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Tobacco Control 2.0: Reasonable Regulation Can End Combustion-Related Death and Disease

Part 2 of 3

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By implementing the recommendations presented herein, policymakers, regulatory officials, the public health community, and manufacturers can refocus on the same goal: eliminating the death and disease burden associated with smoking cigarettes.

Introduction

In 2009, the United States passed the Family Smoking Prevention and Tobacco Control Act (TCA), a law focused on reducing the burden of combustible tobacco products on population health.[1] The act provided a guideline for restricting how tobacco manufacturers promote their products, both in terms of marketing toward youth and in clearly disclosing their products' health risks. It also gave the U.S. Food and Drug Administration (FDA) the authority to act as a monitor for the tobacco industry with few specific guidelines other than a number of guardrails that precluded the newly established Center for Tobacco Products (CTP) from completely removing any product from the U.S. marketplace.[2] At the time, the primary tobacco products in the marketplace were traditional combustible products (cigarettes, cigars, etc.) and oral tobacco products (chew, dip, etc.).[3]

Under the initial structure of the act, if a tobacco product was not in the U.S. marketplace before Feb. 15, 2007, product manufacturers would either have to provide data to show that the new product was similar to existing products (substantially equivalent [SE]) or submit a more extensive application (premarket tobacco product application [PMTA]) to legally market the product in the United States.[4] Unfortunately, the SE application process created an unforeseen pathway for manufacturers to introduce novel combustible products into the marketplace without having to move through the more rigorous review process that a PMTA would require.[5] This strategy to circumvent the PMTA became inherently problematic with regard to the CTP's overarching goal of reducing tobacco-related death and disease because the PMTA process was designed to ensure that any new tobacco product would meet the standard of being appropriate for the protection of public health (APPH) before receiving a marketing-granted order (MGO).[6]

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As a result, the CTP has not made significant headway in reducing tobacco-related death and disease. In 2009, researchers estimated that 480,000 Americans died of smoking-related disease, and the most recent data available indicate that number has remained largely unchanged over the past 15 years.[7] In addition, although smoking prevalence rates have decreased by roughly 40 percent overall, that decrease has primarily been concentrated among younger adults; smoking rate declines have been much lower in older adults.[8]

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The CTP also had to rapidly evolve, as the tobacco and nicotine marketplace began to change shortly after the TCA was passed. During the early 2010s, new, reduced-risk, non-combustible products began to enter the market, and the CTP used the leeway in the TCA to extend its oversight to include these products.[9] By 2016, the prevalence of electronic nicotine delivery systems, heated tobacco products, and other non-traditional oral products (snus and non-tobacco nicotine products) began to grow.[10] The growth of these products, along with the increase in youth use of such products, diverted the focus of the CTP from the original enforcement of the TCA.[11] Instead, the Center's focus shifted to determining how to quell the growth of these new products while expanding its enforcement authority, all under the guise of the APPH standard.[12]

The outcome of these dynamics is visible in the proliferation and continued use of the most dangerous tobacco products (combustibles); an uncertain, unclear, and delayed review process for non-combustible, reduced-risk products; the persistence of a pervasive, illicit reduced-risk product marketplace; and an environment that has hindered innovation and led to many new businesses failing (due to a confusing and costly regulatory process)—all of which have resulted in a concentrated marketplace of just a few legal, reduced-risk offerings.[13] Though regulatory oversight is needed within the tobacco and nicotine marketplace, it must be smart, effective, and efficient to ensure that it both protects the American consumer and facilitates a vibrant marketplace for the reduced-risk products that consumers want.

This paper recommends key steps stakeholders should take to break the country's 15-year stall on reducing tobacco-related deaths. It explains why this is a particularly ideal time to renew these efforts and then outlines four key approaches that legislators and regulators can take to create a more reasonable regulatory space for life-saving, reduced-risk products. These approaches include amending the TCA to establish a clear regulatory processes for reduced-risk products, rebuilding the PMTA system, clearly communicating scientifically based data on the comparative risks/benefits of reduced-risk products, and embracing the role of a tobacco-control referee.

Now Is the Time to Act

Though major changes in law take time and can be challenging to undertake, the U.S. Supreme Court's recent repeal of the *Chevron* doctrine (a precedent established in 1984 that allowed regulatory agencies to reasonably interpret a law if it was ambiguous or silent on an issue) may accelerate the opportunity to more quickly resolve many of the issues that have emerged from unmanaged regulatory overreach.[14] Before its repeal, some regulatory agencies were overusing *Chevron* deference to modify their approaches beyond the intention of the initial precedent.[15] The Court decided to reel in

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this leniency, which means that laws granting regulatory oversight must now be specific, and regulatory agencies will have to defend any interpretations of their authority in court, if challenged.

