

## VIEWPOINT

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## The Tobacco Industry and Harm Reduction

**As the US Food and Drug Administration (FDA)** embarks on historic regulatory actions that could fundamentally reshape the future of public health, chances of progress depend heavily on the nature of the response of the tobacco industry. Global tobacco use, involving 1.14 billion smokers consuming 5.19 trillion cigarettes annually,<sup>1</sup> caused 100 million deaths in the 20th century. The death toll could rise by another billion in the 21st century. Until now, the tobacco industry has, in addition to producing and marketing cigarettes and other combustible products, systematically blocked evidence-based tobacco control measures, such as tobacco taxes and graphic warning labels. They have recently added yet another layer of business strategy that complicates the landscape even further.

The industry's updated efforts are reflected in Altria's current website trademark: "Moving Beyond Smoking: from tobacco company to tobacco harm reduction company." That message may seem unfathomable for a company that has long sold Marlboro, the leading US cigarette brand. Philip Morris International has also, since 2018, funded the Foundation for a Smoke-Free World to promote research on noncombustible nicotine alternatives to cigarettes. However, such startling developments are understandable when noting that globally, de-

In 2017, the FDA first announced its commitment to a tobacco product standard for nicotine that would mandate very low-nicotine cigarettes (and other combustible products) to render them nonaddictive while encouraging less harmful nicotine product alternatives. Specifically, the FDA emphasized the need for a "greater awareness that nicotine—while highly addictive—is delivered through products that represent a continuum of risk and is most harmful when delivered through smoke particles in combustible cigarettes. ...Envisioning a world where cigarettes would no longer create or sustain addiction and where adults who still need or want nicotine could get it from alternative and less harmful sources needs to be... common ground."<sup>5</sup> A future tightly regulated marketplace could feature nicotine alternatives that help adult smokers either quit or move down a continuum of risk—ranging from lethal combustible products at one end to safe and effective FDA-approved nicotine medicines at the other.

Given these developments, the tobacco industry has, in recent years, embraced e-cigarettes. Although independent companies initially jump-started this category, major tobacco companies now dominate. In the US, 4 of the 5 top e-cigarette brands (as of June 2022) are tied to major tobacco companies—the top 2 are JUUL

(35.1% market share; owned by Juul Labs with a 35% stake held by Altria) and Vuse (31.2% market share; owned by British American Tobacco).<sup>6</sup> The third-ranked brand NJOY (3.0% market share) is owned by the independent company NJOY, but the fourth- and fifth-ranked

brands are Blu (2.2% market share; owned by Imperial Tobacco) and Logic (0.8% market share; owned by Japan Tobacco).<sup>6</sup>

Debates about how to interpret the evolving e-cigarette science to guide future potential harm reduction policy currently roil the tobacco control community. On one hand, a 2021 Cochrane review notes "moderate-certainty evidence that electronic cigarettes with nicotine increase quit rates compared to nicotine replacement therapy." Yet, it cautions that studies are small, the effect size is unconfirmed, and the longest follow-up was 2 years.<sup>7</sup> Moreover, although past-30-day high school e-cigarette use has declined from a 2019 peak of 27.5% (4.1 million),<sup>8</sup> 2022 rates of 14.1% still translate to 2.1 million high schoolers exposed, with more than 8 in 10 reporting flavored e-cigarette use<sup>9</sup> (the same Centers for Disease Control and Prevention caveat regarding comparability applies to the 2022 estimates). Such continued levels of use raise many concerns for youth health, especially the risks and consequences of nicotine addiction for developing brains.<sup>10</sup>

The FDA has yet to complete a comprehensive review of e-cigarette manufacturer marketing applica-

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spite a cigarette market valued at more than \$850 billion (in 2020), cigarette consumption has dropped each year since 2012 (from a peak of 5.96 trillion).<sup>1</sup> Notably, the remarkable decline of US past-30-day high school cigarette use, from 21.9% in 2003<sup>2</sup> to 1.9% in 2021,<sup>3</sup> presages a future with many fewer adult smokers (the Centers for Disease Control and Prevention notes that 2021 estimates cannot be directly compared to prior years because of pandemic-related disruptions in survey methodologies).

