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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

ERIC N. LINDBLUM*

ABSTRACT

The Premarket Tobacco Product Application (PMTA) provisions in the U.S. Tobacco Control Act (TCA) prohibit any new or substantially different types or brands of tobacco products from entering the U.S. market unless FDA first finds that allowing the product's marketing is "appropriate for the protection of the public health." Similarly, the Act's Modified Risk Tobacco Product (MRTP) provisions prohibit the marketing of any tobacco product with modified-risk claims unless FDA first finds that allowing such marketing will reduce health harms and risks to the population as a whole. At a minimum, these public health standards require FDA to determine that allowing the new tobacco product marketing will produce harm reductions (e.g., from prompting smokers to switch to the less-harmful product) which are larger than any new related health harms (e.g., from increasing youth use or prompting smokers to switch instead of quitting all use). Because of the inevitable uncertainties when trying to predict how new tobacco product marketing will affect future consumer behavior and health, the TCA gives FDA considerable discretion as to how it will administer the PMTA and MRTP procedures to protect the public health. As this article explains, however, FDA has failed to exercise that discretion appropriately, and has violated the TCA's public health standard and other applicable laws in the permissive PMTA and MRTP orders it has issued to date.

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In particular, the permissive PMTA and MRTP orders FDA has issued have: (a) failed to explain how FDA is interpreting and applying the TCA's public health standard; (b) were not sufficiently comprehensive or rigorous to support a reasonable determination that the orders were "appropriate for the protection of the public health" under any possible interpretation of the standard; and (c) failed to include readily available restrictions and requirements on the products and their labeling, marketing, and sale in the final orders to prevent unnecessary individual and public health harms and risks.

These orders and FDA's Final PMTA Guidance regarding e-cigarettes and Proposed PMTA Rule indicate that these agency failings could continue in the future; and the stakes are high. Numerous applications for new PMTA and MRTP orders are already pending, and FDA will be facing a wave of new applications to meet a court-ordered deadline for all e-cigarettes and certain other tobacco products currently on the U.S. market to apply for PMTA orders. If FDA does not begin to comply with applicable legal standards and act more responsibly to protect the public health, it could be forced to do so. Based on the analysis presented here, successful legal challenges could come either from members of the tobacco industry legally challenging permissive orders given to their competitors or from public health groups that want to strike down any PMTA or MRTP orders that directly cause unnecessary health harms or risks.

I. BACKGROUND

Under the Tobacco Control Act (TCA), no new or substantially changed tobacco products, including any new or substantially changed individual brands or sub-brands, that were not on the U.S. market on February 15, 2007 may be legally marketed or sold in the United States unless they first obtain an order from FDA allowing them on the market.¹ To secure a permissive order, the tobacco product manufacturer (or importer) must either submit an application establishing that the product is "substantially equivalent" to a product that was legally on the U.S. market on February 15, 2007,² or must submit a Premarket Tobacco Product Application (PMTA) and secure an order from FDA finding that it would be "appropriate for the protection of the public health" to allow the new or substantially changed tobacco product to be marketed in the United States.³ The TCA's PMTA provisions were designed, primarily, to prevent any

1. Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111-31 [hereinafter TCA], sec. 1, tit. I, § 101-110, 123 Stat. 1776, 1783-1857 (2009) (codified at 21 U.S.C. § 387-387t (2012)). Title I of the Family Smoking and Tobacco Control Act amends the Food, Drug, and Cosmetic Act (FDCA). *Id.*

2. *Id.* sec. 101, § 905(j) (codified at 21 U.S.C. § 387e(j)).

3. *Id.* sec. 101, § 910(c) (codified at 21 U.S.C. § 387j(c)).

new types or variants of tobacco products appearing in the U.S. market that could increase public health harms.⁴

Initially, only cigarettes, smokeless tobacco products, and roll-your-own tobacco for cigarette smoking, and reduced-risk claims relating to those products, were subject to the TCA.⁵ But the TCA empowered FDA to “deem” any or all other tobacco products to be under its tobacco control jurisdiction, as well, and FDA issued a rule to do that, effective August 8, 2016.⁶ Because of other provisions in the TCA, all the newly deemed cigars, pipe tobaccos, e-cigarettes, and other nicotine-based tobacco products that had not been on the U.S. market as of February 15, 2007 immediately became new tobacco products that required a permissive new product order to stay on market legally.⁷ To address this odd situation, FDA’s Deeming Rule announced that it would exercise its enforcement discretion to allow these products to stay on the market so long as they submitted substantial equivalence (SE) applications by February 10, 2018 or PMTA applications by August 10, 2018.⁸ FDA later extended those deadlines to August 10, 2022 for SE or PMTA applications for e-cigarettes and August 2021 for SE or PMTA applications for the newly deemed combustible products.⁹ However, in response to a lawsuit by a collection of public health groups, a federal district court in May 2019 issued an order rejecting FDA’s general policy of not requiring new product applications from the newly deemed tobacco products until 2022 or 2021 as an improper use of agency enforcement discretion.¹⁰ The court subsequently ordered that the SE or PMTA applications must be submitted no later than May 12, 2020, which was later extended to September 9, 2020, with FDA generally required to rule on the applications within a year of receipt.¹¹

4. *Id.* § 3 (highlighting the purpose of the TCA, including to ensure oversight of the development and introduction of tobacco products).

5. *See id.* sec. 101, § 901(b) (codified at 21 U.S.C. § 387a(b)) (defining the applicability of the FDA’s authority).

6. *Id.*; FDA Deeming Rule, 81 Fed. Reg. 28,974 (May 10, 2016) (codified at 21 C.F.R. §§ 1100, 1140, 1143).

7. *See* FDA Deeming Rule, 81 Fed. Reg. at 28,977, 29,009–10.

8. *Id.* at 28,974, 29,011.

9. U.S. FOOD & DRUG ADMIN., EXTENSION OF CERTAIN TOBACCO PRODUCT COMPLIANCE DEADLINES RELATED TO THE FINAL DEEMING RULE: GUIDANCE FOR INDUSTRY i, 9 (2019), <https://www.fda.gov/media/105346/download>. It also appears that FDA is exercising its enforcement discretion not to take any action against a number of new and substantially changed e-cigarettes that have appeared on the market since the Deeming Rule went into effect. While the FDA has acknowledged this widespread issue, it has not stated or explained any such enforcement discretion policy in any public statements or formal documents. *See, e.g.*, Press Release, Campaign for Tobacco-Free Kids, Leading Health Groups Urge FDA to Stop Sales of New, Juul-Like E-Cigarettes Illegally Introduced Without Agency Review (Aug. 7, 2018), www.tobaccofreekids.org/press-releases/2018_08_07_new_ecig_products.

10. *Am. Acad. of Pediatrics v. FDA*, 379 F. Supp. 3d 461, 497–98 (D. Md., 2019).

11. *Am. Acad. of Pediatrics v. FDA*, 399 F. Supp. 3d 479, 487 (D. Md., 2019); *appeal dismissed as moot*, In re Cigar Ass’n of Am., 2020 U.S. App. LEXIS 14205 (4th Cir. May 4, 2020); *see also* FDA News Release, U.S. Food & Drug Admin., *Coronavirus (COVID-19) Update: Court Grants FDA’s*

Because of the difficulty in finding a substantially equivalent e-cigarette that was on the U.S. market on February 15, 2007 which might support an SE application, FDA expects that e-cigarette manufacturers will submit PMTA applications.¹² Although FDA does not publicly disclose all PMTA submissions, some PMTAs for major e-cigarette brands have already been submitted since the court issued its order.¹³ While the e-cigarettes illegally on the U.S. market have been generally free from any enforcement efforts for failing to have required new product orders, FDA has initiated enforcement actions against some e-cigarettes for violating other TCA requirements.¹⁴ Because of continued increases in youth use of e-cigarettes, in September 2019, President Trump and FDA announced that, to prevent youth use, the agency would soon begin exercising its discretion to take enforcement action, before the September application deadline, against any e-cigarettes on the market without a permissive PMTA or SE order that have any added flavors.¹⁵ But in response to industry and user pressure, President Trump changed his mind, and FDA subsequently announced that it will remove

Request for Extension of Premarket Review Submission Deadline for Certain Tobacco Products Because of Impacts from COVID-19, Food & Drug Admin. (Apr. 23, 2020), <https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-court-grants-fdas-request-extension-premarket-review-submission-deadline>.