Though this has yet to be tested, the Court has agreed to hear *FDA v. Wages and White Lion* (a case in which the arguments are focused explicitly on the arbitrary nature of CTP decision-making) in the next session. If the Court provides an opinion that supports the argument the respondents offer in this case or other cases that may question the manner in which the CTP executes its efforts based on the TCA, legislators would be required to clarify and amend the TCA to define the process the CTP must follow under the law.[16]

Approaches to Create a More Reasonable Regulatory Space

In the sections that follow, we outline four key approaches for creating a more reasonable regulatory space around reduced-risk tobacco and nicotine products. Specifically, we suggest that legislators amend the TCA and establish new standards to improve the PMTA process and post-marketing surveillance for reduced-risk products. In addition, we suggest that the CTP clearly communicate the benefits and risks of reduced-risk products and lean into its role as a tobacco-control referee.

Amend the TCA

MORE REASONABLE REGULARTORY SPACE APPROACH

First and foremost, legislators must amend the TCA to establish a distinction between traditional tobacco products and novel nicotine products that carry less risk. Applying the TCA as an omnibus umbrella that treats all nicotine products the same and that imposes the same rules and limitations on different types of products is a flawed approach that has led to a dysfunctional regulatory process and a consumer marketplace flooded with illicit products.[17]

Although traditional tobacco product and novel reduced-risk nicotine products share some similar characteristics, considering them equal in terms of potential health risks and the need for regulatory scrutiny is problematic.[18] Over the last decade, as reduced-risk products have been both widely used by consumers and placed under tremendous scientific scrutiny, enough evidence has accumulated to justify claims that: (1) these products have fewer health risks than combustible products, and (2) these products help individuals in their smoking-cessation journey.[19] As such, a regulatory framework that impedes legal consumer access to most of these products while continuing to approve new combustible products via the SE pathway is in direct conflict with the spirit of the TCA and will always stymie efforts to reduce the death and disease burden of combustible tobacco products.[20]

Improve the CTP's PMTA Process and Post-Market Monitoring of Reduced-Risk Products

MORE REASONABLE REGULARTORY SPACE APPROACH

Lawmakers must also improve the PMTA process in a number of ways. First, they must write specifics into the TCA to establish a standards-based application process that clearly articulates the requirements for approving new tobacco and nicotine products and to outline guidelines that ensure transparency in the PMTA review

process. These steps are necessary because millions of PMTAs have entered the review process, but most receive some form of denial. In addition, the review period often extends well beyond the 180-day period mandated by law.[21] In some instances, PMTA decisions have taken as long as four years.[22] These issues suggest that the PMTA process needs more than simple tinkering; it must be completely overhauled.[23]

Although many agree with this stance, one organization conducted a comprehensive review of the current system and suggested particularly relevant improvements for the CTP to consider.[24] Specifically, they suggested that the CTP:

- Articulate the critical scientific questions that must be answered to effectively run the tobacco program.
- Improve the transparency of application reviews so stakeholders understand how products are being evaluated.
- Evaluate applications in a timely manner and include opportunities for communication and clarification between the Center and the manufacturers so questions regarding the regulatory process can be resolved.
- Become proactive instead of reactive in responding to and adapting processes to reflect changes in the marketplace and scientific knowledge base so the Center's practices can align with current needs and knowledge.[25]

In addition to these changes, the PMTA process should be adjusted so that the standards for approving a reduced-risk tobacco/nicotine product are different than the standards set forth to approve a new combustible product. The impact of combustible products on public health is well understood; the same cannot be said for non-combustible products because they are a relatively new product.[26] As such, the approval criteria for non-combustible products should be different from those of combustible products. The CTP should consider the components of the product, the ingredients used within the product, how the design is meant to be implemented, and expected uses of the product.[27] In addition, modern toxicology techniques can provide data that will help guide product approvals. Importantly, fear of unknown long-term outcomes should not be a guiding principle in considering whether these novel products should be introduced into the marketplace.[28]

Of note, this same concept should also be applied to the post-marketing surveillance of reduced-risk products: they should be evaluated against product-specific standards instead of against the standards used for combustible products. If any unforeseen consequences exist once these newer types of products are placed into the hands of consumers, regulatory mechanisms should be in place to remove the product until any negative outcomes are understood and resolved. Given that reduced-risk products will likely continue to evolve, this adaptive approach would support marketplace growth and make regulatory oversight sustainable and enforceable.

