

What Is “Appropriate for the Protection of the Public Health” Under the U.S. Tobacco Control Act?

ERIC N. LINDBLOM*

ABSTRACT

In 2009, the U.S. Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) gave the U.S. Food and Drug Administration (FDA) extensive new powers to issue rules and take other regulatory actions to reduce tobacco use and its massive harms, so long as FDA determined that doing so was “appropriate for the protection of the public health” (AFPPH). What exactly that phrase means and how much it constrains or facilitates effective FDA tobacco control efforts has not been determined, and FDA has yet to implement a rule that would sharply reduce U.S. tobacco use harms. Through a careful analysis of the Tobacco Control Act, applicable case law, and other relevant sources, this Article reveals what FDA must, may, and must not do when issuing tobacco control rules or orders; identifies the remaining gray areas and how they might be clarified; and suggests new FDA approaches to insulate its regulatory actions against future legal challenges and better protect the public health.

Some assume that FDA must evaluate costs, illicit trade impacts, and other non-health effects when determining whether a regulatory action is “appropriate” or must put a higher priority on protecting youth than helping adult smokers. However, this Article’s analysis finds that the Tobacco Control Act’s unique public health standard focuses exclusively on ensuring that any FDA tobacco control rules or orders will benefit *the health* of the U.S. population *as a whole*. FDA may consider non-health impacts or subpopulation health impacts when deciding what regulatory actions to take. But such impacts are irrelevant to FDA appropriate-for-the-protection-of-the-public-health determinations (or related court review), except to the extent they contribute to the regulatory action’s net public health impact.

Gaps in the statute leave certain aspects of this public health standard unsettled. It does not tell us what “appropriate” means, how large and likely a net gain to the public health must be to qualify as AFPPH, or how to estimate such inevitably uncertain future health impacts. Nor does it say whether an FDA regulatory action that creates a risk of a negative public health impact could be “appropriate,” or, if so, what ratios of likelihood and size between the potential net public health benefits and the potential net harms would be AFPPH. The Act leaves resolving these issues almost entirely to

* Eric N. Lindblom is a Senior Scholar at Georgetown Law’s O’Neill Institute for National & Global Health Law. He was Director of the Office of Policy at FDA’s Center for Tobacco Products from 2011 to 2014, and previously served as General Counsel and Director for Policy Research at the Campaign for Tobacco-Free Kids. The development of this Article was supported by a Greenwall Foundation “Making a Difference in Real-World Bioethics Dilemmas” grant.

FDA's discretion, subject only to the Administrative Procedure Act's "not arbitrary or capricious" standard. But, as detailed herein, FDA must find certain tobacco control orders AFPPH even if they create a risk of producing a negative public health impact. At the same time, FDA still has a legal duty to minimize any risk that an otherwise AFPPH regulatory action might produce a net public health harm, and FDA must also take steps to refine its final AFPPH tobacco control rules and orders to reduce certain non-health harms and negative individual or subpopulation health impacts, at least when that can be done without reducing the expected net public health gains.

When developing tobacco control rules and orders and trying to predict their public health impacts, FDA unavoidably works in areas of considerable uncertainty. As shown here, however, FDA has enormous discretion in terms of evaluating research and other evidence, making projections of future impacts, and, should it choose to do so, moving forward with aggressive tobacco control actions even when real-world experience and directly relevant research are scarce or nonexistent.

This Article's comprehensive analysis of the Tobacco Control Act's public health and evidentiary standards provides important new insights for FDA, tobacco industry members, and other parties interested in commenting on FDA's proposed rules and orders (or challenging or defending them in court).

I. INTRODUCTION

To protect the public health, the U.S. Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act or TCA) provides the U.S. Food and Drug Administration (FDA) with broad new authorities to regulate tobacco products and their sale, distribution, advertising, and promotion.¹ Despite receiving these extensive new tobacco control powers in 2009, FDA has yet to implement a substantive rule to reduce the ongoing toll of tobacco in the United States.² Each year, roughly half a

¹ Family Smoking Prevention and Tobacco Control and Federal Retirement Reform Act (TCA), Pub. L. No. 111-31 (2009). Section 101 amends the Federal Food, Drug, and Cosmetic Act (FDCA), creating a new Chapter IX with new §§ 900 to 919 (codified at 21 U.S.C. § 387 et seq.). The statute defines "tobacco product" to include any product "made or derived from tobacco," including components, parts, and accessories. 21 U.S.C. § 321(rr)(1). That definition has been interpreted to include both products containing tobacco and products that contain no tobacco but include nicotine, such as e-cigarettes, unless they are marketed with therapeutic claims and, therefore, are regulated as medical drugs, not "tobacco products." *Sottera, Inc. v. FDA*, 627 F.3d 891 (D.C. Cir. 2010). The Act initially provided FDA with authorities relating only to cigarettes, smokeless tobacco, and roll-your-own tobacco, but also provided FDA to deem other tobacco products under its tobacco control authorities; and FDA issued a final rule to deem all tobacco products subject to its TCA authorities in 2016. *Deeming Tobacco Products to be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Restrictions on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products*, 81 Fed. Reg. 28,974 (May 10, 2016) (codified at 21 C.F.R. pts. 1100, 1140, 1143) [hereinafter *Deeming Rule 2016*].

² Pursuant to a statutory mandate, in 2011, FDA issued a final rule to require graphic health warnings on cigarette packs. *Required Warnings for Cigarette Packages and Advertisements*, 76 Fed. Reg. 36,628 (June 22, 2011). But the courts struck the rule down on First Amendment grounds prior to implementation. *Id.* at 36,721, *R.J. Reynolds Tobacco Co. v. FDA*, 696 F.3d 1205 (D.C. Cir. 2012). Moreover, FDA's estimates in the Final Rule indicated that it would have had only a relatively small impact on overall U.S. smoking levels. *Required Warnings for Cigarette Packages and Advertisements*, 76 Fed. Reg. at 36,721. Forced by court rulings, FDA issued a new cigarette warning label rule in March 2020. *Am. Acad. of Pediatrics v. FDA*, 330 F. Supp. 3d 657 (D. Mass. 2018); *Tobacco Products; Required Warnings for Cigarette Packages and Advertisements*, 8 Fed. Reg. 15,638 (March 18, 2020). The new final rule does not estimate how much the new warnings might reduce U.S. smoking levels, summarizing its benefits as being

million people still die prematurely from smoking and other tobacco use, and more than sixteen million suffer from tobacco-caused disease and disability.³

In most cases, the Tobacco Control Act permits FDA to take its tobacco control regulatory actions whenever FDA determines that doing so is “appropriate for the protection of the public health” (AFPPH).⁴ This new standard for FDA tobacco control action was included in the Tobacco Control Act because the agency could not regulate tobacco products (non-therapeutic nicotine-delivery products) as drugs or devices under FDA’s “safe and effective” standard.⁵ Although it would certainly be AFPPH for FDA to issue reasonable rules to reduce tobacco-related health harms as quickly as possible, the AFPPH standard does not require FDA to take action. Nor does it require FDA to issue only those rules that are the most AFPPH. The standard applies only to require that FDA not implement any specific tobacco control rule or order unless it first determines that doing so is, by itself, AFPPH.⁶

While the Act provides some clarification and guidance regarding what is relevant in making those determinations, it does not define the phrase precisely. Nor does the Act’s legislative history provide any more specific definition or direct clarifications beyond just reciting the related statutory text.⁷ The phrase or its key terms are not

solely from helping people better understand the consequences from smoking. *Id.* at 15,639. But research in other countries (with stronger graphic warnings than those in the FDA rule) suggest its impact will be only marginal. *See, e.g.,* Anh Ngo, *Global Evidence on the Association Between Cigarette Graphic Warning Labels and Cigarette Smoking Prevalence and Consumption*, 15 INTL J. ENVIRONMENTAL RESEARCH & PUBLIC HEALTH 421 (Feb. 28, 2018). FDA implemented its tobacco product deeming rule in 2016. Deeming Rule 2016, *supra* note 1. But that rule did not include any strong, new substantive provisions, and did not do anything directly about cigarette smoking (still the major cause of tobacco-related deaths and health harms).

³ *See, e.g.,* Maddy Bolger, *Toll of Tobacco in the United States of America*, CAMPAIGN FOR TOBACCO-FREE KIDS (Jan. 13, 2020), <https://www.tobaccofreekids.org/assets/factsheets/0072.pdf> [<https://perma.cc/4R4Z-9NVS>] (also identifying major economic harms from tobacco use).

⁴ For the major explicit uses of the AFPPH standard in the Act, see 21 U.S.C. § 387f(d)(1), (3), reissuing rules to restrict the sale and distribution of tobacco products, including access to, and the advertising and promotion of, tobacco products; 21 U.S.C. § 387g(a)(3)–(4) and § 387g(c)(2)–(3) reissuing tobacco product standards; and 21 U.S.C. § 387j(c)(2)(A), § 387j(c)(4)–(5), and § 387j(c)(d)(1)(A) reissuing orders to allow or refuse to allow onto the U.S. market new or changed tobacco products, which are not substantially equivalent to certain tobacco products already on the U.S. market. *See also* 21 U.S.C. § 387 Definitions (21)(C); 21 U.S.C. § 387e(j)(3)(A)(ii). For a directly parallel public health standard in the Act, see 21 U.S.C. § 387k(g)(1), reissuing orders allowing tobacco products to be marketed with “modified-risk” claims.

⁵ COMM. ON ENERGY AND COMMERCE, FAMILY SMOKING PREVENTION AND TOBACCO CONTROL ACT, H.R. REP. NO. 111-58, pt. 1, at 3 (2009) [hereinafter 2009 House Report]. *See also* FDA v. Brown & Williamson Tobacco Corp., 529 U.S. 120 (2000).

⁶ 21 U.S.C. § 387, *supra* note 4. On FDA’s ethical duty to use its TCA authorities to issue effective tobacco control rules, see Eric N. Lindblom, *What Tobacco Control Rules Would an Ethically Responsible FDA Implement (If the White House and OMB Would Let It)? Would a Nicotine-Reduction Rule Pass Muster?* (forthcoming) (on file with author).

⁷ 2009 House Report, *supra* note 5, at 2, 3, 33, 37, 39, 41–42, 44. For a Circuit Court ruling citing the 2009 House Report as informative legislative history, see Nat’l Ass’n of Tobacco Outlets, Inc. v. City of Providence, 731 F.3d 71, 82 (1st Cir. 2013). *See also* COMMITTEE ON ENERGY AND COMMERCE, FAMILY SMOKING PREVENTION AND TOBACCO CONTROL ACT, H.R. REP. NO. 110-762 (2008) [hereinafter 2008 House Report] (legislative history for the almost identical legislation considered but not passed the prior year). The Congressional Record mentioned the AFPPH standard only twice during the deliberations over the legislation in the House and Senate. Senator Snowe simply mentioned the standard before stating: “It is imperative that we provide the FDA the flexibility to respond to inevitable tobacco industry attempts to circumvent restrictions, while acknowledging the rights of the tobacco industry to sell its products to consenting adults.” 155 CONG. REC. S6353 (daily ed. June 9, 2009) (statement of Sen. Snowe). Senator

clarified by any of the other sections of the Federal Food, Drug, and Cosmetic Act (FDCA), where much of the Tobacco Control Act now sits.⁸ Despite the long passage of time, FDA has not yet published any final guidance or rules that try to define the phrase more precisely.⁹ And, despite numerous tobacco industry lawsuits challenging the Act and various FDA actions pursuant to its authorities, no court has yet provided any significant clarification of how FDA may or must interpret and apply the Act's AFPPH standard.¹⁰

Nevertheless, looking closely at the Act's text, in light of other relevant sources and existing case law, can provide substantial insights into which factors, issues, or questions are relevant to determining whether an FDA tobacco control rule or regulatory action is AFPPH, and which are not, and can offer at least some guidance

Burr, in remarks opposing the legislation, expressed a concern that it might be impossible for companies to show that allowing their new tobacco products onto the U.S. market would be "appropriate for the protection of the public health," as the Act requires, possibly impeding the marketing of new, less harmful tobacco products. 155 CONG. REC. S6004-05 (daily ed. June 3, 2009) (statement of Sen. Burr).

⁸ Other than in the TCA provisions, the Federal Food, Drug, and Cosmetic Act (FDCA) references "appropriate for the protection of the public health" only once, relating to when FDA may place additional conditions on its extension of a medical product's expiration date regarding its emergency use. 21 U.S.C. § 360bbb-3a(b)(2)(C). But neither legislative history nor court rulings define or clarify the phrase in that context. An expired FDCA provision relating to FDA authority to take action regarding a manufacturer's dissemination of drug or device treatment information also used the phrase "appropriate for the protection of the public health." 21 U.S.C. § 360aaa-4(a)(1). There, too, the statute used the phrase without any further definition or clarification by statute, legislative history, or court rulings.

⁹ FDA draft, proposed, and final guidance and rules that mention the AFPPH standard typically only recite the related statutory text or use the phrase on its own. *See, e.g.,* Menthol in Cigarettes, Tobacco Products; Request for Comments, 78 Fed. Reg. 44,484 (proposed July 24, 2013); *see infra* notes 136–39 and accompanying text. In a public presentation, a senior staff person from the FDA Center for Tobacco Products stated that, in the context of FDA determinations relating to whether to allow a new tobacco product on the market: "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." But nothing was said as to whether that potential had to be larger than the potential that it would increase morbidity and/or mortality, instead. 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.fdpi.org/wp-content/uploads/2019/10/945-1030-Premarket-Tobacco.pdf> [<https://perma.cc/YEX5-8PH6>].

¹⁰ There are only a few court rulings that mention the TCA's AFPPH standard, but none explore the standard's meaning. *See* Nicopure Labs, LLC v. FDA, 266 F. Supp. 3d 360, 373, 375, 404, 406 (D.D.C. 2017), *aff'd* 944 F.3d 267 (D.C. Cir. 2019); R.J. Reynolds Tobacco Co. v. FDA, 810 F.3d 827, 830 (D.C. Cir. 2016); U.S. Smokeless Tobacco Mfg. Co. v. City of N.Y., 708 F.3d 428, 430–31 (2d Cir. 2013); Disc. Tobacco v. United States, 674 F.3d 509, 542 (6th Cir. 2012); Nicopure Labs, LLC v. FDA, 922 F.3d 267 (D.C. Cir. 2019); Cigar Ass'n of Am. v. FDA, 315 F. Supp. 3d 143, (D.D.C. 2018); Philip Morris USA Inc. v. FDA, 202 F. Supp. 3d 31, 39, 53 (D.D.C. 2016); U.S. Smokeless Tobacco Mfg. Co. v. City of N.Y., 703 F. Supp. 2d 329, 339, 343–44 (S.D.N.Y. 2010). Two court rulings that struck down FDA's attempted implementation of a rule requiring graphic health warnings on cigarette packs did so on First Amendment grounds without discussing the public health standard. R.J. Reynolds Tobacco v. FDA, 696 F.3d 1205 (D.C. Cir. 2012); R.J. Reynolds Tobacco Co. v. FDA, 845 F. Supp. 2d 266 (D.D.C. 2012). In other, non-tobacco, non-FDA contexts, one Supreme Court ruling mentions "appropriate for the protection of the public health and comfort," and one Supreme Court dissent refers to "appropriate for the protection of public health and safety," but neither clarifies nor defines the phrases. *Lucas v. S.C. Coastal Council*, 505 U.S. 1003, 1052–53 (1992) (Blackmun, H., dissenting); *Cal. Reduction Co. v. Sanitary Reduction Works*, 199 U.S. 306, 318 (1905). Only one appellate court ruling appears to mention a similar phrase in a non-tobacco context, also with no additional clarification or definition. *Benson v. Walker*, 274 F. 622, 624–25 (4th Cir. 1921) (referring to "reasonable, necessary and appropriate, for the protection of the public health and comfort").

as to the relative weight FDA may or must give different relevant factors. But no such careful analysis of the Act's public health standard has yet been published.¹¹ This Article fills that gap by providing a carefully constructed, statute-based framework that can be used by FDA, public health groups, the tobacco industry, other interested parties, and, ultimately, the courts to further refine how the standard may and should be applied by FDA.

II. THE TOBACCO CONTROL ACT'S CORE PURPOSE: PROTECTING THE PUBLIC HEALTH BY REDUCING TOBACCO USE AND HARMS

Protecting the public health through reducing tobacco use and harms is the Tobacco Control Act's controlling purpose, with every other goal either a means toward achieving that primary public health purpose or a desired secondary benefit from reducing tobacco use harms.

The very first words of the Tobacco Control Act in its preamble are "To protect the public health," and there are no references in the Act to its tobacco control provisions also being directed at any goals unrelated to protecting the public health.¹²

¹¹ Among the handful of law review articles and other scholarly publications that mention the AFPPH standard in more than a cursory way, none provide any careful, detailed analysis, and most simply restate the statutory text. See, e.g., Olga Yevtukhova, *The Food and Drug Administration Kicks the Habit—The FDA's New Role in Regulation of Tobacco Products*, 35 AM. J. L. & MED. 700, 700–01 (2009). Some also provide a few related questionable assumptions, or even misread the Act. See Daniel Carpenter et al., *Substantial Equivalence Standards in Tobacco Governance: Statutory Clarity and Regulatory Precedent for the FSPTCA*, 42 J. HEALTH POL., POL'Y & L. 607, 625 (2017) (inaccurately stating that the standard applies to FDA evaluations of whether new tobacco products may be allowed to enter the U.S. market because they are "substantially equivalent" to products previously on the market); Michael J. A. Freiberg, *Federal Approaches to the Regulation of Noncigarette Tobacco Products*, 43 AM. J. PREVENTIVE MED. S249, S250 (2012) (inaccurately stating that the standard does not apply to FDA's § 910 review of new tobacco products seeking entry to the U.S. market); James T. O'Reilly, *FDA Regulation of Tobacco: Blessing or Curse for FDA Professionals?*, 64 FOOD & DRUG L. J. 459, 463 (2009) (suggesting that the Act puts new First Amendment restrictions on FDA—when 21 U.S.C. § 387f(d)(1) actually permits advertising restrictions "to [the] full extent permitted by the first amendment"); Kevin Gauntt Barker, *Thank You for Regulating: Why Philip Morris's Embrace of FDA Regulation Helps the Company but Harms the Agency*, 61 ADMIN. L. REV. 197, 209–13 (2009) (suggesting that the standard and related requirements make legally challenging FDA product standards easy). For a more careful, still cursory, description of the Act's standard, with some related analysis, see, for example, Micah L. Berman et al., *Providing a Science Base for the Evaluation of Tobacco Products*, 1 TOBACCO REG. SCI. 76 (2015). For two articles that describe how the standard might apply in real-world situations, see Eric N. Lindblom, *Effectively Regulating E-Cigarettes and Their Advertising—and the First Amendment*, 70 FOOD & DRUG L. J. 57 (2015) [hereinafter Lindblom, *Effectively Regulating E-Cigarettes*]; and Eric N. Lindblom et al., *FDA-Required Tobacco Product Inserts & Onsets—and the First Amendment*, 72 FOOD & DRUG L. J. 1 (2017) [hereinafter Lindblom et al., *FDA-Required Tobacco Product Inserts*]. See also Clive Bates et al., *Eight Tobacco Harm Reduction Proposals for the Federal Government*, R Street Institute Study No. 81 at 9–10 (2017), <https://www.rstreet.org/wp-content/uploads/2017/01/81.pdf> (discussing perceived problems with the standard's focus on whole-population, public health impacts in regard to new, less harmful tobacco products trying to obtain FDA orders allowing them on the U.S. market).

¹² The preamble also mentions that the Act means "to make certain modifications to the Thrift Savings Plan, the Civil Service Retirement System, and the Federal Employees' Retirement System," but that refers to Division B of the Act, which is separate and substantively unrelated to the Act's Division A provisions relating to FDA's regulation of tobacco products. But see Timothy Westmoreland, *Invisible Forces at Work: Health Legislation and Budget Processes*, in THE OXFORD HANDBOOK OF U.S. HEALTHCARE LAW 882–86 (I. Glenn Cohen et al. eds., 2017).

The Act further confirms this overriding, public-health-focused goal in its text requiring the Comptroller General of the United States to issue a single report within the first five years after enactment concerning the adequacy of the authority and resources provided to FDA to carry out the Act's goals and purposes and "any recommendations for strengthening *that authority to more effectively protect the public health* with respect to the manufacture, marketing, and distribution of tobacco products."¹³

In addition, the most important documentation of the Tobacco Control Act's legislative history, the 2009 report on the Act by the U.S. House of Representatives Committee on Energy and Commerce (House Committee Report) states: "For too long, the tobacco industry in the United States has escaped the type of ordinary product regulation that applies to most other consumer products. This legislation levels the playing field with respect to tobacco products *so that the public health may be protected and improved.*"¹⁴

The Act's "Purpose" section lists ten purposes which each appear different from just protecting and promoting the public health. But each is either a means toward achieving the Act's ultimate public health goal or simply reflects benefits that can be achieved only by securing net reductions to tobacco-related health harms.¹⁵ For example, Purpose (1) is to provide FDA with authority to regulate tobacco products "by recognizing it as the primary Federal regulatory authority with respect to the manufacture, marketing, and distribution of tobacco products," clearly a means toward an end. Purpose (2)—"to ensure that the Food and Drug Administration has the authority to address issues of particular concern to public health officials, especially the use of tobacco by young people and dependence on tobacco"—even more explicitly links the means of providing FDA with new authorities to the end of achieving actual public health goals relating to tobacco. Purposes (3), (4), (5), and (8) simply complement Purpose (1), describing specific regulatory authorities the Act means to provide FDA (without explicitly stating the public health end those means are directed toward).

Purpose (6)—"to ensure that consumers are better informed . . . relating to the health and dependency effects or safety of tobacco products"—might initially appear directed at a separate, new goal. But it presents just another means toward the Act's primary goal of better protecting the public health. The most logical and important reasons to inform consumers about tobacco product health harms, risks, and addictiveness are to prevent consumers from being misled by inaccurate or incomplete information, or tobacco product marketing, and to help them make more accurate and informed decisions about initiating, maintaining, or changing their tobacco use behaviors in ways that reduce their individual health risks and harms and improve the public health.¹⁶ Indeed, the Act repeatedly expresses concern about tobacco product

¹³ 21 U.S.C. § 387u(b) (emphasis added).

¹⁴ 2009 House Report, *supra* note 5, at 4 (emphasis added). *See also id.* at 14, 37; 2008 House Report, *supra* note 7, at 50, 57.

¹⁵ 21 U.S.C. § 387 note.

¹⁶ A much more strained reading of Purpose (6) would argue that its reference to better informing consumers means to require FDA to protect and preserve adult consumer choice, even when that would interfere with securing net public health gains. But there is no indication that "consumer" means to refer only to adults. *See infra* note 86. Also, no other text in the Act suggests that FDA must consider adult

advertising misleading consumers to the detriment of the public health, and § 911 is expressly designed to prevent industry claims that are false or, even if accurate, are misleading or could otherwise increase public health harms.¹⁷ The public health justification for better informing consumers is also reflected in the Tobacco Control Act provisions that require FDA to publish a not-misleading public list of harmful and potentially harmful constituents (HPHCs) in each tobacco product by brand and sub-brand.¹⁸ Conversely, nothing in the Act suggests that Purpose (6) means to establish a separate, new goal of increasing consumer knowledge simply for knowledge's sake or to support a regulatory system that puts providing for informed consumer choice (even where it increases overall health harms) ahead of protecting the public health.¹⁹

The part of Purpose (7) that states, “to continue to permit the sale of tobacco products to adults,” might be seen to contradict the overriding goal of the Act to protect the public health by improving the health of the population as a whole. But Purpose (7) simply confirms the intent of Congress to provide FDA with extensive authorities to protect the public health through *regulating* tobacco products and their manufacture, marketing, distribution, and sale but not by *banning* tobacco products.²⁰ Purpose (7) articulates a constraint on the means FDA may use to promote the Act's public goal but does not change or add to that ultimate public health goal.²¹

After Purpose (2), Purpose (9)—“to promote cessation to reduce disease risk and the social costs associated with tobacco-related disease”—most explicitly and directly reflects the Act's overarching purpose: to protect the public health by preventing and reducing tobacco-related disease and other health harms. As the text states, the reduced

consumer choice in any context or may allow such concerns to influence its AFPPH determinations. See *infra* notes 60–64 and accompanying text.

¹⁷ See, e.g., 21 U.S.C. § 387k; Pub. L. No. 111-31, Div. A, § 2, June 22, 2009, 123 Stat. 1776.

¹⁸ 21 U.S.C. § 387d(d)–(e). Like § 911, this subsection's stress on the list not being misleading to lay persons reinforces the primacy of the Act's public health goal over better informing consumers. It reflects the fact that providing accurate HPHC information to consumers could mislead some into taking responsive actions that they mistakenly think will improve their health (e.g., switching to brands with lower HPHC levels) but will actually produce no reduction in harms or risks and could increase harms if done instead of quitting all use.

¹⁹ Purpose (6) might also reflect the fact that §§ 201–205 of the Act amend the Federal Cigarette Labeling and Advertising Act (15 U.S.C. § 1331 et seq.) and the Comprehensive Smokeless Tobacco Health Education Act (15 U.S.C. § 4401 et seq.) to provide FDA with additional, separate authorities, outside of the FDCA, to amend the warning label requirements for cigarette and smokeless tobacco product packages and ads when FDA determines that “such a change would promote greater public understanding of the risks associated with the use of tobacco products” or of “smokeless tobacco products,” respectively. 15 U.S.C. § 1333(d); 15 U.S.C. § 4402(d). But those greater-public-understanding determinations would still have to be made consistently with the overriding public health purpose of the TCA that created those authorities. Accordingly, efforts to increase consumer awareness that would not benefit the public health would fall outside those authorities. In addition, FDA could separately require or change warning labels, pursuant to the AFPPH standard, through §§ 906, 907, 910, or 911 of the FDCA, which include no text suggesting that increasing consumer or public understanding might be an independent goal. 21 U.S.C. § 387f, g, j, k.

²⁰ See 2009 House Report, *supra* note 5, at 38, 39–40; § 907(d)(3)(A) (prohibiting FDA from banning all tobacco products or certain entire categories of tobacco products); U.S. Smokeless Tobacco Mfg. Co. v. City of N.Y., 708 F.3d 428, 433 (2d Cir. 2013). See also *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 137–41 (2000).

²¹ Although attempts have been made, Purpose (7), alone or in conjunction with other Purposes or provisions, also cannot be interpreted to create any right of adult consumers to choose to use tobacco products that would trump the public health purpose of the Act. See *infra* notes 58–62 and accompanying text.

social costs will come directly from tobacco use cessation reducing tobacco-related disease, so Purpose (9) does not create any new non-health goal.²² In addition, no other text in the Act indicates that FDA has any authority to take any action solely or primarily to reduce non-health social costs, whether or not associated with tobacco-related disease.

Purpose (10)—“to strengthen legislation against illicit trade in tobacco products”—might also initially appear to establish an additional new goal, separate from protecting the public health. But effectively regulating tobacco products to protect and promote the public health necessarily includes preventing and reducing any illicit trade in tobacco products, which can increase initiation and reduce cessation by offering tobacco products at lower, tax-evading prices and can reduce the health benefits from FDA tobacco product standards by making non-complying tobacco products available to users. Moreover, Title III of the Act, which specifically relates to the prevention of illicit trade in tobacco products, is controlled by the same public health purposes and objectives of the whole Act. That Title does not identify any new or different purposes, but it does endorse the public health goal of the Act by directing the Comptroller General to conduct a study and publish a report that collects data on “the health effects . . . resulting from cross border trade in tobacco products, including the health effects resulting from—(A) the illicit trade of tobacco products and the trade of counterfeit tobacco products; and (B) the differing tax rates relating to tobacco products.”²³

Other than in Title III and the purposes and findings sections, the only reference to illicit trade appears in § 907(b), which says that FDA must consider all information submitted in connection with a proposed product standard, and specifically mentions information about “the creation of a significant demand for contraband or other tobacco products that do not meet the requirements of this chapter and the significance of such demand” as an example of such information FDA must consider.²⁴ However,

²² Similarly, Finding (7) states that “[f]ederal and [s]tate governments have lacked the legal and regulatory authority and resources they need to address comprehensively the public health *and societal* problems caused by the use of tobacco products,” and Finding (12) notes that the benefits to the American people from providing FDA with the authority to regulate tobacco products and the advertising and promotion of such products “would be significant in human *and economic* terms.” Pub. L. No. 111-31, Div. A, § 2, 123 Stat. 1776 (2009) (emphasis added). These findings are about the need to provide FDA with new tobacco control authorities to secure public health benefits, while also mentioning additional non-health benefits that would be automatically secured by FDA using those authorities to reduce tobacco use and its harms to achieve the Act’s overarching public health goal. Similarly, Finding (14) states that public health efforts to reduce youth smoking will also sharply reduce health care costs, and Finding (37) refers to the “huge costs to our health care system” caused by the widespread use of tobacco products sold or distributed as modified risk products that do not in fact reduce risk (which the Act’s MRTP provisions mean to stop). *Id.* Finding (10) states that the sale, distribution, marketing, advertising, and use of tobacco products “have a substantial effect on the Nation’s economy,” but that reference, with other Findings, means only to show that tobacco products are sold, marketed, advertised, and distributed in interstate commerce on a nationwide basis, thereby providing a constitutional basis for federal regulation (not to suggest a separate non-health goal for the Act). *Id.*; see U.S. CONST. art. I, § 8, cl. 3.