12. See, e.g., U.S. FOOD & DRUG ADMIN., *PREMARKET TOBACCO PRODUCT APPLICATIONS FOR ELECTRONIC NICOTINE DELIVERY SYSTEMS: GUIDANCE FOR INDUSTRY* (2019), <https://www.fda.gov/media/127853/download> [hereinafter *Final PMTA Guidance*]. Many cigars and pipe tobacco products, however, will be able to submit SE applications, as there were numerous cigar and pipe tobacco products on the market on February 15, 2007 that could be used as SE predicates. However, it would be extremely difficult, if not impossible, for any addictive cigar or other smoked tobacco product that could not secure an SE order (e.g., cigars or pipe tobacco with flavors or other product characteristics not on the market in 2007) to secure a PMTA order, instead. That would require a showing that allowing the addictive, smoked cigar on the market would be “appropriate for the protection of the public health.” See *id.* at 11–16. Yet it is hard to imagine any way a cigar could be smoked that could significantly reduce health harms among existing smokers, much less new initiates, or any way a cigar’s marketing could reduce overall smoking or otherwise produce a net public health gain.

13. See, e.g., Press Release, Reynolds Am. Inc., Reynolds American Inc. Submits Premarket Tobacco Product Application for VUSE products (Oct. 11, 2019), <https://www.prnewswire.com/news-releases/reynolds-american-inc-submits-premarket-tobacco-product-application-for-vuse-products-300937224.html> (stating that Reynolds American submitted a PMTA for its VUSE e-cigarette product). See also *Premarket Tobacco Product Marketing Orders*, U.S. FOOD & DRUG ADMIN., www.fda.gov/tobacco-products/premarket-tobacco-product-applications/premarket-tobacco-product-marketing-orders (last visited July 15, 2020) (listing FDA’s issued premarket tobacco product marketing orders); see also *Marketing Orders for SE*, U.S. FOOD & DRUG ADMIN., www.fda.gov/tobacco-products/substantial-equivalence/marketing-orders-se (last visited July 15, 2020) (listing FDA’s issued substantial equivalence marketing orders).

14. See, e.g., *Warning Letters and Civil Money Penalties Issued to Retailers for Selling JUUL and Other E-Cigarettes to Minors*, U.S. FOOD & DRUG ADMIN., www.fda.gov/tobacco-products/ctp-newsroom/warning-letters-and-civil-money-penalties-issued-retailers-selling-juul-and-other-e-cigarettes (last visited July 15, 2020).

15. See Press Release, U.S. Food & Drug Admin., *Trump Administration Combating Epidemic of Youth E-Cigarette Use with Plan to Clear Market of Unauthorized, Non-Tobacco-Flavored E-Cigarette Products* (Sept. 11, 2019), <https://www.fda.gov/news-events/press-announcements/trump-administration-combating-epidemic-youth-e-cigarette-use-plan-clear-market-unauthorized-non>.

from the market only those e-cigarettes without permissive PMTA orders that are cartridge-based (such as Juul e-cigarettes) and have flavors other than menthol or tobacco.¹⁶

As of July 2020, FDA has considered only a small number of PMTAs and granted permissive PMTA orders for: (1) eight similar Swedish Match snus smokeless tobacco products, (2) a Philip Morris IQOS “heat-not-burn” tobacco products system with several different types of IQOS heatsticks, and (3) two 22nd Century Group very-low-nicotine cigarettes.¹⁷ Hundreds of applications for additional PMTA orders are pending,¹⁸ and hundreds more will likely be submitted by the court-ordered deadline, even if applications were submitted for only a fraction of the thousands of different brands, sub-brands, and variants of e-cigarettes and e-cigarette liquids currently sold in the United States.¹⁹

It is also possible that some of the e-cigarette products submitting PMTAs will also submit modified-risk-tobacco-product (MRTP) applications to obtain FDA permission to make reduced-risk or reduced-exposure claims in their labeling or advertising.²⁰ To issue a permissive MRTP order, FDA must determine, first, that using the proposed e-cigarette instead of the comparison

16. See Annie Karni et al., *Trump Retreats From Flavor Ban for E-Cigarettes*, N.Y. TIMES (Nov. 17, 2019), <https://www.nytimes.com/2019/11/17/health/trump-vaping-ban.html> (describing the political pressure put on the President causing him to retract his prior commitment); see also 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> (noting statements made by Trump officials declaring that FDA regulation of tobacco is a “waste of time”); see also *User Clip: Joe Grogan – White House Domestic Policy Council – Discusses e-cigarette Regulation* (CSPAN television broadcast clip Nov. 8, 2019), <https://www.c-span.org/video/?c4828413/user-clip-joe-grogan-white-house-domestic-policy-council> (discussing growing issues revolving around e-cigarette regulation); U.S. FOOD & DRUG ADMIN., *Guidance Document: Enforcement Priorities for Electronic Nicotine Delivery System (ENDS) and Other Deemed Products on the Market Without Premarket Authorization, Guidance for Industry* (April 2020), <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-priorities-electronic-nicotine-delivery-system-ends-and-other-deemed-products-market>.

17. *Premarket Tobacco Product Marketing Orders*, *supra* note 13. The Philip Morris of the IQOS PMTA is Philip Morris Products S.A., a subsidiary of Philip Morris International (PMI). IQOS will be distributed in the United States through an agreement between PMI and Altria Client Services LLC (Altria), whereby Altria and its Philip Morris USA subsidiary are licensed to distribute and sell IQOS in the U.S.

18. *Tobacco Product Marketing Orders*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/tobacco-products/market-and-distribute-tobacco-product/tobacco-product-marketing-orders>.

19. See Shu-Hong Zhu et al., *Four Hundred and Sixty Brands of E-cigarettes and Counting: Implications for Product Regulation*, 23 TOBACCO CONTROL iii3 (2014) <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4078673/pdf/tobaccocontrol-2014-051670.pdf>; Greta Hsu et al., *Evolution of Electronic Cigarette Brands From 2013-2014 to 2016-2017: Analysis of Brand Websites*, 20 J. MED. INTERNET RES. e80 (2018) <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5869180/?report=classic>.

20. See *Modified Risk Tobacco Products*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/tobacco-products/advertising-and-promotion/modified-risk-tobacco-products#Overview> (last visited July 15, 2020).

product (e.g., regular cigarettes) will actually significantly reduce user health harms or risks or reduce exposure to the specified harmful or potentially harmful constituents (e.g., nitrosamines, acrolein, naphthalene); and, second, that allowing the MRTP e-cigarette on the market with the claim will “benefit the health of the population as a whole” (relative-risk claims) or be “appropriate to promote the public health” (relative-exposure claims).²¹ These MRTP public health standards directly parallel the appropriate-for-the-protection-of-the-public-health standard that applies to PMTA orders, with all of them focusing exclusively on the impacts of the regulatory action on the health risks and harms of the population as a whole, taking into account both users of tobacco products and persons who do not currently use tobacco products, and also considering other behavioral impacts.²²

No MRTP applications have yet been submitted for any e-cigarettes.²³ However, FDA issued its first permissive MRTP order, for the Swedish Match snus, in October 2019, and a second permissive MRTP order, for the PMTA IQOS products, in July 2020, and additional MRTP applications are pending for Copenhagen moist snuff smokeless tobacco products, Camel snus, and 22nd Century Group’s very-low-nicotine cigarettes.²⁴

21. TCA, Pub. L. No. 111-31, sec. 101, § 911(g), 123 Stat. 1776 (2009) (codified at 21 U.S.C. § 387k(g) (2012)). To issue a permissive MRTP order, FDA must also make some other secondary or related findings. *Id.*

22. *See id.* (regarding the standard as it applies to MRTP orders; *cf. id.* § 910(c)(4) (codified at § 387j(c)(4)) (regarding the standard as it applies to PMTA orders); Eric N. Lindblom, *What Is ‘Appropriate for the Protection of the Public Health’ Under the U.S. Tobacco Control Act*, 74 FOOD & DRUG L. J. 523, 532 (June 2020). If anything, the standard for issuing MRTP orders requires even stronger likelihoods of producing solid public gains than for PMTA orders because of the MRTP text’s reference to how allowing the MRTP must “benefit” the health of the population as a whole or “promote” the public health, while the PMTA text says that PMTA orders must only be “appropriate” for “protecting” the public health. For simplicity’s sake, this paper will refer to the public health standards that apply to PMTA and MRTP orders, collectively, as AFPPH, except when any differences in the statutory text becomes relevant to the paper’s analysis.

