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R Street Shorts
No. 137
September 2024

Tobacco Control 2.0: A Modern Approach to a Decades-Old Problem

Part 1 of 3

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No one entity is solely responsible for protecting consumers from the harms of combustible products. To further reduce mortality and disease, public health advocacy groups, tobacco/nicotine product manufacturers, and regulatory bodies must work together.

Introduction

The history of tobacco control in the United States spans more than six decades, beginning with the landmark 1964 Surgeon General's report that called attention to the severe health risks of smoking.[1] This report catalyzed a series of public health initiatives, including restricted smoking in public places, increased cigarette excise taxes, reduced access to cigarettes, and enhanced public awareness campaigns.[2] These efforts led to significant declines in smoking rates, from nearly 42 percent in the 1960s to less than 14 percent in 2019, and have generated reductions in smoking-related diseases such as lung cancer.[3]

Despite some successes, the United States still records nearly 500,000 smoking-related deaths each year, which signals that more can be done.

Despite these successes, the United States still records nearly 500,000 smoking-related deaths each year, which signals that more can be done.[4] The persistent impasse between tobacco control advocates and the tobacco industry, however, has created a challenging environment for further progress. Tobacco companies have historically employed misleading practices to counteract public health measures, and this oppositional relationship has hindered the development of comprehensive and effective tobacco control policies.[5]

This analysis highlights current challenges within the tobacco control landscape and proposes modern science- and policy-based solutions to overcome them. With a broader understanding of historical context, ongoing issues, and potential solutions, policymakers can initiate a reboot of tobacco control efforts that emphasizes advocacy/industry collaboration, scientific rigor, regulatory innovation, and community education to save lives and improve public health outcomes.

Issues with Current Tobacco Control Efforts

A number of ongoing issues have prevented tobacco control measures from reaching their full potential in the United States. Specifically, efforts have been hampered by

the competing interests of advocacy and industry leaders, issues with tobacco-related research studies, rampant misinformation, and problematic regulatory frameworks.

The Advocacy-Industry Impasse

CURRENT TOBACCO CONTROL EFFORTS ISSUE

For decades, the conflict between tobacco control advocates and the tobacco industry has resulted in higher-than-necessary levels of smoking-related harm. Consumers have faced smoking-related health issues, confusion about smoking alternatives, and limited access to reduced-risk products. This ongoing impasse has also hindered progress and innovation in tobacco control strategies, preventing the implementation of comprehensive harm reduction approaches and the development of effective public health policies. If these two key stakeholder groups fail to evolve and collaborate with each other, consumers will continue to suffer from preventable smoking-related disease and death.

Poorly Designed Research

CURRENT TOBACCO CONTROL EFFORTS ISSUE

To ensure that public health studies provide actionable insights to improve population-level health, they must be designed carefully, with rigor and reproducibility in mind. Unfortunately, in the tobacco control space, poorly designed studies abound, muddying conversations about the utility of tobacco harm reduction.[6] In a recent review, researchers evaluated 24 of the most-often-cited studies on the use of electronic nicotine-delivery systems (ENDS) products and determined that most contained methodological flaws.[7] Specifically, many of the studies lacked basic components of sound scientific research, such as clear hypotheses, appropriate design, and pre-identified intended outcomes. Additionally, many of the studies contained inaccurate statements of findings and lacked appropriate controls.[8]

Although the tobacco industry itself also has a checkered past in terms of the rigor and bias of internal research, the quality of industry-generated research has significantly improved over the last few decades.[9] This is in large part because the Center for Tobacco Products (CTP) must now review most, if not all, data generated by the tobacco industry as part of the process of vetting novel, reduced-risk products. To pass this additional level of scrutiny, tobacco industry researchers have adopted many of the rigorous clinical and laboratory practices set forth in guidelines issued by the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use.[10]

Misinformation Amplification

CURRENT TOBACCO CONTROL EFFORTS ISSUE

In today's fast-paced research and communication environment, information—regardless of its accuracy—travels to consumers at record speeds. The tobacco control information sphere has been particularly influenced by misinformation regarding reduced-risk products like ENDS, heated tobacco products, and oral tobacco/nicotine products. From e-cigarette, or vaping, product use-associated lung injury (EVALI) to popcorn lung, unsubstantiated claims of increased health risks associated with reduced-risk products have generated uncertainty among consumers who smoke.[11] Although public health officials in the United States are taking steps to better communicate the benefits of reduced-risk products in supporting a transition away from combustible tobacco products—including updating the CTP's online resources to convey key aspects of tobacco harm reduction and the continuum of risk associated with tobacco products—the information landscape is still heavily dominated by sensationalism and misinformation that undermines the proven benefits of tobacco harm reduction.[12]

Ineffective Regulatory Apparatus

Regulatory agencies play a key role in monitoring a functioning marketplace. With regard to consumable products, the United States Food and Drug Administration (FDA) serves as a referee between the established laws related to the safety and effectiveness of consumer and medicinal products and those who produce the products for consumers.[13] The overarching objective of the agency is to maintain a fair and safe marketplace to ensure that consumers' purchases will meet their intended objectives in a safe and effective manner.[14] The FDA's role in this regard has historically served consumers well and fostered a mostly safe and effective commerce environment, which is key to maintaining a successful and open free market.[15] Unfortunately, some centers under the FDA's purview, including the CTP, fall short of FDA objectives.