²³ Tobacco Regulation, Federal Retirement Reform Act, Pub. L. No. 111-31, Div. A, § 302, 123 Stat. 1776, 1851–52 (2009). Finding (35) states that illicit trade in tobacco products has been linked to organized crime and terrorist groups, thereby identifying another extra benefit from the Act’s public health efforts. Pub. L. No. 111-31, Div. A, § 2, 123 Stat. 1776, 1779 (2009). Organized crime and terrorist groups will be weakened not only by any public-health-directed efforts by FDA to reduce illicit trade but also by FDA’s broader tobacco control efforts to reduce overall tobacco use (which will also reduce the potential demand for illicit tobacco products).

²⁴ 21 U.S.C. § 387g(b).

nothing in § 907(b) or elsewhere in § 907 or the Act suggests that any increased contraband demand or other illicit trade information would be relevant to FDA's AFPPH determinations in regard to product standards (or other FDA tobacco control rules or orders), except to the extent the illicit trade would impact the health benefits, risks, or harms of the population as a whole. Moreover, § 907(b) references increased contraband demand directly in the context of providing FDA with information regarding “countervailing effects of the tobacco product standard on the health of adolescent tobacco users, adult tobacco users, or nontobacco users.”²⁵ In reference to § 907, the Committee report on the Act similarly refers to a concern about how the “prohibition of a product that is used regularly by a large number of heavily addicted adult users . . . might unnecessarily increase the illegal black market risk, *which could also pose a health hazard to users.*”²⁶

More generally, the Committee report confirms that “the overall intent” of the Act is “to protect the public health.”²⁷ In addition, most of the provisions of the Act are amendments to the FDCA, which has the “overriding purpose to protect the public health.”²⁸

III. THE ACT'S “APPROPRIATE FOR THE PROTECTION OF THE PUBLIC HEALTH” STANDARD

The controlling public health purpose of the Tobacco Control Act is primarily implemented through the central role of the Act's “appropriate for the protection of the public health” (AFPPH) standard.

Three of FDA's most powerful tobacco control authorities under the Tobacco Control Act are explicitly governed by the AFPPH standard:

(1) Section 906 provides FDA with the authority to issue rules to restrict “the sale and distribution of a tobacco product, including restrictions on the access to, and the advertising and promotion of, the tobacco product” if FDA “determines that such a regulation would be appropriate for the protection of the public health.”²⁹

²⁵ Family Smoking Prevention and Tobacco Control Act, Pub. L. 111-31, § 907(b)(2), 123 Stat. 1801 (2009). Section 907(b) also applies only to product standard rules, and none of the other sections of the Act providing FDA authority to issue tobacco control rules or orders, other than Title III, make any mention of illicit trade considerations. One of the few law review articles considering the TCA's standards for FDA action argues that § 907(b) makes any legal claim against an FDA tobacco product standard more legitimate if it can show a related significant increase in demand for contraband tobacco products. Barker, *supra* note 11. But any legal challenge based on § 907(b) and increased contraband demand that did not also show negative health impacts from the increased illicit trade could not claim that the standard was not “appropriate for the protection of the public health.” See *infra* Section III. To succeed, a § 907(b)-based legal challenge would have to show that FDA had failed even to “consider” some relevant submitted information about the product standard significantly increasing contraband demand. Assuming FDA at least thought about the provided information, the § 907(b) legal challenge could likely survive only if it were able to show that FDA's decision to implement the AFPPH product standard was “arbitrary or capricious” in violation of the Administrative Procedure Act (APA) because of its likely impacts on contraband demand. See 5 U.S.C. § 706(2)(A); see also *infra* Section X (discussing the not-arbitrary-or-capricious standard and the possible relevance of non-health impacts from FDA tobacco control rules or orders).

²⁶ H.R. Rep. No. 111-58, at 38 (2009) (emphasis added). The report does not reference any other concerns relating to illicit trade.

²⁷ *Id.* at 37; see also *id.* at 4, 14; H.R. Rep. No. 110-762, *supra* note 7, at 50, 57.

²⁸ See, e.g., *FDA v. Brown & Williamson*, 529 U.S. 120, 162 (2000).

²⁹ 21 U.S.C. § 387f(d).

(2) Section 907 provides FDA with authority to adopt a tobacco product standard (a rule regulating the structure of the tobacco product itself) if FDA “finds that a product standard is appropriate for the protection of the public health.”³⁰

(3) Section 910 provides that no substantially new or changed tobacco product may enter the U.S. market unless the manufacturer or importer submits a pre-market tobacco application (PMTA) to FDA and FDA determines that the application shows “that permitting such tobacco product to be marketed would be appropriate for the protection of the public health.”³¹

In addition, the Act’s Modified Risk Tobacco Product (MRTP) provisions—which prevent tobacco products from being marketed in the United States with any explicit or implicit reduced-risk or reduced-exposure claims in their labeling, advertising, or other public communications without first obtaining a permissive order from FDA—uses a whole-population health-directed standard that directly parallels the AFPPH standard without using those exact words.³² For certain reduced-exposure products that cannot meet that standard, the MRTP provisions also provide a second pathway for obtaining a permissive order that explicitly requires that the applicant show, among other things, that the order would be “appropriate to promote the public health.”³³

Numerous other provisions in the Tobacco Control Act establish parallel or similar public-health-directed standards for other FDA tobacco control regulatory actions.³⁴

³⁰ Family Smoking Prevention and Tobacco Control Act § 907(a)(3), 21 U.S.C. § 387g(a)(3) (2018). There does not appear to be any significance to § 907 using “finds” and § 906 using “determines.” Elsewhere, § 906(d)(1) refers to FDA’s AFPPH determination as a “finding;” and § 907(a)(3)(B) refers to that Section’s AFPPH finding under a “Determinations” heading. The Act does not specifically define “tobacco product standard,” but describes it as including rules that regulate “nicotine yields of the product;” reduce or eliminate “other constituents, including smoke constituents or harmful components;” regulate “the construction, components, ingredients, additives, constituents, including smoke constituents, and properties of the tobacco product;” or “require the use and prescribe the form and content of labeling for the proper use of the tobacco product.” Family Smoking Prevention and Tobacco Control Act § 907(a)(3), 21 U.S.C. § 387g(a)(3) (2018).

³¹ Family Smoking Prevention and Tobacco Control Act § 910(c)(2)(A). Section 910 differs from Sections 906 and 907 primarily by placing the burden of establishing that the FDA PMTA order is “appropriate for the protection of the public health” directly on the application seeking the order. In contrast, whether an FDA tobacco product standard or other rule is AFPPH can be established by the entire record of proceedings created by the rulemaking. *See* Family Smoking Prevention and Tobacco Control Act § 912.

³² 21 U.S.C. § 387k(g)(1). For brevity’s sake, subsequent general references to the AFPPH standard in the Act include the parallel MRTP public health standard.

³³ 21 U.S.C. § 387k(g)(2).

³⁴ *See* 21 U.S.C. § 387c(a)(8)(B)(ii) (2018) (using “appropriate to protect the public health”); *see also id.* at § 387f(c)(1)(A) (using “to assure that the public health is protected”); *id.* at § 387g(d)(2) (using “necessary for the protection of the public health” and “consistent with the public health”); *id.* at § 387h(a)(1) (using “unreasonable risk of substantial harm to the public health”); *id.* at § 387i(a) (using “otherwise protect the public health,” “the need for the protection of the public health,” and “to determine risks to public health of a tobacco product”); *id.* at § 387j(a)(3)(A)(ii) (using “different questions of public health”); *id.* at § 387k(g)(1) (using “benefit the health of the population as a whole”); *id.* at § 387k(g)(2)(A)(i) (using “appropriate to promote the public health”); *id.* at § 387k(i)(2) (using “necessary to protect the public health”); *id.* at § 387k(i)(2) (using “consistent with the protection of the public health”); *id.* at § 387o(b)(1)–(2) (using “to protect the public health”); *id.* at § 387r(b) (using “best protects and promotes the public health”); Family Smoking Prevention and Tobacco Control Act § 103(l) (conforming amendment creating a new 21 U.S.C. § (p)(1)(C) “to reduce any negative public health impact”); Family Smoking Prevention and Tobacco Control Act § 106(b) (requiring a U.S. Government Accountability Office report with recommendations “to more effectively protect the public health”); Family Smoking Prevention and Tobacco Control Act § 206 (amending the Federal Cigarette Labeling and Advertising Act at 15 U.S.C. § 1333(e)(2) to give FDA authority to disclose tobacco product constituents when that “would be of benefit

Several other provisions of the Act further establish the primacy of its public health purpose by specifically qualifying various restrictions or requirements they place on FDA by stating that the agency need not comply if it determines that doing otherwise is necessary for the protection of the public health.³⁵

IV. THE IRRELEVANCE OF NON-HEALTH IMPACTS UNDER THE AFPPH STANDARD

The Tobacco Control Act does not allow FDA to evaluate any non-health impacts when determining whether a tobacco control rule or order is “appropriate for the protection of the public health.”

Although the public health standards in the Tobacco Control Act focus directly and exclusively on the public health, some argue that an FDA rule or order could not be “appropriate” for the protection of the public health if it produced certain substantial, undesirable non-health harms or risks (e.g., large burdens on the regulated tobacco industry, increases in illicit trade, or reduced tobacco-related employment).³⁶ Yet nothing in the text establishing those standards indicates that FDA must or may consider any possible non-health impacts when determining whether an FDA rule or order is AFPPH—except to any extent that the non-health impacts also produce health consequences.³⁷

Given the overarching public health purpose of the Tobacco Control Act, it cannot be interpreted to require or even authorize FDA to evaluate any non-health impacts or

to the public health”); H.R. Rep. No. 111-58 (2009), *supra* note 5, at 26 (indicating that “in the interest of the public health” means the same as “appropriate for the protection of the public health”).

³⁵ 21 U.S.C. § 387g(d)(2); *see also id.* at § 387e(j)(3)(A)(ii); *id.* at § 387f(d)(3)(B); *id.* at § 387i(a)(3), (6).

³⁶ *See, e.g.*, Jose Luis Murillo, Altria Client Services, Inc., Comment Letter on Proposed Rule: Tobacco Product Standard for Nicotine Level of Certain Combusted Cigarettes (July 16, 2018), <https://www.regulations.gov/document?D=FDA-2017-N-6189-7074>; James E. Dillard III, Altria Client Services, Inc., Comment Letter on Proposed Rule: Menthol in Cigarettes, Tobacco Products [hereinafter Dillard III 2013 Comments] (Nov. 22, 2013), <https://www.regulations.gov/document?D=FDA-2013-N-0521-0315>; James E. Dillard III, Altria Client Services, Inc., Comment Letter on Notice: Regulation of Tobacco Products; Extension of Comment Period [hereinafter Dillard III 2009 Comments] (Dec. 22, 2009) (“The Act should be implemented in a way that achieves Congress’s public health objectives without unnecessarily impacting the millions of adult consumers, employees, tobacco growers, and retailers who will be affected by regulation.”), <https://www.regulations.gov/document?D=FDA-2009-N-0294-1014>.

³⁷ For example, if a rule or order increased illicit trade, the increased criminal activity itself would not be relevant to whether the rule or order was AFPPH, but any health harms or benefits caused by that illicit trade would be relevant. Although not directly relevant for AFPPH determinations, FDA may still consider non-health impacts or other non-health factors when exercising its discretion regarding what AFPPH rules to develop or implement. *See, e.g.*, *Norton v. S. Utah Wilderness All.*, 542 U.S. 55, 66–67 (2004) (stating that it is the task of the regulatory agency, not the supervising court, “to work out compliance with the broad statutory mandate” and determine “the manner and pace of agency compliance with such congressional directives”); *see also* *Armstrong v. Exceptional Child Center, Inc.*, 135 S. Ct. 1378, 1390 (2015) (Breyer, J., concurring) (stating that “the law may give the federal agency broad discretionary authority to decide when and how to exercise or to enforce statutes and rules”); *Bethlehem Steel Corp. v. EPA*, 782 F.2d 645, 655 (7th Cir. 1986) (stating that “[w]hen an agency has discretion as to whether or not to undertake rulemaking, the courts cannot tell it how to exercise that discretion”); *Heckler v. Chaney*, 470 U.S. 821, 830 (1985); *Massachusetts v. EPA*, 549 U.S. 497, 527 (2007). As discussed in Section X, certain undesirable non-health impacts from an FDA tobacco control rule or order could also be relevant in determining whether FDA’s decision to implement a rule or order structured in a certain way was arbitrary or capricious, in violation of the APA, despite the rule or order being “appropriate.”

concerns when determining whether an FDA tobacco control rule or order is “appropriate,” unless specific Act text brings such non-health impacts into those determinations. But no such text exists.

As discussed more fully below, the Act does identify some impacts on consumer behaviors relating to tobacco use that FDA must consider when determining whether a rule or order is AFPPH, such as tobacco use cessation and initiation.³⁸ But the Act directs FDA to consider those behaviors only to the extent that they will have an impact on the health of the population as a whole.³⁹ Except for that, the Act does not mention any other possible non-health impacts in the context of making AFPPH determinations.⁴⁰

A. Technical Achievability, Burdens on the Industry, Illicit Trade, and Other Non-Health Impacts

The Tobacco Control Act’s references to non-health impacts—such as technical achievability, burdens on the industry, and illicit trade—provide no authority for FDA to consider non-health impacts when making appropriate-for-the-protection-of-the-public-health determinations.

For § 907 tobacco product standard rulemaking (placing restrictions or requirements on the tobacco products themselves), the Tobacco Control Act states that FDA “shall consider information submitted in connection with a proposed standard regarding the technical achievability of compliance with such standard.”⁴¹ It also states that FDA shall consider:

all other information submitted in connection with a proposed standard, including information concerning the countervailing effects of the tobacco product standard on the health of adolescent tobacco users, adult tobacco users, or nontobacco users, such as the creation of a significant demand for contraband or other tobacco products that do not meet the requirements of this chapter and the significance of such demand.⁴²

But these requirements relating to possible non-health-related impacts are not linked by the statute to FDA’s AFPPH determinations for product standards. They simply identify information that, if submitted to FDA after the agency issues a proposed rule to establish a product standard, FDA must consider as it exercises its discretion regarding how to structure any subsequent final rule (within its statutory

³⁸ See *infra* text accompanying notes 68, 69, 71–73; see also *infra* Section IV.C.

³⁹ *Id.* There is nothing in the Act’s text to suggest that the increased or decreased likelihood of initiation or cessation are relevant except to the extent they have impacts on overall health harms relating to tobacco use.

⁴⁰ The TCA and the APA establish various procedural steps that FDA must take when issuing a proposed and then final rule. But those do not substantively affect what rules may or may not be found “appropriate.” The TCA also prohibits certain types of tobacco product standards (e.g., those banning all cigarettes or requiring the reduction of tobacco product nicotine yields to zero) and certain § 906 rules (e.g., those establishing a minimum age of sales for tobacco products). 21 U.S.C. § 387g(d)(3) (2018); see also § 387f(d). But those restrictions of FDA’s tobacco control authorities do not affect what rules FDA issues within its authorities may or may not be “appropriate for the protection of the public health.”

⁴¹ 21 U.S.C. § 387g(b)(1).

⁴² 21 U.S.C. § 387g(b)(2).

authorities and any applicable constitutional or other legal constraints).⁴³ To the extent that the provided information were relevant to the potential impact of the product standard on the public health, it would also be relevant to FDA’s related AFPPH determinations. But nothing in this statutory text indicates that it means to require FDA also to consider any submitted information unrelated to the public health when determining whether a proposed or final rule is “appropriate.” Moreover, as previously noted, the Act refers to considering the potential impact of a product standard on the demand for contraband tobacco products only in the context of considering the possible “countervailing effects” from any such products on “the health of adolescent tobacco users, adult tobacco users, or nontobacco users.”⁴⁴

The fact that the Act mentions technical achievability only in § 907, relating to tobacco product standards, indicates that the Act does not consider technical achievability relevant to other types of FDA tobacco control rules or to any FDA tobacco control orders. Even for product standards, § 907 indicates that technical achievability is relevant only regarding whether FDA has established acceptable compliance deadlines. After § 907(b) states that FDA shall consider submitted information on technical achievability, § 907(d) states that, when establishing an effective date, FDA “shall consider information submitted in connection with a proposed product standard by interested parties . . . regarding the technical achievability of compliance with the standard, and including information concerning the existence of patents that make it impossible to comply in the timeframe envisioned.”⁴⁵ And the Act makes no other references to technical achievability outside of those two subsections.⁴⁶

Beyond its references to considering submitted information about technical achievability when setting effective dates, § 907(d)(2) states that FDA should set effective dates for compliance “so as to minimize . . . economic loss to, and disruption or dislocation of, domestic and international trade”—but only when doing that is “consistent with the public health.” It also states that the effective date for a new tobacco product standard shall not be earlier than one year after the date of its publication unless FDA “determines that an earlier effective date is necessary for the protection of the public health.”⁴⁷ Similarly, § 906(e) states that, when setting the

⁴³ In regard to these and other provisions in § 907 of the Family Smoking Prevention and Tobacco Control Act, the 2009 House Report states: “In issuing a final standard as with any rulemaking, the Secretary shall review and consider all information and scientific evidence and data, presented by any party that comments on the proposed standard, including any information, evidence, or other submitted documentation concerning the population impact or any other matter related to the proposed standard.” 2009 House Report *supra* note 5, at 39.

⁴⁴ See *supra* notes 23–26 and accompanying text.

⁴⁵ 21 U.S.C. § 387g(d)(2) (2018). The requirement that FDA “consider” technical achievability is also largely procedural, requiring only that FDA show that it has reasonably considered any submitted technical achievability information when setting compliance deadlines or other effective dates. For example, the text requires FDA to consider submitted information about patents that make it impossible to comply in the timeframe envisioned but does not require FDA to extend the timeframe (or provide alternative ways to comply) if such patents exist.

⁴⁶ The submitted technical achievability information could also enable FDA to determine whether no manufacturers could possibly comply by the proposed effective date or any future date, which could constitute a de facto ban, which might be outside of FDA’s authority under 21 U.S.C. § 387g(d)(3)(A). But that has nothing to do with whether the product standard would be “appropriate.”

⁴⁷ 21 U.S.C. § 387g(d)(2).

effective dates for any rule establishing manufacturing practices for tobacco products “to assure that the public health is protected,” FDA shall:

take into account the differences in the manner in which the different types of tobacco products have historically been produced, the financial resources of the different tobacco product manufacturers, and the state of their existing manufacturing facilities, and shall provide for a reasonable period of time for such manufacturers to conform to good manufacturing practices.⁴⁸

In all these provisions, the Act clearly means for FDA to reduce economic burdens, disruptions, or dislocations only when caused by too-short deadlines for complying with new FDA tobacco product standards, and only when that can be done without interfering with FDA’s efforts to protect the public health.

All of the other references to industry burdens or business costs in the Act are in the context of compliance and reporting deadlines, avoiding duplicative or overly burdensome reporting requirements, and helping small tobacco product manufacturers to comply with the Act or related rules.⁴⁹ Beyond that, the Act does not require FDA rules or orders to be cost-effective or require FDA to identify or evaluate costs or cost-effectiveness when developing rules or orders, either generally or when determining whether a rule or order is AFPPH. Following a similar analysis, the D.C. District Court in the *Nicopure Labs v. FDA* case rejected the plaintiffs’ claim that the Tobacco Control Act required FDA to engage in a cost-benefit analysis or assess the costs of compliance before deeming e-cigarettes to be tobacco products subject to the Act.⁵⁰

The House Committee Report on the Act adopts a Congressional Budget Office estimate of the Act’s costs—including projections of reduced tobacco industry sales, reduced tobacco product tax revenues for all levels of government, and reduced Master Settlement Agreement payments from tobacco companies to the states and territories (because of declining cigarette sales)—with the government declines in revenues totaling over \$1 billion just in the first four years after the Act’s enactment.⁵¹ Yet nothing in the report or Act expresses any concern about the tobacco industry losing

⁴⁸ 21 U.S.C. § 387f(e)(1). *See also* *Mexichem Fluor, Inc. v. EPA*, 866 F.3d 451, 464 (D.C. Cir. 2017) (for purposes of arbitrary or capricious review, agency adequately considered transition costs of regulated industry when it decided to give certain product manufacturers extra time to comply with the rule).

⁴⁹ *See* 21 U.S.C. § 387e(i) (requiring FDA to consult with the Treasury Department to minimize burdens on those persons (e.g., tobacco product manufacturers and importers) required to register with both FDA and the Tax and Trade Bureau of the Treasury Department); § 387i(a) (any new FDA record-keeping or reporting requirements to assure that tobacco products are not adulterated or misbranded must not be “unduly burdensome to a tobacco product manufacturer or importer, taking into account the cost of complying with such requirements and the need for the protection of the public health and the implementation of this subchapter”); § 387t(b)(4) (FDA “shall take into account the size of a business in promulgating regulations under this section” (relating to labeling, recordkeeping, and records inspections to prevent illicit trade in tobacco products)). *See also* § 387a(f) (FDA shall establish “an identifiable office to provide technical and other nonfinancial assistance to small tobacco product manufacturers to assist them in complying with the requirements of this chapter”); § 387f(e)(1)(B)(v) (requiring a minimum amount of four years from date of enactment for small tobacco product manufacturers to conform to any new FDA rule establishing good manufacturing practices); § 387o(d), € (setting extended time periods for small tobacco product manufacturers having to comply with new FDA requirements regarding tobacco product testing, reporting, and disclosures).

⁵⁰ *Nicopure Labs, LLC v. FDA*, 266 F. Supp. 3d 360, 400–03 (D.D.C. 2017).

⁵¹ 2009 House Report, *supra* note 5, at 14–27.

sales revenues or being charged user fees, or about any increased government costs or lost revenues from FDA tobacco control efforts.⁵² Nor does the Act anywhere require FDA to consider any of those costs or lost revenues in the agency's development or implementation of its tobacco control rules or orders.⁵³

Even when costs are a statutory concern, the courts generally leave it to the regulatory agency to determine whether the benefits from a regulatory action are worth the costs.⁵⁴

Separate from the Tobacco Control Act, the Regulatory Flexibility Act requires federal agencies to assess the impact of their proposed regulations on "small entities"—which, for FDA tobacco control rules, would include smaller tobacco businesses—and to identify alternative regulatory actions that would accomplish the relevant statutory objectives with less of an impact on the small entities.⁵⁵ Similarly, the Unfunded Mandates Reform Act requires regulatory agencies issuing rules that place costly federal mandates on the private sector to develop and consider analyses of the budgetary impact on the private sector; consider a reasonable number of regulatory alternatives; and choose the least costly, most cost-effective or least burdensome alternative that achieves the objectives of the rule, or provide an explanation why a different option was needed.⁵⁶ In addition, Presidential Executive Order 12291 and related Office of Management and Budget (OMB) publications separately place a number of internal, administrative requirements on federal regulatory agencies regarding the costs and benefits of new regulations, including burdens on the regulated entities.⁵⁷ But none of these separate requirements are

⁵² See Westmoreland, *supra* note 12. The only expression of any related concern in the 2009 House Report is in only the "Dissenting Views" section, which states: "If Congress deems this regulation necessary for the protection of the public health then it should be important enough to appropriate funds for these activities," rather than fund it through a user fee, which is characterized as a "a dangerous precedent that grows the size of government and taxes the American people through secrecy and synonyms." 2009 House Report, *supra* note 5, at 129. But Congress rejected the dissenting views (and any concerns about burdening the industry) and required members of the tobacco industry to fund FDA's tobacco control efforts pursuant to the Act, with payments starting at \$85 million in the first year, \$235 million in the second year, and then ratcheting up to \$712 million per year in 2019 and beyond. 21 U.S.C. § 387s(b).

⁵³ As noted earlier, FDA may exercise its discretion to consider these or other non-health impacts when deciding which AFPPH rules to develop for implementation, and certain non-health impacts could also be relevant in determining whether FDA's decision to implement a rule or order structured in a certain way might be arbitrary or capricious, despite being "appropriate." See *supra* note 37.

⁵⁴ See, e.g., *State of La., ex rel. Guste v. Verity*, 853 F.2d 322, 331 n. 20 (5th Cir. 1988) (noting that the regulatory agency had determined that the benefits from its regulatory action outweighed the costs and stating that "if the trade-off . . . has been skewed in the wrong direction, it is for the legislative and executive branches, not the courts, to correct that imbalance"); *Market Synergy Group, Inc. v. U.S. Dep't of Labor*, 885 F.3d 676, 685–86 (10th Cir. 2018) (not arbitrary or capricious if the agency, relying on the record before it, reasonably concludes that the statutorily relevant benefits outweigh the costs of compliance); *Charter Commc'ns, Inc. v. FCC*, 460 F.3d 31, 42 (D.C. Cir. 2006) ("cost-benefit analyses epitomize the types of decisions that are most appropriately entrusted to the expertise of an agency" (internal citations and quotations omitted)); *Chemical Mfrs. Ass'n v. EPA*, 870 F.2d 177, 183, 207 (5th Cir. 1989) (even where the statute directs the agency to consider costs, "identifying the point of diminishing returns" in regard to benefits and costs is within the discretion of the agency, citing *Am. Petroleum Inst. v. EPA*, 540 F.2d 1023 at 1038 (10th Cir. 1976)).

⁵⁵ 5 U.S.C.A. § 601 et seq. (Westlaw through P.L. 116-108).

⁵⁶ 2 U.S.C.A. § 1501 et seq. at § 1535 (Westlaw through P.L. 116-108).

⁵⁷ Exec. Order No. 12,291, 46 Fed. Reg. 13,193 (Feb. 17, 1981). See also OFFICE OF MGMT. & BUDGET, CIRCULAR A-4, REGULATORY ANALYSIS (2003), <https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/circulars/A4/a-4.pdf> [<https://perma.cc/JL2C-M847>]; TODD GARVEY, CONG. RESEARCH SERV., R41546,

relevant to whether an FDA rule or order is appropriate for the protection of the public health.

In fact, the requirements of the Regulatory Flexibility Act and Unfunded Mandates Reform Act are purely procedural and put no substantive constraint on agency rulemaking.⁵⁸ Similarly, an FDA failure to comply with the Executive Order and OMB requirements could prevent an FDA rule or order from being cleared for implementation by other federal agencies and the White House. But non-compliance with such internal executive branch requirements (which have not been passed into law by Congress) could not provide the legal grounds for a court to strike down a final FDA rule or order, much less change what is or is not legally relevant to FDA's AFPPH determinations.⁵⁹

As for other non-health impacts that the tobacco industry or others might think relevant to FDA tobacco control decision making, the Act makes no reference to any smoker or consumer having any right to smoke or use tobacco products or to choose to do so.⁶⁰ One of the ten listed Purposes of the Act is “to continue to permit the sale of tobacco products to adults,”⁶¹ and the Act also states that FDA has no authority to issue a rule “banning all cigarettes, all smokeless tobacco products, all little cigars, all cigars other than little cigars, all pipe tobacco, or all roll-your-own tobacco

A BRIEF OVERVIEW OF RULEMAKING AND JUDICIAL REVIEW 11–13 (2017), <https://fas.org/sgp/crs/misc/R41546.pdf> [<https://perma.cc/ZYC6-S2HW>].

⁵⁸ 5 U.S.C.A. § 611 (Westlaw through P.L. 116-108); 2 U.S.C.A. § 1571(a)(3), (4) (Westlaw through P.L. 116-108). See also *Nat'l Tel. Coop. Ass'n v. FCC*, 563 F.3d 536, 540 (D.C. Cir. 2009); *Nicopure Labs, LLC v. FDA*, 266 F. Supp. 3d 360, 407–08 (D.D.C. 2017); *Am. Trucking Ass'n, Inc. v. EPA*, 175 F.3d 1027, 1043 (D.C. Cir. 1999); *Ctr. for Sci. in the Pub. Interest v. U.S. Dep't of Treasury*, 797 F.2d 995, 1002 n. 7 (D.C. Cir. 1986) (stating that “[a]gencies can consider the economic impact of their regulations, pursuant to executive orders . . . when the underlying statute permits such consideration” (internal citations omitted)).