23. *See Modified Risk Tobacco Products*, *supra* note 20.

24. *See id.*; *Modified Risk Orders*, U.S. FOOD & DRUG ADMIN., www.fda.gov/tobacco-products/advertising-and-promotion/modified-risk-orders (last visited July 15, 2020). A single Order Letter covers all the MRTP Swedish Match snus, allowing them to be marketed with the following reduced-risk claim: “Using General Snus instead of cigarettes puts you at a lower risk of mouth cancer, heart disease, lung cancer, stroke, emphysema, and chronic bronchitis.” Modified Risk Granted Orders – Risk Modification, Letter from Matthew R. Holman, Dir., Office of Sci., Ctr. for Tobacco Prods., to Gerard Roerty, Vice President, Swedish Match USA, Inc. (Oct. 22, 2019), <https://www.fda.gov/media/131922/download> [hereinafter Snus MRTP Order]. Another single Order Letter covers all the IQOS products allowing them to be marketed with reduced exposure (but not reduced risk) claims. Modified Risk Granted Orders—Exposure Modification, Letter from Matthew R. Holman, Dir., Office of Sci., Ctr. for Tobacco Prods., to Philip Morris Products, S.A. (July 7, 2020), <https://www.fda.gov/media/139797/download> [hereinafter IQOS MRTP Order].

II. WHAT LEGAL STANDARDS APPLY TO PMTA AND MRTP APPLICATIONS?

When FDA evaluates PMTA or MRTP applications to determine whether issuing a permissive order would be “appropriate for the protection of the public health” (AFPPH), it is clear from the Tobacco Control Act that FDA may consider only the order’s impact on the public health (i.e., on the health risks and harms to the population as a whole).²⁵ Non-health impacts are not directly relevant.²⁶ Evaluating possible public health impacts necessarily includes FDA’s consideration of how the availability and marketing of the new PMTA or MRTP products might influence youth and adult tobacco-product initiation, cessation, switching, dual use, consumption levels, relapse, and other related behaviors that have public health consequences.²⁷ However, any impacts on illicit trade, government or industry costs and other burdens, or personal autonomy could be relevant to FDA’s related AFPPH determinations only to the extent that they also produced public health consequences.²⁸

By requiring FDA to focus exclusively on the health harms and risks to the population *as a whole*, the Act also does not allow FDA to give more weight to health harms or harm reductions experienced by youths compared to those experienced by adults when determining net public health impacts.²⁹ Nor does the Act allow FDA to give more weight to health harms or harm reductions among any specific sub-populations or disadvantaged groups compared to others.³⁰ For FDA’s AFPPH determinations, the overriding concern must be the net impact on the health risks and harms to the population *as a whole*.³¹ But the impacts of a PMTA or MRTP order on the health harms and risks of youth, other

25. TCA sec. 101, § 911(g) (codified at 21 U.S.C. § 387k(g)); *id.* sec. 101, § 910(c)(4) (codified at § 387j(c)(40)).

26. *Id.*; Lindblom, *supra* note 22, at 533–34, 540.

27. TCA sec. 101, § 911(g)(4) (codified at 21 U.S.C. § 387k(g)(4)); *id.* sec. 101, § 910(c)(4) (codified at 21 U.S.C. § 387j(c)(4)).

28. Lindblom, *supra* note 22, at 541.

29. *Id.* at 546. In an Appendix to the Decision Summary for its PMTA Order allowing the IQOS tobacco products onto the U.S. market, FDA refers to “FDA’s statutory mandate to protect young people from the dangers of tobacco use,” but FDA cites no sources and does not state whether it interprets the statute as placing a higher priority on reducing health harms to youth than reducing health harms to adults. U.S. FOOD & DRUG ADMIN., No. PM0000424–PM0000426, PM0000479, PMTA COVERSHEET: TECHNICAL PROJECT LEAD REVIEW (TPL) 111, 120 (2019), <https://www.fda.gov/media/124247/download> [hereinafter IQOS PMTA Decision Summary]. Nor has FDA elsewhere attempted to provide any reasoned interpretation of the AFPPH standard that would place a greater priority on preventing and reducing harms to youth compared to harms to adults; and the TCA does not appear to create any such priority or directly allow it. Lindblom, *supra* note 22, at 547–49. However, preventing a youth from ever becoming a regular tobacco product user will, on average, prevent considerably more harm than the harm reductions secured by prompting an adult user of the same type of tobacco product to quit all use, given that the adult user has already been harmed by that tobacco use.

30. Lindblom, *supra* note 22, at 543–46.

31. *Id.* at 546.

vulnerable subpopulations, disadvantaged subpopulations, and other subpopulations are all relevant to the extent they factor into determining the overall impact on the health of the population as a whole.³²

Despite these limits on what FDA may consider, making AFPPH determinations can be complicated when it is not clear how harmful the use of the new PMTA or MRTP products will be to brand-new youth or adult tobacco product users, those who switch from using other tobacco product use, dual users, or users of multiple tobacco-nicotine products, both generally and in comparison to other types of tobacco use. Another major complication comes from the inescapable uncertainties in predicting how the manufacturers will market the new PMTA or MRTP tobacco products in the future, how other industry members will respond, how that marketing will affect youth and adult user and nonuser behaviors, and how those future behavior changes will impact the individual health of users and exposed nonusers and, consequently, the public health.

Moreover, even if FDA developed a reasonable way to make these necessary estimates of future health impacts, the TCA does not tell FDA whether issuing a permissive PMTA or MRTP could still be AFPPH if FDA determines that allowing the new products on the market is likely to create a net public health gain but will also produce brand-new individual or subpopulation health harms or will also create a risk of producing a negative net public health impact. Even if we assume that the TCA's silence in this regard could, in some situations, allow a new PMTA or MRTP product on the market even when FDA determined it would produce some new health harms or create a risk of a negative net impact on the public health, the Act is silent as to how large the likelihood and size of the expected public health gains from allowing the new product on the market would have to be to make incurring those new harms or running the risk of new net public health harms AFPPH.

