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Don't Rush FDA's Vaping Products Review

— The process must be based in evidence, not politics

by Clifford E. Douglas, JD September 11, 2021

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Last month, 15 past presidents of the venerable Society for Research on Nicotine and Tobacco (SRNT), the top tobacco research society in the world, co-authored a courageous, groundbreaking article that argues that the media, legislators, and the general public have developed a negative view of e-cigarettes (vaping products) because of the heavy emphasis public health organizations have placed on protecting youth from vaping while ignoring the potentially substantial benefits of e-cigarettes in helping tens of millions of addicted adults quit smoking. The authors lay out thoughtful policy recommendations on how to balance concerns about the risks with the potential benefits.

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The statement from these scientific and medical leaders comes at an inflection point in the decades-long effort to defeat the epidemic of smoking-related illness and death. The FDA is under enormous pressure to make decisions on which e-cigarettes can benefit adults who smoke, while minimizing the risk to those who do not use tobacco, especially youth.

The Review Process

The agency is tasked by Congress with undertaking careful review of new tobacco products to assess whether each application has "provided sufficient product-specific scientific evidence to demonstrate enough of a benefit to adult smokers to overcome the risk posed to youth." This is a challenging standard for applicants to prove scientifically and for the agency to assess.

As part of its premarket tobacco product application (PMTA) process, FDA received more than 6.5 million applications and was expected to render key decisions on September 9 on which products would be authorized for sale in the U.S. The agency has made progress, having acted on a "substantial majority" (around 93%) of the e-cigarettes that were under review by ordering millions of individual products removed from the market. So far, FDA has declined to authorize for sale any e-cigarette, and they have missed the review deadline for several of the most popular brands, including JUUL, Vuse, and NJOY. They're continuing to assess applications on a rolling basis.

The stakes are enormous. Careful review of the scientific merits of these applications, along with thoughtful post-marketing surveillance requirements and restrictions on the advertising and marketing of e-cigarettes, is vital to preserve the public health benefits while limiting potential harm. As part of this process, FDA can (and should) impose restrictions on where these products can be sold, require strict age-verification, and impose limits on the amount of product one person can buy to reduce the likelihood of e-cigarettes winding up in the hands of youth.

This complex process takes time, and all stakeholders should prioritize the need to protect the scientific integrity of FDA's assessments rather than politicize the process or pressure the agency to reach predetermined conclusions regarding any products still under review.

Risks Versus Benefits

Cigarette smoking remains the leading preventable cause of death in our society. Every one of the 480,000 tobacco-related fatalities suffered annually in the U.S. results from direct smoking and, to a lesser but significant degree, exposure to secondhand cigarette smoke. That figure does not include the use of any other tobacco product, including e-cigarettes, which pose some risk but are much less harmful than continued smoking.

When combusted (burned), tobacco produces smoke that contains 7,000 chemicals, including more than 60 known human carcinogens, an unmatched toxic and cancer-causing mixture. No other tobacco or nicotine product, e-cigarettes included, compares. While long-term data are not yet available, leading health authorities in the U.S. and the U.K. have determined that vaping is substantially less dangerous than cigarette smoking.

But many adults, including a majority of those who smoke, believe that vaping is as dangerous as, or even more dangerous than, cigarette smoking. This misunderstanding reflects, in part, the media's skewed coverage of the issue in recent years. A study last year found that 70% of U.S. news coverage on vaping mentioned the risks of vaping risks to youth, while only 37% noted the potential benefits for adult smokers. Meanwhile, a survey of physicians found that 80% strongly but incorrectly agreed that nicotine causes cancer, cardiovascular disease, and chronic obstructive pulmonary disease.

For its part, FDA set forth an inspired comprehensive plan in 2017 premised on the concept of a "continuum of risk" for all nicotine-containing products, ranging from conventional, combusted cigarettes (by far the most harmful product) on one end to nicotine-replacement therapies (which FDA classifies as "safe") on the other. As part of the plan, the agency proposed the reduction of nicotine in cigarettes to levels incapable of creating or sustaining addiction, while ensuring the availability of reduced-risk nicotine products acceptable to consumers who are unable or otherwise unwilling to quit using nicotine entirely. FDA has estimated that implementing this comprehensive plan would avert 8 million premature deaths and recover over 100 million life-years in this century, which would be a monumental public health achievement.

This vision has been placed on hold, hopefully only temporarily, as various factions grapple with the place of nicotine in our society while FDA addresses the delicate public health calculus that pits the well-being of adults who smoke against that of nonsmokers, predominantly youth.

It is also important for the public -- including clinicians -- to be aware of the rapidly growing evidence that vaping can be effective in quitting smoking. Indeed, the CDC reports that more adult smokers use, and have success using, e-cigarettes than other products in their attempts to quit smoking. And vaping is likely more effective for smoking cessation than FDA-approved nicotine replacement medicines, such as gum and patches, according to multiple credible sources, including the respected Cochrane Review.

But the widespread misunderstanding among clinicians and the public seriously impedes progress. The role of nicotine in addiction, disease formation, and harm reduction are poorly understood, pointing to the need for better education to clinicians, the public, and policymakers. With at least 34 million adults smoking cigarettes and millions now using e-cigarettes and other nicotine-containing products in efforts to reduce health risks and quit smoking, the ramifications for clinical and public health outcomes could not be more significant and immediate.

Evidence-Based Decisions

An additional, and quite profound concern is the rampant politicization of the current debate and, specifically, the role of FDA in making evidence-based policy decisions that will affect the health of millions of Americans. It is inappropriate for anyone to interfere with the agency's expert, congressionally mandated, scientific mission. And yet, leading tobacco control organizations and members of Congress have applied inordinate pressure on FDA to make predetermined decisions to outright ban many, if not all, e-cigarettes apparently disregarding the agency's scientific expertise and the impact that such decisions, pro or con, will have on the lives of tens of millions of adults currently addicted to cigarettes.

FDA's scientific review process must be protected. Unfortunately, unless the warring factions find ways to join hands in support of the health and well-being of everyone, youth and adults alike, the heat and rhetoric around these questions may only increase, and so will the cost to the health of our nation.

The opinions expressed are the author's and do not necessarily reflect the views of any organization with which he is affiliated.

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Disclosures

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