⁵⁹ Exec. Order 12,291, *supra* note 57 (“This Order is intended only to improve the internal management of the Federal government, and is not intended to create any right or benefit, substantive or procedural, enforceable at law by a party against the United States, its agencies, its officers or any person.”). See also *Meyer v. Bush*, 981 F.2d 1288, 1296 n.8 (D.C. Cir. 1993) (stating “[a]n Executive Order devoted solely to the internal management of the executive branch—and one which does not create any private rights—is not, for instance, subject to judicial review”); *Michigan v. Thomas*, 805 F.2d 176, 187 (6th Cir. 1986). However, gross violations of those internal executive branch rulemaking requirements or the Regulatory Flexibility Act, or the information provided to satisfy these requirements, could be used as evidence that FDA's decisions on how to structure a final tobacco control rule were arbitrary or capricious or to show that the agency or the rule violated other legal requirements, even if the rule or action were “appropriate.” See, e.g., *Allied Local & Reg'l Mfrs. Caucus v. EPA*, 215 F.3d 61, 78–79 (D.C. Cir. 2000); *Nat'l Tel. Coop. Ass'n*, 563 F.3d at 540; *R.J. Reynolds Tobacco Co. v. FDA*, 696 F.3d 1205, 1219–20 (D.C. Cir. 2012). See also Caroline Cecot & W. Kip Viscusi, *Judicial Review of Agency Benefit-Cost Analysis*, 22 GEO. MASON L. REV. 575 (2015). Sections VIII to X, below, discuss the application of the not-arbitrary-or-capricious standard to FDA tobacco control actions and its considerations of costs and other non-health impacts.

⁶⁰ The Act's only explicit reference to a legal right is to the right to judicial review of “any person” adversely affected by an FDA tobacco product standard or denial of a PMTA application. See 21 U.S.C. § 387l(a) (Westlaw through P.L. 116-108). *But see* Dillard III 2013 Comments, *supra* note 36 (“In passing the FSPTCA, Congress wanted ‘to continue to permit the sale of tobacco products to adults in conjunction with measures to ensure that they are not sold or accessible to underage purchasers. Congress also prohibited banning all cigarettes. Together, these provisions reflect a deliberate policy determination that FDA should preserve adult consumers’ ability to decide whether and what type of tobacco products they wish to use.” (internal footnotes omitted)).

⁶¹ See 21 U.S.C. § 387 note.

products.”⁶² But it is clear from the legislative history of the Act that these provisions were included to avoid the risk that a tobacco product ban might increase illicit trade, thereby posing a health hazard to users, or might produce a sudden increase in demand for cessation assistance that could overwhelm the capacity of the health system and leaves users without medical support—not to create or protect any alleged adult right to use or choose to use tobacco products.⁶³ Moreover, the Act specifically authorizes FDA to make fundamental changes to the permitted characteristics of tobacco products, which directly contradicts the idea that the Act recognized any adult right to choose among the full range of available tobacco products that existed when the Tobacco Control Act first became law.⁶⁴

B. *FDA May Not Consider Non-Health Impacts When Making AFPPH Determinations*

Given the overriding public health purpose of the Tobacco Control Act and the absence of any text either requiring or authorizing FDA to evaluate non-health impacts when making its AFPPH determinations, FDA does not have any discretion to choose to consider any non-health impacts when determining whether a tobacco control rule or order is “appropriate for the protection of the public health.”

For example, in the 2001 *Whitman v. American Trucking Associations* ruling, the U.S. Supreme Court held that when the Clean Air Act directs the Environmental Protection Agency to set primary air quality standards, “the attainment and maintenance of which . . . are requisite to protect the public health” with “an adequate margin of safety,” the agency is not permitted to take costs or any other non-health factors into consideration when setting those levels.⁶⁵ In this regard, the Tobacco Control Act differs from the Clean Air Act provisions because it generally does not *require* specific FDA actions to protect the public health but only *authorizes* FDA to take such actions, and those actions must only be “appropriate,” not “requisite,” for the protection of the public health. Nevertheless, following *American Trucking* means that FDA does not have any discretionary authority to bring non-health costs or other non-health impacts into its AFPPH determinations because of the Tobacco Control Act’s overarching public health purpose and the absence of any text suggesting that other factors may come into play in FDA’s determinations.

The Supreme Court confirmed its *American Trucking* constraint on agency discretion in its 2015 *Michigan v. EPA* decision, which characterized the earlier ruling as “the modest principle” that when a statute expressly directs an agency “to regulate on the basis of a factor that does not include cost, the Act normally should not be read

⁶² § 907(d)(3)(A) [21 U.S.C. § 387g(d)(3)(A)].

⁶³ 2009 House Report, *supra* note 5, at 38. The only reference to so-called smokers’ rights in the Committee Report is in its “Dissenting Views” section, which quotes the London-based Royal College of Physicians as saying that smokers who either cannot or will not otherwise quit “have a right to be able to obtain and choose from a range of safer nicotine products, and they have a right to accurate and unbiased information to guide that choice.” *Id.* at 128.

⁶⁴ 21 U.S.C. § 387g. Section 387g(a)(1)(A) also completely banned all flavored cigarettes (other than those with tobacco or menthol flavor) without any mention in the Act or the 2009 House Report about how that might reduce adult consumer choice or impact any alleged adult right to choose among the full range of previously available tobacco products.

⁶⁵ *Whitman v. Am. Trucking Ass’n*, 531 U.S. 457, 464–65 (2001).

as implicitly allowing the Agency to consider cost anyway.”⁶⁶ Given that the Tobacco Control Act expressly directs FDA to regulate tobacco products solely on a public health basis that does not include non-health costs or impacts, the Act should not be read as implicitly allowing FDA to consider costs or any other unmentioned non-health impacts in its AFPPH determinations.⁶⁷

A parallel analysis constrains FDA’s ability to consider any health impacts except to the extent that they contribute to the health of the population as a whole.

⁶⁶ *Michigan v. EPA*, 135 S. Ct. 2699, 2709 (2015). In *Michigan*, the Court did not apply the modest *American Trucking* principle because it found that the statute’s requirement that EPA take regulatory action if it found the action “appropriate and necessary” required EPA to consider costs because of the “capaciousness” of that phrase and because “‘appropriate’ is ‘the classic broad and all-encompassing term that naturally and traditionally includes consideration of all the relevant factors.’” 135 S. Ct. at 2707 (emphasis added) (quoting *White Stallion Energy Ctr., LLC v. EPA*, 748 F.3d 1222, 1266 (D.C. Cir. 2014)). See also *Metlife, Inc. v. Fin. Stability Oversight Council*, 177 F. Supp. 3d 219, 239–43 (D.C. Cir. 2016), which extends *Michigan* to find an agency failure to consider costs arbitrary or capricious, thereby invalidating the action, when the relevant statute (the Dodd-Frank financial regulation Act) authorized the agency to consider “any other risk-related factors that [it] deems appropriate.” As detailed herein, however, the “appropriate” in “appropriate for the protection of the public health” is a much more limited, clearly defined term that does not include considerations of costs, contrasting sharply with the undefined and general use of “appropriate” in the Clean Air Act and the Dodd-Frank Act. 42 U.S.C.A. § 7412(n)(1)(A) (Westlaw through P.L. 116-108); 12 U.S.C.A. § 5323(a)(2)(K) (Westlaw through P.L. 116-108). Nor does the TCA direct or authorize FDA to consider any risk-related factors unrelated to the public health. Along those lines, the *Michigan* ruling describes the Clean Air Act’s “appropriate and necessary” standard as a far more comprehensive criterion, which subsumes consideration of costs, than the “requisite to protect the public health” standard in *American Trucking*, which did not. 135 S. Ct. at 2709. The Court in *Michigan* also stated that there “are undoubtedly settings in which the phrase ‘appropriate and necessary’ does not encompass cost.” 135 S. Ct. at 2707. See *Nicopure Labs*, 266 F. Supp. 3d 360, 401–03 (D.D.C. 2017) (finding that the “deeming” provision of the TCA at issue “does not include the words that led the Supreme Court in *Michigan v. EPA* to call for some assessment of costs as part of the decision that had been delegated to the agency . . . [and] does not limit the Secretary’s authority to deem to when he finds it ‘appropriate and necessary’ to do so”); *Am. Textile Mfrs. Inst., Inc. v. Donovan*, 452 U.S. 490, 491–92 (1981) (“reasonably necessary and appropriate” in 29 U.S.C. § 652(8) does not require cost-benefit analysis or balancing of costs and benefits because that would eviscerate other language in statute requiring regulations to “prevent material health impairment to the extent feasible”). See also *Nat’l Ass’n of Home Builders v. EPA*, 682 F.3d 1032, 1039 (D.C. Cir. 2012) (no duty to show that benefits of rule outweighed costs, even when statute specifically required consideration of economic impacts); *Judulang v. Holder*, 565 U.S. 42, 55 (2011) (agencies may not take regulatory actions based on factors that are arbitrary or irrelevant to the authorizing statute’s purpose); *Nat’l Ass’n of Home Builders v. Defenders of Wildlife*, 551 U.S. 644, 658 (2007) (an agency’s decision will be vacated as arbitrary or capricious if “it has relied on factors which Congress had not intended it to consider”); *South Carolina ex rel. Tindal v. Block*, 717 F.2d 874, 885 (4th Cir. S.C. 1983) (if an agency exercises its statutory discretion to take action based on the factors the statute requires, the courts “are not free to add substantive or procedural hurdles for agencies to overcome if Congress has not established such requirements”).

⁶⁷ However, non-health costs or impacts would be relevant to FDA AFPPH determinations to the limited extent that they also directly or indirectly produced public health consequences. For example, if an illicit trade in non-complying tobacco products emerged in response to an FDA tobacco product standard minimizing nicotine in cigarettes, that could reduce the rule’s public health benefits if some smokers used illicit full-nicotine cigarettes instead of quitting smoking. Conversely, a rule with high compliance costs could force tobacco product manufacturers to raise their product prices significantly, which would translate to reduced initiation and increased cessation, with related public health gains. See, e.g., U.S. DEP’T OF HEALTH & HUM. SERVS., CTRS. FOR DISEASE CONTROL & PREVENTION, NAT’L CTR. FOR CHRONIC DISEASE PREVENTION & HEALTH PROMOTION, OFF. ON SMOKING & HEALTH, THE HEALTH CONSEQUENCES OF SMOKING—50 YEARS OF PROGRESS: A REPORT OF THE SURGEON GENERAL at 788–91 (2014).

V. THE ACT’S EXCLUSIVE FOCUS ON THE HEALTH OF THE POPULATION AS A WHOLE

When FDA evaluates whether a tobacco control rule or order is appropriate for the protection of the public health, only the overall health impact on the population as a whole is relevant. Health impacts on specific subpopulations are relevant only to the extent they contribute to the overall net public health impact.

In the Tobacco Control Act, § 906 (authorizing FDA to regulate the marketing, distribution, and sale of tobacco products) and § 910 (requiring new product orders for market entry) use identical text to state that FDA’s related AFPPH findings:

shall be determined with respect to the risks and benefits to the population as a whole, including users and nonusers of the tobacco product and taking into account: (A) the increased or decreased likelihood that existing users of tobacco products will stop using such products; and (B) the increased or decreased likelihood that those who do not use tobacco products will start using such products.⁶⁸

Similarly, § 907 states that, when making its AFPPH finding relating to rules creating product standards, FDA:

shall consider scientific evidence concerning

(I) the risks and benefits to the population as a whole, including users and nonusers of tobacco products, of the proposed standard;

(II) the increased or decreased likelihood that existing users of tobacco products will stop using such products; and

(III) the increased or decreased likelihood that those who do not use tobacco products will start using such products.⁶⁹

Although the § 907 text differs somewhat from the identical text used in § 906 and § 910, the three sections consistently establish that FDA’s determination of whether an FDA rule or order is AFPPH depends on FDA’s determination of its impact on the health of the U.S. “population as a whole.”⁷⁰

Section 911 does not use the AFPPH phrase in its core provisions. But it has parallel text stating that FDA shall issue permissive MRTP orders only if the applicant has demonstrated that the order will not only “significantly reduce harm and the risk of tobacco-related disease to individual tobacco users” but will also “benefit the *health*

⁶⁸ 21 U.S.C. § 387f(d)(1); 21 U.S.C. § 387j(c)(4). *See also* Deeming Rule 2016, *supra* note 1 at 29,001 (In reviewing § 910 applications, the “public health standard requires the Agency to consider the impact of the products on the “population as a whole,” not simply the adult population that may be using such products.”).

⁶⁹ 21 U.S.C. § 387g(a)(3)(B). There does not appear to be any significance to § 907 using “shall consider” and § 906 and § 910 using “shall take into account,” as the Act appears to use the two phrases interchangeably. *See, for example,* 21 U.S.C. § 387t(b)(2) (2009) (“the Secretary shall consider”), 21 U.S.C. § 387t(b)(4) (2009) (“[t]he Secretary shall take into account”), and § 103(b)(9)(B)(iii) (“the Secretary shall take into consideration”).

⁷⁰ Neither 21 U.S.C. § 387g’s somewhat different text nor any of its other text indicates that it means to use a different AFPPH standard than §§ 387f and 387j. As discussed more fully below, § 387g’s different text, with its reference to “scientific evidence,” does not change the standard but refers only to the evidence FDA must consider when applying the standard. *See infra* text accompanying notes 133–36.

of the *population as a whole* taking into account both users of tobacco products and persons who do not currently use tobacco products.”⁷¹ Continuing the parallels, § 911 also offers a second pathway to permissive MRTP orders for tobacco products with certain limited types of MRTP claims that requires FDA to determine that issuing the order is “appropriate to promote the public health” and “is expected to benefit *the health* of the population *as a whole* taking into account both users of tobacco products and persons who do not currently use tobacco products.”⁷² As in the sections explicitly using the AFPPH phrase, both § 911 pathways also require FDA to take into account “the increased or decreased likelihood that existing users of tobacco products who would otherwise stop using such products will switch to the tobacco product that is the subject of the application” and “the increased or decreased likelihood that persons who do not use tobacco products will start using the tobacco product that is the subject of the application.”⁷³

When §§ 906, 907, 910, and 911 refer to “the risks and benefits to the population as a whole,” it is clear from the context and from the overarching public health purpose of the Act that they all mean *health* risks and benefits (as § 911 states explicitly), just as their references to FDA considering the increased likelihood that users or non-users will stop or start using tobacco products means for FDA to consider the *health* effects of such behavior changes.⁷⁴

⁷¹ 21 U.S.C. § 387k(g)(1) (2018) (emphasis added). It is possible, however, that FDA could interpret the requirement that MRTP orders “benefit” the health of the population as a whole as being somewhat more strict than the other sections’ requirement that the related rules or orders be “appropriate” for the health of the population as a whole. For example, it is possible that FDA could determine that providing certain non-misleading product information to consumers was “appropriate” under §§ 906, 907, and 910 if it enabled them to make more informed decisions about tobacco product use, even if it were not certain that providing the information would actually improve the public health significantly (at least so long as providing the information would not produce new public health harms). But providing such information to consumers could not be permissible under § 911 unless FDA also determined that doing so would actually improve or benefit the public health.

⁷² 21 U.S.C. § 387k(g)(2) (emphasis added).

⁷³ 21 U.S.C. § 387k(g)(4). Both § 911 pathways also require FDA to take into account “the relative health risks to individuals of the tobacco product that is the subject of the application” and “the risks and benefits to persons from the use of the tobacco product that is the subject of the application as compared to the use of products for smoking cessation approved under chapter V to treat nicotine dependence.” *Id.* These added considerations relate directly to the purpose of § 911, to allow tobacco products to be marketed with *accurate* claims of reducing risk or reducing exposure compared to other tobacco products when that is also “beneficial” or “appropriate” for the public health. The main difference between these § 911 public health standards and the explicit “appropriate” provisions in §§ 906, 907, and 910 is that the § 911 standards require FDA to determine, first, that the use of the applicant tobacco product by users instead of other tobacco products will reduce their harms and risks, a necessary but not sufficient condition both for finding the claims accurate and not misleading and for determining that allowing the claims would produce benefits to the health of the population as a whole (i.e., would be AFPPH).

⁷⁴ Other text in the Act also uses the word “risk” when meaning “health risk.” *See, e.g.*, Family Smoking Prevention and Tobacco Control and Federal Retirement Reform Act, Pub. L. 111-31, § 2(39), 123 Stat. 1780 (“Recent studies have demonstrated that there has been no reduction in risk on a population-wide basis from ‘low tar’ and ‘light’ cigarettes, and such products may actually increase the risk of tobacco use.”); Family Smoking Prevention and Tobacco Control and Federal Retirement Reform Act, Pub. L. 111-31, § 2(36), 123 Stat. 1779 (manufacturers of products distributed or sold to reduce “risks” must be required to demonstrate that the products “will benefit the *health* of the population as a whole” (emphasis added)); Family Smoking Prevention and Tobacco Control and Federal Retirement Reform Act, Pub. L. 111-31, § 2(37), (40), (42), (43), (44) 123 Stat. 1780. On the references to user and nonuser behavior changes referring to the health impact of those changes, see Section IV.C.

The focus of the Act's AFPPH standard on whole-population health impacts follows commonly used definitions of the "public health." For example, the *Oxford English Dictionary* defines "public health" as, "The health of the population as a whole, esp. as monitored, regulated, and promoted by the state (by provision of sanitation, vaccination, etc.)."⁷⁵ More importantly, the Tobacco Control Act's legislative history states, in reference to the AFPPH standard, that: "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."⁷⁶

As only whole-population health effects are relevant to FDA AFPPH determinations, FDA need not evaluate either the non-health impacts of a tobacco-control rule or order nor its health impacts on specific subpopulations—except to the extent that such non-health or subpopulation impacts are relevant for determining the net health impact on the population as a whole. Nothing in the Act indicates otherwise.

A. *The Act's Public Health Focus Overrides Any Concern for Specific Subpopulations or Disadvantaged Groups*

The Tobacco Control Act shows little concern regarding specific health impacts on any subpopulation or disadvantaged or vulnerable groups, other than youth, users, and nonusers.

Well before the Tobacco Control Act went into effect, some prominent conceptions of the public health and major strategies for protecting or promoting the public health explicitly included references to reducing health disparities or promoting health equity and to putting a priority on helping disadvantaged subpopulations or groups. For example, the federal government's Healthy People 2010 initiative, launched in January 2000, included as one of its two overarching goals to "eliminate health disparities among different segments of the population, including differences that occur by gender, race or ethnicity, education or income, disability, geographic location, or sexual orientation."⁷⁷ Indeed, many public health organizations and experts believe, with good reason, that efforts to improve the public health should include special efforts to reduce health disparities, whereby certain vulnerable or disadvantaged groups or subpopulations suffer greater health harms than other, more

⁷⁵ *Public Health*, OXFORD ENGLISH DICTIONARY (3d ed. 2007). See also *Whitman v. Am. Trucking Ass'n*, 531 U.S. 457, 466 (2001) (when the statute directed the agency to protect the public health, the "primary definition" of "public health" was the relevant one: "the health of the public").

⁷⁶ 2009 House Report, *supra* note 5, at 39. See also 2008 House Report, *supra* note 7, at 78; Family Smoking Prevention and Tobacco Control and Federal Retirement Reform Act, Pub. L. 111-31, § 2(31), 123 Stat. 1779 (referring to the federal government's substantial interest (materially advanced by provisions of the TCA) "in reducing the number of children and adolescents who use cigarettes and smokeless tobacco and in preventing the life-threatening health consequences associated with tobacco use"); *Star Sci., Inc. v. Beales*, 278 F.3d 339, 360–61 (4th Cir. 2002) ("it is generally recognized that 'tobacco use, particularly among children and adolescents, poses perhaps the single most significant threat to public health in the United States'" (quoting *Lorillard Tobacco Co.*, 533 U.S. 525 (2001) (internal quotation marks and citation omitted))).

⁷⁷ U.S. DEP'T HEALTH & HUM. SERVS., HEALTHY PEOPLE 2010: UNDERSTANDING AND IMPROVING HEALTH 11 (2d ed. 2000), <https://www.healthypeople.gov/2010/Document/pdf/uih/2010uih.pdf> [<https://perma.cc/W2WZ-V4HY>]. *Healthy People 2020*, which replaced *Healthy People 2010*, also contained an overarching goal to "[a]chieve health equity, eliminate disparities, and improve the health of all groups." U.S. DEP'T HEALTH & HUM. SERVS., HEALTHY PEOPLE 2020 3 (2010), https://www.healthypeople.gov/sites/default/files/HP2020_brochure_with_LHI_508_FNL.pdf [<https://perma.cc/U34C-QBRC>].

socially advantaged subpopulations.⁷⁸ Accordingly, their intuitive readings of the AFPPH standard could see it as requiring FDA to determine that its tobacco control rules and orders are not only likely to improve the overall public health but also will either do nothing to increase health disparities or will work to reduce them.

Such an interpretation would complicate FDA's analysis of its proposed tobacco rules and orders by requiring evaluations of the health impacts on specific disadvantaged subpopulations compared to other subpopulations. It could also impede certain effective tobacco control measures. For example, an FDA order allowing an e-cigarette to be marketed with reduced-risk claims could be blocked for increasing health disparities, even if it would produce substantial net public health gains and subpopulation gains, if it helped certain more-educated and otherwise more-advantaged subpopulations more than it helped certain less-educated and otherwise disadvantaged subpopulations.

But nothing in the Tobacco Control Act indicates that FDA must give any special consideration to reducing or not increasing health inequities or must otherwise be more concerned about the impact of a rule or order on any specific subpopulations compared to others when determining whether a rule or order is "appropriate for the protection of the public health." Remarkably, the Act does not even mention health disparities or health equity, nor does it anywhere include the terms "subpopulation," "sub-population," or "disadvantaged group," or any variants of the terms "disparities," "disadvantaged," "socioeconomic," "women," "female," "gender," "low-income," "less-educated," "sexual orientation," "mentally ill," or "disabled."⁷⁹

The Act references specific subpopulations or population groups only three times: when it references "Indian Tribes" in the context of reaching tobacco products on Tribal Lands, protecting Tribal sovereignty, and treating Indian Tribes and Tribal lands similarly to states or localities;⁸⁰ when it mentions "minority communities" in relation to a required action plan for enforcing the Act's restrictions on the promotion of menthol and other cigarettes to youth, and in the 1996 FDA tobacco product rule the Act directs FDA to reestablish;⁸¹ and when it requires an FDA Tobacco Products

⁷⁸ See, e.g., NAT'L RESEARCH COUNCIL, ELIMINATING HEALTH DISPARITIES: MEASUREMENT AND DATA NEEDS (2004), https://www.ncbi.nlm.nih.gov/books/NBK215751/pdf/Bookshelf_NBK215751.pdf [<https://perma.cc/PVK3-MFQ7>]; INST. OF MED., CHALLENGES AND SUCCESSES IN REDUCING HEALTH DISPARITIES: WORKSHOP SUMMARY (2008), https://www.ncbi.nlm.nih.gov/books/NBK215371/pdf/Bookshelf_NBK215371.pdf [<https://perma.cc/9Q93-QSCT>]; David Satcher & Eve J. Higginbotham, *The Public Health Approach to Eliminating Disparities in Health*, 98 AM. J. OF PUB. HEALTH 400 (2008), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2253560/> [<https://perma.cc/9Q93-QSCT>].

⁷⁹ The Act uses the word "group" relating to types of people only when noting that the illicit trade in tobacco products has been linked to "terrorist groups," Family Smoking Prevention and Tobacco Control and Federal Retirement Reform Act, Pub. L. 111-31, § 2(35), 123 Stat. 1779, and when stating that free samples of tobacco products may not be distributed to a "sports team or entertainment group," 21 U.S.C. § 387a-1(d)(3)(A).

⁸⁰ See Family Smoking Prevention and Tobacco Control and Federal Retirement Reform Act, Pub. L. 111-31, § 2(9), 123 Stat. 1777; Family Smoking Prevention and Tobacco Control and Federal Retirement Reform Act, Pub. L. 111-31, § 4 (a)(2), 123 Stat. 1782; 21 U.S.C. § 387p(a)(1) (2018); 21 U.S.C. § 387a-1.(a)(5); 21 U.S.C. § 372(a)(1)(B)(ii); 21 U.S.C. § 387t(c); TCA, Pub. L. 111-31, § 103(p), 123 Stat. 1838; 21 U.S.C. § 387f-1(b)(1).

⁸¹ 21 U.S.C. § 387f-1(a). In 2010, FDA reissued a revised version of the 1996 tobacco product rule (which the Supreme Court struck down in 2000 as outside of FDA's authorities at that time), and then issued the related Action Plan. 21 U.S.C. § 387a-1; 21 U.S.C. § 387f-1; Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco To Protect Children and Adolescents, 75 Fed. Reg. 13,225, 13,232 (March 10, 2010); OFFICE OF COMPLIANCE & ENF'T, CTR. FOR TOBACCO PRODS., FOOD &

Science Advisory Committee report (completed in 2011) on the impact of menthol in cigarettes on the public health, “including such use among children, African-Americans, Hispanics, and other racial and ethnic minorities.”⁸² These references show that Congress clearly knew how to mention specific subgroups when it wanted to do so. But there are no references in the Tobacco Control Act to any disadvantaged subpopulations or minority groups in the context of the AFPPH standard or in relation to FDA developing or implementing new tobacco control rules or orders.

The only other subpopulations or human groups the Act mentions are, not surprisingly, “smokers,” “nonsmokers,” “consumers,” tobacco product “users” and “nonusers,” and “youth” (or “minors,” “persons under the age of 18,” “adolescents,” or “children”), and “adults.”

“Smokers” appears only in three of the Act’s findings,⁸³ and “nonsmokers” appears only once, in text for graphic warnings on cigarette packs that the Act requires FDA to implement in a new rule.⁸⁴ None of these references, in quite different contexts, have anything to do with the AFPPH standard. Nor do any of them indicate that the Act prioritizes reducing harms to smokers above or below preventing or reducing any other tobacco use harms.⁸⁵

The Act uses the term “consumer,” in singular and plural form, more than forty times, but almost exclusively as a definitional or technical term. For example, the Act uses the term in some of its definitions; in references to First Amendment protections for manufacturer communications to consumers; in phrases such as “consumer behavior,” “consumer research,” or “consumer perception;” and in references to informing and not misleading consumers.⁸⁶ Although the term appears numerous times in § 911 and makes appearances in § 906 and § 907, none of these references pertain to FDA’s AFPPH determinations.⁸⁷ Moreover, none of the references to “consumer” or “consumers” anywhere in the Act suggest a higher priority for reducing tobacco use or harms among current consumers of tobacco products compared to preventing tobacco use initiation or tobacco-related harms among non-consumers.

DRUG ADMIN., ENFORCEMENT ACTION PLAN FOR PROMOTION AND ADVERTISING RESTRICTIONS (2010), <https://www.fda.gov/downloads/TobaccoProducts/Labeling/RulesRegulationsGuidance/UCM227882.pdf> [<https://perma.cc/E4PV-HAFK>].

⁸² 21 U.S.C. § 387g(e)(1); Tobacco Products Scientific Advisory Committee, *Menthol Cigarettes and the Public Health: Review of the Scientific Evidence and Recommendations* (2011), [<https://perma.cc/S8ZZ-SESV>].

⁸³ Family Smoking Prevention and Tobacco Control and Federal Retirement Reform Act, Pub. L. 111-31, § 2(14), (34), (38), 123 Stat. 1777–80.

⁸⁴ Family Smoking Prevention and Tobacco Control and Federal Retirement Reform Act, Pub. L. 111-31, § 201(a), 123 Stat. 1842–45.

⁸⁵ However, stopping people from becoming smokers or prompting smokers to quit all use would secure larger public health gains than preventing people from becoming only smokeless users or prompting exclusive smokeless users to quit all use.

⁸⁶ See 21 U.S.C. § 387 Definitions (3), (4), (13), (15); 21 U.S.C. § 387e(a)(1) (2018); 21 U.S.C. § 387f(d)(4)(A); Family Smoking Prevention and Tobacco Control and Federal Retirement Reform Act, Pub. L. 111-31, § 102(32), (41), (44), (45), (46) 123 Stat. 1779–81; *id.* § 3 (6); 21 U.S.C. § 387d(d)(2); *id.* § 387e(i)(1)(B); *id.* 387g(a)(6); *id.* § 387k(b)(2)(A)(iii), (d)(6), (g)(1), (g)(B), (g)(C)(ii), (i)(1), (l)(C), (l)(D), (m); *id.* § 387o(b)(2); *id.* § 387a-1(d)(2)(D) (creating new prohibited acts at 21 U.S.C. § 331(tt) (2018)); 15 U.S.C. § 1333(e)(3) (2018).

⁸⁷ The terms do not appear at all in § 910.

As discussed previously, the Act specifically directs FDA to consider the impacts of its rules and orders on both “users” and “nonusers” when making AFPPH determinations—but only in the context of determining the impact of the rules or orders on the health risks and benefits to the *population as a whole*.⁸⁸ None of these references suggests that the Act places a higher priority on protecting nonusers from tobacco use harms than on reducing tobacco use harms among users. Nor do any of the few other references in the TCA to “users” or “nonusers” suggest that.⁸⁹

B. The Equal Priority Given to Reducing Youth and Adult Tobacco Use and Harms

The Tobacco Control Act does not put a higher priority on preventing or reducing youth tobacco use or harms than it does on preventing or reducing use and harms among existing adult users.