These complications are simplified somewhat by the fact that the TCA through its silences and ambiguities leaves FDA with substantial discretion to determine how it will interpret and apply the AFPPH standard (within the framework established by the TCA), and how it will handle the significant

32. *See id.* at 546, 549. As discussed more fully below, impacts on vulnerable or disadvantaged subpopulations could also become relevant to AFPPH determinations when FDA is deciding whether the expected net public health gains from a PMTA or MRTP order are worth running a related risk of producing a negative net public health impact, instead (e.g., if the harms from the possible negative impact would be centered primarily on vulnerable or disadvantaged subpopulations while the expected health gains are centered primarily on more advantaged subpopulations). Similarly, a PMTA or MRTP order that might qualify as AFPPH under the TCA's population-as-a-whole criteria could still be legally invalid if its negative impacts on health disparities or inequities, its health impacts on specific subpopulations, or its negative non-health impacts, were so large and disproportionate that they made the order "arbitrary or capricious" under the Administrative Procedure Act despite its expected net public health gains. *See* TCA sec. 101, § 912(b) (codified at 21 U.S.C. § 3871(b)); Administrative Procedure Act 5 U.S.C. § 706(2)(A) (1966).

uncertainties inherent in trying to determine what public health and other relevant impacts might be produced by the marketing of a tobacco product receiving a permissive PMTA or MRTP order.³³

Under the Administrative Procedure Act (APA), however, any such FDA actions must not be “arbitrary or capricious, or an abuse of discretion.”³⁴ Accordingly, an FDA interpretation of the AFPPH standard or an FDA determination that a PMTA or MRTP order was AFPPH could be struck down if a court determined that the FDA process for making that interpretation or determination was seriously flawed or the end result was irrational, incomprehensible, or clearly wrong.³⁵ In addition, an otherwise AFPPH PMTA or MRTP order could also be found “arbitrary or capricious” if FDA failed to take advantage of readily available means to modify the order to avoid or reduce any unnecessary individual or public health harms or risks, or to reduce certain undesirable non-health costs (at least when that could be done without also disproportionately reducing the likelihood or size of the desired net public health gains).³⁶ Beyond that, the APA places very few constraints on how FDA might exercise its discretion under the TCA, as long as FDA follows any statute-required procedures; considers relevant available evidence and analysis, including contrary facts, analyses, and alternatives; and provides a reasonable explanation for its decisions.³⁷

33. See *Utility Air Regulatory Grp. v. EPA*, 573 U.S. 302, 326 (2014) (“Agencies exercise discretion only in the interstices created by statutory silence or ambiguity”); *United States v. Bean*, 537 U.S. 71, 77 (2002) (“the ‘public interest’ standard calls for an inherently policy-based decision best left in the hands of an agency”); *Chevron v. Nat. Res. Def. Council*, 467 U.S. 837, 843 (1984) (“Rather, if the statute is silent or ambiguous with respect to the specific issue, the question for the court is whether the agency’s answer is based on a permissible construction of the statute”); *WildEarth Guardians v. EPA*, 728 F.3d 1074, 1082 (10th Cir. 2013) (explaining an agency “is entitled to considerable judicial deference”). See also Lindblom, *supra* note 22, at 550–51.

34. Administrative Procedure Act 5 U.S.C. § 706(2)(A) (1966); TCA sec. 101, § 912(b) (codified at 21 U.S.C. § 3871(b)).

35. See *Fed. Energy Regulatory Comm’n v. Elec. Power Supply Ass’n*, 136 S. Ct. 760, 782 (2016) (stating that agency must examine relevant considerations and articulate a satisfactory explanation for its actions, showing a rational connection between the facts found and the choice made); *Nat’l Ass’n of Home Builders v. Defenders of Wildlife*, 551 U.S. 644, 658–59 (2007) (explaining that an agency can change its mind throughout the rulemaking process so long as proper procedures were followed and its rationale can be followed); *Associated Fisheries of Maine, Inc. v. Daley*, 127 F.3d 104, 110 (1st Cir. 1997) (discussing whether the decision of the Secretary of Commerce “exercised his discretion in an irrational, mindless, or whimsical manner”); *U.S. Dep’t of Justice Fed. Bureau of Prisons Fed. Corr. Complex v. Fed. Labor Relations Auth.*, 737 F.3d 779, 785 (D.C. Cir. 2013) (clarifying that a court reviewing an agency’s action must consider if the decision was an unexplained departure from previous agency action, how coherent the decision was, and whether deference is owed to the agency’s expertise). See generally Lindblom, *supra* note 22.

36. See *State of La. ex rel. Guste v. Verity*, 853 F.2d 322, 331 (5th Cir. 1988); *S. Terminal Corp. v. EPA*, 504 F.2d 646, 655–56, 676 (1st Cir. 1974). See Lindblom, *supra* note 22, at 568.

37. See *Fed. Energy Regulatory Comm’n v. Elec. Power Supply Ass’n*, 136 S. Ct. at 782. 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*,

For example, FDA might reasonably determine that a permissive PMTA or MRTP order could not be AFPPH if it would produce large new individual or subpopulation health harms (even if it would produce larger net public health gains) or if it created a significant risk of producing a non-trivial net increase in public health harms (even if it were more likely to create a net public health gain) – so long as FDA explained the basis for its decision and showed that it had considered contrary evidence and analysis. Or FDA might follow the same process to make a reasonable determination that an order is AFPPH so long as the likelihood and size of its expected net public health benefit were at least some multiple larger than both any new health harms it might cause and the likelihood and size of any possible negative public health impact. However, even if FDA clearly explained its reasoning and showed that it had considered contrary positions, it is likely the courts would still find FDA “arbitrary or capricious” if FDA’s conclusion contradicted common sense (e.g., if FDA determined that a permissive PMTA or MRTP order could be AFPPH even if it were just as likely or more likely to create a negative net public health impact as a comparable or smaller positive one).³⁸

So far, however, FDA has not taken any public action to fill in the gaps in the AFPPH standard left by the statute, either generally or as it relates to PMTA or MRTP orders.³⁹ Nor has FDA clearly explained how it is applying the AFPPH standard when evaluating PMTA or MRTP applications or issuing related orders, much less provide a reasoned justification for its interpretation and application of the standard in the documentation relating to the orders it has issued.

No matter how FDA (or the courts) ultimately refine or clarify the AFPPH standard in the context of PMTA or MRTP orders, FDA would need to develop viable estimates of the likelihood and size of the different possible net public health impacts a permissive order might produce to determine whether issuing it meets the AFPPH standard. At a minimum, FDA would need to determine whether, under any reasonably possible worst-case scenario, the availability and

526 F.2d 1027, 1047 (3rd 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”) (citing *Bowman Transp., Inc. v. Arkansas-Best Freight System, Inc.*, 419 U.S. 281, 286 (1974)). *But see* *Encino Motorcars, LLC v. Navarro*, 136 S. Ct. 2117, 2127 (2016) (“It 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.”) (quoting *Motor Vehicle Mfrs. Ass’n, Inc. v. State Farm Mutual Auto. Ins. Co.*, 463 U.S. 29, 43 (1983)); *Judulang v. Holder*, 565 U.S. 42, 53 (2011) (“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 error of judgment.’ That task involves examining the reasons for agency decisions—or, as the case may be, the absence of such reasons.”) (quoting *Motor Vehicle Mfrs. Ass’n* 463 U.S. 29 at 43) (internal citations omitted).

38. *See* Lindblom, *supra* note 22, at 570–71.

39. *Id.* at 573–77.

marketing of the product might produce a non-trivial negative net public health impact. Assuming that the standard will be interpreted to allow at least some risk of a net public health loss, FDA would then need to determine whether issuing a permissive order would produce a sufficiently higher likelihood of producing a large-enough net public health gain to make running the risk of the new public health loss AFPPH.⁴⁰

The inherent difficulties in predicting future industry and consumer behavior, coupled with gaps in available research, make developing precise reliable estimates of the future public health impacts from issuing a permissive PMTA or MRTP order difficult, if not impossible. Despite these challenges, FDA could reasonably exercise its discretion to rely on any reasonable process for estimating the range of reasonably possible future health impacts – based on available or readily developed evidence and expertise – that would be highly likely to keep not-AFPPH products off the market while still allowing AFPPH products on. For example, FDA might reasonably determine that using mortality impacts or using impacts on quality adjusted life years (QALYs) is a valid proxy for quantifying public health impacts, and that it is reasonable to project those impacts through using relevant experts' evidence-based worst-case, best-case, and most-likely-case estimates relating to product harmfulness, possible harm-increasing consumer uses, and possible consumer harm-reducing uses, including considerations of different ways the industry might respond.⁴¹ FDA might then develop these estimates informally by having its own tobacco control experts or hired outside experts review available relevant data, research, and analysis to develop conclusions regarding the likelihood and size of the permissive order's worst possible public health impact and, if negative, compare those estimates to their conclusions about the likelihood and size of the potential positive impacts. Or the estimates could be developed through more formal modeling, with expert elicitations or other reasonable procedures to develop any of the model's needed inputs that have uncertain values which could not otherwise be reasonably quantified.⁴²

40. It is theoretically possible that the worst-case scenario for some permitted PMTA or MRTP tobacco products would not be negative (i.e., that issuing certain PMTA or MRTP orders could not possibly produce a negative net public health impact). But issuing a permissive order for an addictive tobacco product that causes any non-trivial health risks and harms to users would almost certainly produce at least some risk of producing net public health harms because of the powerful incentives for manufacturers to maximize sales. Further, permitting a new product could produce net public health harms because anyone using less-harmful products may switch completely to the new, more-harmful product and would not have otherwise quit or switched.

