



# THE TOBACCO CONTROL ACT'S PUBLIC HEALTH STANDARD



## Background

The 2009 Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) gave the U.S. Food and Drug Administration (FDA) broad authority over the regulation of commercial tobacco products. The statute also established a new standard to guide the FDA's decision-making: its actions must be "appropriate for the protection of the public health" – commonly referred to as the public health standard. This standard is the required threshold the agency must meet for many of the FDA's important regulatory functions. Two of those functions that we will focus on during the convening are:

(1) *Issuing product standards.* Product standards regulate tobacco product ingredients, constituents, additives, and other properties (e.g., menthol).<sup>1</sup> Product standards must meet the public health standard.

(2) *Serving as a regulatory gatekeeper.* Under the Tobacco Control Act, new tobacco products are only allowed to enter the market if they have received a marketing order from the FDA. New tobacco products must meet the public health standard in order to receive an affirmative marketing order.<sup>2,3</sup> This is referred to as premarket review.

## Public Health Standard Criteria

The Tobacco Control Act dictates what the FDA must consider when determining what is "appropriate for the protection of the public health" in the context of both product standards and marketing orders. In the context of product standards, the FDA must consider scientific evidence concerning:

- the risks and benefits to the population as a whole, including users and nonusers of tobacco products, of the proposed standard;
- the increased or decreased likelihood that existing users of tobacco products will stop using such products; and (Cessation)

- the increased or decreased likelihood that those who do not use tobacco products will start using such products.<sup>4</sup> (Initiation)

The FDA is also charged with reviewing and issuing marketing orders for new products using the same standard.<sup>5</sup>

The public health standard therefore requires FDA to examine three basic considerations (often referred to as the three prongs), namely: (1) population-wide risks and benefits; (2) the likelihood of cessation by tobacco users; and (3) the likelihood of initiation by non-tobacco users.

Beyond these three very general considerations, however, the Tobacco Control Act provides no further detail about what the FDA should take into account in determining whether an action meets the public health standard. The Tobacco Control Act gives the FDA wide latitude to determine which risks to consider when assessing “risks and benefits to the population as a whole,” as well as how much weight to give to which studies supporting likelihood of initiation and cessation. Even the Congressional discussion during the law’s passage provides little additional context, stating only:

*“Appropriate for the protection of public health” is used because tobacco products are not ‘safe’ or ‘safe and effective,’ the standards used by FDA for foods, drugs, and medical devices. The public health standard is intended to be a flexible standard that focuses on the overall goal of reducing the number of individuals who die or are harmed by tobacco products.<sup>6</sup>*

Because commercial tobacco products cause harm and death when used as directed, the standard is focused on reducing that death and harm. This sentiment was shared by an FDA senior staff person during a public presentation: “Although there is not a regulatory definition, FDA considers a product ‘Appropriate for Protection of the Public Health’ (APPH) if we determine marketing of the product has the potential to result in decreasing morbidity and/or mortality.”<sup>7</sup>

Typically, if an agency is given discretion to make decisions, it will issue more detailed regulations spelling out how its decision-making process will occur, with the language in the statute passed by Congress serving as guardrails. However, the FDA has yet to issue any regulations identifying how it assesses what regulatory actions are “appropriate for the protection of the public health.”

## Health Equity Implications

Of course, having a standard that focuses narrowly on benefits to the “population as a whole” is a concerning standard from a health equity standpoint. Painting with such a broad brush runs the risk of minimizing unique impacts on subpopulations—most concerningly, Black or African American, LGBTQ+, Hispanic or Latinx, American Indian/Alaska Native (AI/AN), low wealth, and other communities that

have been targeted by the tobacco industry and/or experience disproportionate harm. In other words, it runs the risk of replicating existing commercial tobacco control efforts, which have disproportionately benefitted white, higher-resourced populations, leaving out communities that are historically marginalized. This is particularly concerning in light of the tobacco industry's well-documented practice of predatorily targeting of these communities with its deadly products.

It is unacceptable that an action could be “appropriate for the protection of the public health” as a whole, yet disproportionately harm distinct communities, particularly those experiencing intersecting and compounding impacts from commercial tobacco use, environmental racism, prejudice, economic injustice, criminal injustice, food insecurity, and many other structurally created and maintained injustices and inequities. In fact, harms to communities that are marginalized should be at the forefront of a regulatory agency's mind when considering “risks” to the population as a whole. Just as racism saps our collective health, policies, and practices that have disproportionate negative impacts on communities that are marginalized are harmful to the population as a whole—tobacco users and nonusers alike. It is therefore critical to establish a framework for the Tobacco Control Act's public health standard that contemplates and prioritized the elimination of health disparities.

This is not just an ethical argument, however—there are laws and agency directives that require consideration of racial and health equity in taking agency action. For example, the National Environmental Policy Act (NEPA), along with a [1994 Presidential Executive Order](#) on Environmental Justice,<sup>8</sup> requires agencies to consider the health and socio-economic effects of proposed regulations on minority, low-income, and AI/AN communities and address significant and adverse environmental effects of their actions. The U.S Department of Health and Human Services (HHS) has an [Environmental Justice Strategy and Implementation Plan](#) adopted in 2012 that specifically sets out its plan to address disproportionate impacts of its actions on minority populations and acknowledges that it is required to mitigate those harms. To date, however, the FDA's Center for Tobacco Products (CTP) has issued no rules, regulations, product standards, or marketing orders that have adequately assessed environmental justice impacts under NEPA. Thus, any operationalization of the public health standard in the form of any federal action will have to take these considerations into account.