Despite the Tobacco Control Act’s focus on protecting the public health and producing health benefits for the population as a whole, its equal treatment of users and nonusers, and the lack of favorable treatment for any other subpopulations, some still might think that the Act requires FDA to give greater weight to reducing harms among youth, compared to adults, and avoiding the risk of new harms to youth, when determining whether a new tobacco control rule or order is “appropriate for the protection of the public health.” That impression might come, first, from the common belief, supported by a range of ethical and practical arguments, that it is appropriate to put a higher priority on protecting minor children from public health harms and risks than on preventing or reducing health risks and harms among mature adults.⁹⁰ Or it could come from the view that adults should be allowed to freely choose what products they use (at least so long as their use does not harm others), but it is still appropriate to protect youth by restricting their choice and access.⁹¹

⁸⁸ See *supra* notes 68–74 and accompanying text. See also Family Smoking Prevention and Tobacco Control and Federal Retirement Reform Act, Pub. L. 111-31, § 2(36) 123 Stat. 1779.

⁸⁹ See Family Smoking Prevention and Tobacco Control and Federal Retirement Reform Act; 21 U.S.C. § 387c(a)(5) (2018); 21 U.S.C. § 387g(b)(2) (2018); *id.* § 387k(g)(2)(A)(iv). The term “users,” including its singular form, appears more than twenty times in the Act, typically in conjunction with a reference to “nonusers.” See, e.g., Family Smoking Prevention and Tobacco Control and Federal Retirement Reform Act, Pub. L. 111-31, § 2(36), 123 Stat. 1779; Family Smoking Prevention and Tobacco Control and Federal Retirement Reform Act, Pub. L. 111-31, § 906(d)(1), 123 Stat. 1796; *id.* § 907(a)(3)(B) and (b)(2); *id.* § 910(c)(4); *id.* § 911(g)(1)(B), (2)(B)(iv), (4). While references to nonusers always appear in conjunction with references to users, some of the Act’s references to “users” as a subpopulation make no mention of nonusers. See, e.g., Family Smoking Prevention and Tobacco Control and Federal Retirement Reform Act, Pub. L. 111-31, § 2(1), (4), (5), (6), (16), 123 Stat. 1779; 21 U.S.C. § 387i(a)(6) (2018). By itself, the more frequent use of “users” compared to “nonusers” and the use of “users” without “nonusers” (but not the reverse) might suggest that the Act considers users to be more important than nonusers, but, as previously discussed, nothing in the substance of the references indicates any such prioritization.

⁹⁰ For example, FDA has recently stated, informally, that it places a higher priority on protecting youth from initiating into tobacco use than on reducing adult tobacco use. See, e.g., *Statement from FDA Commissioner Scott Gottlieb, M.D., on Meetings with Industry Related to the Agency’s Ongoing Policy Commitment to Firmly Address Rising Epidemic Rates in Youth E-Cigarette Use*, FOOD & DRUG ADMIN. (Oct. 31, 2018), <https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm624657.htm> [<https://perma.cc/H9XH-EX5A>]; *Statement From FDA Commissioner Scott Gottlieb, M.D., On New Steps to Address Epidemic of Youth E-Cigarette Use*, FOOD & DRUG ADMIN. (Sept. 10, 2018), <https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm620185.htm> [<https://perma.cc/2LCQ-38SF>].

⁹¹ See, e.g., Dillard III 2013 Comments, *supra* note 36.

If the AFPPH standard incorporated or reflected either of these perspectives, FDA's evaluations of the likely health impacts of possible tobacco control rules or orders would be complicated by having to carefully identify and analyze the impacts on youth versus adults and figure out how to give them different weights. In addition, certain effective tobacco control measures might be blocked if they were found to reduce adult harms only at the expense of youth. For example, an FDA rule or order that effectively encouraged smokers to switch to less harmful, non-combusted tobacco products might be seen as "inappropriate" if it also increased initiation among otherwise non-using youth by making the non-combusted products appear less risky and more acceptable or attractive. Accordingly, it is important to determine what the Tobacco Control Act actually requires.

It might initially appear that the Act supports such a youth-favoring view of the AFPPH standard. "Youth" and other terms relating to non-adults appear more than sixty times in the Act, while "adult" and terms referring specifically to non-youth appear only about twenty times.⁹² Moreover, the disproportionate references to youth and non-adults typically refer to youth vulnerabilities and harms, such as the Act's very first Finding, which states that "[t]he use of tobacco products by the nation's children is a pediatric disease of considerable proportions."⁹³ In contrast, more than half of the references to adults and non-youth do not express any special concern for protecting adults or reducing adult tobacco use harms, but appear in the context of protecting youth from exposure to tobacco product marketing or in text about how youths are more price-sensitive than adults and more susceptible to tobacco industry advertising.⁹⁴

Yet the only text in the Act that expresses a special concern for youth and also actually directs or authorizes government action is a parenthetical reference in § 302 that directs the Comptroller General (not FDA) to conduct a study of cross-border trade in tobacco products, including data collection on "the health effects (particularly with respect to individuals under 18 years of age)."⁹⁵

Moreover, well over half of the references to youth and non-adults in the Act are in the Findings section, presumably to build support for the Act and, even more clearly, to provide congressional findings helpful for protecting the Act's reinstatement of a 1996 FDA tobacco control rule. That 1996 rule (which the courts struck down based on First Amendment and other legal challenges) was directed at protecting children

⁹² This imbalance would disappear if all or most of the forty-plus references to "consumer" in the Act were referring only to legal *adult* consumers. But most of the references to "consumer" are more technical or definitional in nature and, to be consistent with the public health goals of the Act, necessarily include both adult and youth consumers—for example, when referring to preventing consumers from being misled in harmful ways or reducing consumer exposure to harmful substances. Moreover, in two instances the text specifically references "adult consumers," suggesting that other references to just "consumers" mean to be more inclusive. Family Smoking Prevention and Tobacco Control and Federal Retirement Reform Act, Pub. L. 111-31, § 2(32) 123 Stat. 1779; 21 U.S.C. § 387a-1(a)(2)(G).

⁹³ Family Smoking Prevention and Tobacco Control and Federal Retirement Reform Act, Pub. L. 111-31, § 2(32) 123 Stat. 1779.

⁹⁴ See, e.g., Family Smoking Prevention and Tobacco Control and Federal Retirement Reform Act, Pub. L. No. 111-31, 123 Stat. 1778 (2009); 21 U.S.C. § 387a-1(a)(2)(G).

⁹⁵ Family Smoking Prevention and Tobacco Control and Federal Retirement Reform Act, Pub. L. No. 111-31, § 302(a)(3), 123 Stat. 1784, 1851-52 (2009). The Act also mentions health impacts on youth, without giving youth any special priority, in requiring two other reports. 21 U.S.C. § 387g(e)(1); 21 U.S.C. § 387g(f)(1).

and adolescents.⁹⁶ Many other references to youth and non-adults in the Act also relate to reestablishing that 1996 rule, and also have nothing to do with the Act's AFPPH standard or related authorities.⁹⁷ Another dozen references to youth and non-adults simply reflect the fact that Congress decided that tobacco products may be legally sold to adults but may not be legally sold to youth (i.e., those under the new federal minimum age of eighteen) and designed the Act to reflect that decision.⁹⁸ Along the same lines, several Act references to youth or non-adults simply reflect the fact that most smoking and other tobacco use begins during youth and neither adult nor overall tobacco use harms can be substantially reduced without reducing initiation among youth (who become addicted adults).⁹⁹

More importantly, there are only three other places where the Act mentions youth or non-adults that also directly relate to establishing FDA's tobacco control authorities or directing FDA to take specific actions, and none expresses a priority for protecting youth more than adults, or vice versa. Section 903 indicates that protecting tobacco product users is just as important as protecting children, stating that a tobacco product would be misbranded if it did not follow completely any future FDA rule that requires labeling which provides "adequate directions for use, or adequate warnings against use by children, that are necessary for protection of users."¹⁰⁰ Section 913 directs FDA to issue regulations to require adult-only retail outlets that primarily sell tobacco products to comply with any tobacco product advertising restrictions that apply to retail outlets that allow youth, indicating that protecting adult users from tobacco product advertising is just as important as protecting youth from such advertising.¹⁰¹ In the only reference to children or non-adults in provisions relating to the Act's AFPPH standard, § 907 indicates that youth are no more or less important than adults, stating that FDA shall consider all information submitted relating to a proposed tobacco product standard "including information concerning the countervailing effects

⁹⁶ See, e.g., Family Smoking Prevention and Tobacco Control and Federal Retirement Reform Act, Pub. L. No. 111-31, § 101(b)(3), 123 Stat. 1784, 1777-79; see also 21 U.S.C. § 387a-1; *Lorillard Tobacco Co. v. Reilly*, 533 U.S. 525 (2001); *FDA v. Brown & Williamson*, 529 U.S. 120 (2000).

⁹⁷ 21 U.S.C. § 387a-1; 21 U.S.C. § 387f-1.

⁹⁸ See 21 U.S.C. § 387f(d)(4)(A) (2009); 21 U.S.C. § 387a-1(d)(2) (2009); Family Smoking Prevention and Tobacco Control and Federal Retirement Reform Act, Pub. L. No. 111-31, § 103, 123 Stat. 1784, 1833; Family Smoking Prevention and Tobacco Control and Federal Retirement Reform Act, Pub. L. No. 111-31, § 104, 123 Stat. 1784, 1841; 21 U.S.C. § 387f-1; see also Family Smoking Prevention and Tobacco Control and Federal Retirement Reform Act, Pub. L. No. 111-31, § 2, 123 Stat. 1784, 1777. The many other references to adults in the Act that relate directly to the minimum age for selling tobacco products and the Act's intent to allow legal sales of tobacco products to adults also do not indicate that reducing tobacco use harms among adults is more or less important than doing so for youth. See Family Smoking Prevention and Tobacco Control and Federal Retirement Reform Act, Pub. L. No. 111-31, § 2, § 387, 123 Stat. 1784; 21 U.S.C. § 387f(d)(3)(A)(iii) (2009); 21 U.S.C. § 387a-1(d)(2), (6) (2009).

⁹⁹ See Family Smoking Prevention and Tobacco Control and Federal Retirement Reform Act, Pub. L. No. 111-31, § 2, 123 Stat. 1784, 1777-79. Other parts of the Act make clear the critical importance of promoting cessation, among all users, for reducing tobacco use harms—and the vast majority of all current users are adults. See, in particular, Family Smoking Prevention and Tobacco Control and Federal Retirement Reform Act, Pub. L. No. 111-31, § 3, 123 Stat. 1774, 1782, and Family Smoking Prevention and Tobacco Control and Federal Retirement Reform Act, Pub. L. No. 111-31, § 2, 123 Stat. 1774, 1779.

¹⁰⁰ 21 U.S.C. § 387c(a)(5) (2010).

¹⁰¹ 21 U.S.C. § 387m (2011).

of the tobacco product standard on the health of adolescent tobacco users, adult tobacco users, or nontobacco users.”¹⁰²

Similarly, the Purposes section puts reducing tobacco use among youth and adults on an equal footing, with Purpose (2) to ensure that FDA can address issues of particular concern to public health officials, “especially the use of tobacco by young people and dependence on tobacco” (with the vast majority of those dependent on tobacco being adults).¹⁰³ Even more telling, the House Committee Report on the unsuccessful legislation to create the Tobacco Control Act in 2008 referred to “the overall intent of the bill to reduce the number of children and adolescents who smoke cigarettes,” but the 2009 House Committee Report (on the bill that passed into law) revised that text to refer to “the overall intent of the bill to protect the public health, including by reducing the number of children and adolescents who smoke cigarettes.”¹⁰⁴

The fact that the Act expresses no priority for reducing youth harms over reducing adult harms directly reflects the overarching public health purpose of the Act and the focus of the AFPPH standard on reducing the health harms and risks to the population as a whole.¹⁰⁵

C. *The Critical Importance of Behavioral Impacts*

To determine whether a tobacco control rule or order is “appropriate for the protection of the public health,” FDA must consider its impact on a broad range of possible tobacco-related behaviors that affect the health of the population as a whole.

Sections 906, 907, and 910 each direct FDA to consider the increased or decreased likelihood that existing users of tobacco products will stop using such products and that those who do not use tobacco products will start. Looking only at those words, it might be possible to interpret them to refer only to the likelihood that existing tobacco product users will quit all use or that non-users will become any type of tobacco product user. But such a narrow interpretation that does not look at other possible responsive behavior changes with health impacts would contradict both the Act’s public health purpose and the sections’ requirement that FDA make its determinations based on the regulatory action’s impact on the health risks and benefits to the population as a whole.

¹⁰² 21 U.S.C. § 387g(b)(2) (2010).

¹⁰³ Tobacco Regulation, Federal Retirement Reform, sec. 3, § 387, Pub. L. No. 111-31, 123 Stat. 1776, 1781 (2009). Purpose (7) makes the only other reference to youth, stating the intent of Congress is “to continue to permit the sale of tobacco products to adults in conjunction with measures to ensure that they are not sold or accessible to underage purchasers.” *Id.* at 1782. It is followed by Purpose (9), to promote cessation—which applies to far more adults than youth because the lion’s share of current tobacco product users are adults. *Id.* For the same reason, Purpose (6), “to ensure that consumers are better informed,” has much more to do with adults than youth. *Id.*

¹⁰⁴ 2008 House Report, *supra* note 7, at 77; 2009 House Report, *supra* note 5, at 37.

¹⁰⁵ While the TCA clearly provides no basis for FDA weighing identical amounts of health harms or benefits differently if they are experienced by youth instead of adults, the total health gains to the population as a whole from each youth prevented from a shortened lifetime of addicted smoking (e.g., the increase in quality-adjusted life years) will be far larger than for each adult smoker prompted to quit (who have already experienced health losses from smoking and will gain fewer quality-adjusted life years or QALYs). *See, e.g.,* Tammy O. Tengs et al., *Public Health Impact of Changes in Smoking Behavior: Results From the Tobacco Policy Model*, MED. CARE 39(10): 1131–41 (2001).

The Act's requirement that FDA consider the impact of a rule or order on both users and nonusers simply acknowledges that FDA could not possibly determine the impact on the public health without considering the many different health-impacting behavior changes the order or rule might cause both in the short term and over time. Such health-impacting behavior changes include changes to the initiation, cessation, or relapse patterns for different types of tobacco products; switching among different types or sub-types of tobacco products, or to FDA-approved nicotine-replacement therapies (or possibly to some non-nicotine alternative); dual use or multiple tobacco-product use; and changes to consumption levels—as well as the impact of such behavior changes on non-user exposure and related harms. To evaluate the overall net impact on the health of the population as a whole, FDA must also consider how all of these behavioral changes might evolve over time (e.g., the extent to which new or relapsed users of less-harmful tobacco or medical-nicotine products will quit all use, continue using, reduce or increase consumption, or move on to using more harmful products, or the extent to which dual use might be a stepping stone to smoking or total cessation).

Unlike §§ 906, 907, and 910, § 911 (regarding FDA consideration of applications to market tobacco products with modified-risk claims) does not explicitly require FDA to consider the increased or decreased likelihood that existing users of tobacco products will stop using such products and that those who do not use tobacco products will start. But, paralleling those other sections, § 911 requires FDA to consider whether allowing the product to be marketed with such claims would either “benefit the health of the population as a whole taking into account both users of tobacco products and persons who do not currently use tobacco products,” or be AFPPH—and doing that necessarily requires FDA to consider all of the different possible behavioral impacts outlined above that could have positive or negative health consequences.

Considering all these different possible behavior responses to determine whether a new tobacco control rule or order would be AFPPH might sound quite complicated. As described below, however, precise projections would not be necessary. FDA would need to evaluate and consider the behavioral impacts only to the extent necessary to determine whether a significant net public health gain was highly likely and whether there was any significant risk of a non-trivial net public health loss. FDA's analysis is further simplified by not having to consider non-health impacts or the health impacts on specific subpopulations (except to the extent they separately contribute to the net impact on the health of the population as a whole), and by FDA not needing extensive real-world examples or research to support its evaluations of the health-impacting behavior changes.

VI. FDA'S ENORMOUS DISCRETION TO CLARIFY GRAY AREAS AND MANAGE UNCERTAINTIES

FDA cannot contradict what the Tobacco Control Act clearly establishes. But the Act provides FDA with enormous discretion regarding how it chooses to clarify the remaining gray areas of the appropriate-for-the-protection-of-the-public-health standard and how it chooses to handle the inevitable uncertainties regarding individual and net health impacts when determining whether a tobacco control rule or order is “appropriate.”

The Tobacco Control Act does not mention the unavoidable uncertainties involved in FDA trying to determine the net public health impact of a rule or order before implementation, given the many different possible tobacco industry and consumer

responses and the many other factors at play, especially when no historical precedent exists or if the available research and other evidence is otherwise incomplete or of poor quality.¹⁰⁶ Nor does the Act acknowledge that, in many cases, FDA will have to rely on modeling or other estimates of the best-case and worst-case scenarios, or related ranges of possible net public health impacts, with related estimates or ranges of probabilities, based on incomplete research, data, and experience.¹⁰⁷ Nor does the Act state how FDA should determine whether issuing a rule or order is AFPPH once it has developed its projected range of possible net public health impacts with related probability estimates.

The Act does indicate that any tobacco control rule or order that will definitely produce at least some net gain of any significance to the health of the population as a whole would be “appropriate for the protection of the public health.” But the Act does not provide any guidance or insights as to whether an FDA tobacco control rule or order could be AFPPH if it did not create at least some benefit to the health of the population as a whole, or if it created some relative risk of producing a net negative impact instead of a net public health gain.¹⁰⁸ Or, to the extent running such risks of a net public health harm might be “appropriate,” the Act provides no guidance as to how much larger the likelihood and size of the net public health benefit of a tobacco control rule or order would have to be, compared to the likelihood and size of the potential net public health harm, for the rule or order to qualify. Because of these silences, the Act gives FDA enormous discretion as to how it clarifies and applies the AFPPH standard¹⁰⁹

¹⁰⁶ Further complicating matters, the health-related impacts from an FDA rule or order could vary considerably depending on what other FDA or other government tobacco control measures might be put in place. For example, the risk that a permissive PMTA or MRTP order would prompt some otherwise non-user youth or adults to not only initiate into using the subject product but also move on to more-harmful smoking would be sharply reduced or eliminated if FDA issued a new rule to minimize nicotine levels in cigarettes and similarly smoked tobacco products at some point after granting the permissive order or if federal and state governments sharply increased taxes on smoked tobacco products but not non-smoked products. At the same time, the potential number of smokers prompted to switch by issuing the permissive order would shrink considerably, as the new nicotine-reduction rule or higher taxes would work much more powerfully to prompt smoker quitting and switching. *See, e.g.,* Eric N. Lindblom, *Should FDA Try to Move Smokers to E-cigarettes and Other Less-Harmful Tobacco Products and, If So, How?*, 73 FOOD & DRUG L.J. 276, 298–309 (2018). Accordingly, FDA evaluations of possible final rules or permissive PMTA or MRTP orders need to consider their potential net public health impacts not only in the existing regulatory environment but also if other scheduled or highly likely changes to the regulatory environment come into play.

¹⁰⁷ For examples of how FDA has handled such uncertainty to date, see *infra* notes 142–44, 146–49 and accompanying text. For examples of other tobacco control modeling in areas of uncertainty, see Kalkhoran & Glantz, *infra* note 111; Levy et al., *infra* note 117; Pearson et al., *infra* note 117; and van der Deen et al., *infra* note 117.

¹⁰⁸ Section 911 requires FDA to determine that any MRTP order it issues will “benefit” the public health, while §§ 906, 907, and 910 require FDA to determine that rules or orders under those sections will be “appropriate” for the protection of the public health. But whether a rule or order could be “appropriate” for the public health without benefiting the public health is not explained anywhere in the statute or its legislative history. *See supra* note 71.

¹⁰⁹ *See, e.g.,* Utility Air Regulatory Group v. EPA, 573 U.S. 302, 325 (2014) (“Agencies exercise discretion only in the interstices created by statutory silence or ambiguity.”); United States v. Bean, 537 U.S. 71, 77 (2002) (“[T]he ‘public interest’ standard calls for an inherently policy-based decision best left in the hands of an agency.”); Chevron, U.S.A., Inc. v. Nat’l Res. Def. Council, Inc., 467 U.S. 837, 843 (1984); WildEarth Guardians v. EPA, 228 F.3d 1075, 1082 (10th Cir. 2013).

However, creating unnecessary risks to the public health could not be “appropriate for the protection of the public health.” Even if an FDA tobacco control rule or order that produced a significant risk of producing net harms to the public health were much more likely to produce a much larger net public health gain, it could not be found AFPPH if there were readily available ways that FDA could have refined the final rule or order to eliminate or reduce that negative risk, at least where that could be done without significantly reducing the likelihood or size of the expected net public health gains.¹¹⁰

A. *FDA’s Bounded Discretion to Risk Causing Public Health Harms*

The Tobacco Control Act leaves it to FDA to decide whether the appropriate-for-the-protection-of-the-public-health standard allows FDA tobacco control rules or permissive PMTA or MRTP orders to create non-trivial risks of producing net negative public health harms.

The Tobacco Control Act’s silence in this context leaves FDA with considerable discretion as to how it refines and clarifies the AFPPH standard. But the Act appears to require an interpretation that would allow FDA permissive orders to produce at least a statistical or trivial risk of producing net public health harms. Given the inevitable uncertainties involved in anticipating other factors and predicting the various health-related impacts from issuing a permissive PMTA or MRTP order, a standard that did not allow for any possibility of producing a net public health loss, no matter how small, might make granting any permissive orders impossible.¹¹¹ Yet Congress would not have included procedures for applying for and receiving PMTA and MRTP applications in the Act unless it expected that at least some permissive orders for some products could be granted.¹¹² In addition, the Act specifically empowers FDA to

¹¹⁰ Even if it did not violate the AFPPH standard, FDA would be arbitrary or capricious if it failed to take advantage of such readily available ways to reduce the risks to the public health created by an FDA tobacco control rule or order without reducing its ability to secure net public health gains. *See infra* Section IX.

¹¹¹ For example, issuing permissive PMTA or MRTP orders for e-cigarettes found to be less harmful than cigarettes could secure health gains by increasing smoker switching and shifting youth initiation from smoking to e-cigarette use. But the order might also increase health harms by prompting some smokers to engage in dual use instead of quitting all smoking or to switch completely to using only e-cigarettes instead of quitting all tobacco-nicotine use, by reducing cessation among e-cigarette users, by increasing relapse to e-cigarette use among smokers who had quit all use, and by prompting initiation among those who would otherwise not use any tobacco-nicotine product. *See, e.g.,* Sara Kalkhoran & Stanton A. Glantz, *Modeling the Health Effects of Expanding E-Cigarette Sales in the United States and United Kingdom: A Monte Carlo Analysis*, 175 JAMA INTERNAL MED. 1671, 1675 (2015). In addition, considerable uncertainties persist regarding the relative harmfulness of e-cigarette use, smoking, and dual use, making estimates of the possible harms and benefits from the different possible behavioral impacts difficult and imprecise. *See, e.g.,* NAT’L ACADEMIES OF SCI., ENG’G, & MED., PUBLIC HEALTH CONSEQUENCES OF E-CIGARETTES, (Kathleen Stratton et al. eds., 2018). It is also difficult to predict tobacco industry actions subsequent to permissive PMTA and MRTP orders, and their impacts on consumers, especially over the longer term. Accordingly, it could be quite difficult to rule out the possibility, either logically or statistically, that issuing a permissive order could not possibly produce a net public health loss.

¹¹² *See, e.g.,* Advocate Health Care Network v. Stapleton, 137 S. Ct. 1652, 1659 (2017) (referring to the “so-called surplusage canon—the presumption that each word Congress uses is there for a reason” and the Supreme Court practice to “give effect, if possible, to every clause and word of the statute” (internal citations omitted)). *But see* 111 CONG. REC. 6,004–05 (2009) (statement of Sen. Burr) (stating, in the Senate debate

withdraw PMTA or MRTP orders if they become no longer AFPPH, clearly anticipating the possibility that such orders could be issued even if FDA could not be certain that they would produce a net benefit to the public health or not produce any risk of creating negative net impact on the public health.¹¹³

Without contradicting this statutory text, however, FDA could still exercise its discretion to interpret the AFPPH standard as requiring the highest possible certainty that a PMTA or MRTP order would not produce any significant net harm to the public health, while still accommodating the impossibility or impracticability of completely eliminating any chance of any such risk.

Unlike with PMTA or MRTP orders—which are prompted by industry applications and inevitably create at least some risk of negative net public health impacts by allowing the new marketing of tobacco products—FDA could choose and structure its tobacco control rules so that any it implemented would produce new public health gains that would certainly be larger than any possible new public health losses, even under the most pessimistic assumptions and projections. Accordingly, it is possible that FDA could exercise its discretion to establish a more protective interpretation and application of the AFPPH standard for its tobacco control rulemaking than for its PMTA and MRTP orders that did not allow its rules to produce any risk of a negative net public health impact.¹¹⁴ However, to make it much more difficult for the tobacco industry to bring successful outcome-based legal challenges, it would make sense for FDA to exercise its discretion to interpret the AFPPH standard as not requiring FDA to eliminate completely any statistical possibility that its tobacco control rules might produce a net negative impact on the public health, no matter how trivial.¹¹⁵

FDA could exercise its discretion to establish an even more permissive standard if it reasonably determined that being able to run even larger risks of net public health

prior to the Act's passage, that it might be impossible for companies to show that allowing their new tobacco products onto the U.S. market would be AFPPH, as the Act requires).

¹¹³ 21 U.S.C. § 387j(1)(a) (2012); 21 U.S.C. § 387k(j)(1) (2010).

¹¹⁴ Section 907 anticipates the possibility that FDA might revoke a tobacco product standard that is no longer AFPPH and provides a process for doing so. 21 U.S.C. § 387g(a)(4), (c)(3) (2010). While that text establishes that FDA could interpret the AFPPH standard as allowing product standards that create a risk of a negative net public health impact, it does not necessarily mean that FDA must interpret the AFPPH standard as allowing that. There is no similar text in § 906 or elsewhere in the Act directly referring to any § 906 tobacco control rules being revoked or withdrawn if they turn out not to be AFPPH (although FDA would clearly have the authority to do so). 21 U.S.C. § 387f (2015).

¹¹⁵ For example, the Circuit Court ruling striking down FDA's 2011 final rule requiring graphic warnings on cigarette packs, although based on First Amendment concerns, specifically referred to FDA's projection of the likely reduction in smoking from the rule as "overly optimistic" and "a number the FDA concedes is 'in general not statistically distinguishable from zero,'" noting that FDA "could not even reject the statistical possibility that the Rule would have *no* impact on U.S. smoking rates." *R.J. Reynolds Tobacco Co. v. FDA*, 696 F.3d 1205, 1220 (D.C. Cir. 2012). In fact, the FDA economists' statistical Monte Carlo simulations, described in the final rule, produced results showing both positive and negative projected net results, although FDA stated that the negative results were "almost certainly due to survey noise." Required Warnings for Cigarette Packages and Advertisements, 76 Fed. Reg. 36,628, 36,776–77 (June 22, 2011) (to be codified at 21 C.F.R. pt. 1141). Other economists and researchers subsequently sharply criticized those projections and other evaluations of the rule by FDA economists for understating the likelihood and size of the expected public health benefits. See, e.g., Frank J. Chaloupka et al., *An Evaluation of the FDA's Analysis of the Costs and Benefits of the Graphic Warning Label Regulation*, 24 TOBACCO CONTROL 112, 115–18 (2015). But the FDA estimates and the court's comments provide a clear example of the difficulties in completely ruling out any statistical chance that certain tobacco control policy interventions directed at changing consumer behavior will not produce unexpected or undesired impacts.

harms would better support more rapid tobacco control progress to reduce health harms and risks to the population as a whole. For example, nothing in the Act indicates that a rule or order would or would not be AFPPH if it ran the risk of producing a relatively smaller, reversible risk of producing a public health harm to secure larger net public health gains. Accordingly, the Act leaves it to FDA's discretion to determine which way to proceed. However, common sense tells us that it could not be AFPPH to issue a rule or permissive order just as or more likely to cause a net public health harm as a net public health gain of roughly the same size. At some point, the courts would also likely find FDA "arbitrary or capricious" for interpreting the standard to allow quite likely, substantial risks of net public health harms, even when done to secure somewhat larger and more likely net public health gains.¹¹⁶ Where, exactly, the size of an FDA-permitted risk-reward ratio might be found arbitrary or capricious is difficult to predict. But FDA has no public health or other reason to come anywhere near that point when interpreting and applying the AFPPH standard.