41. For examples of such modeling, see, e.g., John La Puma & Edward F. Lawlor, *Quality-Adjusted Life-Years: Ethical Implications for Physicians and Policymakers*, 263 JAMA 2917 (1990); Yves Arrighi et al., *To Count or Not to Count Deaths: Reranking Effects in Health Distribution Evaluation*, 24 HEALTH ECON. 193, 194 (2015).

42. For examples of such modeling, see M. Granger Morgan, *Use (and Abuse) of Expert Elicitation in Support of Decision Making for Public Policy*, 111 PROC. NAT'L ACAD. SCI. USA 7176 (2014)

As discussed below, however, the permissive PMTA and MRTP orders FDA issued so far do not indicate that FDA has taken any of these types of actions when making its AFPPH determinations.⁴³ Nor has FDA issued any publicly available proposed or final rules or other materials indicating that it will necessarily do so when evaluating and issuing future PMTA or MRTP orders.⁴⁴

To be more transparent, create a stronger substantive and legal foundation for its regulatory actions, and provide needed guidance to tobacco-product manufacturers, tobacco control researchers, and other interested parties, FDA should clearly articulate and explain its concept of the AFPPH standard and its remaining gray areas. In particular, FDA should explain whether it has determined that it could be AFPPH to allow a new tobacco product on the market if it also creates new health harms or any significant risk of producing a net increase in health harms to the population as a whole. If so, FDA should also explain, in at least general terms, how much larger the likelihood and size of the potential net public health gains need to be compared to the new health harms or to the risk and size of the possible net public health harms to make the product's marketing AFPPH. Going further, FDA should explain what specific procedures it has determined can reasonably be used to develop viable estimates of the possible future behavioral and health impacts from issuing permissive PMTA or MRTP orders that FDA can and will use to evaluate and determine whether permitting a tobacco products' marketing would be AFPPH and not "arbitrary or capricious."

As detailed below, FDA's failure to provide these clarifications and explanations makes each of the permissive PMTA and MRTP orders it has issued to date highly vulnerable to legal challenges that could prompt the courts to strike down the orders as "arbitrary or capricious" or not AFPPH.

(discussing the value in scientific and technical judgments from experts in public policy decision making); 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 (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 (2011).

43. See *Premarket Tobacco Product Marketing Orders*, *supra* note 13 (providing information on all PMTA orders FDA has issued); see also *Modified Risk Orders*, *supra* note 20 (providing information on all MRTP orders issued by FDA).

44. Although FDA has issued a final guidance and a proposed rule relating to PMTAs, neither requires any of the types of modeling or estimated projections of possible health impacts discussed here nor indicates that FDA will do such modeling, itself. Final PMTA Guidance, *supra* note 12; Premarket Tobacco Product Applications and Recordkeeping Requirements, 84 Fed. Reg. 50,556 (Sept. 25, 2019) (to be codified at 21 C.F.R. pts. 1100, 1107, 1114) [hereinafter Proposed PMTA Rule].

III. FDA HAS FAILED TO EXPLAIN OR JUSTIFY HOW IT IS INTERPRETING AND APPLYING THE AFPPH STANDARD WHEN EVALUATING NEW PRODUCT ORDERS AND ISSUING PMTA ORDERS

FDA has not yet publicly disclosed any deliberative effort it has made to clarify the gray areas left by the Tobacco Control Act, nor has FDA explained with any specificity how it has interpreted and applied the AFPPH standard, or its gray areas, in any of the permissive PMTA or MRTP orders it has issued to date.⁴⁵ All FDA does, explicitly, in the PMTA and MRTP decision summaries

45. FDA's order letters, decision summaries, and other documentation for each of the permissive PMTA orders it has issued – are available at the FDA website. *Premarket Tobacco Product Marketing Orders supra* note 13. The Decision Summary for each of the Swedish Match snus is contained in the same document. U.S. FOOD & DRUG ADMIN., NO. PM0000010-PM0000017, PREMARKET TOBACCO APPLICATION (PMTA) TECHNICAL PROJECT LEAD (TPL) REVIEW, 1–3, 8 (2015), <https://www.fda.gov/media/94582/download> [hereinafter Snus PMTA Decision Summary] (providing little AFPPH analysis or explanation). The letter orders for each of the eight snus products are slightly different, however none provide any explanation or analysis of the AFPPH finding. While each of these letters are slightly different, for purposes of this article, the marketing order for PM0000010 will serve as an example representative of the other Snus PMTA Orders. Marketing Order Letter No. PM0000010 from David Ashley, Dir., Office of Sci., Ctr. for Tobacco Prods., U.S. Food & Drug Admin., to Gerard Roerty, Vice President, Swedish Match USA, Inc. (2015), <https://www.fda.gov/media/94616/download> [hereinafter Snus PMTA Order]. *See also* Marketing Order Letter No. PM0000011 from David Ashley, Dir., Office of Sci., Ctr. for Tobacco Prods., U.S. Food & Drug Admin., to Gerard Roerty, Vice President, Swedish Match USA, Inc. (2015), <http://wayback.archive-it.org/7993/20180127062338/https://www.fda.gov/downloads/TobaccoProducts/Labeling/TobaccoProductReviewEvaluation/UCM472133.pdf>; Marketing Order Letter No. PM0000012 from David Ashley, Dir., Office of Sci., Ctr. for Tobacco Prods., U.S. Food & Drug Admin., to Gerard Roerty, Vice President, Swedish Match USA, Inc. (2015), <http://wayback.archive-it.org/7993/20180127062340/https://www.fda.gov/downloads/TobaccoProducts/Labeling/TobaccoProductReviewEvaluation/UCM472134.pdf>; Marketing Order Letter No. PM0000013 from David Ashley, Dir., Office of Sci., Ctr. for Tobacco Prods., U.S. Food & Drug Admin., to Gerard Roerty, Vice President, Swedish Match USA, Inc. (2015), <http://wayback.archive-it.org/7993/20180127062342/https://www.fda.gov/downloads/TobaccoProducts/Labeling/TobaccoProductReviewEvaluation/UCM472137.pdf>; Marketing Order Letter No. PM0000014 from David Ashley, Dir., Office of Sci., Ctr. for Tobacco Prods., U.S. Food & Drug Admin., to Gerard Roerty, Vice President, Swedish Match USA, Inc. (2015), <http://wayback.archive-it.org/7993/20180127062345/https://www.fda.gov/downloads/TobaccoProducts/Labeling/TobaccoProductReviewEvaluation/UCM472138.pdf>; Marketing Order Letter No. PM0000015 from David Ashley, Dir., Office of Sci., Ctr. for Tobacco Prods., U.S. Food & Drug Admin., to Gerard Roerty, Vice President, Swedish Match USA, Inc. (2015), <http://wayback.archive-it.org/7993/20180127062347/https://www.fda.gov/downloads/TobaccoProducts/Labeling/TobaccoProductReviewEvaluation/UCM472140.pdf>; Marketing Order Letter No. PM0000016 from David Ashley, Dir., Office of Sci., Ctr. for Tobacco Prods., U.S. Food & Drug Admin., to Gerard Roerty, Vice President, Swedish Match USA, Inc. (2015), <http://wayback.archive-it.org/7993/20180127062349/https://www.fda.gov/downloads/TobaccoProducts/Labeling/TobaccoProductReviewEvaluation/UCM472141.pdf>; Marketing Order Letter No. PM0000017 from David Ashley, Dir., Office of Sci., Ctr. for Tobacco Prods., U.S. Food & Drug Admin., to Gerard Roerty, Vice President, Swedish Match USA, Inc. (2015), <https://www.fda.gov/media/94633/download>. A single PMTA Decision Summary and single Order letter cover all of the subject IQOS products. IQOS PMTA Decision Summary, *supra* note 29; Marketing Order Letter Nos. PM0000424-PM0000426, PM0000479 from Matthew Holman, Dir., Office of Sci., Ctr. for Tobacco Prods., U.S. Food & Drug Admin., to Jeffrey Walker, Chief Exec. Officer, Teton Regulatory Scis., Philip Morris Prods. (2019),