CURRENT TOBACCO CONTROL EFFORTS ISSUE

When the CTP was established nearly 15 years ago by the Family Smoking Prevention and Tobacco Control Act (TCA), combustible cigarettes were the primary product the Center was directed to oversee.[16] Lawmakers could not have predicted the immense growth of the reduced-risk marketplace, the diversity of products that would enter the market, or the challenges of reviewing, approving, and regulating these products. Because such products were not specifically anticipated or mentioned in the TCA, the CTP extended its oversight to include them.[17]

Although reduced-risk products now abound, the CTP has yet to communicate its interpretation of how these products fall under the TCA, share its methodology for evaluating these and other tobacco products, or establish rules or guidelines for the marketplace to follow to ensure that consumers can easily understand how the tobacco/nicotine products they choose might affect their health.[18]

Absent specific legislation within the TCA to direct the regulatory needs of this new class of products, the CTP established its own framework, becoming both the rule maker and referee for reduced-risk tobacco/nicotine products.[19] Because the rules for these products and the manner in which the rules are enforced are ill-defined, consumers lack a clear understanding of product risks, and manufacturers lack a clear understanding of the premarket tobacco application (PMTA) process for bringing novel, reduced-risk products to the marketplace.[20] As a result, alternative tobacco/nicotine products that have not been evaluated for safety or efficacy by the FDA have flooded the illicit market, and the handful of products that have been approved by the CTP for sale in the legal marketplace have an unfair market advantage over those that have not been evaluated.[21]

The primary criticisms of the CTP PMTA process are the nebulous requirements of the PMTA and the lack of transparency in the CTP's review of the PMTA. Specifically, the driving requirement of the PMTA is that the applicant must demonstrate that a product is appropriate for the protection of public health (APPH).[22] Unfortunately, the CTP has never defined APPHs, so manufacturers are left to guess what constitutes APPH and how much data they must provide to the CTP. This has led to two categories of PMTAs: those that provide limited information about the product (usually submitted by smaller companies with limited resources) and those that contain hundreds of thousands of pages of information, research studies, and data (usually submitted by larger companies with more resources). Regardless of which type of application is submitted, the overwhelming majority are rejected, which has led manufacturers to file lawsuits and request clarity on the documentation required for a successful application.

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Modernizing U.S. Tobacco Control: Policy- and Science-Based Solutions

Tobacco control experts agree that too many people are continuing to use the most harmful form of nicotine products, and too many are suffering because of this continued use. To address this issue, stakeholders in the tobacco control space must work together to find solutions that will both meet the needs of those who choose to continue to use nicotine products and greatly reduce the negative health consequences of the products. Below, we suggest practical solutions for modernizing U.S. tobacco control in a way that would put the needs of individuals affected by the consequences of smoking first.

Industry and Public Health Should Collaborate to Save Lives

MODERNIZING U.S. TOBACCO CONTROL SOLUTIONS

In the tobacco control space, much time has been spent focusing on "big tobacco's" history of questionable practices and excluding industry leaders from meaningful, potentially transformative conversations. Yet a collaboration between industry and public health could support an evolution within the tobacco industry that would ultimately benefit the public. Such evolutions are possible, as even public health research itself has notably improved in the past century. Studies such as the Tuskegee syphilis study, the Jewish chronic disease studies, and the Willowbrook hepatitis study are just three examples of past unethical public health research initiatives that later led to important changes in research practices like improved oversight (e.g., Institutional Review Boards, International Harmonization Council).[23] We should look to the tobacco industry to rise to new expectations in the same way.

To include the tobacco industry in such conversations, it is important to understand its history, evolving role, and motivations.[24] All major corporations have the same primary responsibility: generating maximum revenue for shareholders. As long as tobacco and nicotine products are legal, companies will exist to provide these products to consumers, regardless of their harms. Thus, any time tobacco companies communicate with the public about their products and associated risks, consumers must view the content through that lens. Still, industry has a unique opportunity to join the conversation and contribute to the transition to a combustion-cigarette-free world.

Lean into Harm Reduction as a Valid Public Health Strategy

MODERNIZING U.S. TOBACCO CONTROL SOLUTIONS HARM REDUCTION

Harm reduction is a well-accepted approach to public health that minimizes the negative consequences of using harmful substances like opioids, other drugs, and combustible cigarettes.[25] With regard to cigarettes, even though most individuals know that smoking any substance is not good for their health, many are not ready or willing to quit. Tobacco harm reduction meets people where they are and purports that any behavioral change that reduces or eliminates inhalation and exposure to the toxins in combustible products should be promoted and supported.