For example, FDA might determine that it would be AFPPH to issue a PMTA or MRTP order if the highest reasonably estimated risk of a negative net public health impact from a proposed PMTA or MRTP order times the largest reasonable estimate of the negative net increase to public health harms were no more than some fraction of the size of the result of multiplying the lowest reasonably estimated likelihood of a positive net public health impact times the smallest reasonably estimated size of the net public health gain.¹¹⁷ Such a bright-line test might seem odd or even arbitrary, but courts have held that regulatory agencies may implement such bright-line tests to provide clear standards and simplify administration and enforcement.¹¹⁸ Such a bright-line interpretation and application of the AFPPH standard would also make it much easier for FDA to avoid applying the standard inconsistently and prevent related arbitrary-or-capricious legal challenges.

However, any bright-line or other interpretation and application of the AFPPH standard to PMTA and MRTP applications and orders must be consistent with the primary, protective purpose of those procedures: to prevent potentially harm-

¹¹⁶ The APA's "not arbitrary and capricious" standard and its application to FDA action under the TCA are discussed *infra* in Sections VIII to X.

¹¹⁷ Such estimates of the likelihood of net harms or benefits and their potential size could be made using readily available modeling techniques, with estimated harms and benefits quantified, for comparison purposes, through using such proxies as caused or averted deaths or life years or quality-adjusted life years (QALY) gained or lost. *See, e.g., infra* note 116; Kalkhoran & Glantz, *supra* note 110; Benjamin J. Apelberg et al., *Potential Public Health Effects of Reducing Nicotine Levels in Cigarettes in the United States*, 378 *NEW ENG. J. MED.* 1725, 1725–33 (2018); David T. Levy et al., *Modeling the Future Effects of a Menthol Ban on Smoking Prevalence and Smoking-Attributable Deaths in the United States*, 101 *AM. J. PUB. HEALTH* 1236, 1236–40 (2011); Amber L. Pearson et al., *Tobacco Retail Outlet Restrictions: Health and Cost Impacts From Multistate Life-Table Modelling in a National Population*, 26 *TOBACCO CONTROL* 579, 579–85 (2017); Frederieke S. van der Deen et al., *Impact of Five Tobacco Endgame Strategies on Future Smoking Prevalence, Population Health and Health System Costs: Two Modelling Studies to Inform the Tobacco Endgame*, 27 *TOBACCO CONTROL* 278, 278–86 (2018); John La Puma & Edward F. Lawlor, *Quality-Adjusted Life-Years: Ethical Implications for Physicians and Policymakers*, 263 *JAMA* 2917, 2919–20 (1990).

¹¹⁸ *Actavis Elizabeth LLC v. FDA*, 625 F.3d 760, 766 (D.C. Cir. 2010) ("[A]gencies may employ bright-line rules for reasons of administrative convenience, so long as those rules fall within a zone of reasonableness and are reasonably explained." (internal quotes and citations omitted)); *Mary V. Harris Found. v. FCC*, 776 F.3d 21, 28–29 (D.C. Cir. 2015). *See also In re EPA*, 803 F.3d 804, 807–08 (6th Cir. 2015); and *Macon Cty. Samaritan Mem'l Hosp. v. Shalala*, 7 F.3d 762, 768 (8th Cir. 1993) ("[B]right-line tests are a fact of regulatory life . . .").

increasing tobacco products or relative-risk claims from entering the market.¹¹⁹ In fact, that defensive purpose can be seen as authorizing or perhaps even requiring FDA to apply the AFPPH standard more cautiously or less permissively when evaluating PMTA and MRTP applications than when FDA takes affirmative action to reduce tobacco-related harms through its rulemaking.¹²⁰ A more cautious, less-permissive application of the standard to PMTA and MRTP applications and orders also makes sense because tobacco companies that want to maximize profits, rather than public health gains, will be seeking the permissive orders to increase sales of their harmful and addictive new tobacco products and then marketing the products and delivering the reduced-risk claims the orders allow accordingly. Conversely, FDA will be in charge of choosing and developing its tobacco control rules, exclusively directed toward reducing tobacco-related public health, and will be directly administering the rules itself.¹²¹

Moreover, a highly protective interpretation of the AFPPH standard that allowed either no non-trivial risk of a net public health harm or only very small risks when associated with much larger and more likely potential public health gains would not constrain FDA tobacco control rulemaking. Numerous rule-making options are readily available to FDA that would produce important public health gains with little risk of also producing any serious new public health harms, much less any that might come close to offsetting the likely public health gains. Examples include rules to minimize nicotine levels or ban menthol and all other flavors in smoked tobacco products or to allow the sale of flavored or smoked tobacco products only in stores that do not allow youth to enter.¹²² It is also quite difficult to identify any effective tobacco control options FDA might implement that would create any significant risk of producing a *net* increase in public health harms.¹²³ Although the tobacco industry argues that FDA

¹¹⁹ Tobacco Regulation, Federal Retirement Reform, sec. 2, § 387, Pub. L. No. 111-31, 123 Stat. 1784 (2009); Tobacco Regulation, Federal Retirement Reform, sec. 3, § 387, Pub. L. No. 111-31, 123 Stat. 1784 (2009); 21 U.S.C. § 387j (2012); 21 U.S.C. § 387k (2010).

¹²⁰ Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111-31, § 2, 123 Stat. 1776 ¶¶ 6, 12 (2009 West); *Id.* at § 3, ¶¶ 1–3; 21 U.S.C. § 387f (2010); 21 U.S.C. § 387g (2010).

¹²¹ Although any tobacco products able to secure PMTA permissive orders will likely be significantly less harmful than at least some other tobacco products on the market, they will still be harmful, at least to some extent, because they contain consumable tobacco or nicotine. *See generally Nicotine and Health*, 52 DRUG THERAPY BULL. 78 (July 2014).

¹²² *See, e.g.,* Apelberg et al., *supra* note 117; Levy et al., *supra* note 117; Pearson et al., *supra* note 117; van der Deen et al., *supra* note 117. FDA has said that reducing nicotine levels in smoked tobacco product is its top tobacco control priority and has also said it is actively considering menthol and other flavor bans and restricting certain flavored product sales to adult-only outlets. Alex M. Azar & Scott Gottlieb, *We Cannot Let E-Cigarettes Become an On-Ramp for Teenage Addiction*, WASH. POST (Oct. 11, 2018), https://www.washingtonpost.com/opinions/we-cannot-let-e-cigarettes-become-an-on-ramp-for-teenage-addiction/2018/10/11/55ce424e-ccc6-11e8-a360-85875bac0b1f_story.html [https://perma.cc/6BU9-B3MC]; *Statement From FDA Commissioner Scott Gottlieb, M.D., on Proposed New Steps to Protect Youth by Preventing Access to Flavored Tobacco Products and Banning Menthol in Cigarettes*, FOOD & DRUG ADMIN. (Nov. 15, 2018), <https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-proposed-new-steps-protect-youth-preventing-access> [https://perma.cc/PJZ8-AT7J].

¹²³ One possibility might be a rule that placed major restrictions or requirements, such as a comprehensive flavor ban, on e-cigarettes but not on cigarettes and other smoked tobacco products. Such a rule might produce significant new health harms by reducing the number of smokers who would otherwise switch from smoking to e-cigarettes or by shifting youth from initiating into e-cigarette use to initiating into smoking, instead. But FDA could reduce those risks and eliminate any possibility of net negative public

product standards minimizing nicotine levels or banning menthol in cigarettes would prompt the emergence of a new illicit trade in non-complying cigarettes,¹²⁴ the health harms from any such illicit trade could not possibly exceed the health gains from those new rules working even more effectively to prompt smokers to quit and reducing initiation.¹²⁵

Regardless of how FDA interprets the gray areas of the AFPPH standard left by the Tobacco Control Act, the agency also needs to evaluate potential rules and PMTA and MRTP orders, and the research and other evidence supporting or opposing them, in a legally viable way to ensure that they meet that standard.

VII. THE DIFFERING EVIDENTIARY STANDARDS FOR AFPPH DETERMINATIONS UNDER §§ 906, 907, 910, AND 911

Although the determinations FDA must make under the appropriate-for-the-protection-of-the-public-health standards under §§ 906, 907, 910, and 911 are the same, the Act requires different levels of evidence for those determinations.

Section 910 states that FDA determinations of “whether permitting a new tobacco product to be marketed in the United States would be appropriate for the protection of the public health shall, when appropriate, be determined on the basis of well-controlled investigations, which may include 1 or more clinical investigations by experts qualified by training and experience to evaluate the tobacco product”—unless FDA determines “there exists valid scientific evidence (other than evidence derived from [such] investigations) which is sufficient to evaluate the tobacco product.”¹²⁶

health outcomes by taking the logical step of applying any new restrictions or requirements on e-cigarettes to smoked tobacco products, as well, or by placing even more rigorous restrictions and requirements on the smoked tobacco products. *See, e.g.,* John Buckell et al., *Should Flavours Be Banned in Cigarettes and E-Cigarettes? Evidence on Adult Smokers and Recent Quitters from a Discrete Choice Experiment*, 28 TOBACCO CONTROL 168, 168–75 (2019).

¹²⁴ *See* Murillo, *supra* note 36; *see also* Dillard III 2013 Comments, *supra* note 36.

¹²⁵ *See, e.g.,* Apelberg et al., *supra* note 117; Levy et al., *supra* note 117. More generally, a large majority of smokers want to quit. Stephen Babb et al., *Quitting Smoking Among Adults—United States, 2000–2015*, 65 MORBIDITY & MORTALITY WKLY. REP. 1457, 1457 (2017). Consequently, any new FDA rule that makes smoked tobacco products less readily available, less palatable and attractive, or unable to satisfy or sustain smokers’ nicotine addictions would prompt many smokers to try either to quit all tobacco product use or switch to using non-smoked tobacco-nicotine products, and some would succeed, thereby securing substantial public health gains. Illicit sales of non-complying cigarettes might enable some smokers to continue smoking cigarettes, instead. But that would only reduce net public health gains from the rule, not create any risk of producing net harms, especially as the illicit cigarettes would not be significantly more harmful than the enormously harmful pre-rule cigarettes. In most cases, the illicit cigarettes would be cigarettes still legally offered in other countries smuggled or mailed into the U.S. There are also a range of practical obstacles that would make it extremely difficult to establish the kind of large-scale illicit trade in non-FDA-compliant tobacco products necessary to reduce substantially the net public health gains from a new FDA tobacco product standard. *See, e.g.,* Eric N. Lindblom., *Illicit Trade Poses No Threat to an FDA Rule to Minimize Nicotine in Smoked Tobacco Products*, 109 AM. J. PUB. HEALTH 960 (2019); Eric N. Lindblom, *Filling in the Blanks on Reducing Tobacco Product Addictiveness in the FTC Partial Guidelines for Articles 9 & 10* (O’Neill Institute, Working Paper No. 1, 2014) [<https://perma.cc/7JA6-5D3N>].

¹²⁶ 21 U.S.C. § 387j(c)(5) (2011). The burden of proof for obtaining a permissive order rests exclusively on the applicant, so it is the tobacco product manufacturer or importer who must provide FDA with the well-controlled investigations or other valid scientific evidence. 21 U.S.C. § 387j(c)(2) (2012). On the other hand, § 910 states that FDA may withdraw an order when FDA determines that the continued marketing of the product is no longer “appropriate,” with no reference to required investigations or scientific evidence, just

Section 911 (relating to FDA evaluations of applications seeking permission to market a tobacco product with reduced-risk or reduced-exposure claims) also requires that FDA’s related AFPPH determinations be based on “scientific evidence.”¹²⁷ But, unlike § 910, § 911 also requires FDA to issue and regularly revise a rule or guidance establishing minimum standards for the scientific evidence required to support FDA’s § 911 findings and determinations and its ongoing review of modified risk tobacco products.¹²⁸ This requirement suggests that the scientific evidence required for a § 911 modified-risk order could be more stringent than for a § 910 new-product order. Along the same lines, the Act requires FDA to send all applications received under § 911 to the Tobacco Products Scientific Advisory Committee for recommendations, but § 910 makes such FDA referrals discretionary.¹²⁹

In addition, § 911 appears to make it easier for FDA to withdraw orders allowing modified-risk claims, based on their no longer being appropriate for the protection of the public health, than to withdraw § 910 permissive new product orders on the same grounds. Section 910 states that FDA shall withdraw a permissive order if “upon obtaining, where appropriate, advice on scientific matters from the Tobacco Products Scientific Advisory Committee” FDA determines that the continued marketing of the product is no longer “appropriate for the protection of the public health.”¹³⁰ But § 911’s withdrawal provisions makes no reference to the Tobacco Products Scientific Advisory Committee or to scientific matters but states that FDA shall withdraw a permissive order if FDA determines that “the applicant, based on new information, can no longer make the demonstrations required under subsection (g)” (i.e., that the order will significantly reduce harm to individual users and benefit the health of the population as a whole or be “appropriate to promote the public health”).¹³¹

These apparent differences in the evidentiary standards for making the parallel public health determinations under §§ 910 and 911—making it harder to get a § 911 permissive order and easier to have one withdrawn—make sense. Allowing a tobacco

“upon obtaining, where appropriate, advice on scientific matters from the Tobacco Products Scientific Advisory Committee.” 21 U.S.C. § 387g(d)(1) (2010).

¹²⁷ 21 U.S.C. § 387k(g)(3) (2010). Section 911 also places the burden of proof on the manufacturer or importer submitting the application. 21 U.S.C. § 387k(g)(1)–(3)(A) (2010).

¹²⁸ 21 U.S.C. § 387k(l) (2010). FDA has not issued a final version of any guidance or either a final or proposed version of any rule to satisfy this requirement. In early 2012, FDA issued a draft guidance “pursuant to section 911(l)(1)” for “comment purposes only.” FOOD & DRUG ADMIN., CENTER FOR TOBACCO PRODUCTS, DRAFT GUIDANCE FOR INDUSTRY: MODIFIED RISK TOBACCO PRODUCT APPLICATIONS (2012), <https://www.fda.gov/media/83300/download> [<https://perma.cc/DY4E-SUCA>]. See also Draft Guidance for Industry: Modified Risk Tobacco Product Applications; Availability; Agency Information Collection Activities; Proposed Collection; Comment Request, 77 Fed. Reg. 20,026, 20,026–30 (April 3, 2012) [<https://perma.cc/SRS9-Q5TY>]; Agency Information Collection Activities; Proposed Collection; Comment Request; Draft Guidance for Industry: Modified Risk Tobacco Product Applications, 83 Fed. Reg. 3,158, 3,158–61 (Jan. 23, 2018) [<https://perma.cc/8RRL-VVUR>]; see also FOOD & DRUG ADMIN., CENTER FOR TOBACCO PRODUCTS, GUIDANCE FOR INDUSTRY: APPLICATIONS FOR PREMARKET REVIEW OF NEW TOBACCO PRODUCTS—DRAFT GUIDANCE (2011) [<https://perma.cc/2YND-STDH>] (providing parallel draft guidance for applications for § 910 orders).

¹²⁹ 21 U.S.C. § 387k(f) (2013); 21 U.S.C. § 387j(b)(2) (2012).

¹³⁰ 21 U.S.C. § 387j(d)(1) (2012).

¹³¹ 21 U.S.C. § 387k(j) (2011). Section 907(e), which pertains just to the special case of a new rule establishing good manufacturing practices requirements for tobacco products, also requires that FDA afford the Tobacco Products Scientific Advisory Committee an opportunity to submit recommendations before promulgating the rule. 21 U.S.C. § 387g(d) (2010).

product to be marketed with relative-risk claims, even if they are accurate, will likely present a greater risk of misleading consumers and increasing harms among consumers (e.g., by the claims preventing or delaying cessation or increasing initiation or relapse) compared to allowing a tobacco product on the market without any such claims.¹³²

Less directly than §§ 910 or 911, § 907 states that FDA “shall consider scientific evidence” when determining whether a tobacco product standard is “appropriate for the protection of the public health.”¹³³ As noted in the House Committee Report, however, FDA is already required to review and consider all information, including scientific evidence, presented by any party that comments on a proposed tobacco product standard or on any other rule.¹³⁴ So there must be some other reason for § 907’s requirement that FDA specifically consider scientific evidence, presumably to emphasize the importance of FDA using scientific evidence in the context of developing and implementing tobacco product standards compared to developing other tobacco control rules under § 906, which makes no reference at all to “scientific evidence.” Indeed, the House Committee Report states that, specifically for FDA tobacco product standards, the Act intends that FDA will base its AFPPH determinations “on sound information and scientific evidence and data.”¹³⁵ But it says nothing about sound information or scientific evidence, or other evidentiary standards, in the context of § 906. Accordingly, the Act appears to allow FDA to make its AFPPH determinations for rules to regulate the distribution, marketing, or sale of a tobacco product based on less-than-scientific evidence or data, at least when adequate scientific evidence or data is not available.

Having a more permissive evidentiary standard for § 906 rules, compared to § 907 product standards, makes sense because the likely behavioral and health impacts from placing new restrictions or requirements on tobacco product distribution, advertising, other marketing, or sales (e.g., to reduce exposure to advertising or to make tobacco products less readily available) are typically much more straightforward and readily understood. In contrast, securing public health gains through regulating the characteristics of a tobacco product through a product standard, especially to reduce their harmfulness, is much more complex. Cigarettes and most other tobacco products deliver a broad array of toxins and other chemicals, which work together in not fully understood ways to create the health harms and risk from the products’ consumption.

¹³² On the potential of reduced-risk claims to change smoker and other consumer behavior, see, for example, Sherine El-Toukhy et al., *Impact of Modified Risk Tobacco Product Claims on Beliefs of US Adults and Adolescents*, 27 TOBACCO CONTROL (Supp. 1) s62, s62–s69 (2018); Erin Keely O’Brien et al., *US Adult Interest in Less Harmful and Less Addictive Hypothetical Modified Risk Tobacco Products*, 20 NICOTINE & TOBACCO RES. 1317, 1317–26 (2018); Jennifer L. Pearson et al., *Adult Interest in Using a Hypothetical Modified Risk Tobacco Product: Findings From Wave 1 of the Population Assessment of Tobacco and Health Study (2013-14)*, 113 ADDICTION 113, 113–24 (2018); Mark Parascandola et al., *Characteristics of Current and Recent Former Smokers Associated With the Use of New Potential Reduced-Exposure Tobacco Products*, 11 NICOTINE & TOBACCO RES. 1421, 1431–38 (2009); see also Stephen Babb et al., *supra* note 122 (vast majority of smokers want to quit).

¹³³ 21 U.S.C. § 387g(a)(3)(B) (2010).

¹³⁴ 2009 House Report, *supra* note 5, at 39; see also 5 U.S.C. § 553(c) (2011) (rulemaking agency must provide interested persons with an opportunity to submit “written data, views, or arguments” and agency must consider all submitted “relevant matter”).

¹³⁵ 2009 House Report, *supra* note 5, at 39; see also 21 U.S.C. § 387g(a)(5) (2010) (FDA shall periodically reevaluate issued tobacco product standards “to determine whether such standards should be changed to reflect new medical, scientific, or other technological data”).

That makes it quite difficult to identify or predict the public health impacts from reducing or even eliminating certain toxins. At the same time, some users who become aware that certain toxins have been reduced or eliminated in the tobacco products they consume might increase their consumption or postpone attempts to quit (regardless of whether the product change did actually reduce harms and risks significantly).¹³⁶

It also makes sense to subject FDA to less stringent evidentiary requirements for placing new § 906 marketing and sales restrictions on tobacco product manufacturers and importers than the evidentiary requirements placed on tobacco manufacturers and importers seeking permission to put brand new types of tobacco products on the U.S. market under § 910 or to market tobacco products with relative-risk claims under § 911. Most fundamentally, FDA's goal for any § 906 rule it might issue would be to reduce the massive public health harms caused by tobacco; so FDA is unlikely to issue any rule that creates any risk of making the situation worse. In contrast, manufacturers applying for either a § 910 or § 911 permissive order would be seeking to increase profits through increasing the sales and use of their tobacco products (not to protect the public health). If permitted by FDA, they could maximize their profits by securing an order that would not only prompt harm-reducing uses of their products (e.g., via switching from more-harmful tobacco product use) but prompt harm-increasing uses, as well (e.g., switching instead of total cessation, or increased initiation by otherwise nonusers). Given this context and these powerful market incentives, the behavior changes and public health impacts from allowing commercial entities to market new tobacco products or market their tobacco products with reduced-risk claims can be much more difficult to predict or evaluate, and will more likely be negative, compared to the behavior changes and public health impacts from FDA issuing a § 906 rule designed to produce net public health gains.

To accommodate the special situation when FDA issues tobacco product standards, § 907 also appears to allow FDA to find a product standard AFPPH solely by determining that the additive, constituent, or other component the rule reduces or eliminates “is or may be harmful.”¹³⁷ Going further, § 907 states that any party objecting to such a tobacco product standard on the ground that the proposed standard will not reduce or eliminate the risk of illness or injury “may provide for [FDA’s] consideration scientific evidence that demonstrates that the proposed standard will not reduce or eliminate the risk of illness or injury.”¹³⁸ As the Administrative Procedure Act (APA) already allows interested persons to submit any information relating to a proposed rule and requires regulatory agencies to consider all submitted information,¹³⁹ this § 907 language must mean, at a minimum, that for these specific types of tobacco product standards, an objecting party can successfully prevent its implementation, as not AFPPH, only by providing FDA with convincing scientific

¹³⁶ The Act acknowledges this risk and tries to reduce it through § 911, which prohibits relative-risk claims without a prior FDA permissive order, by prohibiting false or misleading claims in tobacco product labeling or ads, and by directly prohibiting tobacco product businesses from representing that a tobacco product is approved or deemed safe by FDA. 21 U.S.C. § 387k (2011); 21 U.S.C. § 387c(a)(1), (7)(A) (2011); § 103(b), amending 21 U.S.C. § 331 by adding new (tt); 21 U.S.C. § 331(tt) (2010); see also Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111-31, § 2, 123 Stat. 1776 ¶ 46 (2009).

¹³⁷ 21 U.S.C. § 387g(a)(3)(B)(ii) (2010).

¹³⁸ *Id.*

¹³⁹ 5 U.S.C. § 553(e) (2011).

evidence (as opposed to any less rigorous evidence) that the product standard will not reduce or eliminate any risk of illness or injury.

VIII. FDA'S ENORMOUS DISCRETION REGARDING AFPPH EVIDENTIARY REQUIREMENTS

Under the Tobacco Control Act, FDA has enormous discretion to determine how much research, other evidence, and certainty it needs to determine whether a tobacco control rule or permissive PMTA or MRTP order is “appropriate for the protection of the public health.”

Beyond the references in §§ 907, 910, and 911 to scientific evidence and § 910's conditional reference to well-controlled investigations, the Act is silent as to how FDA should evaluate the available, relevant scientific and other evidence when making AFPPH determinations. It says nothing about what levels of evidence are required to support FDA estimates or projections of the possible behavioral impacts of a rule or order or its estimates of the possible health risks, harms, and benefits it could produce, or about how those estimates or projections should be done. Nor does it say how FDA should deal with the inevitable uncertainties regarding the impacts of its rules or orders or the frequent absence of directly relevant research or experience. That silence means that the Act leaves such decisions entirely to FDA's discretion and provides no statutory basis for legally challenging how FDA exercises that discretion.¹⁴⁰

Given frequent gaps in research and knowledge and the inability to predict future impacts with complete certainty or precision (even when extensive relevant research of high quality exists), FDA can, at best, use available research, other evidence, and various modeling and analytic techniques to develop imprecise estimates of the net impact of a rule or order on the future health of the population as a whole.¹⁴¹ Yet these logical, research-based, but inevitably imprecise, estimates can still show with considerable certainty that the net impact will be positive with little or no risk of a negative net outcome.

For example, in its 2016 final deeming rule bringing cigars, e-cigarettes, and hookah and pipe tobacco under its tobacco control jurisdiction, FDA concluded—after reviewing related research and submitted comments—that “the restrictions included with this final deeming rule are appropriate for the protection of the public health because they will reduce youth access to and, therefore, likely limit use of tobacco products” (which will thereby reduce tobacco use harms).¹⁴² In a legal challenge brought by cigar manufacturers, the D.C. District Court found that FDA's determination that the deeming rule and its warning label requirement for cigars were AFPPH and were not arbitrary or capricious, despite FDA's reliance on general conclusions about likely public health impacts based on incomplete available research

¹⁴⁰ See *supra* note 109. However, FDA must still comply with the APA's not-arbitrary-or-capricious standard when exercising its broad discretionary authorities under the TCA. See *infra* Sections VIII to X.

¹⁴¹ FDA could, for example, also exercise its discretion to discount research funded by the tobacco industry, given their self-interested biases and their long history of inappropriately influencing researchers and research. See, e.g., Lisa A. Bero, *Tobacco Industry Manipulation of Research*, 120 PUB. HEALTH REP. 200, 200–08 (2005).

¹⁴² Deeming Rule 2016, *supra* note 1 at 29,058–59 (vending machine restriction “is appropriate for the protection of the public health because it will eliminate one more method of youth access to tobacco products”).

and extrapolating from research pertaining to cigarettes to make determinations regarding cigars.¹⁴³

After reviewing relevant research and considering submitted comments, FDA's 2011 final rule to establish graphic warning labels on cigarettes similarly concluded that including information about how to get cessation assistance in the warnings "will increase the likelihood that smokers will quit smoking and thereby provide substantial public health benefits by reducing the life-threatening consequences associated with continued cigarette use," and "is appropriate for the protection of the public health because of the benefits, and lack of risks, to the population as a whole."¹⁴⁴ The tobacco industry challenged that 2011 final rule and the courts struck it down for violating the First Amendment, indicating that there were no non-constitutional grounds for invalidating the rule, such as FDA's abusing its discretion or being "arbitrary or capricious" in its determination that the rule was AFPPH.¹⁴⁵

FDA's long-pending proposed rule to reduce certain carcinogenic toxins in smokeless tobacco products presents more carefully modeled, research-based estimates of the approximate related reduced cancer risk to smokeless users and the approximate number of oral cancer deaths that would consequently be prevented (a purely positive contribution toward protecting the health of the population as a whole), and then, after describing relevant available evidence, states "we do not anticipate the proposed standard would have behavioral impacts on smokeless tobacco initiation, cessation, switching to other products, or dual use in a way that would offset the public health benefits of the reduced cancer risk that would result from the proposed standard."¹⁴⁶

FDA's 2013 report on the impact of menthol cigarettes on smoking initiation, cessation, and harms used a "weight of scientific evidence" approach to reach a range of different conclusions on product harmfulness and different behavioral impacts.¹⁴⁷ After reviewing published research studies and other available evidence, FDA determined whether the weight of evidence supported a conclusion that menthol in cigarettes "is associated" with "X" (e.g., increased initiation, reduced cessation, greater harm from smoking), or "is likely associated," "likely not associated," or "not associated," or whether the evidence is not sufficient to support any conclusion

¹⁴³ *Cigar Ass'n of Am. v. FDA*, 315 F. Supp. 3d 143, 159–63 (D.D.C. May 15, 2018).

¹⁴⁴ Required Warnings for Cigarette Packages and Advertisements, 76 Fed. Reg. 36,628, 36,687, 36,682 (June 22, 2011) (codified at 21 C.F.R. pt. 1141).

¹⁴⁵ *R.J. Reynolds Tobacco Co. v. FDA* 696 F.3d 1205 (D.C. Cir. 2012), affirming 845 F. Supp. 2d 266 (D.D.C. 2012).

¹⁴⁶ Tobacco Product Standard for N-Nitrosornicotine Level in Finished Smokeless Tobacco Products, 82 Fed. Reg. 8,004, 8,028 (Jan. 23, 2017). As this quote indicates, FDA's presentation of why the proposed rule is AFPPH consistently focuses on impacts on the health of the population as a whole and indicates that the standard is met by achieving a *net* improvement. *Id.* at 8,020–26. For example, FDA noted that the rule would have to prompt a tripling in overall smokeless tobacco use (e.g., by making smokeless appear less harmful and more attractive) to offset the health benefits from the rule's expected cancer risk reductions. *Id.* at 8,025. But the text does not explore the different ways such increased smokeless use might occur (e.g., from non-user initiation, complete switching by smokers who would or would not have otherwise quit all use, increased dual use by smokers, increased relapse from former smokeless users or former smokers), their likelihood, or how they might be curtailed.

¹⁴⁷ FOOD & DRUG ADMIN., PRELIMINARY SCIENTIFIC EVALUATION OF THE POSSIBLE PUBLIC HEALTH EFFECTS OF MENTHOL VERSUS NONMENTHOL CIGARETTES (2013) [<https://perma.cc/3F9M-E4SW>].

regarding an association.¹⁴⁸ In an area with much more sparse relevant research or other evidence, or real-world experience, FDA staff used simulation modeling with inputs from an “expert elicitation” to determine the likelihood that a new FDA rule reducing nicotine levels in cigarettes and certain other smoked tobacco products to estimate the likelihood and size of the potential population-level impacts and related health consequences. As a publication of the results described it, “a formal expert elicitation . . . is a systematic process of formalizing and quantifying judgments [from subject matter experts] about uncertain quantities.”¹⁴⁹

All of these described procedures FDA has used for handling the inevitable uncertainties involved when trying to predict future public health and other relevant impacts appear quite reasonable in these contexts. In particular, reasonably making AFPPH determinations is quite easy when evaluating rules that will clearly promote the public health with little or no risk of producing significant new health harms, much less a negative net public health impact. However, FDA’s exercise of its discretion must still avoid violating the APA’s not-arbitrary-or-capricious standard, which is quite permissive but also places some clear duties on FDA when issuing tobacco control rules and orders and making related AFPPH determinations.