and orders is restate the TCA text that outlines the AFPPH standard, without identifying the remaining gray areas or gaps relevant to PMTA determinations or doing anything to clarify or fill them.⁴⁶ Accordingly, FDA has either issued those permissive orders without first clarifying how the AFPPH standard should be interpreted within the framework created by the TCA and then applying it

<https://www.fda.gov/media/94616/download> [hereinafter IQOS PMTA Order]. A single Decision Summary and Order letter covers the two 22nd Century Group low-nicotine cigarettes receiving a PMTA Order. U.S. FOOD & DRUG ADMIN., Marketing Granted Order Letter Nos. PM0000491 – PM0000492 from Matthew R. Holman, Dir., Office of Sci., Ctr. for Tobacco Prods., U.S. Food & Drug Admin., to 22nd Century Group, Inc. (2020), <https://www.fda.gov/media/133635/download> [hereinafter 22nd Century PMTA Order]; U.S. FOOD & DRUG ADMIN., No. PM0000491 – PM0000492, PREMARKET TOBACCO APPLICATION (PMTA) TECHNICAL PROJECT LEAD (TPL) REVIEW (2015), <https://www.fda.gov/media/133633/download> [hereinafter 22nd Century PMTA Decision Summary]. FDA's documentation for the permissive MRTP orders it has issued are available at the FDA website. *Modified Risk Orders*, *supra* note 23. *See also* Snus MRTP Order and IQOS MRTP Order, *supra* note 24. A single MRTP Decision Summary applies to all of the Swedish Match snus products receiving MRTP orders or analysis relating to the AFPPH determination. U.S. FOOD & DRUG ADMIN. NOS. MR0000020-MR0000022, MR0000024-MR0000025, MR0000027-MR0000029, SCIENTIFIC REVIEW OF MODIFIED RISK TOBACCO PRODUCT (MRTP) APPLICATION UNDER SECTION 911 (D) OF THE FD&C ACT - TECHNICAL PROJECT LEAD (TPL) REVIEW 10–11, 45–46 (Oct. 2019), <https://www.fda.gov/media/131923/download> [hereinafter Snus MRTP Decision Summary]. A single Decision Summary also applies to all of the IQOS products receiving MRTP orders. U.S. FOOD & DRUG ADMIN., STNs MR000059–MR000061, MR0000133 SCIENTIFIC REVIEW OF MODIFIED RISK TOBACCO PRODUCT APPLICATION (MRTPA) UNDER SECTION 911(D) OF THE FD&C ACT – TECHNICAL PROJECT LEAD, (July 2020), <https://www.fda.gov/media/139796/download> [hereinafter IQOS MRTP Decision Summary].

46. For example, all of the PMTA decision summaries state: “The statute provides that the finding as to whether the marketing of a product for which a PMTA is submitted would be appropriate for the protection of the public health 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.” IQOS PMTA Decision Summary, *supra* note 29, at 11; Snus PMTA Decision Summary, *supra* note 45, at 8. *See also* 22nd Century PMTA Decision Summary, *supra* note 45 (using similar language to describe the standard). *Compare* Snus PMTA Decision Summary, *supra* note 45, at 8, *and* IQOS PMTA Decision Summary, *supra* note 29, at 11, *and* 22nd Century PMTA Decision Summary, *supra* note 45, *with* TCA, sec. 101, § 910(c)(4) (codified at § 387j(c)(4)). Along the same lines, FDA also states that “the broad overall objective of authorizing new tobacco products to be marketed through the PMTA process is to reduce the morbidity and mortality from tobacco use.” Snus PMTA Decision Summary, *supra* note 45, at 34. Much less detail regarding the AFPPH standard is provided in the final orders, and no other text in the orders or summaries explicitly offers any further clarification of the AFPPH standard. Similarly, the Decision Summary for the Swedish Match snus MRTP Order simply refers to assessing “the potential benefits and harms to 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,” without any further clarification, other than listing the various ways the product’s marketing might impact behaviors of users and nonusers with related impacts on the health of the population as a whole. *See, e.g.*, Snus MRTP Decision Summary, *supra* note 45, at 10. For similar text relating to the IQOS MRTP, *see, e.g.*, IQOS MRTP Decision Summary, *supra* note 44, at 8. For the most part, these references simply restate the statutory text or slightly paraphrase it. *Compare* Snus MRTP Decision Summary, *supra* note 45, at 10, *and* IQOS MRTP Decision Summary, *supra* note 44, *and* Snus PMTA Decision Summary, *supra* note 45, at 34, *and* 22nd Century PMTA Decision Summary, *supra* note 45, *with* TCA, sec. 101, § 911(g)(1, 4) (codified at § 387k(g)(1, 4)).

accordingly, or FDA developed or adopted its own concept of how the AFPPH standard should be interpreted and applied but has not disclosed that concept, explained the reasoning behind it, or revealed how that concept has been applied in these PMTA and MRTP determinations and orders.

At the same time, FDA's publicly released documentation for most of its permissive PMTA and MRTP orders clearly acknowledge the possibility that the marketing of the new products could or would cause some new individual health harms or could even create an overall negative net public health impact, and, therefore, might end up not being AFPPH.⁴⁷ For example, the Snus PMTA Decision Summary stated that allowing the marketing of the snus "may" decrease some individual users health risks without posing increased risk to the general population "unless use patterns change in unfavorable ways," and acknowledged a "low likelihood" that the snus marketing would increase nonuser uptake and decrease or delay cessation.⁴⁸ Similarly, the Decision Summary for the snus MRTP Order stated that although FDA's review found that the products will benefit the health of the population as a whole, that determination may change over time as a function of how the product is actually used by consumers.⁴⁹ The IQOS PMTA Decision Summary concluded that current evidence indicated that IQOS uptake among youth and nonsmokers would occur, but would be low, even though "the potential for rapid uptake of a novel tobacco product among youth exists."⁵⁰ Moreover, the IQOS PMTA and the snus MRTP orders included some specific restrictions and requirements to prevent youth use and possibly other harmful uses.⁵¹ But FDA clearly saw that the marketing of the products could still cause more individual and public health harms than FDA anticipated or expected. For example, the IQOS PMTA Order stated that compliance with its requirements "is not a guarantee that the marketing of the products will remain appropriate for the protection of the public health, particularly if, despite these measures, there is a significant uptake in youth initiation," and the snus MRTP

47. As this article was largely completed and processed prior to FDA's release of the PMTA Order for the 22nd Century Group reduced nicotine cigarettes and the IQOS MRTP Order, its analysis and illustrative examples from FDA documentation focuses primarily on the IQOS PMTA Order and the Swedish Match Snus MRTP Order, including the PMTA Order underlying the Swedish Match Snus MRTP Order. With some exceptions, this article will reference those later orders only when their documentation presents something relevant that is new or different from the others. Unfortunately, these newer orders and their underlying documentation show that FDA has continued to review PMTA and MRTP applications and issue related permissive orders with all of the same problems and flaws this paper identifies in its analysis of the agency's prior review of PMTA and MRTP applications and subsequent permissive orders.