Harm reduction (eg, substituting methadone for opioids) offers the tobacco industry an opportunity for reinvention. Its potential dates back at least to 1976, when Dr Michael Russell observed that "people smoke for the nicotine but die from the tar."<sup>4</sup> Since 1994, the Institute of Medicine (now the National Academies of Sciences, Engineering, and Medicine) has noted the potential of harm reduction for lowering disease risk for smokers unable or unwilling to quit in a series of major tobacco policy reports, including the 2001 report *Clearing the Smoke: Assessing the Science Base for Tobacco Harm Reduction*.

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tions that has been marked by regulatory delays. To determine what products are “appropriate for the protection of public health,” the FDA requires premarket tobacco product applications for alternative tobacco products (eg, e-cigarettes). Although the FDA reports, to date, denying marketing applications for more than 1 million flavored e-cigarette products, it has not yet acted definitively on those with the largest market share. In June 2022, the FDA first issued marketing denial orders requiring Juul Labs to stop selling and distributing all products, but then promptly suspended the denial to allow time for additional review.<sup>11</sup> Meanwhile, Juul Labs has faced a wave of lawsuits regarding its early marketing to teenagers (in 2019 it ceased all US advertising and sales of fruit and candy flavors). In September 2022, Juul Labs agreed to pay nearly \$440 million to settle an investigation brought by 33 states regarding its marketing practices.

Nevertheless, in 2022, the FDA finally advanced 2 historic policy changes that, if fully realized, could accelerate cessation for adults and shift most remaining tobacco use to FDA-authorized noncombustible products and nonaddictive cigarettes. It proposes to ban menthol in cigarettes and all flavors in cigars and advance, as part of President Biden’s Cancer Moonshot Initiative, the tobacco product standard for nicotine (initially announced in 2017). The intent is to render cigarettes nonaddictive by reducing their nicotine content to near zero while also supporting a marketplace featuring noncombustible products meeting regulatory standards. Full implementation is projected to help most smokers stop smoking, virtually eliminate young people from becoming addicted in the first place, reduce harm, reduce health disparities, and save millions of lives.

Although such outcomes would be transformative, the current state of vigorous disagreement vastly complicates efforts to achieve them. At this critical time for public health, we believe all stakeholders, despite differences, can coalesce behind 3 major principles: devalue cigarettes and other combustibles; support a future where cessation medications and FDA-authorized reduced-harm

products help adult smokers either quit all tobacco product use or move down the continuum of risk<sup>4</sup> to substantially less harmful forms of nicotine delivery; and protect children, adolescents, and young adults from tobacco addiction and exposure.

Yet, the tobacco industry severely compromises progress through a fundamental hypocrisy—promoting harm reduction while continuing to market and sell combustible cigarettes that cause harm in the first place. They have announced opposition to the FDA’s proposed menthol ban and the tobacco product standard for nicotine. They continue to create a halo of activities, such as funding the arts and sporting events, to burnish their public image. Moreover, most recently, Philip Morris International has convinced a number of major newspapers to reverse previous longstanding no-tobacco advertising decisions and run paid company-sponsored research “advertisements,”<sup>7</sup> which are virtually indistinguishable from editorials and news articles.<sup>12</sup>

The tobacco industry has unique power to advance their stated goals of harm reduction and a smoke-free future. They can accept, not oppose, key FDA proposals regarding the reduced nicotine product standard for combustible tobacco products, the ban on menthol in cigarettes and all flavors in cigars, and the requirement for graphic warning labels on combustible tobacco products. Further, the tobacco industry can accept, not oppose, excise tax increases that would particularly disincentivize combustible tobacco product use; stop marketing, advertising, price promotions, and discounts for combustible tobacco products; and set a target date to end the marketing and sale of combustible products in the US (as the Philip Morris International CEO has already expressed willingness to consider for the UK<sup>13</sup>).

Altria and other major tobacco companies must make “moving beyond smoking” a reality, not just a tagline. Doing otherwise only perpetuates a public health catastrophe that has claimed millions of lives for far too long.

#### ARTICLE INFORMATION

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