Indeed, a strong argument can be made that the procedures FDA has used, to date, to make its AFPPH determinations in the permissive PMTA and MRTP orders it has issued were “arbitrary and capricious” or an abuse of discretion because each of the orders created an FDA-acknowledged risk of producing a negative net public health impact, yet FDA did not make any attempt to identify all of the major ways the orders might produce new health harms and risks or to weigh the likelihood and size of the possible negative health impacts against the likelihood and size of the possible health gains.¹⁵⁰ Without developing a reasonable process to produce or secure such estimates, FDA will not have the information it needs to make reasonable determinations that issuing a PMTA or MRTP order will be AFPPH, even if FDA were able to reasonably interpret the standard to allow permissive orders to create considerable public health risks as they try to secure new public health gains (which FDA has not done).¹⁵¹

¹⁴⁸ *Id.* at 4; *see, e.g., id.* at 96 (“[F]rom the available studies, the weight of evidence supports the conclusion that menthol in cigarettes is likely associated with increased initiation and progression to regular use of cigarette smoking.”).

¹⁴⁹ Apelberg et al., *supra* note 117. For more on expert elicitations, *see, for example*, M. Granger Morgan, *Use (and Abuse) of Expert elicitation in support of decision making for public policy*, *PROC. NAT. ACAD. SCI. USA* 111(2): 7176–84 (2014). For other examples of modeling FDA might use, *see supra* note 117.

¹⁵⁰ Eric N. Lindblom, *The Tobacco Control Act’s PMTA & MRTP Provisions Mean to Protect the USA From Any New Tobacco Products That Will Not Reduce Health Harms—But FDA Isn’t Cooperating*, *J. HEALTH CARE L. & POL’Y* (forthcoming May, 2020) [hereinafter Lindblom, *PMTA & MRTP Provisions*] <https://oneill.law.georgetown.edu/wp-content/uploads/Comments-Draft-Lindblom-FDA-PMTA-Article-10-24-19.pdf> [<https://perma.cc/E2YZ-FPHD>]. To date, FDA has issued three permissive PMTA orders and one permissive MRTP order, which are discussed below. *Premarket Tobacco Product Marketing Orders*, U.S. FOOD & DRUG ADMIN., www.fda.gov/tobacco-products/premarket-tobacco-product-applications/premarket-tobacco-product-marketing-orders [<https://perma.cc/FL9W-R8LY>] (last updated Jan. 21, 2020); *MRTP Application Actions (Orders, Denials, and Responses)*, U.S. FOOD & DRUG ADMIN., www.fda.gov/TobaccoProducts/Labeling/MarketingandAdvertising/ucm522422.htm [<https://perma.cc/2QG6-S8GH>] (last updated Oct. 22, 2019).

¹⁵¹ Lindblom, *PMTA & MRTP Provisions*, *supra* note 150.

IX. THE “ARBITRARY OR CAPRICIOUS” STANDARD PLACES FEW CONSTRAINTS ON FDA’S AFPPH DETERMINATIONS

As long as FDA follows established procedures, considers contrary analysis and options, and explains its decisions, the “not arbitrary or capricious” standard places few constraints on FDA’s determinations of what is appropriate for the protection of the public health.

The APA subjects all final federal regulatory actions to judicial review pursuant to 5 U.S.C. § 706—which has six different subparts identifying grounds for setting aside an agency action—unless the authorizing statute precludes judicial review or commits the regulatory action exclusively to agency discretion.¹⁵² Section 912 of the Tobacco Control Act, pertaining to judicial review, includes such a preclusion, specifically providing that courts shall review legal challenges to FDA tobacco product standard rules under § 907 and to denials of applications for new product orders under § 910(c) solely “in accordance with § 706(2)(A) of Title 5, United States Code.” That section states that agency action, findings, and conclusions shall be held unlawful if found “arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.”¹⁵³ Because the statute is silent as to judicial review of other FDA rules or orders, they would be subject not only to § 706(2)(A)’s not-arbitrary-or-capricious standard, but also to the other provisions of 5 U.S.C. § 706.¹⁵⁴ This difference, however, might have limited significance because § 706(2)(A)’s reference to invalidating an agency action “otherwise not in accordance with law” has considerable scope, likely encompassing many of the grounds for invalidating an agency action identified elsewhere in § 706. Section 912 of the Tobacco Control Act can be interpreted only as intending to subject legal challenges to § 907 product standards and § 910 new product orders to some less-comprehensive legal review than other FDA regulatory actions under the Act. But exactly what that less-comprehensive review might be is hard to discern.¹⁵⁵

¹⁵² 5 U.S.C. § 701(a) (2011).

¹⁵³ 21 U.S.C. § 3871(a), (b) (2010). Under a plain reading of this provision, an agency action is unlawful if it is arbitrary *or* capricious *or* an abuse of discretion *or* otherwise not in accordance with law. Yet many court rulings simply refer to “arbitrary *and* capricious” without distinguishing the one from the other or discussing how the two standards differ. *See, e.g.*, *FERC v. Elec. Power Supply Ass’n*, 136 S. Ct. 760, 782, (2016) (quoting *Motor Vehicle Mfrs. Ass’n. Inc. v. State Farm Mutual Auto. Ins. Co.*, 463 U.S. 29, 43 (1983) (internal citations omitted)). *See also* *Advocate Health Care Network v. Stapleton*, 137 S. Ct. 1652, 1659 (2017) (referring to the “the presumption that each word Congress uses is there for a reason” and the Supreme Court practice to “give effect, if possible, to every clause and word of the statute” (internal citations omitted)).

¹⁵⁴ *See* 5 U.S.C. § 706(1) (2012), which empowers courts to compel agency action unlawfully withheld or unreasonably delayed; *see also* 5 U.S.C. § 706 (2)(B) through (F) (2012), which empower courts to hold unlawful and set aside agency action, findings, and conclusions found contrary to constitutional right, in excess of statutory jurisdiction, without observance of procedure required by law, unsupported by substantial evidence in certain underlying hearings, or unwarranted by the facts to the extent the facts are subject to trial de novo by the reviewing court.

¹⁵⁵ *Elec. Power Supply Ass’n*, 136 S. Ct. at 782. But even when an agency fails to fully articulate the reasons for its decision, it will not be found arbitrary or capricious if the court “can reasonably discern the basis for the agency’s action.” *Am. Iron & Steel Inst. v. EPA*, 526 F.2d 1027, 1047 (3d Cir. 1975) (citing *Bowman Transp., Inc. v. Arkansas-Best Freight System, Inc.*, 419 U.S. 281, 286 (1974)). *See also* *FCC v. Fox Television Stations*, 556 U.S. 502, 513–14 (2009) (courts should “uphold a decision of less than ideal clarity if the agency’s path may reasonably be discerned” (citations omitted)). However, “[i]t is not the role of the courts to speculate on reasons that might have supported an agency’s decision. ‘[W]e may not supply

In any case, all FDA tobacco control rules and orders clearly must not be arbitrary or capricious, and numerous Supreme Court and Circuit Court rulings have clarified how that standard applies to agency regulatory actions. Although none of these court rulings have yet explicitly applied the arbitrary-or-capricious standard in the context of the Tobacco Control Act, they provide a clear framework for how that would be done.

In one of its more recent rulings generally discussing and applying the standard, the Supreme Court in the 2016 *FERC v. Electric Power Supply* case confirmed that:

The “scope of review under the ‘arbitrary and capricious’ standard is narrow.” A court is not to ask whether a regulatory decision is the best one possible or even whether it is better than the alternatives. Rather, the court must uphold a rule if the agency has “examine[d] the relevant [considerations] and articulate[d] a satisfactory explanation for its action[,] including a rational connection between the facts found and the choice made.”¹⁵⁶

Along the same lines, the Supreme Court’s earlier arbitrary or capricious case, *Judulang v. Holder*, confirmed that “‘a court is not to substitute its judgment for that of the agency’ . . . [which has] expertise and experience in administering their statutes that no court can properly ignore.”¹⁵⁷ But the *Judulang* ruling also stated that:

[C]ourts retain a role, and an important one, in ensuring that agencies have engaged in reasoned decisionmaking. When reviewing an agency action, we must assess, among other matters, “whether the decision was based on a consideration of the relevant factors and whether there has been a clear

a reasoned basis for the agency’s action that the agency itself has not given.” *Encino Motorcars, LLC v. Navarro*, 136 S. Ct. 2117, 2127 (2016) (quoting *State Farm*, 463 U.S. at 43). *See also* *Cigar Ass’n of Am. v. FDA*, 315 F. Supp. 3d 143, 184 (D.D.C. May 15, 2018) (“‘if we find that an agency’s stated rationale for its decision is erroneous, we cannot sustain its action on some other basis the agency did not mention’ . . . [n]or can the court ask the parties for further explanations . . . [or] accept ‘*post hoc* rationalizations for agency actions’” (quoting *PDK Labs. Inc. v. DEA*, 362 F.3d 786, 798 (D.C. Cir. 2004) (citing *State Farm* 463 U.S. at 50))).

¹⁵⁶ *Elec. Power Supply Ass’n*, 136 S. Ct. at 782 (internal citation omitted). But even when an agency fails to fully articulate the reasons for its decision, it will not be found arbitrary or capricious if the court “can reasonably discern the basis for the agency’s action.” *Am. Iron and Steel Inst. v. EPA*, 526 F.2d 1027, 1047 (3d Cir. 1975) (citing *Bowman Transp., Inc. v. Arkansas-Best Freight System, Inc.*, 419 U.S. 281, 286 (1974)). *See also* *FCC v. Fox Television Stations*, 556 U.S. 502, 513-14 (2009) (courts should “uphold a decision of less than ideal clarity if the agency’s path may reasonably be discerned” (citations omitted)). However, “[i]t is not the role of the courts to speculate on reasons that might have supported an agency’s decision. ‘[W]e may not supply a reasoned basis for the agency’s action that the agency itself has not given.’” *Encino Motorcars, LLC v. Navarro*, 136 S. Ct. 2117, 2127 (2016) (quoting *State Farm*, 463 U.S. at 43). *See also* *Cigar Ass’n of Am. v. FDA*, 315 F. Supp. 3d 143, 184 (D.D.C. May 15, 2018) (“‘if we find that an agency’s stated rationale for its decision is erroneous, we cannot sustain its action on some other basis the agency did not mention’ . . . [n]or can the court ask the parties for further explanations . . . [or] accept ‘*post hoc* rationalizations for agency actions’” (quoting *PDK Labs. Inc. v. DEA*, 362 F.3d 786, 798 (D.C. Cir. 2004) (citing *State Farm* 463 U.S. at 50))).

¹⁵⁷ *Judulang v. Holder*, 565 U.S. 42, 53 (2011) (quoting *State Farm*, 463 U.S. at 43) (internal citations omitted). Several circuits have noted that the not-arbitrary-or-capricious standard is the least demanding form of judicial review of administrative action. *See, e.g.*, *Wolf v. Causley Trucking, Inc.*, 719 F. App’x 466, 473 (6th Cir. 2017); *Semien v. Life Ins. Co.*, 436 F.3d 805, 812 (7th Cir. 2006); *Simi Inv. Co., Inc. v. Harris County*, 236 F.3d 240, 253 (5th Cir. 2000). *See also* *U.S. Postal Service v. Gregory*, 534 U.S. 1, 7–8 (2001) (“the arbitrary and capricious standard is extremely narrow” (internal citations omitted)).

error of judgment.” That task involves examining the reasons for agency decisions—or, as the case may be, the absence of such reasons.¹⁵⁸

More specifically, the Supreme Court has stated that when an agency analysis “requires a high level of technical expertise,” we must defer to “the informed discretion of the responsible federal agencies;”¹⁵⁹ and “[w]hen examining this kind of scientific determination . . . a reviewing court must generally be at its most deferential.”¹⁶⁰

The D.C. Circuit has not only repeatedly confirmed that the “court owes extreme degree of deference to the agency when it is evaluating scientific data within its technical expertise,”¹⁶¹ but, when considering agency regulatory action in areas of incomplete or uncertain information, has stated that:

When . . . an agency is obliged to make policy judgments where no factual certainties exist or where facts alone do not provide the answer, our role is more limited; we require only that the agency so state and go on to identify the considerations it found persuasive . . . in face of uncertainty, agency must “exercise its expertise to make tough choices about which of the competing estimates is most plausible, and to hazard a guess as to which is correct, even if . . . the estimate will be imprecise.”¹⁶²

Similarly, the Supreme Court has acknowledged that:

¹⁵⁸ 565 U.S. at 53 (quoting *State Farm*, 463 U.S. at 43) (internal citations omitted).

¹⁵⁹ *Marsh v. Or. Nat. Res. Council*, 490 U.S. 360, 377 (1989) (quoting *Kleppe v. Sierra Club*, 427 U.S. 390, 412 (1976)).

¹⁶⁰ *Id.* (quoting *Balt. Gas & Elec. Co. v. Nat. Res. Def. Council*, 462 U.S. 87, 103 (1983)).

¹⁶¹ *Chamber of Commerce v. SEC*, 412 F.3d 133, 143 (D.C. Cir. 2005) (quoting *Hüls Am. Inc. v. Browner*, 83 F.3d 445, 452 (D.C. Cir.1996) (internal quotations and citations omitted)); *Del. Dep’t of Nat. Res. & Env’tl. Control v. EPA*, 895 F.3d 90, 100 (D.C. Cir. 2018). *See also Anderson v. Evans*, 371 F.3d 475, 489 (9th Cir. 2004) (“the fact that the record also contains evidence supporting a different scientific opinion does not render the agency’s decision arbitrary and capricious” (internal quotes and citation omitted)); *Okla. v. EPA*, 908 F.2d 595, 630 (10th Cir. 1990) (overturned on other grounds by *Ark. v. Okla.* 503 U.S. 91 (1992) (usual deference to agency’s special expertise undermined by its failure even to consider an important scientific principle)); *N.J. Bd. of Pub. Utilities v. FERC*, 744 F.3d 74, 111 (3d Cir. 2014) (agency “is free to eschew the proposals of other parties and invoke its own expertise, as long as it does so in a manner that is not arbitrary or capricious”). *See also Nat. Res. Def. Council v. U.S. Nuclear Regulatory Comm’n*, 685 F.2d 459, 531 n. 97 (D.C. Cir. 1982) (quoting J. Skelly Wright, *The Courts and the Rulemaking Process: The Limits of Judicial Review*, 59 CORNELL L. REV. 375, 392 (1974) (“In drawing empirical conclusions, [the rule maker] must give actual, good faith consideration to all relevant evidentiary factors. If he (sic) has in fact given serious attention to a factor, the weight which he assigns to it in his final judgments is of virtually no concern to the reviewing court.”)).

¹⁶² *Chamber of Commerce v. SEC*, 412 F.3d 133, 143 (D.C. Cir. 2005) (internal quotations and citations omitted). “[W]e are acutely aware that an agency need not—indeed cannot—base its every action upon empirical data; depending upon the nature of the problem, an agency may be entitled to conduct . . . a general analysis based on informed conjecture.” *Id.* at 142 (internal quotations and citations omitted). *See also U.S. Dep’t of Interior v. FERC*, 952 F.2d 538, 546 (D.C. Cir. 1992) (rejecting idea that an agency must have perfect information before it takes action and stating: “More practically, a perfect information standard would hamstring the agency. Virtually every decision must be made under some uncertainty.”); *Cent. Ariz. Water Conservation Dist. v. EPA*, 990 F.2d 1531, 1540 (9th Cir. 1993) (“We are particularly deferential when reviewing agency actions involving policy decisions based on uncertain technical information” (quoting *New York v. Reilly*, 969 F.2d 1147, 1150–51 (D.C. Cir. 1992)); and “[a]s long as Congress delegates power to an agency to regulate on the borders of the unknown, courts cannot interfere with reasonable interpretations of equivocal evidence” (quoting *Pub. Citizen Health Research Grp. v. Tyson*, 796 F.2d 1479, 1505 (D.C. Cir. 1986))).

[An agency rule] would not be arbitrary and capricious simply because there was no evidence in direct support of the agency's conclusion. It is not infrequent that the available data does not settle a regulatory issue and the agency must then exercise its judgment in moving from the facts and probabilities on the record to a policy conclusion.¹⁶³

Moreover, in those cases where a regulatory agency "is making predictions, within its area of special expertise, at the frontiers of science" (e.g., to predict the future impacts of a new license, rule, or order), the Supreme Court has similarly stated that "[w]hen examining this kind of scientific determination, as opposed to simple findings of fact, a reviewing court must generally be at its most deferential."¹⁶⁴ More recently, the D.C. Circuit similarly held that:

In circumstances involving agency predictions of uncertain future events, complete factual support in the record . . . is not possible or required since a forecast of the direction in which future public interest lies necessarily involves deductions based on the expert knowledge of the agency. . . . Thus, when an agency's decision is primarily predictive, our role is limited; we require only that the agency acknowledge factual uncertainties and identify the considerations it found persuasive.¹⁶⁵

As the Supreme Court concluded:

Recognizing that policymaking in a complex society must account for uncertainty, however, does not imply that it is sufficient for an agency to merely recite the terms "substantial uncertainty" as a justification for its actions. The agency must explain the evidence which is available, and must offer a "rational connection between the facts found and the choice made."¹⁶⁶

This case law indicates that many of the different, previously described procedures FDA has used or could use to evaluate available research and other evidence and to develop estimates or projections to inform its determinations of whether a tobacco control rule or order is AFPPH would not necessarily be found arbitrary or capricious,

¹⁶³ *Motor Vehicle Mfrs. Ass'n, Inc. v. State Farm Mutual Auto. Ins. Co.*, 463 U.S. 29, 51 (1983).

¹⁶⁴ *Balt. Gas and Elec.*, 462 U.S. at 103; *see also in re Core Commc'ns, Inc.*, 455 F.3d 267, 282 (D.C. Cir. 2006) ("[U]nder the arbitrary and capricious standard of review, 'an agency's predictive judgments about areas that are within the agency's field of discretion and expertise' are entitled to 'particularly deferential' review, as long as they are reasonable." (internal citation omitted)).

¹⁶⁵ *Rural Cellular Ass'n v. FCC*, 588 F.3d 1095, 1105 (D.C. Cir. 2009). Quoted to the same effect by *In re FCC 11-161*, 753 F.3d 1015, 1103 (10th Cir. 2014) (internal quotations and citations omitted). *See also Cellnet Commc'ns, Inc. v. FCC*, 149 F.3d 429, 441 (6th Cir. 1998) ("While we must be particularly deferential when reviewing such predictive judgments, such judgments are of course not unimpeachable. . . . An agency must still engage in reasoned decision-making, although predictive judgments may often involve "dramatic departures from longstanding policy." (citing *Int'l Ladies' Garment Workers' Union v. Donovan*, 722 F.2d 795, 821, 822 (D.C. Cir. 1983))).

¹⁶⁶ *State Farm*, 463 U.S. at 52 (quoting *Burlington Truck Lines, Inc. v. United States*, 371 U.S. 156, 168 (1962)). *See also Nat. Res. Def. Council v. Herrington*, 768 F.2d 1355, 1391 (D.C. Cir. 1985) (A rulemaking agency "may resolve even substantial factual uncertainties in the exercise of its informed expert judgment; but it may not tolerate needless uncertainties in its central assumptions when the evidence fairly allows investigation and solution of those uncertainties."); *Texas v. EPA*, 499 F.2d 289, 319 (5th Cir. 1974) ("[T]he agency's use of uncertain data is necessary if it is to perform its statutory duty. In these circumstances we can only require that its data be the best that is feasibly available.").

despite being considerably imprecise or uncertain. They would not be invalidated as arbitrary or capricious unless FDA failed to consider relevant available information or analysis, failed to explain its decisions, or exhibited a clear error of judgment—e.g., by making a decision or taking an action that was incoherent or incomprehensible;¹⁶⁷ clearly wrong;¹⁶⁸ irrational, mindless, or whimsical;¹⁶⁹ did not make sense;¹⁷⁰ or was “so implausible that it could not be ascribed to a difference in view or the product of agency expertise.”¹⁷¹

In much the same way, this case law indicates that FDA could, without being arbitrary or capricious, reasonably determine that a rule or order could not be AFPPH if it produced any significant risk of producing a net increase in health harms and risks to the population as a whole. Or FDA could, instead, exercise its considerable discretion to reasonably determine that a tobacco control rule or order could be AFPPH even if FDA determined it would create some risk of producing a net public health harm, so long as it would be even more likely to produce a larger net public health gain (especially as FDA could revoke or amend the rule or order if it began to produce net public health harms).¹⁷²

But there are some constraints. It cannot be AFPPH and would be arbitrary or capricious to create unnecessary risks to the public health. Accordingly, a rule or order that created a small but significant risk of producing net harms to the public health could not be legally justified because it was much more likely to produce a

¹⁶⁷ See, e.g., U.S. Dep’t of Justice Fed. Bureau of Prisons Fed. Correctional Complex v. Fed. Labor Relations Authority, 737 F.3d 779, 785 (D.C. Cir. 2013) (quoting Coburn v. McHugh, 679 F.3d 924, 926 (D.C.Cir.2012)) (“[P]ursuant to arbitrary and capricious review, if an agency’s explanation for its determination . . . lacks any coherence, a court owes no deference to [the agency’s] purported expertise . . . because the agency decisions were largely incomprehensible, they were unworthy of any deference.” (internal quotes and citations omitted)).

¹⁶⁸ Nat’l Ass’n of Home Builders v. Defenders of Wildlife, 551 U.S. 644, 658 (2007); see also St. Louis v. Dep’t of Transp., 936 F.2d 1528, 1533 (8th Cir. 1981).

¹⁶⁹ Associated Fisheries of Maine, Inc. v. Daley, 127 F.3d 104, 110 (1st Cir. 1997).

¹⁷⁰ NLRB v. Beverly Enterprises-Massachusetts, 174 F.3d 13, 24 (1st Cir. 1999). But see Stereo Broad., Inc. v. FCC, 652 F.2d 1026, 1032 (D.C. Cir. 1981) (Nichols, J., concurring) (“[L]ooking ridiculous and being arbitrary and capricious are not the same.”).

¹⁷¹ Nat’l Ass’n of Home Builders, 551 U.S. at 658 (quoting *State Farm*, 463 U.S. at 43) (stating that an agency would be arbitrary and capricious if it “entirely failed to consider an important aspect of the problem [or] offered an explanation for its decision that runs counter to the evidence before the agency”).

¹⁷² Sections 910(d) and 911(j), respectively, authorize FDA to withdraw permissive PMTA or MRTP orders with only a prior informal hearing if FDA determines they are producing net public health harms, with § 910(d)(3) also empowering FDA to temporarily suspend PMTA orders. 21 U.S.C. §§ 387j(d), 387k(j) (2009). To stop or amend implemented rules that unexpectedly produce net public health harms, FDA could issue a new rule via normal rule-making procedures, or it could issue a “direct final rule” (where a final rule published with no prior proposed rule becomes final on a stated date unless the agency receives an adverse comment within thirty days or some other reasonable time period) or an “interim final rule” (where the agency issues a new final rule with no prior proposed rule but with a post promulgation period for public comment and possible revision). See, e.g., Ronald M. Levin, *More on Direct Final Rulemaking: Streamlining, Not Corner Cutting*, 51 ADMIN. L. REV. 757, 757–66 (Summer 1999); Michael Asimow, *Interim Final Rules: Making Haste Slowly*, 51 ADMIN. L. REV. 703, 703–55 (Summer 1999). Section 907(d)(4) also authorizes FDA to make the amendment of a product-standard rule effective as of the date of the *proposed* rule to amend it, if FDA determines that such an earlier effective date would be in the public interest. 21 U.S.C. § 387g(d)(4) (2009). Stopping a rule from producing unexpected net public health harms should qualify as in the public interest. Although the Act does not define “in the public interest,” it indicates that benefiting the American people in human or economic terms and reducing public health harms caused by actions of the tobacco industry are each in the public interest. 21 U.S.C. § 387 (2010).

considerably larger net public health gain if there were readily available ways that FDA could have refined the final rule or order to eliminate or reduce that negative risk without substantially reducing the likelihood or size of the expected net public health gains. Existing case law regarding the not-arbitrary-or-capricious standard further supports this conclusion and indicates that FDA must also take certain other available actions to reduce any unnecessary individual health risks and costs caused by its final rules or orders.

X. FAILING TO REDUCE PUBLIC HEALTH HARMS AND RISKS IS “ARBITRARY OR CAPRICIOUS”

Even after FDA reasonably interprets the AFPPH standard and reasonably determines that a permissive PMTA or MRTP order or tobacco control rule meets that standard, FDA could still be found arbitrary or capricious if it fails to take advantage of readily available ways to revise the order or rule to make it even more clearly beneficial and less risky to the public health. To avoid being arbitrary or capricious, FDA must take advantage of all readily available measures to structure its tobacco control rules and permissive PMTA and MRTP orders to minimize the likelihood and size of any possible negative net impact on the public health.

Existing case law indicates that any regulatory agency that issues a rule can be found arbitrary or capricious if it does not take advantage of any obvious, readily available steps that will reduce any undesirable new harms caused by the rule without hindering the rule's ability to secure its statutory goals. In *State of La., ex rel. Guste v. Verity*, the Fifth Circuit held that “the protections afforded by the regulations before us have not been shown to be achievable through less costly means. Thus, the costs shouldered by the industry are not arbitrary, but reasonably related to Congress's purpose.”¹⁷³ Similarly, in *South Terminal Corp. v. EPA*, the First Circuit stated:

[W]e must bear in mind that Congress lodged with EPA, not the courts, the discretion to choose among alternative strategies. Unless demonstrably capricious—such as much less costly but equally effective alternatives were rejected or the requisite technology is unavailable—the Administrator's choices may not be overturned. . . . Although we do not read the Act as requiring EPA to engage in exhaustive cost benefit studies or to initiate elaborate planning exercises, it could be arbitrary and capricious for the Agency to reject obviously less burdensome but equally effective controls in favor of more expensive or onerous ones.¹⁷⁴

¹⁷³ *State of La., ex rel. Guste v. Verity*, 853 F.2d 322, 331 (5th Cir. 1988).

¹⁷⁴ *South Terminal Corp. v. EPA*, 504 F.2d 646, 655–56, 676 (1st Cir. 1974) (internal footnotes and citations omitted). See *City of Bridgeton v. FAA*, 212 F.3d 448, 461–62 (8th Cir. 2000) ([E]ven when a statute states that a transportation project located on public lands “must include all possible planning to minimize harm to the park, recreation area, wildlife and waterfowl refuge, or historic site resulting from the use . . . [.] we doubt whether the statute mandates a rigid least-harm standard” because that “might well conflict with the congressional mandate.” (internal quotations and citations omitted)); *Competitive Telecomms. Ass'n v. FCC*, 309 F.3d 8, 18 (D.C. Cir. 2002) (court could not decide whether agency “might have solved the problem in a different and less burdensome way” because complaining parties did not deal with the issue in their legal briefs). See also *Village of Barrington, Ill. v. Surface Transp. Bd.*, 636 F.3d 650, 670–71 (D.C. Cir. 2011) (court aware of no authority “for the proposition that the APA's arbitrary and capricious standard alone requires an agency to engage in cost-benefit analysis”).

These rulings find that a regulatory agency's failure to use obvious or known ways to reduce regulatory costs, when doing so will not interfere with achieving statutory goals, would be arbitrary or capricious, even when the authorizing statute did not mention any concern about costs or reducing them.¹⁷⁵

This strictly limited duty to reduce the costs of regulatory actions only when doing so will not interfere with achieving statutory purposes is fully consistent with the rich case law on the primacy of promoting statutory purposes compared to secondary impacts, such as costs, and how concerns over the latter cannot be used to justify or allow weaker agency efforts at promoting statutory purposes.¹⁷⁶ Going further, this case law also supports a logical extension of the cost-reduction rulings that requires agencies, to avoid being found arbitrary or capricious, to take advantage of obvious, readily available ways not only to reduce the costs of their regulatory actions (when that will not interfere with achieving statutory purposes) but also to reduce any other equally or more undesirable impacts, especially if reducing those other undesirable secondary impacts, unlike reducing costs, will directly support achieving the statutory purpose or is otherwise directly related to the statutory purpose.¹⁷⁷

For example, the Supreme Court has stated that to determine whether an agency action was arbitrary or capricious, “we must determine whether the agency adequately considered the factors . . . that will best serve the purposes of the statute.”¹⁷⁸ While reducing the costs of a regulatory action will not best serve the purposes of the Tobacco

¹⁷⁵ *State of La.* pertained to the Endangered Species Act, which authorizes the Commerce and Interior Departments to issue protective regulations that either Department “deems necessary and advisable” to protect endangered species, without any reference to other impacts or costs. 853 F.2d at 325, 333; 16 U.S.C. § 1533(d) (2003). *South Terminal Corp.*, concerned with the Clean Air Act, noted that “the material portions of the Act do not mention economic or social impact, and it seemed plain that Congress intended the Administrator to enforce compliance with air quality standards even if the costs were great.” 504 F.2d at 675.

