect focus to an alternative framing that should underlie decision making on the place of e-cigarettes in the tobacco marketplace. The key principle is captured in the public health impact standard for modified risk products of the Family Smoking Prevention and Tobacco Control Act. Such products must:

> (1) significantly reduce harm and the risk of tobacco-related disease to individual tobacco users; and (2) benefit the health of the population as a whole taking into account both users of tobacco products and persons who do not currently use tobacco products.[1(p123)]

However, lacking from this principle of the act and from the commentary by Balfour et al. (p. 1661) and others is a sufficiently deep explication of the risk trade-offs inherent in advancing e-cigarettes as a harm-reduction strategy for smokers. If switching to e-cigarettes has benefits, they accrue to the smokers who may perhaps quit or reduce their use of cigarettes because of the switch, thus lowering their risk of tobacco-related morbidity and mortality while remaining nicotine addicted. If there are harms, they largely fall on youths and young adults, who are at risk for becoming addicted to nicotine across their lifetimes and sustaining the inevitable consequential adverse health effects. This is an intergenerational trade-off: possible immediate health benefits for older persons versus longer term and quite uncertain health risks for younger individuals.

The authors' review leads them to conclude that e-cigarettes' risk trade-off benefits population health overall. We do not agree that the evidence presented is sufficient to support their conclusion. Their evidence comes from a selective and opaque review process that does not meet standards for systematic review or for evidence integration, as in the US Surgeon General reports on smoking and health.[2] In particular, the risks of nicotine (and e-cigarettes specifically) for youths are minimized in the face of much (uncited) longitudinal evidence of its dangers (e.g., increase in the frequency and intensity of cigarette smoking, risk of nicotine dependence).[3] Nicotine is a known addictive chemical; disposable and pod-based products that administer nicotine in very high concentrations with little adverse sensory effect are addicting youths now. E-cigarettes do harm the adolescent's still-developing lungs, and e-cigarette– and vaping-associated lung injury outbreak points to the dangers of inhaling unregulated aerosols from carefully engineered devices intended to maximize the aerosol dose reaching the lungs.

Balfour et al. conclude that the potential for harm reduction for smokers should motivate action, given the

evidence they cite and their judgment on e-cigarettes' potential for risk reduction. Although the authors find the balancing of e-cigarettes' risks and benefits to be acceptable, doesn't that weighing depend on who you are? For those who benefit directly and perhaps their families, e-cigarettes would likely seem a preferable alternative to combustible cigarettes. Change the perspective to that of a parent whose underage child becomes nicotine addicted; for that perspective, we propose that the child's addiction is an unacceptable outcome of a harm-reduction strategy for adults. Remember that the nicotine-addicted smoker has alternatives—quitting "cold turkey" or turning to Food and Drug Administration (FDA)-approved agents and other interventions.[4] Moreover, if e-cigarettes can be an effective cessation aid, why have companies not sought their approval as a cessation aid through the FDA's Center for Drug Evaluation and Research?

The question to be answered for decisions on e-cigarettes—and the risk trade-offs—needs to be better specified; in the current marketplace for tobacco products (or in a better regulated future marketplace), does the availability of e-cigarettes in commercial outlets lower the prevalence of tobacco product use among adult cigarette smokers and reduce the frequency of tobacco-caused disease without increasing nicotine addiction among young people? This question is not addressed by the highly artificial randomized clinical trials on e-cigarettes and cigarette-smoking cessation, which focus only on the method of nicotine delivery (i.e., via e-cigarettes). There is some evidence that e-cigarettes may be associated with increases in smoking cessation among those who use e-cigarettes daily (compared with those who use alternative cessation methods).[4] The findings of trials that provide free e-cigarettes (vs conventional cessation therapy) also indicate increased cessation with the e-cigarette intervention.[5] However, we do not know whether the effectiveness and reach of e-cigarettes as a cessation aid depend on ready availability in retail locations (e.g., in vape shops, pharmacies, and convenience stores), which has the consequence of making them more accessible to youths.

How will the evidence be generated to better inform decisions on the least risky approach for youths that makes e-cigarettes available to smokers for harm reduction? Much research is in progress with support from the Tobacco Regulatory Science Program of the National Institutes of Health. That research is directed at many of the critical gaps for decisions on e-cigarettes, but only "real-world" experience will provide an answer to this question. Modeling is critical for bringing together the evidence and forecasting what might happen, but projections are inevitably subject to uncertainty, particularly as they are extended further and further into the future, into a marketplace with completely unknown features.

Notably, Balfour et al. do not discuss the tobacco industry in their article. The authors' silence on the industry is remarkable; we do not trust the tobacco industry, despite Philip Morris International's protestation of a new direction, which is an echo of past false promises. The media are currently carrying a pronouncement from the chief executive officer—"A Letter to All Who Aspire to a Better Future"—with the tagline "Unsmoke the Future."[6] The verbiage does not say "Unnicotine the future." Many of the editorial's authors have been through the "tobacco wars." Are they willing to trust the industry not to sacrifice public health for profit? The authors conclude this article with a discussion of the social justice issues related to cigarette smoking and the disproportionately high burden of tobacco-related disease morbidity and mortality in certain populations, including those of low socioeconomic status, racial and ethnic minorities, sexual and gender minorities, and those with comorbid conditions. We point out that the tobacco industry generated many of these disparities using egregious marketing tactics to target the most vulnerable of individuals.

We agree that the FDA is at a critical decision-making juncture on e-cigarettes and public health, as the marketplace continues to diversify with noncombustible tobacco products, including not only e-cigarettes but other heated tobacco products. Since the FDA took jurisdiction over e-cigarettes with the Deeming Rule in 2016, its approach to e-cigarettes has not been aggressive, coherent, or consistent.[7] Action was finally proposed in 2020 to counter the surge in youths' e-cigarette use driven by flavored products, particularly those of JUUL.[8] The national strategy of reducing nicotine delivery by combustible cigarettes has been set aside, and the FDA's overall course in the Biden administration is undeclared.[9] The public health research and practice communities can be most helpful to setting this course by providing the needed evidence and facilitating its interpretation in a well-framed decision context. An unneeded schism and polarization are antithetical to what should be happening now. AJPH

CORRESPONDENCE

Correspondence should be sent to Jonathan M. Samet, Dean and Professor, Colorado School of Public Health, Mailstop B119, 13001 E 17th Place, Fitzsimons Bldg, 3rd Fl, Rm C3000, Aurora, CO

80045 (e-mail: jon.samet@cuanschutz.edu).
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CONFLICTS OF INTEREST

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