MORE REASONABLE REGULARTORY SPACE APPROACH

CORE RECOMMENDATIONS

Clarify and Share the Relative Risks of Tobacco and Nicotine Products

MORE REASONABLE REGULARTORY SPACE APPROACH

The unfortunate reality is that, regardless of the topic, misinformation and disinformation abound within modern communication channels.[29] This is particularly true in the tobacco control space. For example, some major health organizations assert that abstinence from all nicotine products is the only healthy choice.[30] These groups cite studies that equate the use of reduced-risk products with smoking combustible products, assert that nicotine is the source of harm, and emphasize that the only option for those who smoke is to quit (either through cold-turkey efforts or by using nicotine replacement products and/or pharmacological interventions).[31] Other organizations promote the exclusive use of reduced-risk products as a substitute for combustibles.[32] These conflicting reports make it difficult to know which guidance to follow.

Government agencies play a key role in situations such as this, as they are typically seen as providing accurate information to the population, guided by science and reason.[33] The CTP should therefore work to clarify and disseminate important information about the tobacco and nicotine marketplace, provide evidence-based guidance on the risks profiles of different types of products, and explain the potential health benefits of switching from the most dangerous forms of tobacco products to products that have been scientifically evaluated and determined to carry much lower risks.[34] Additionally, the CTP should clarify its messaging around nicotine to align with science: Nicotine use does lead to nicotine dependency, but the health consequences of nicotine exposure in healthy adults are minimal.[35] The Center should clearly communicate that the smoke (i.e., the combustion byproduct) poses the biggest health risk and should be eliminated.[36] All pathways that lead to a smoke-free lifestyle are acceptable, and migration toward any reduced-risk product should be supported and celebrated as a health win.

This approach requires embracing the full body of available scientific evidence; the CTP must avoid selectively applying data to endorse one reduced-risk approach over another. Their messaging should be straightforward, easy for the consumer to understand, and promoted widely through trusted sources. The takeaway from the information the CTP provides should be simple: Smoking leads to death and disease, and non-combustible products have significantly fewer risks than combustible products.[37] Clearly articulating the full arsenal of options available to those who smoke provides them with multiple pathways to make better health decisions.

Act as a Referee, Not a Player

MORE REASONABLE REGULARTORY SPACE APPROACH

The FDA's primary objective is to protect public health by acting as an inspector and evaluator that upholds the standards of food and drug products, as set forth by law.[38] The organization does not legislate; it simply (to paraphrase its own words) acts as a referee.[39] However, because the TCA does not provide clarity on how the CTP should evaluate non-combustible nicotine products, the Center has been acting more like a player and has spent a significant amount of time defending its interpretation of the TCA in court instead of meeting its legislatively determined responsibilities.[40] Once the TCA is amended to codify the mechanisms for evaluating non-combustible products, the CTP will be able to better serve its role as an oversight agency.

Furthermore, if the meaning of APPH were codified in a manner that identified the specific risks it aims to alleviate, and if the CTP clearly conveyed how those risks would be attributed to the various nicotine products over which it has regulatory oversight, the legitimacy of the CTPs actions would be clear for both the regulatory agency itself and manufacturers.[41] The CTP could then focus on monitoring the marketplace and quickly responding to any safety concerns or inappropriate marketing that may arise within it.

Of course, acting as a referee in the tobacco and nicotine space is not easy; not only do key stakeholders (advocacy groups, industry, consumers) have markedly different motivations and needs, but the marketplace is vast. Because of these factors, as new products enter the market, there must be a diligent sentinel on watch to ensure that consumers are protected from harms.[42] If the CTP were supported and the TCA revised to establish guardrails to set the organization up for success, the Center's value would be celebrated instead of questioned.[43]

Conclusion

The CTP was formed to oversee a well-established industry just as a new class of reduced-risk products began to emerge and change the tobacco/nicotine product landscape in unforeseeable ways; this was clearly a challenge from the CTP's inception, and, without clear legislative direction, the Center has continued to founder. Policymakers and lawmakers should focus on revamping the CTP's regulatory framework so that it can function effectively as an authoritative source of information for consumers and as a referee in the tobacco control space. Though many aspects of the CTP's practices need to be improved, two primary areas of focus should be that: (1) the CTP be provided with clear guidelines through a clarified TCA that enables the Center to both protect public health and support a growing marketplace of reduced-risk products, and (2) the responsibilities of the Center be driven by consumer needs, serving as a monitor and valued resource for easy-to-understand, trusted information.

With these changes implemented, policymakers, regulatory officials, the public health community, and manufacturers can refocus on the same goal: eliminating the death and disease burden associated with smoking cigarettes. Nearly 500,000 American lives are needlessly lost to tobacco-related health issues every year. With a wealth of scientific evidence to support the benefits of reduced-risk products, we can no longer justify not leveraging these new reduced-risk products to minimize the negative health effects of smoking.

About the Author

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