Most recently, on January 20, 2021, President Biden issued an [Executive Order on Advancing Racial Equity and Support for Underserved Communities Through the Federal Government](#), which directs agencies to assess whether agency actions and policies create or exacerbate barriers to accessing benefits produced by those actions. Additionally, President Biden renewed the [2000 Executive Order 13175 on Tribal Consultation and Strengthening Nation-to-Nation Relationships](#), which directs agencies to consult and coordinate with Tribes when making regulations that have a significant impact on Tribes. These could present further opportunity to request specific regulations or guidance documents explicitly stating how

implementation of a population-wide public health benefit assessment can address health inequity by considering barriers experienced by historically marginalized communities.

Finally, data is power. Equity-focused research provides a unique opportunity to influence the information that is in front of the FDA when FDA determines what is “appropriate for the protection of the public health”—particularly in the context of product standards. Like other regulations, product standards can be proposed to the agency by public health groups in the form of a citizen petition. Take, for example, the [Menthol Citizen Petition](#) submitted by public health groups in 2013 asking the agency to prohibit menthol as a characterizing flavor in cigarettes. In that case, the information supporting the proposed standard was collected and submitted by the public health community—not industry. Industry responded with its own data, of course, but the conversation was framed at the outset with public health—and health equity—in mind. This is how the agency itself should begin regulatory processes – by centering health equity in the process from the beginning. This means funding equity-focused commercial tobacco research to ensure that the agency has a good evidence base as a starting point for regulatory action.

## **The Takeaway**

The Tobacco Control Act gives the FDA broad authority to regulate commercial tobacco products in ways that are “appropriate for the protection of the public health.” This requires the FDA to consider risks and benefits to the population as a whole, including cessation and initiation risks and benefits to users and nonusers. The agency could operationalize this standard to focus resources and regulatory action on reducing health disparities caused by commercial tobacco use. Such a conception of the public health standard would be consistent with the broader federal framework and would require each of the FDA Center for Tobacco Products’ regulatory, research, communications, and administrative functions to be reoriented to advancing equity. The public health standard can—and should—be a tool to guide agency decisionmaking in a way that places health equity at the forefront.

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## Endnotes

- 1 Family Smoking Prevention and Tobacco Control Act § 907(a)(3), 21 U.S.C. § 387g(a)(3) (2018).
- 2 There are three marketing pathways, but only the premarket tobacco product application (PMTA) process uses the public health standard. Products seeking marketing approval via the other two marketing pathways, “substantial equivalence (SE)” and “substantial equivalence exemption” (SE Exemption), must meet different standards.
- 3 Some version of the “appropriate for the protection of the public health” standard appears in 21 U.S.C. § 387f(d); 21 U.S.C. § 387g(a)(3) and (4); 21 U.S.C. § 387j(c)(2), (4), and (5); 21 U.S.C. § 387e (j)(2). Other iterations use slightly different language, such as “necessary for the protection of the public health,” *id.* at § 387g(d)(2); “necessary to protect the public health,” *id.* at § 387k(i)(2); “appropriate to promote the public health,” and “consistent with the protection of the public health,” *id.* at § 387k(g)(2)(A)(i); and “otherwise protect the public health,” *id.* at § 387i(a). The Act also uses more varied language to refer to public health benefits, including “benefit the health of the population as a whole,” *id.* at § 387k(g)(1); “to protect the public health,” *id.* at § 387o(b)(1)–(2); and “best protects and promotes the public health,” *id.* at § 387r(b), to provide a few examples.
- 4 21 U.S.C. § 387g(a)(3)(B).
- 5 21 U.S.C. § 387j(c)(4).
- 6 COMM. ON ENERGY AND COMMERCE, FAMILY SMOKING PREVENTION AND TOBACCO CONTROL ACT, H.R. Rep. 111-58, pt. 1, at 39 (2009). See also Eric N. Lindblom, *What is “Appropriate for the Protection of the Public Health” Under the U.S. Tobacco Control Act?* 74 Food and Drug Law J. 523, 525, n.7 (discussing lack of elaboration on the public health standard in the Act’s legislative history).
- 7 See Eric N. Lindblom, *What is “Appropriate for the Protection of the Public Health” Under the U.S. Tobacco Control Act?* 74 Food and Drug Law J. 523, n. 9 (citing presentation by Priscilla Callahan-Lyon, Deputy Dir., Div. of Individual Health Sci., FDA Ctr. for Tobacco Prods., Presentation at Food and Drug Law Institute’s Tobacco and Nicotine Products Regulation and Policy Conference: The ENDS Guidance, IQOS Marketing Authorization, and the Future of Premarket Tobacco Applications: the FDA Perspective (Oct. 25, 2019), <https://www.fdli.org/wp-content/uploads/2019/10/945-1030-Premarket-Tobacco.pdf> [https://perma.cc/YEX5-8PH6]).
- 8 On February 11, 1994, President Clinton signed Executive Order 12898, *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations*, <https://www.archives.gov/files/federal-register/executive-orders/pdf/12898.pdf>.