¹⁷⁶ See, e.g., *South Carolina ex rel. Tindal v. Block*, 717 F.2d 874, 885 (4th Cir. 1983) (“[I]t cannot be said that the [agency’s] actions were arbitrary and capricious for failure to consider the factors which a court might feel are appropriate but which were either considered and rejected by Congress, or simply not included by Congress as factors which the administrative agency must consider.”); *South Terminal*, 504 F.2d at 676 n. 33 (“Turning down necessary controls because they are economically burdensome is impermissible”); *Pub. Citizen, Inc. v. Mineta*, 340 F.3d 39, 57–58 (2d Cir. 2003) (although statute directed the agency to consider costs, agency was arbitrary and capricious for choosing less-costly alternative that did not fully achieve the statute’s specified goal); *Ctr. for Sci. in the Pub. Interest v. U.S. Dep’t of Treasury*, 797 F.2d 995, 1002 n. 7 (D.C. Cir. 1986) (“Agencies can consider the economic impact of their regulations, pursuant to executive orders . . . when the underlying statute permits such consideration.” (internal citations omitted)); *Am. Iron and Steel Inst. v. EPA*, 526 F.2d 1027, 1052, 1054 (3d Cir. 1975) (even when required to consider costs to regulated industry, agency action to promote purpose of statute that would force some firms to close was not arbitrary or capricious); see *supra* notes 54, 65–66 and accompanying text.

¹⁷⁷ One of the few court rulings to date concerning arbitrary or capricious issues in the context of the TCA also confirmed the primacy of statutory purposes. *Nicopure Labs, LLC v. FDA*, 266 F. Supp. 3d 360, 393–94 (D.D.C. 2017) (not arbitrary or capricious for FDA to exercise its authority to deem electronic nicotine delivery systems (ENDS) subject to the TCA, thereby placing significant new regulatory requirements and burdens on manufacturers, because “plaintiffs’ objections do not overcome the agency’s scientific judgment that regulation of ENDS products under the TCA is in the interest of public health”).

¹⁷⁸ *Am. Paper Inst., Inc. v. Am. Elec. Power Serv. Corp.*, 461 U.S. 402, 413 (1983) (quoting *Citizens to Preserve Overton Park v. Volpe*, 401 U.S. 402, 416 (1971)). See also *St. Louis v. Dep’t of Transp.*, 936 F.2d 1528, 1533 (8th Cir. 1981) (“So long as the agency considers all of the relevant factors, is not significantly influenced by any irrelevant factor, and comes up with a conclusion after mixing all the proper factors together that is not clearly wrong, there is no abuse of discretion, and we must affirm.”).

Control Act,¹⁷⁹ it would still be arbitrary or capricious for FDA to fail to do so when that would not interfere with the action's ability to secure net public health gains.¹⁸⁰ Accordingly, it must be even more arbitrary or capricious for FDA to fail to consider and address non-cost impacts that are directly relevant to the Act's public health purpose.

More specifically, these cases indicate that issuing an otherwise AFPPH tobacco control rule or order would still be arbitrary or capricious if there were readily available ways FDA could have refined the final rule or order, without interfering with its ability to secure net public health gains, not only to produce a smaller risk of producing a negative net public health impact but also to reduce any underlying health harms or risks to persons who would not have been harmed or put at risk but for the regulatory action.¹⁸¹ Given the Act's overriding public health purpose (and silence about reducing costs), such a failure to refine the final rule or order to reduce related individual and public health harms and risks (without reducing the likelihood or size of the expected net public health gains) would be an even more fundamental and egregious error of judgment than failing to take the similar actions to reduce unnecessary costs that existing case law requires.¹⁸² If making those available health-protecting modifications would also make the rule or order more likely to secure larger net public health gains, FDA's failure to take advantage of them would be even more incomprehensible, clearly wrong, whimsical, and nonsensical.¹⁸³

Indeed, this analysis of relevant case law indicates that FDA would also be arbitrary or capricious if it did not take advantage of obvious, viable ways to refine or modify its final rules or orders to increase the likelihood and size of the expected net public

¹⁷⁹ On the TCA and costs, see *supra* subsections III.A. and III.B, especially at notes 47–54, 65–67 and accompanying text.

¹⁸⁰ See *supra* notes 173–75 and accompanying text.

¹⁸¹ For example, a rule or MRTP order could prompt smokers to switch completely to less harmful non-smoked tobacco products through reduced-risk communications. But those communications could also reach otherwise non-using adults and youth and prompt some to try the less harmful tobacco products, become addicted users, and possibly move on to smoking, with all the attendant health harms and risks. If the rule or order prompted more complete smoker switching than new initiation, the net public health impact could be quite positive. But restricting the reduced-risk communications to limit exposure among non-using adults and youth could reduce the likelihood and size of any harmful new initiation from the rule or order, thereby also reducing the likelihood and size of any possible negative net public health impact, without reducing the likelihood and size of the expected net public health gain (and possibly increasing it). For additional examples of how PMTA or MRTP orders allowing the marketing of new products or the use of reduced-risk claims in product marketing could be structured to minimize the likelihood and size of any related new harms without disproportionately reducing the likelihood and size of the expected harm reductions and net public health gains, see *infra* notes 200–05 and accompanying text; Lindblom, *PMTA & MRTP Provisions*, *supra* note 150.

¹⁸² See *supra* notes 173–75. Even if preventing or reducing addiction-caused suffering and death were not generally considered more important than reducing regulatory costs, the TCA, with its primary purpose of preventing such tobacco-related suffering and death, certainly considers it much more important.

¹⁸³ See *supra* notes 167–71. As discussed above, such a failure would also make the rule or order not “appropriate for the protection of the public health.” See *supra* text accompanying notes 110, 172. It would also contradict the Hippocratic oath maxim “do no harm” and the related axiom to “maximize possible benefits and minimize possible harms,” which have both been incorporated into the “beneficence” principle of the Belmont Report that FDA and other federal agencies must follow in regard to human-subject research. NAT'L COMMISSION FOR THE PROTECTION OF HUMAN SUBJECTS OF BIOMEDICAL & BEHAV. RES., THE BELMONT REPORT: ETHICAL PRINCIPLES AND GUIDELINES FOR THE PROTECTION OF HUMAN SUBJECTS OF RESEARCH (Department of Health, Education, and Welfare, April 18, 1979), available at https://www.hhs.gov/ohrp/sites/default/files/the-belmont-report-508c_FINAL.pdf.

health gains—at least whenever that could be done without increasing the likelihood or risk of producing a negative net public health impact. Given that an agency is arbitrary or capricious for not taking advantage of obvious ways to modify its regulatory actions to reduce unnecessary costs (even when not a statutory concern),¹⁸⁴ how could FDA not be arbitrary or capricious for failing to take advantage of obvious ways to adjust its final tobacco control rules or orders to reduce unnecessary tobacco-related deaths and health harms more sharply (thereby better achieving its statutory purpose)?

If any of these obvious or otherwise readily available health-protecting and harm-reducing revisions to a final rule or order would not only avoid interfering with its ability to secure net public health harms but also would not increase the costs or other undesirable secondary impacts of the rule or order, FDA's failure to implement them would be an even more obvious error of judgment and even more incomprehensible.¹⁸⁵ However, even if those rejected revisions would have increased costs, or other undesirable secondary impacts, the primacy of achieving statutory purposes suggests the failure to adopt them would still be arbitrary or capricious.¹⁸⁶

But there are limits to these FDA duties. The Act does not require FDA to exercise its rulemaking discretion to implement only those tobacco control rules that will most effectively promote the Act's goal of reducing tobacco-related public health harms. In addition, regulatory agencies have considerable discretion as to how they choose to use their discretionary rulemaking authorities.¹⁸⁷ Accordingly, FDA could not be found arbitrary or capricious for not implementing entirely different alternative rules or for failing to make new major substantive additions or changes to a final rule it chooses to implement, even if doing so would better protect the public health.¹⁸⁸

¹⁸⁴ See *supra* notes 173–175; see also *Pub. Citizen, Inc. v. Mineta*, 340 F.3d 39, 57–58 (2d Cir. 2003).

¹⁸⁵ *Id.*; see *supra* notes 167–71.

¹⁸⁶ See, e.g., *supra* notes 178–79 and accompanying text.

¹⁸⁷ See, e.g., *Norton v. S. Utah Wilderness All.*, 542 U.S. 55, 66–67 (2004) (It is the task of the regulatory agency, not the supervising court, “to work out compliance with the broad statutory mandate” and determine “the manner and pace of agency compliance with such congressional directives.”). *Armstrong v. Exceptional Child Center, Inc.*, 135 S.Ct. 1378, 1390 (2015) (Breyer, J., concurring) (“[T]he law may give the federal agency broad discretionary authority to decide when and how to exercise or to enforce statutes and rules.”); *Bethlehem Steel Corp. v. EPA*, 782 F.2d 645, 655 (7th Cir. 1986) (“When an agency has discretion as to whether or not to undertake rulemaking, the courts cannot tell it how to exercise that discretion.”); *Heckler v. Chaney*, 470 U.S. 821, 830 (1985). See also *Massachusetts v. EPA*, 549 U.S. 497, 527 (2007). However, the courts often support their deference to agency discretion as to whether or not to implement a rule or which rules to implement by referencing a need to provide agencies with “broad discretion to choose how best to marshal its limited resources and personnel to carry out its delegated responsibilities.” *Id.* at 526. But FDA's tobacco control resources and personnel are supported by large mandatory fees from the tobacco industry. See *generally* 21 U.S.C. § 387s (2012). Despite receiving that funding since 2009, FDA has yet to implement a major substantive tobacco control rule, suggesting that its resources and capacities in that regard should be quite robust, perhaps diminishing any concerns about FDA needing discretion to marshal limited resources and personnel.

¹⁸⁸ For example, complainants could not invalidate an FDA tobacco control rule as arbitrary or capricious simply by showing that there were substantially different alternative rules FDA could have issued instead to secure larger net public health gains. FDA may certainly exercise its discretion to issue final rules with major, substantive differences from its proposed rules, when permitted as logical outgrowths of the notice and comments. See, e.g., *Env'tl. Def. Ctr. v. EPA*, 344 F.3d 832, 851 (9th Cir. 2003); *BASF Wyandotte Corp. v. Costle*, 598 F.2d 637, 642 (1979). But the “not arbitrary and capricious” standard discussed here likely would not require FDA to make any such legally allowed changes that went beyond just refining the

As outlined above, however, once FDA chooses to implement a specific final rule, it must, to avoid being found arbitrary or capricious, consider any obvious or readily available adjustments to the structure of the rule, within its FDA-chosen reach or scope, that could reduce any health risks or harms it might cause (without reducing its potential net public health gains) or could increase its potential net public health gains (without increasing any negative public health risks). But FDA would be required to implement those refinements to its final rule only if FDA determined that doing so would actually produce the reductions to individual or population-wide health risks or harms. Any interference with agency discretion under such an application of the not-arbitrary-or-capricious standard would be no more intrusive than the requirement that agencies reduce the costs of their regulatory actions when possible without interfering with the achievement of statutory purposes.¹⁸⁹ But such an application of the standard to FDA tobacco control rulemaking would, unlike the cost-reduction requirement, directly promote the Act's statutory purposes.

These limits on what types of proposed or readily available changes FDA needs to consider or implement to avoid being found arbitrary or capricious in its tobacco control rulemaking would not apply to the development of its permissive PMTA or MRTP orders. Unlike with rules, FDA has very little discretion regarding which orders it might choose to issue or about what strategy or scope it might choose for its permissive orders. The Act requires FDA to consider all submitted PMTA or MRTP applications and either reject the applications or issue permissive orders, and the Act clearly defines the permitted scope and content of any permissive orders.¹⁹⁰ There is also a much more serious risk that a permissive order might produce a non-trivial negative net public health impact compared to rules, making it even more important that FDA take advantage of available measures to reduce those risks.¹⁹¹ Moreover, the Act directly authorizes FDA to include additional restrictions or requirements on the labeling, advertising, and sale of any new or substantially changed tobacco product it allows on the market and on the labeling, marketing, and sale of any product allowed to make modified-risk claims (as long as the FDA restrictions or requirements are AFPPH).¹⁹²

final rule FDA decided to implement and altered the basic strategy or approach FDA had exercised its discretion to choose. *See supra* note 37.

¹⁸⁹ *See supra* notes 173–75 and accompanying text. Such an application of the not-arbitrary-or-capricious standard also avoids the kind of disfavored “pervasive oversight by federal courts” that injects judges into day-to-day agency management that underlies many of the rulings favoring agency discretion. *See, e.g., Norton*, 542 U.S. at 66–67. It also fully respects the well-established principle that certain discretionary regulatory decisions are best left to the regulatory agency’s special expertise. *See, e.g., supra* notes 159–65 and accompanying text.

¹⁹⁰ *See generally* 21 U.S.C. § 387j (2012); 21 U.S.C. § 387k (2012).

¹⁹¹ *See, e.g., supra* notes 119–23 and accompanying text.

¹⁹² *See* 21 U.S.C. § 387j(c)(1)(B) (2012); 21 U.S.C. §§ 387k(h)(1), (h)(2), (h)(5) (2010). Going further, § 387k(h)(1) states that FDA “shall require” that any advertising and labeling delivering an FDA-permitted modified-risk claim enable the public to comprehend the information and understand its relative significance in the context of total health and in relation to all the diseases and health-related conditions associated with using tobacco products. 21 U.S.C. § 387k(h)(1) (2010). However, §§ 387j and 387k also leave FDA free to reject inadequate PMTA or MRTP applications and proposed orders rather than make any effort to fix them. In fact, FDA has no obligation to consider any information that might support the application or its proposed order other than what the application itself offers. 21 U.S.C. § 387j(c)(2) (2012); 21 U.S.C. §§ 387k(g)(1), (g)(2), (g)(3)(A) (2010).

Accordingly, to avoid being found arbitrary or capricious, FDA must include in its final PMTA and MRTP permissive orders any legally viable proposed or otherwise obvious readily available requirements or restrictions on the subject products or their labeling, marketing, or sale, or on any permitted relative-risk claims, that FDA determines would make issuing the final orders less likely to produce negative individual or net public health impacts (without reducing the likely net public health gains) or more likely to secure net public health gains (without increasing the risk of negative impacts).¹⁹³

Even if doing so were not required to avoid being found arbitrary or capricious, these kinds of adjustments to its final rules and permissive orders to reduce secondary health harms and risks and better protect the public health would be the right thing for FDA to do to promote the Act's public health purpose more safely and effectively.

A. *How FDA Has Failed to Reduce Public Health Harms and Risks*

To date, FDA's proposed and final rules and final permissive PMTA orders do not reveal any active agency efforts to reduce possible risks that the final rules or orders will produce negative net impacts on the public health.

As discussed previously, FDA's still-pending proposed rule to reduce certain carcinogens in smokeless tobacco products simply concluded that any negative health impacts caused by the rule were likely to be small and would not offset the likely health gains from the rule.¹⁹⁴ Even more cursory analyses and statements relating to likely public health gains and possible underlying health harms or risks were made in FDA's final deeming rule and the struck-down 2011 final rule to require graphic warning labels on cigarette packs.¹⁹⁵ None of these rules referenced any FDA effort to try to reduce any individual or public health harms or risks they might cause.¹⁹⁶

¹⁹³ None of the handful of the court rulings to date pertaining to the TCA that mention the not-arbitrary-or-capricious standard raise or address these issues. In perhaps the most applicable ruling, the District Court in *Cigar Association of America v. FDA* found that FDA had not been arbitrary or capricious in determining that the deeming rule and its various components were "appropriate for the protection of the public health." *Cigar Ass'n of Am. v. FDA*, 315 F.Supp.3d 143, 159–63 (D.D.C. 2018). But the plaintiffs did not claim that the rule or any of its components might cause individual health harms or create a risk of producing net negative public health impacts, or that FDA should have structured the rule or any of its components to make them better protect the public health. *Id.*

¹⁹⁴ See *supra* note 146 and accompanying text.

¹⁹⁵ *Deeming Tobacco Products*, *supra* note 142; *Required Warnings*, *supra* note 144. Unlike the 2011 graphic warnings rule, FDA's new final rule to establish graphic warnings does not discuss the AFPPH standard, as it was issued solely on the basis of other provisions in the Act, primarily relating to promoting greater public understanding of the risks associated with tobacco products. Tobacco Products; Required Warnings for Cigarette Packages and Advertisements, 8 Fed. Reg. 15,638 (March 18, 2020) (to be codified at 21 C.F.R. pt. 1141). It also does not reveal any FDA effort to identify or reduce any possible negative health impacts from the rule. *Id.*

¹⁹⁶ This lack of discussion or action by FDA could partially be explained by the rules not presenting any strong risk of producing new health harms. It is difficult, for example, to think of any serious new health risks that issuing the graphic health warning rules might cause. But FDA acknowledged that the smokeless tobacco rule could prompt some health-harming consumer responses, simply saying that they would be offset by the rule's gains, instead of doing anything to reduce those possible increased harms. See *supra* note 146. The deeming rule might have also caused some new health harms by prompting some to think that the deemed products were safer now that FDA was regulating them. But FDA did not discuss that risk or take any action relating to it. See *supra* note 142.

To date, FDA has issued permissive PMTA orders and related decision summaries for eight Swedish Match snus smokeless tobacco products, four Philip Morris IQOS “heat-not-burn” inhalable tobacco products, and two 22nd Century Group reduced-nicotine cigarettes, and has subsequently issued permissive MRTP orders for the Swedish Match snus.¹⁹⁷ In each case, FDA fully recognized that issuing the orders could actually produce a negative net public health impact and could produce new health harms and risks even if they did secure their expected new net public health gains (e.g., by increasing youth initiation or prompting smokers to switch or engage in dual use instead of quitting all use or quitting all smoking).¹⁹⁸ For the snus PMTA order, however, there is no indication that FDA made any effort to ensure that the permissive orders, and the underlying products, were structured to reduce the risk of any net public health harm or otherwise reduce any possible health harms or risks

¹⁹⁷ FDA’s documentation for the permissive PMTA orders it has issued are available at the FDA website. *Premarket Tobacco Product Marketing Orders*, FOOD & DRUG ADMIN. (last visited Nov. 15, 2019), <https://www.fda.gov/TobaccoProducts/Labeling/TobaccoProductReviewEvaluation/PremarketTobaccoApplications/ucm472108.htm> [<https://perma.cc/Q8ZF-SN25>]. This analysis does not consider the PMTA orders issued for the 22nd Century Group reduced-nicotine cigarettes, as it was released after this Article had completed peer review and been accepted for publication. Moreover, there is no indication that those PMTA orders or the underlying FDA decision summaries would change the analysis presented here. The PMTA decision summary for each of the Swedish Match snus products is the same: Office of Science, Center for Tobacco Products, FDA, *Premarket Tobacco Application (PMTA) Technical Project Lead (TPL) Review* (Nov. 3, 2015) (“Snus PMTA Decision Summary”), <https://www.fda.gov/media/94582/download>. The PMTA letter orders for each of the snus products are slightly different: David Ashley, Director, Office of Science, Center for Tobacco Products, FDA, Marketing Order letter to Swedish Match (Nov. 10, 2015) for FDA Submission Tracking Numbers (STN): PM0000010, 011, 012, 013, 014, 015, 016, 017, respectively (“Snus Final PTMA Orders”). The PMTA decision summary and the order letter for each of the IQOS products are the same: Matthew R. Holman, Director, Office of Science, Center for Tobacco Products, FDA, Marketing Order letter to Philip Morris Products, S.A., FDA Submission Tracking Numbers (STNs): PM0000424-PM0000426, PM0000479 (April 30, 2019) (“IQOS Final PMTA Order”); Office of Science, Center for Tobacco Products, FDA, *PMTA Coversheet: Technical Project Lead Review (TPL)* (April 29, 2019) (“IQOS Decision Summary”). FDA’s documentation for the permissive MRTP orders it has issued are available at the FDA website. *Modified Risk Orders*, FOOD & DRUG ADMIN. (last visited Nov. 15, 2019), www.fda.gov/tobacco-products/advertising-and-promotion/modified-risk-orders [<https://perma.cc/W4NF-5MPT>]. The MRTP letter order and decision summary for each of the Swedish Match snus products are the same: Matthew R. Holman, Director, Office of Science, Center for Tobacco Products, FDA, *Modified Risk Granted Orders – Risk Modification*, to Swedish Match USA, Inc. (October 22, 2019) (“Snus Final MRTP Orders”); Matthew R. Holman, Director, Office of Science, Center for Tobacco Products, FDA, *Scientific Review of Modified Risk Tobacco Product Application (MRTPA) Under Section 911 (d) of the FD&C Act – Technical Project Lead* (not dated) (“Snus MRTP Decision Summary”).

¹⁹⁸ *Id.* For example, the orders require extensive post-market surveillance and reporting to “help FDA determine whether continued marketing of [the] product is appropriate for the protection of the public health or whether there are or may be grounds for withdrawing or temporarily suspending [the permissive] order.” Snus PMTA Orders at 3 or 4, *id.*, with similar text in IQOS PMTA Order at 9 and Snus MRTP Order at 8, 11, 14, *id.* See also Lindblom, *PMTA & MRTP Provisions*, *supra* note 150. The risks of increased individual or public health harms loom even larger with permissive MRTP orders than with PMTA orders, given that commercial tobacco product marketing with reduced-risk and reduced-exposure claims can work more powerfully than marketing without them to promote both beneficial and harmful responses by consumers. See *supra* note 132. Because IQOS would be the first smoking-alternative product to secure a permissive MRTP order, its marketing with reduced-risk claims could also prompt some youth and adults to misperceive IQOS as less harmful than other tobacco-nicotine products on the market that are actually less harmful, possibly increasing youth initiation and prompting not only smokers but also some users of less harmful or equally harmful tobacco products, including some who would otherwise have quit all use, to increase their harms and risks by switching to IQOS or to dual use with IQOS. See, e.g., Wendy B. Max et al., *Modelling the Impact of a New Tobacco Product: Review of Philip Morris International’s Population Health Impact Model as Applied to the IQOS Heated Tobacco Product*, 27(Supp. 1) TOBACCO CONTROL s82 (2018).

issuing the order might produce or allow.¹⁹⁹ For the IQOS PMTA and the Snus MRTP, however, FDA acknowledged that the permissive orders needed to include some restrictions on the products' marketing to make the orders AFPPH.²⁰⁰ Most notably, to protect youth from being exposed to the products' advertising and to block youth access to product sales, both orders require strict age and identification verification prior to allowing any person to be exposed to any advertising or sales of the products using any electronic medium.²⁰¹ But the information and analysis provided in the related decision summaries to support those advertising and sales restrictions also directly supported including additional advertising and sales restrictions in the orders to reduce youth exposure and access even more effectively.²⁰² In addition, there were numerous other readily available restrictions and requirements that FDA could have included in each of the final PMTA and MRTP orders to reduce related health risks and harms to youths and adults (without interfering with the orders' ability to secure net public health gains).

For example, to discourage harm-increasing uses of the products (without discouraging harm-reducing uses), FDA could have required the products' labeling and ads to include warnings stating something like "For use only as a complete substitute for smoking [or, for the snus: or other non-snus smokeless tobacco use]; any other use will increase user harms and risks." Similarly, FDA could have required each of the products to be sold with package inserts describing how the products can be used to reduce user harms and risks linked with tobacco, how other uses will increase harms and risks, how quitting all use (or never starting) is the best way to reduce all health harms and risks, and where users who want to quit can get further information and assistance.²⁰³

Going further, FDA could have specifically required that the products' advertising be restricted to ads that would directly reach only those persons who could possibly benefit from using them (i.e., smokers and, for the snus, users of other smokeless tobacco products) while minimizing exposure to the ads among anyone else (who could only be harmed from using the products). For example, FDA could have restricted IQOS advertising to only: a) direct mail, email, or social media only to pre-verified adults who also state that they are current or former smokers; b) ads at adult-only stores or websites where tobacco products are sold (with the ads not externally visible); and c) materials offered upon request at other sales outlets only to pre-verified adults who also state that they are current or former smokers.

Or FDA could have required that any ads for the products likely to be seen by youth or non-using adults consist only of black text on a white background (with some exceptions necessary for conveying relevant product information) or be restricted in other ways to prevent or reduce the use of images, phrases, or text that regularly mislead consumers or otherwise attract youth or nonusers into tobacco use.²⁰⁴

¹⁹⁹ Snus PMTA Orders and Snus PMTA Decision Summaries, *supra* note 197.

²⁰⁰ IQOS PMTA Order and Decision Summary and Snus MRTP Order and Decision Summary, *supra* note 197. See the appendices to each of the decision summaries at 111–20 and at 64–77, respectively.

²⁰¹ IQOS PMTA Order and Snus MRTP Order, *supra* note 197.

²⁰² See IQOS PMTA Decision Summary at 111–20 (Appendix); Snus MRTP Decision Summary at 111–20 (Appendix), *supra* note 197.

²⁰³ See generally Lindblom et al., *FDA-Required Tobacco Product Inserts*, *supra* note 11 at 1.

²⁰⁴ Any advertising restrictions FDA might include in a permissive order might encounter First Amendment constraints relating to protected commercial speech, but they can be overcome if the restrictions

But FDA does not appear to have considered any of these readily available options for reducing the health harms and risks associated with issuing the permissive PMTA or MRTP orders. Nor does it appear that FDA considered whether Swedish Match or Philip Morris could have made the snus or IQOS products themselves less harmful or risky (e.g., by eliminating certain harmful or potentially harmful additives, using different tobaccos, using other less harmful and risky ingredients instead of those currently in the products, further reducing contamination, or using different tobacco curing and processing techniques). Instead of including additional requirements and restrictions in the final orders to prevent unnecessary new individual and public health harms and risks from ever occurring, FDA apparently decided to rely on post-market surveillance and periodic reports from Swedish Match and Philip Morris so that it could possibly take remedial action if and when any new health harms appeared in the future.²⁰⁵

As a result, nothing in FDA's permissive PMTA and MRTP orders (or other applicable laws and rules) prevent Swedish Match or Philip Morris from advertising the snus and IQOS products in a variety of ways that would both promote their use by persons who can only be harmed by using them (anyone other than users of more harmful tobacco products) and encourage harm-increasing uses by those who could possibly benefit from using the snus or IQOS products (e.g., by encouraging smokers to use them other than as a complete substitute for smoking). For example, the companies may still legally advertise the snus and IQOS in ways that directly reach youth and nonusers and may legally promote them as a cool new alternative to smoking, a way to use tobacco without anyone being able to tell, or a great way to continue using tobacco when and where you are not allowed to smoke.

Thankfully, these kinds of health-harming promotions of the products has not yet visibly occurred to any significant extent (although it is still quite early with the PMTA IQOS and MRTP snus marketing). But leaving these types of unnecessary, health-risking options legally available to these profit-maximizing companies, and failing to include other readily available measures in the orders to discourage health-increasing uses of the product (without disproportionately reducing harm-reducing uses), fails to honor the Tobacco Control Act's purpose: to protect the public health and reduce tobacco-related health harms and risks. These failures by FDA also make its PMTA and MRTP orders both arbitrary and capricious and *not* AFPPH.

Accordingly, FDA should have either rejected the Swedish Match snus PMTA and MRTP applications and the Philip Morris IQOS PMTA applications for failing to include such readily available measures to reduce unnecessary possible health harms

are necessary to promote a substantial government interest (e.g., reducing tobacco use harms or protecting the public health), especially if the manufacturers are left with reasonable ways to communicate relevant product information to their legal adult customers. *See, e.g.,* Lorillard Tobacco Co. v. Reilly, 533 U.S. 525 (2001). Moreover, if FDA's permissive PMTA or MRTP orders allowed the tobacco products on the market only as less harmful alternatives for existing adult smokers (or users of other more-harmful tobacco product users), the potential scope of those First Amendment constraints would shrink considerably, clearly permitting restrictions to prevent advertising to nonsmokers or other illegal customers. Placing advertising restrictions on a product to allow it on the market can also raise weaker First Amendment concerns than placing new constraints on the existing advertising of a product already on the market. *See, e.g.,* Lindblom, *Effectively Regulating E-Cigarettes*, *supra* note 11 at 57–94; Lindblom, *PMTA & MRTP Provisions*, *supra* note 150.