48. Snus PMTA Decision Summary, *supra* note 45, at 36–37.

49. Snus MRTP Decision Summary, *supra* note 45, at 13, 48.

50. IQOS PMTA Decision Summary, *supra* note 29, at 76; *see also id.* at 79 ("[t]he applicant provides very little justification and no specific empirical evidence to support the assumptions that individuals who do not currently smoke cigarettes would not be interested in using the proposed products or that young people would not find them appealing").

51. IQOS PMTA Order, *supra* note 45 at 113–15; Snus MRTP Order, *supra* note 24 at 13–18.

Order has similar text.⁵² Anticipating the possibility of unexpected negative impacts, all the PMTA and MRTP orders also require a range of post-market surveillance and reporting regarding new research, consumer behaviors, and other matters 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.”⁵³

Accordingly, FDA was implicitly using an interpretation of the AFPPH standard that, in at least some situations, allows new tobacco products on the market or allows new reduced risk claims even if they could create new individual health harms or might produce a negative net impact on the overall public health. However, FDA does not provide any explanation or justification for interpreting and applying the AFPPH standard in that way. Nor does FDA otherwise clarify its interpretation of the AFPPH standard or how it applies in these specific situations. In particular, FDA has not explained in even general terms what kinds of larger likelihoods and sizes of potential net public health gain make it AFPPH to allow a new PMTA product on the market that will create new health harms and a risk of an overall negative public health impact. Nor can any such ratios or contrasts be implied or reverse engineered from the snus or IQOS PMTA orders or decision summaries, because they do not identify all the different ways the products could produce harm reductions and harm increases and do not provide any estimates or comparisons of the risk of new harms versus the likelihood of new harm reductions.⁵⁴

52. IQOS PMTA Order, *supra* note 45, at 1; Snus MRTP Order, *supra* note 24, at 2. *See also* IQOS PMTA Decision Summary *supra* note 29, at 111, 115, 116, 120 (containing similar content). The IQOS PMTA Decision Summary also states that continuing research into the compounds found at higher levels in IQOS than in conventional cigarettes and into the long-term health effects from complete and incomplete switching to IQOS would help to ensure that the continued marketing of IQOS is AFPPH. IQOS PMTA Decision Summary *supra* note 29, at 84.

53. Snus PMTA Order, *supra* note 45, at 3. *See also* IQOS PMTA Order, *supra* note 45, at 9; Snus MRTP Order, *supra* note 24, at 14 (using similar language). *See also* IQOS PMTA Decision Summary, *supra* note 29, at 111, 115, 116, 120 (raising parallel concerns of possible undesired impacts). In addition, both the Snus PMTA Orders and the IQOS PMTA Order require annual reports that include a summary of how the marketing of the tobacco products continues to be appropriate for the protection of public health. Snus PMTA Order, *supra* note 45, at 4; IQOS PMTA Order, *supra* note 45, at 9.

54. When speaking about FDA determinations to allow a new tobacco product on the market, a senior staff person from the FDA Center for Tobacco Products stated: “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[.]” however, nothing was said as to whether that potential had to be larger than the potential that it would increase morbidity and/or mortality. Priscilla Callahan-Lyon, Deputy Dir., Div. of Individual Health Sci. FDA Ctr. for Tobacco Prod. et al., Presentation at FDLI Tobacco and Nicotine Prod. Reg. and Pol’y Conf.: A Review of FDA’s ENDS Guidance and the IQOS Marketing Order, 18 (Oct. 25, 2019), <https://www.fdpi.org/wp-content/uploads/2019/10/945-1030-Premarket-Tobacco.pdf> (last visited July 15, 2020). Adding some confusion, the IQOS MRTP Decision Summary distinguishes the standard’s application to MRTP orders allowing reduced-risk claims from those allowing reduced-

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Even if FDA reasonably developed the more detailed interpretation of the TCA's AFPPH standard that is necessary to make valid PMTA and MRTP evaluations, there is nothing in the public record of its PMTA and MRTP deliberations and orders for the snus and IQOS products that would allow the courts or anyone else to determine what that interpretation might be or whether those orders comply, or whether FDA's interpretation and application of the AFPPH in developing these PMTA orders is reasonable and fits within the constraints of the statute and the Administrative Procedure Act. This lack of transparency and the absence of any evidence that the PMTAs and the related permissive orders were evaluated against any rational conception of the AFPPH standard make FDA's orders "arbitrary or capricious," either because FDA failed to engage in a rational, comprehensible decision-making process or did that only behind the scenes and failed to reveal and explain it.⁵⁵ It also means that any court review of FDA's final PMTA orders (if it did not reject them as "arbitrary or capricious" for procedural failings) would have to apply its own concept of the AFPPH standard with no expert or reasoned guidance from FDA as to how the standard's remaining gray areas should be interpreted or applied.

exposure claims by stating that for the former FDA must determine "that the product, as actually used by consumers, *will significantly reduce* harm and risk to individual users; a finding that the product, as actually used by consumers, *will benefit* the health of the population as a whole)" but the latter allows FDA to issue an MRTP order "when risk reduction has not yet been demonstrated but is reasonably likely based on demonstrated reductions in exposure (e.g., a finding that a reduction in morbidity or mortality among individual users is *reasonably likely* in subsequent studies; a finding that issuance of an order is *expected* to benefit the health of the population as a whole)." IQOS MRTP Decision Summary, *supra* note 45. But such a strict standard requiring FDA to determine that any MRTP order it issues to allow reduced-risk claims *will* produce a net public health gain would be impossible to meet given the inevitable uncertainties regarding how the product will actually be marketed and how consumers, including nonusers, will respond. *See supra* notes 48–49, and associated text. Indeed, if FDA were actually interpreting the MRTP standard for reduced-risk claims so strictly, it could not have issued its permissive MRTP order for the Swedish Match Snus, given the possibility that their snus marketing, with or without the MRTP claim, might encourage harm increasing uses of the product more than harm-reducing uses and, as acknowledged by FDA, turn out not to be AFPPH. *See supra* notes 48–49, 53, and accompanying text. *See also infra* notes 143–148 and associated text. Accordingly, this statement by FDA only confirms what was already known — that the standard that applies to allowing reduced-exposure MRTP claims is less stringent than that applying to allowing reduced-risk claims — without providing any new insights into how FDA might be interpreting the remaining gray areas of the standard.

55. *See supra* notes 35, 37 and accompanying text; *see also*, *Teva Pharmaceuticals U.S., Inc. v. FDA*, 441 F.3d 1, 5 (D.C. Cir. 2006) ("The FDA's "stated rationale for its decision is erroneous" and "we cannot sustain its action on some other basis [it] did not mention") (quoting *PDK Labs. Inc. v. U.S. DEA*, 362 F.3d 786 (D.C. Cir. 2003)); *Williams Gas Processing-Gulf Coast Co., L.P. v. Fed. Energy Regulatory Comm'n*, 475 F.3d 319, 328–29 (D.C. Cir. 2006) ("Arbitrary and capricious review strictly prohibits us from upholding agency action based only on our best guess as to what reasoning truly motivated it"); *Cigar Ass'n of Am. v. FDA*, 315 F. Supp. 3d 143, 184 (D.D.C. May 15, 2018) ("Nor can the court ask the parties for further explanations . . . [or] accept 'post hoc rationalizations for agency actions,'" (quoting *Motor Vehicle Mfrs. Ass'n v. State Farm*, 463 U.S. 29, 50 (1983)).