Leaning into tobacco harm reduction as a broadly effective public health strategy requires that consumers who smoke combustible cigarettes be able to access any tools that might reduce the harms of that behavior and improve their health.[26] This includes behavioral support as well as methods to step down from cigarettes to non-combustible, lower-nicotine products or FDA-approved smoking-cessation medications.[27]

Industry plays a key role in tobacco harm reduction, as private corporations and entrepreneurs are responsible for most of the research and development of reduced-risk products. These players are also well-positioned to provide evidence-based information about the relative harms of different products to consumers so they can make informed decisions about how the products they choose to use may raise or lower their health risks.[28]

To be clear, the tobacco industry has an inherent conflict when it supports the vision of a smoke-free world while continuing to sell products that generate smoking harms. This conflict is difficult to resolve and requires that tobacco industry partners have a clear understanding of their role in the tobacco control space and how it must evolve to promote harm reduction and reduce smoking-related deaths and disease. By sharing clear, credible information with consumers about the health risks of all of the different products they sell, industry can empower individuals with a wider variety of reduced-risk options to suit their needs. Consider an analogy from the beverage industry. Diet sodas are not a "healthy" beverage, but clearly communicating the significant reduction of caloric load compared to regular, full-sugar sodas allows the consumer to make decisions about the impact that both soda products might have on their health. The same concept should apply to tobacco control, building on a groundwork of scientific validity, clear communication, and innovation to develop reduced-risk products that consumers will adopt.

Establish a Foundation of Rigorous Science that Nurtures Scientific Debate

MODERNIZING U.S. TOBACCO CONTROL SOLUTIONS

One of the greatest risks to public health is the degradation of scientific debate and discussion, but valid scientific discussions cannot take place without a foundation of compelling, well-designed research. Within the tobacco control space, the lack of strong scientific evidence on certain issues has dramatically impacted the public's ability to make effective decisions about available options to improve their health.[29] To counteract this issue, all valid research—including well-designed studies conducted by industry—should be considered, and flawed studies—regardless of whether they are conducted by industry or public health researchers—should be filtered out as much as possible through the peer-review process.[30]

Currently, most scientific journals do not accept studies funded or run by industry scientists or organizations, nor do they allow industry representatives to join professional medical or scientific societies or participate in scientific conferences.[31] This has to end, as some of the most relevant and insightful data available is currently being generated from within the industry itself.[32] In fact, banning industry-generated research from scientific journals is likely contributing to the maintenance of an unchecked echo chamber of imbalanced science.[33] In reality, because most journals require disclosure statements identifying the sources of funding for published work, blanket bans on industry research in an attempt to prevent bias and conflict of interest from entering the literature only serves to devalue the scientific method and limit free and open scientific debate.

Combat Misinformation with Evidence-Based Consumer Education

MODERNIZING U.S. TOBACCO CONTROL SOLUTIONS

Because reduced-risk products have been validated as useful alternatives to combustible cigarettes in well-designed studies, all stakeholders in the tobacco control

debate should work to provide easy-to-understand messaging to consumers about the health differences of choosing reduced-risk products over combustible products.[34] Specifically, consumers should understand that although reduced-risk products are not without risk, eliminating the use of combustible products greatly outweighs the potential risks of alternative products. Of course, studies clearly demonstrate that abstaining from *all* inhalation products is the best option for an individual's health, but for those who cannot or do not want to quit consuming nicotine products, migrating from combustible products to non-combustible, reduced-risk products is a viable alternative that can lead to improved health outcomes.[35]

MODERNIZING U.S. TOBACCO CONTROL SOLUTIONS

Reboot Regulatory Frameworks to Accelerate Industry Transformation

Moving forward, the most practical model for enabling a larger proportion of reduced-risk tobacco/nicotine products to enter the market to better meet customer needs would be to adopt an approach that approves a product's PMTA with minimal burden and then redirects resources to monitoring approved products for safety (i.e., post-market surveillance). Although this approach differs from the CTP's current framework, it aligns with some successful regulatory approaches that have been implemented in other countries.[36] Furthermore, because manufacturers are responsible for tracking data associated with the consumption of their products, the CTP would be able to act rapidly to remove any product from the market if unreasonable risks emerged, which is not possible with products sold on the illicit market. Finally, lawmakers should consider refining the TCA to add specific requirements for the review of novel non-combustible nicotine products, and the CTP should add transparency to their PMTA process to establish a clear and efficient pathway for products to enter the marketplace. Thus, to optimally protect consumers and to offer a greater variety of lower-risk products, the burden of entry for new products should be lifted, and lawmakers, manufacturers, and regulators should work together to maintain a safe and functioning marketplace for consumers.

Conclusion

Contemporary tobacco control efforts in the United States have notably improved public health, but a policy revamp could offer even greater improvements. Importantly, no one entity is solely responsible for protecting consumers from the harms of combustible products. To further reduce mortality and disease, public health advocacy groups, tobacco/nicotine product manufacturers, and regulatory bodies must work together.

Fortunately, the path to saving lives has never been clearer or more achievable. The strategies suggested herein could translate to population-level health improvements that would appeal to public health officials; new and expanded reduced-risk-product revenue channels that would appeal to tobacco and nicotine product manufacturers; and regulatory framework improvements that would promote a safe and functioning marketplace. By rebooting the tobacco control space with these strategies, we can continue to reduce the death and disease burden associated with combustible products.

About the Author

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