²⁰⁵ Snus and IQOS PMTA Orders and Decision Summaries and Snus MRTP Order and Decision Summary, *supra* note 197.

and risks or inserted those restrictions and requirements into the permissive orders itself.²⁰⁶ Because FDA did neither, the orders FDA issued remain vulnerable to legal challenge, as will any permissive PMTA or MRTP it issues in the future that have similar failures.²⁰⁷

XI. FDA RULES AND ORDERS MUST ALSO AVOID UNNECESSARY NEGATIVE SECONDARY IMPACTS

To avoid being arbitrary or capricious, FDA must take advantage of all obvious, readily available ways to refine its final tobacco control rules and permissive PMTA and MRTP orders to reduce certain unnecessary, undesirable secondary impacts, such as costs and negative health impacts on disadvantaged or vulnerable subpopulations. Following the *State of La.* and *South Terminal* circuit court rulings, issuing a final tobacco control order or rule FDA reasonably found AFPPH, which also was not arbitrary or capricious in regard to the likelihood and size of any individual or net health harms or risks it might produce, would still be arbitrary or capricious if FDA did not also take advantage of any readily available ways to reduce related costs (without interfering with the ability of the rule or order to secure its expected net public health gains).²⁰⁸

These two circuit court cases directly pertain only to costs and, primarily, costs of compliance. But their logic extends to any other secondary impacts from a regulatory action that are roughly as undesirable as compliance costs or even more undesirable, especially if they are more relevant to the statutory purpose at issue. For FDA regulatory actions under the Tobacco Control Act, those secondary impacts would include, among other things, undesirable effects “of particular concern to public health officials,” such as negative health impacts on especially vulnerable or disadvantaged subpopulations or on health disparities.²⁰⁹

²⁰⁶ Although FDA has no duty under the TCA to try to fix, instead of reject, flawed PMTA or MRTP applications or their proposed permissive orders, it clearly has the authority to do so. *See supra* note 192 and accompanying text; *supra* note 189 and accompanying text. *See also* Eric N. Lindblom, *How Might Manufacturers of E-Cigarettes Get New Product and MRTP Orders from FDA More Quickly and Easily?* 73 FOOD & DRUG L. J. 624, 633–34 (2018) [hereinafter Lindblom, *How Might Manufacturers?*]; Eric N. Lindblom, *How Would an Ethically Responsible FDA Evaluate PMTA and MRTP Applications and Issue Related Orders*, FOOD & DRUG L. J. (forthcoming) (pre-publication draft available from author) [hereinafter Lindblom, *How Would an Ethically Responsible FDA Evaluate?*].

²⁰⁷ *See infra* notes 213–22 and accompanying text regarding possible procedural FDA defenses to any such legal challenges. For a more detailed substantive and legal analysis of the problems with FDA’s PMTA and MRTP orders, see Lindblom, *PMTA & MRTP Provisions*, *supra* note 150.

²⁰⁸ *See supra* notes 173–75. There do not appear to be any court rulings finding an agency arbitrary or capricious for not reducing the costs (or any other undesirable secondary impacts) of its discretionary regulatory actions when doing so would make the action *less* effective at promoting the authorizing statute’s purpose. *See also supra*, note 176. But a regulatory action could be found arbitrary or capricious if it would produce only quite small statutory benefits while also causing considerably larger costs or other undesirable secondary impacts, even if there were no way to adjust the specific action to reduce those undesirable impacts without reducing the benefits. *See, e.g., Michigan v. EPA*, 135 S. Ct. 2699, 2707 (2015) (“One would not say that it is even rational . . . to impose billions of dollars in economic costs in return for a few dollars in health or environmental benefits.”).

²⁰⁹ Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111-31, 123 Stat. 1781 (2); *see supra* notes 77–78. However, the likelihood of any such health-related undesirable impacts would be reduced if the rule or order were AFPPH and FDA had, as discussed above, taken advantage of readily available ways to structure the final rule or order to reduce the likelihood and size of any possible negative

Accordingly, the public health community could bring viable legal challenge against any rules or orders that could have been revised to secure the same or larger net public health gains without causing as many underlying new health harms, either generally or to especially vulnerable or disadvantaged subpopulations, or without having as negative an effect on health disparities.²¹⁰

The tobacco industry could also bring this type of legal challenge. For example, a well-drafted tobacco product standard to minimize nicotine in all cigarettes and similarly smoked tobacco products would clearly secure large public health gains and be AFPPH. But it would also place substantial compliance burdens on cigarette and other combustible tobacco product manufacturers and reduce their sales and profits, reduce consumer choice, and create a risk of prompting the emergence of at least some new illicit trade in non-complying tobacco products.²¹¹ To try to protect their sales, escape compliance costs, and otherwise protect their profits, members of the tobacco industry could legally challenge the rule by claiming that FDA was arbitrary or capricious in issuing the rule because it could have reduced these undesirable impacts without interfering with the rule's ability to secure its net public health gains.²¹² To try to protect themselves against more difficult competition, tobacco companies could also bring legal challenges against permissive PMTA or MRTP orders FDA issues to their competitors by showing that the orders caused various undesirable secondary impacts that could have been avoided without reducing the orders' expected public health gains.

net public health impacts and, without reducing its ability to produce net public health gains, to reduce any unnecessary underlying health harms and risks.

²⁰⁹ See *supra* notes 77–78 and accompanying text. See also Jamie Tam, et al., Comment Letter on Proposed Rule: Premarket Tobacco Product Applications and Recordkeeping Requirements (Dec 13, 2019), <https://www.regulations.gov/document?D=FDA-2019-N-2854-1077> [<https://perma.cc/L6PD-AFKM>]. It is unlikely that FDA would choose to implement a tobacco control rule that would create new harms among already disadvantaged or vulnerable subpopulations. But an FDA PMTA or MRTP order might allow marketing likely to produce net public health harm reductions by encouraging smokers to switch to a less harmful product that would also prompt some otherwise nonusers, disproportionately including youth and perhaps members of other vulnerable or disadvantaged subpopulations, to start using the less harmful product. In addition, both FDA tobacco rules and orders could increase health disparities even if they reduced harms among vulnerable and disadvantaged subpopulations but also reduced harms among already advantaged subpopulations more.

²¹⁰ See *supra* notes 77–78 and accompanying text. See also Jamie Tam, et al., *Make Tobacco Use Disparities an Explicit Consideration in PMTA Reviews*, Comment to FDA Docket No. FDA-2019-N-2854, Premarket Tobacco Product Applications and Recordkeeping Requirements (Dec 13, 2019), <https://www.regulations.gov/document?D=FDA-2019-N-2854-1077> [<https://perma.cc/L6PD-AFKM>]. It is unlikely that FDA would choose to implement a tobacco control rule that would create new harms among already disadvantaged or vulnerable subpopulations. But an FDA PMTA or MRTP order might allow marketing likely to produce net public health harm reductions by encouraging smokers to switch to a less harmful product that would also prompt some otherwise nonusers, disproportionately including youth and perhaps members of other vulnerable or disadvantaged subpopulations, to start using the less harmful product. In addition, both FDA tobacco rules and orders could increase health disparities even if they reduced harms among vulnerable and disadvantaged subpopulations but also reduced harms among already advantaged subpopulations more.

²¹¹ See, e.g., *supra* note 125.

²¹² See, e.g., Dillard III 2009 Comments, *supra* note 36 (“The Act should be implemented in a way that achieves Congress’s public health objectives without unnecessarily impacting the millions of adult consumers, employees, tobacco growers, and retailers who will be affected by regulation.”); Murillo, *supra* note 36. To date, however, none of these types of arbitrary-or-capricious issues have been raised in any of the court rulings pertaining to the TCA. See *supra* note 193.

Referring to agency failures to reduce costs, the *South Terminal* ruling stated that an agency would be arbitrary or capricious only if it were to “reject” an “obviously” less burdensome but equally effective alternative, and that “a considerable part of the burden of suggesting attractive alternative strategies is upon those, like the petitioners, who dislike the present ones.”²¹³ But this potential agency defense appears designed to protect agencies against being found arbitrary or capricious for failing to make any special efforts to try to find or develop not-already-obvious regulatory revisions to reduce unnecessary costs or other undesirable impacts only when the statute authorizing the action does not require any efforts to reduce those costs or other impacts and expresses no specific concern about them.²¹⁴ Accordingly, it would be entirely consistent with *South Terminal* for the courts to find that because of the Tobacco Control Act’s overriding public health purpose, FDA did have a duty to make a special effort to find or develop ways to reduce unnecessary health-related harms or other negative health-related impacts caused by its tobacco control rules or orders, beyond just considering those that were presented to FDA by interested parties or otherwise already obvious to FDA.

Similarly, the courts generally will not invalidate a regulation based on a claim that the agency exercised its discretion in an arbitrary-or-capricious way if the complainant had a previous opportunity to raise the same issue with the agency to try to get it resolved and neither the petitioner nor anyone else did.²¹⁵ But this potential agency defense also “is not a license for agency passivity.”²¹⁶ For example, FDA would still “bear the affirmative burden of examining a key assumption when promulgating and explaining a non-arbitrary, non-capricious rule . . . even if no one objects during the comment period.”²¹⁷ Accordingly, even if neither the complaining parties nor anyone else had previously showed FDA the revisions it could have made to its rule or order to reduce unnecessary costs or other undesirable impacts (or to reduce the likelihood and size of producing a negative net public health impact), FDA might still be found arbitrary or capricious if FDA had failed to make any reasonable effort to identify or develop additional ways to improve its rule or order that might have prompted FDA to find and make those revisions. Any such duty to take unilateral agency action would be even greater in regard to reducing unnecessary negative impacts that are clearly of

²¹³ *South Terminal Corp. v. EPA*, 504 F.2d 646, 655–56, 676 (1st Cir. 1974). *See also* *State of La., ex rel. Guste v. Verity*, 853 F.2d 322, 331 (5th Cir. 1988) (stating that the regulations at issue were not arbitrary or capricious because they “have not been shown to be achievable through less costly means”).

²¹⁴ The authorizing statute in *South Terminal* did not express any concern about reducing costs, much less require that. While the court still found an agency duty to adopt presented or otherwise obvious measures that would reduce costs without interfering with regulatory objectives, it also stated that “we do not read the Act as requiring EPA to engage in exhaustive cost benefit studies or to initiate elaborate planning exercises.” 504 F.2d at 676. *See also* *Village of Barrington, Ill. v. Surface Transp. Bd.*, 636 F.3d 650, 671 (D.C. Cir. 2011) (court not aware of any authority “for the proposition that the APA’s arbitrary and capricious standard alone requires an agency to engage in cost-benefit analysis”).

²¹⁵ *See, e.g.*, *Hispanic Affairs Project v. Acosta*, 901 F.3d 378, 388–89 (D.C. Cir. 2018); *Am. Nursing Home Ass’n v. Cost of Living Council*, 497 F.2d 909, 913 (Temp. Emergency Court of Appeals 1974); *see also* *U.S. Airwaves v. FCC*, 232 F.3d 227, 236 (D.C. Cir. 2000) (“As we have said more than once before, a litigant may not ‘sandbag’ agencies by withholding legal arguments . . . until they reach the courts of appeal.” (internal quotations and citations omitted)).

²¹⁶ *Hispanic Affairs Project*, 901 F.3d at 389 (internal citations and quotation marks omitted).

²¹⁷ *Id.* *But see* *Arizona ex re. Darwin v. EPA*, 852 F.3d 1148, 1159 (9th Cir. 2017) (“The asserted duty to examine ‘key assumptions’ has no textual origin.”).

concern to the authorizing statute, such as reducing the amount of underlying health harms and risks an FDA tobacco control rule or order causes while securing its net public health gains.²¹⁸

In addition, any agency defense based on a failure by complaining parties to raise the issue before the regulatory action was taken (e.g., by showing FDA how it could revise a pending tobacco control rule or order to reduce unnecessary health harms, costs, or other equally or more undesirable impacts) depends on the complaining parties having had a reasonable opportunity to do so. Notice-and-comment rulemaking explicitly provides such opportunities. But FDA makes only MRTP applications available for public comment and does not make PMTA applications or proposed PMTA or MRTP decision summaries or orders available for public comment before the final orders are formally issued.²¹⁹ By formally requesting comments on proposed drafts of PMTA and MRTP orders and decision summaries, FDA could not ensure that any parties with possible legal challenges against those orders would have to reveal their concerns during the provided comment period or risk losing their ability to raise them in court.²²⁰

²¹⁸ Following existing case law, however, the courts would presume that FDA's regulatory actions were rational and not arbitrary, and the burden of establishing otherwise would be on the tobacco company or other entity or person filing the legal challenge. *See, e.g.,* Medina County Env'tl. Action Ass'n v. Surface Transp., 602 F.3d 687, 699 (5th Cir. 2010). As one court put it, "we are mindful that a party seeking to have a court declare an agency action to be arbitrary and capricious carries 'a heavy burden indeed.'" Legal Env'tl. Ass'n v. EPA, 276 F.3d 1253, 1256 (11th Cir. 2001) (citing Transmission Access Policy Study Group v. FERC, 225 F.3d 667, 714 (D.C. Cir. 2000)). In addition, the courts would not find FDA arbitrary or capricious for rejecting obvious, possibly beneficial modifications to its final rules or orders if the administrative record showed that FDA considered the possible changes, but its own estimates, projections, or analyses indicated that they would not work as desired to improve the rule or order. *See, e.g., supra* notes 157–66 and accompanying text.

²¹⁹ FDA will likely face a flood of new PMTA applications before the court-ordered May 12, 2022 deadline for all e-cigarettes and other deemed tobacco products that were not on the U.S. market on February 15, 2007 to submit new product applications or be pulled off the market. *See generally* Am. Acad. of Pediatrics v. FDA, 399 F. Supp. 3d 479 (D. Md. 2019). Although FDA has appealed that ruling and its deadline, it appears that any e-cigarettes wanting to stay on the U.S. market legally will, at a minimum, have to submit a PMTA order much earlier than FDA's prior August 2022 deadline or subsequently proposed August 2021 deadline. FOOD & DRUG ADMIN., ENFORCEMENT PRIORITIES FOR ELECTRONIC NICOTINE DELIVERY SYSTEM (ENDS) AND OTHER DEEMED PRODUCTS ON THE MARKET WITHOUT PREMARKET AUTHORIZATION: GUIDANCE FOR INDUSTRY (Jan. 1, 2020), available at www.fda.gov/tobacco-products/rules-regulations-and-guidance/guidance [<https://perma.cc/DDM9-SWXD>]. FDA could invite comments on all these PMTA applications from interested third parties, without being overwhelmed by submissions of the same or similar comments on each individual PMTA application, by inviting only generally applicable suggestions for what restrictions and requirements any permissive orders for each distinct different type of e-cigarette or other category of PMTA tobacco products should include to minimize the risk of producing net public health harms, and to minimize any costs, individual or subpopulation health harms, or other undesirable secondary impacts (whenever that could be done without reducing the likelihood and size of the expected net public health gain from issuing the permissive order). By inviting and processing such comments in a formal way—for example, by presenting proposed generic text regarding product, labeling, and marketing restrictions and requirements that would apply to all tobacco products receiving permissive PMTA (or MRTP) orders—FDA could also develop important information and guidance for industry members regarding what restriction or requirements the proposed orders in their applications could or must contain to receive a permissive order or to receive it more quickly and easily. *See also* Lindblom, *How Might Manufacturers, supra* note 205.

²²⁰ Existing case law might support a more permissive standard, where FDA could be found arbitrary or capricious only if it rejected readily available ways to revise its rules or orders to reduce undesirable costs or other undesirable impacts that were either obvious or actually presented to FDA by those commenting on the proposed rules or applications or by the applicants themselves. *See supra* notes 213–18 and accompanying text. Given the TCA's public health purpose and the agency's overall public health mission,

More proactively and affirmatively, FDA could eliminate any risk of being found arbitrary or capricious in legal challenges relating to unnecessary, undesirable secondary impacts by simply making a good faith effort to make them as AFPPH as possible and to reduce any unnecessary underlying health harms and risks or other undesirable secondary impacts (so long as that did not create any serious risk of disproportionately reducing the likelihood or size of the desired net public health benefits).²²¹ Doing that would reduce FDA's legal risks while also making its rules and orders even more desirable and less controversial. However, FDA might reasonably and legally choose to not to make such an affirmative good faith effort, or even to limit its consideration of constructive proposals for reducing undesirable secondary impacts, whenever FDA reasonably determined that doing so would substantially delay the implementation of an AFPPH rule or order and, therefore, delay some health harms from being averted or reduced.²²²

XII. CONCLUSION

This Article has tried to provide greater clarity, and eliminate some misconceptions, about what FDA must, may, and may not do when determining whether a tobacco control rule or order is "appropriate for the protection of the public health." Its careful analysis of the Tobacco Control Act and its legislative history finds that whether an FDA tobacco control rule or order is AFPPH depends exclusively on its net impact on the health of the population as a whole. Non-health impacts (including industry burdens, increased illicit trade, or reduced consumer choice) and individual or subpopulation health impacts (including impacts on health disparities) are simply irrelevant, except to the extent they also have an impact on the public health. Yet FDA has not publicly acknowledged this aspect of the Act's public health standard, nor has it tried to establish an alternative interpretation.

The Act also says nothing about some important aspects of the AFPPH standard and how it should be applied. Clarifying those remaining gray areas is left entirely to FDA's discretion. Yet in the ten years since the Act went into effect, FDA has done very little publicly to complete or clarify the standard. Doing so soon, in a transparent manner, would provide critically important guidance to those members of the tobacco

however, FDA would still have no logical or public health reason not to exceed that permissive standard by also taking more affirmative, unilateral action to reduce undesirable, secondary health-related impacts, especially as that would also reduce any possible risk of legal fault for creating or accepting unnecessary health harms or risks.

²²¹ Existing case law might support a more permissive standard, where FDA could be found arbitrary or capricious only if it rejected readily available ways to revise its rules or orders to reduce undesirable costs or other undesirable impacts that were either obvious or actually presented to FDA by those commenting on the proposed rules or applications or by the applicants, themselves. *See supra* notes 213–18 and accompanying text. Given the TCA's public health purpose and the agency's overall public health mission, however, FDA would still have no logical or public health reason not to exceed that permissive standard by also taking more affirmative, unilateral action to reduce undesirable, secondary health-related impacts, especially as that would also reduce any possible risk of legal fault for creating or accepting unnecessary health harms or risks.

²²² Such an application of the APA's not-arbitrary-or-capricious standard would directly parallel those TCA provisions that place explicit requirements or restrictions on FDA but then qualify them by saying FDA need not comply if it determines that doing otherwise is necessary for the protection of the public health. 21 U.S.C. § 387g(d)(2) (2010); 21 U.S.C. § 387e(j)(3)(A)(ii) (2013); 21 U.S.C. § 387f(d)(3)(B) (2015); *see also* 21 U.S.C. § 387i(a)(3), (6) (2014).

industry submitting applications to secure permissive PMTA or MRTP orders. It would also enable industry members and other interested parties to provide more relevant and helpful comments on such applications and on proposed FDA tobacco control rules, and it would provide helpful guidance to FDA personnel and to the staff at other federal agencies and the White House that must clear any proposed or final FDA rule before it is issued. By formally explaining how it will be exercising its discretion to refine and apply the Act's core public health standard, FDA would also reduce the risk that the courts will establish their own interpretations when related issues are raised in future legal challenges to FDA tobacco control rules or orders.

Most fundamentally, FDA needs to determine whether tobacco control rules and orders can be AFPPH if their implementation would produce a non-trivial risk of producing a negative net impact on the public health. If FDA determines that running such a risk to the public health could not be "appropriate," its interpretive efforts would be largely done. But determining that running a risk of producing a negative net public health impact could be AFPPH would require additional FDA explication of how large the negative net risk could be, either on its own or in relation to the likelihood and size of the potential net public health gains, to qualify as "appropriate." FDA could even establish a bright-line ratio or test to simplify its own work; provide clearer, easier to follow standards for industry PMTA and MRTP applications; guide related research; and facilitate more informed comments on pending FDA rules and orders. Following this Article's analysis, an FDA determination that running a non-trivial risk of producing net public health harms can be AFPPH would also create a corresponding FDA duty—under both the appropriate-for-the-protection-of-the-public-health standard and the APA's not-arbitrary-or-capricious standard—to take advantage of all readily available ways to refine its final rules and permissive orders to reduce the likelihood and size of any such negative risk, at least to the extent that can be done without significantly reducing the likelihood or size of the expected net public health gains.

FDA publications and public statements relating to these issues are sparse, indirect, and inconclusive. But the agency's few permissive PMTA and MRTP orders indicate that FDA considers a risk that such orders might produce significant net public health harms AFPPH, at least in some situations. At the same time, FDA has failed to take advantage of readily available measures to reduce or eliminate those risks in the orders it has issued. If those permissive orders were challenged in court, perhaps FDA could reveal non-public records of its underlying evaluations that explained with adequate detail how the agency reasonably interpreted and applied the AFPPH standard. But if that information exists, keeping it secret makes no sense; and if FDA has not been doing that kind of work behind the scenes, it needs to start, with greater transparency. Moreover, no matter how carefully FDA might have refined and applied the AFPPH standard behind the scenes, it is hard to imagine any possible legal (or ethical) justification for the agency allowing new PMTA or MRTP tobacco products on the market without including all reasonable, readily available requirements and restrictions in the permissive orders that would reduce unnecessary risks that their marketing might produce net public health harms.²²³

²²³ On FDA's ethical duties when developing and implementing tobacco control rules and orders, see Lindblom, *Tobacco Control Rules*, *supra* note 6; Lindblom, *How Would an Ethically Responsible FDA Evaluate*, *supra* note 206.

When issuing any permissive PMTA or MRTP orders or tobacco control rules, the inevitable uncertainty regarding their future health-related impacts poses a major challenge for FDA, even in those less-frequent instances with plentiful relevant research and real-world experience. Here, too, the Tobacco Control Act and the APA leave FDA with enormous discretion regarding how it will evaluate available research and other evidence, develop projections of possible impacts, and estimate their likelihood. The Act also clearly leaves it entirely to FDA's discretion to determine whether there is adequate evidence to make its AFPPH determinations and take action. To date, various methods and procedures FDA has used to develop related estimates and projections appear quite safe from any legal attacks for being arbitrary or capricious. However, FDA will be legally vulnerable if it does not take advantage of those procedures to ensure that its final tobacco control rules and permissive orders not only meet the AFPPH standard (however FDA fully defines it) but also avoid being found arbitrary or capricious and, consequently, legally invalid, and it appears that FDA has not done that when determining whether its permissive PMTA and MRTP orders are AFPPH.

To avoid being arbitrary or capricious, FDA also has a clear duty under existing case law to take advantage of any obvious, readily available refinements to the final versions of the "appropriate" rules or orders it issues that FDA determines would reduce related costs or other similarly or more undesirable secondary impacts without reducing the ability of the rules or orders to produce net public health gains. Given the overriding public health purpose of the Tobacco Control Act, this legal duty (and ethical responsibility) should be especially demanding in regard to refining final rules and orders to prevent or reduce any underlying individual or subpopulation health risks or harms and to avoid increasing health disparities.²²⁴

To date, FDA's few substantive proposed and final rules and permissive PMTA and MRTP orders do not reveal any explicit FDA efforts to consider these kinds of adjustments to reduce unnecessary negative health impacts. Nor do they suggest any FDA acknowledgement that doing so might be legally required or the right thing to do. Even if taking such readily available steps to improve its tobacco control rules and orders were not required to avoid being arbitrary or capricious, FDA certainly has the authority to take them and has no practical or public health reason to avoid doing so. Indeed, FDA could greatly simplify its work evaluating PMTA and MRTP applications if it announced that it will reject any applications that do not exhibit a good faith effort to identify restrictions and requirements the permissive order should place on the subject tobacco products and their marketing to minimize any risk of producing a net public health harm and to minimize any unnecessary costs or other FDA-specified undesirable secondary impacts. Making these requirements clear would also help to guide the comments interested parties submit pursuant to the notice-and-comment procedures the statute requires for pending MRTP applications. No such system currently exists for submitting formal comments on PMTA applications or on proposed PMTA or MRTP orders, either individually or generically, but FDA could secure more helpful comments by exercising its discretion to establish them.²²⁵

It is impossible to predict whether or when FDA might finally take any of the actions outlined here to acknowledge the core scope of the appropriate-for-the-

²²⁴ *Id.*

²²⁵ *See supra* notes 219–20 and accompanying text.

protection-of-the-public-health standard, exercise its discretion to clarify the remaining gray areas, comply with its dictates when issuing final rules and permissive orders, and reduce related risks of being found arbitrary or capricious. But taking such action is long overdue. More than ten years have passed since the Tobacco Control Act went into effect, and by taking these actions FDA could have simplified its tobacco control work, provided better guidance to the industry and other interested parties, and improved the public health potential of its regulatory actions. Even more extraordinary and distressing is that in those first ten years, FDA has not implemented a single substantive rule to produce major reductions in the ongoing toll of unnecessary death, disease, and disability caused by smoking. But the two failings could be related.

Any fault, of course, is not FDA's alone. The implementation of any major regulatory action requires clearance from other federal agencies, especially the Office of Management and Budget, and permission, if not clear support, from the White House as well. Perhaps the analysis provided here will show those in the clearance procedures, both within FDA and without, that some of the perceived legal threats to FDA tobacco control rules and orders simply have no statutory or other legal basis, that the broad discretion given to FDA by the Act provides considerable additional legal protections, and that relatively simple actions are readily available to FDA to eliminate any foothold for other legal challenges.

But fear of legal problems is just one part of the problem. Neither President Obama nor his Administration gave any political or policy priority to supporting effective FDA action that would substantially reduce tobacco use deaths, harms, and costs, and President Trump and his Administration appear to be following suit.²²⁶ Without White House support, FDA efforts to obtain clearance must overcome time-consuming political and bureaucratic obstacles and concerns that often receive more weight and attention than the public health and economic benefits from reducing the unnecessary death, disease, and disability caused by smoking and other tobacco use.²²⁷

In sharp contrast, the Tobacco Control Act places a powerful, overriding premium on protecting and promoting the public health by reducing tobacco-related harms. As shown by the analysis here, if any Administration decides to support more active FDA efforts to promote that statutory purpose, the Act provides FDA with extensive tools, enormous amounts of discretion, and considerable legal protections to get the job done quickly and effectively, despite a hostile industry, often sparse research and other evidence, and typically large regulatory uncertainties.

Going further, the Act and relevant case law require FDA to take certain actions to protect and promote the public health more effectively whenever it issues final rules or, even more, when required to evaluate pending PMTA and MRTP applications and issue related orders—even when those actions might contradict the ideology or political preferences of those in the formal or informal clearance processes. With luck, these findings will be persuasive and enable FDA to take more effective tobacco control action to protect the public health, at least when faced with pending PMTA

²²⁶ See, e.g., Nathaniel Weixel, *Top Trump Official Questions FDA Tobacco Oversight as Vaping Ban Looms*, THE HILL (Nov. 8, 2019), <https://thehill.com/policy/healthcare/469618-top-white-house-official-questions-fda-tobacco-role-as-vaping-ban-looms> [<https://perma.cc/B4FS-6X3J>]; *User Clip: Joe Grogan—White House Domestic Policy Council Discusses E-Cigarette Regulation*, C-SPAN (Nov. 8, 2019), <https://www.c-span.org/video/?c4828413/user-clip-joe-grogan-white-house-domestic-policy-council> [<https://perma.cc/XK3G-KTUE>].

²²⁷ Bolger, *supra* note 3.

and MRTP applications, when required by the Act or the courts to issue a final tobacco control rule, or when permitted by the Administration to do so.²²⁸

Instead, clearance procedures, the Administration's political priorities, deference to the industry, or other factors might still produce FDA final rules or permissive PMTA and MRTP orders that are not AFPPH (regardless of how FDA might clarify the standard), fail to minimize risks of a negative net public health impact, or fail to take advantage of obvious ways to refine the final actions to reduce undesirable secondary impacts without reducing their ability to secure net public health gains. If that occurs, the analysis here provides a broader, more solid foundation for corrective legal action by the public health community or other interested parties.

Those interested parties that might legally challenge FDA tobacco control rules or orders using this Article's analysis could, unfortunately, include members of the tobacco industry trying to obstruct or delay measures that would reduce tobacco product use, sales, and profits. As detailed herein, however, FDA could eliminate the risks from such legal challenges by simply exercising its discretion constructively, being more transparent, and making its tobacco control rules and orders clearly AFPPH and clearly not arbitrary or capricious.

²²⁸ A recent court ruling found that the TCA's mandate that FDA implement a final rule to establish graphic health warnings on all cigarette packs remains active, despite FDA having issued a final graphic health warning rule in 2011 that the courts struck down, and the court ordered FDA to issue a final rule by March 2020. *See generally* Am. Acad. Pediatrics v. FDA, 330 F. Supp. 3d 657 (D. Mass., 2018). In addition, the Act requires FDA to issue a number of other substantive rules that have not yet appeared in proposed or final form, including rules to regulate the sale, distribution, promotion, and marketing of tobacco products not sold in face-to-face exchanges (deadlines passed); to establish good manufacturing practices for tobacco products (no deadline); and to require recordkeeping for tracking and tracing tobacco products from import or manufacture through distribution to retail outlets (no deadline). 21 U.S.C. §§ 387(f), 387(d)(4), 347(e) (2012); 21 U.S.C. § 387t(b) (2012); *see also* 15 U.S.C. § 1333(e) (2012).