IV. FDA HAS NOT DONE CERTAIN ANALYSES OR MADE CERTAIN FINDINGS NECESSARY FOR EVALUATING WHETHER ITS PERMISSIVE PMTA ORDERS ARE AFPPH (UNDER ANY POSSIBLE VIABLE INTERPRETATION OF THE STANDARD)

While FDA found that its PMTA and MRTP orders for the snus and IQOS created a risk of producing new health harms and at least some risk of producing a net harm to the public health, FDA's documentation does not reveal any effort to identify and quantify all the harms or risks the orders create to individuals or to the public health nor does it evaluate all those new risks and harms against the likelihood and size of the orders' potential individual and public health gains. Yet that kind of analysis is necessary to make a reasonable determination that issuing a permissive PMTA or MRTP order is AFPPH under any legally viable interpretation of the AFPPH standard that might be developed and applied. Even if FDA were using a quite permissive interpretation of the standard that allows an order to produce not only new health harms but also a risk of a negative net public health impact so long as they were significantly smaller than the likelihood and size of the expected net public health gain, FDA would still need to make some kind of reasonable determination that the risk of a negative net public health impact was, indeed, significantly smaller. But as detailed below, FDA's final orders and decision summaries do not show that FDA has done that.⁵⁶

In particular, FDA did not consider what the worst-case scenarios for the public health might be from issuing its permissive PMTA and MRTP orders, nor try to estimate how likely such worst-case scenarios might be. Nor did FDA identify all the different ways that the permitted marketing might increase health harms and risks or estimate the related health harms, or compare those possible harms to the likelihood and size of the possible health gains from the harm-reducing uses of the products. At most, FDA only indicated or implied that the likely or expected health gains from issuing the order would be larger than the likely or expected health harms (without explaining why that was sufficient for an AFPPH determination). Overall, the final PMTA and MRTP orders and their underlying documentation show that FDA evaluated the quality of the research

56. Even if FDA actually did that kind of analysis behind the scenes before making its AFPPH determinations, doing so without describing them in the formal record of its PMTA decisions would be "arbitrary or capricious" and its invisible efforts would not be part of the official public record and could not be cited to support FDA's final determinations if they were challenged in court. *See supra* note 55 and accompanying text. *See also* Cal. Pub. Utils. Comm'n v. Fed. Energy Regulatory Comm'n, 879 F.3d 966, 973 (9th Cir. 2018) ("Our review 'is limited to ... the administrative record' (citation omitted) and to those 'grounds upon which . . . the record discloses that [the agency's] action was based'" (quoting SEC v. Chenery Corp. 318 U.S. 80, 87 (1943)); and "[w]e can only uphold agency action on grounds articulated by the agency in its orders"); *Williams Gas Processing v. Fed. Energy Regulatory Comm'n*, 373 F.3d 1335, 1345 (D.C. Cir. 2004) ("It is axiomatic that we may uphold agency orders based only on reasoning that is fairly stated by the agency in the order under review") citing *SEC v. Chenery Corp.* 318 U.S. 80, 88, 87 (1943)).

and other evidence and analysis provided by the applicants in an oddly passive, vague, and incomplete way that cannot reasonably be characterized as supporting any AFPPH determination.

While all of FDA's permissive PMTA and MRTP orders to date reveal these shortcomings, for brevity's sake this analysis will focus on the PMTA order for the IQOS inhalable "heat-not-burn" tobacco products and the MRTP order for the Swedish Match snus (which builds on FDA's prior PMTA Order for those snus).⁵⁷

A. The Missing Analyses and Questionable Assumptions in FDA's Permissive PMTA Orders for the Philip Morris IQOS Products

FDA's PMTA Order allowing the marketing of the Philip Morris IQOS products and the underlying Decision Summary show that FDA considered the marketing of IQOS quite risky for the public health. Although FDA included some marketing and sales restrictions in the Final Order to reduce those risks, its analysis and findings were still riddled with major errors and omissions that makes the agency's PMTA review process "arbitrary or capricious" and incapable of supporting its final AFPPH determination.

The documentation for FDA's PMTA Order for the Philip Morris IQOS products does not include any statement that provides an overall summary or conclusion as to why FDA found issuing the orders AFPPH. Instead, FDA lists a number of points that its scientific review of the applications has demonstrated and then, without providing additional findings or analysis, states: "In conclusion, . . . [p]ermitting the marketing of the products is appropriate for the protection of the public health . . . (subject to the labeling and advertising changes described above)."⁵⁸

57. See IQOS PMTA Order, *supra* note 45; Snus MRTP Order, *supra* note 24. These two orders, supplemented by the subsequently issued IQOS MRTP Order, are likely the most risky to the public health that FDA has issued, as the IQOS products are considerably more harmful to users and more likely to be used in harm-increasing ways by smokers and nonusers than the PMTA Swedish Match snus and, unlike the PMTA 22nd Century Group very-low-nicotine cigarettes, are highly addictive, and the Swedish Match and IQOS MRTP orders are the only orders to date allowing the marketing of any addictive and harmful tobacco product with reduced-risk or reduced-exposure claims, which could prompt a range of harm-increasing (as well as harm-reducing) uses. *Id.*; IQOS MRTP Order, *supra* note 24.

58. IQOS PMTA Decision Summary, *supra* note 29, at 12. The only clearly identified "changes described above" were requiring a warning on all packaging of IQOS heatsticks stating that they contain addictive nicotine and removal of a warning about cigarette smoke containing carbon monoxide on the IQOS products (as required on conventional cigarettes) because the heatsticks, "although categorized as cigarettes, do not produce carbon monoxide above environmental levels and do not increase CO-related health risks." *Id.* It is possible that the "changes described above" also meant to include the provisions in the final orders that require age and ID verification prior to any electronic advertising or sales and disclosures of Philip Morris's sponsorship in any third-party marketing or promotions done on its behalf. IQOS PMTA Order, *supra* note 45, at 14–15. However, they are "described above" only generally in an Executive Summary bullet with no description or detail, the main text of the Decision Summary

Yet the Executive Summary's bullets listing the key findings from FDA's scientific review are, in many cases, quite tentative and imprecise and based on scarce and inconclusive available research and data, with the main text of the Decision Summary providing little additional fortification or explanation. Indeed, the following discussion of some of the key bulleted text from the Decision Summary (in italics) also shows that there is no way to connect the dots, using those bullets, to establish any reasonable pathway to support FDA's AFPPH determination:

Although the studies conducted by the applicant do not demonstrate reduction in long-term disease risks, the currently available evidence indicates [conventional cigarette] smokers who switch completely to IQOS will have reduced toxic exposures and this is likely to lead to less risk of tobacco-related diseases.⁵⁹

While the Decision Summary discusses related research and evidence, it does not make this conclusion any more specific or detailed, but it does suggest some weaknesses. For example, FDA states that the applicant provided an inadequate assessment of four carcinogens and 20 other potentially harmful chemicals that IQOS users are exposed to at higher levels than conventional cigarette smokers or that are not even found in conventional cigarette smoke, and failed to support a conclusion that the IQOS does not pose any risk to users.⁶⁰ But FDA nevertheless concludes that the exposure levels appear low and, when considered with other data, that “does not preclude a conclusion the products are appropriate for protection of public health.”⁶¹ Then FDA notes, without any

provides no discussion or analysis of those restrictions and requirements, and its conclusion section also describes the AFPPH determination as subject only to the changed warning label requirements. IQOS PMTA Decision Summary, *supra* note 29, at 12, 86–90, 98–99. Moreover, the Decision Summary twice states that allowing IQOS on the market would not be AFPPH without the required addiction warning but makes no such statement about the electronic advertising and sales restrictions or the disclosure requirement. *Id.* at 12, 98. Those restrictions are first described only at the end of the Decision Summary, in its proposed language for the final orders, with no related analysis or justification. *Id.* at 108–09. However, the Decision Summary Appendix states that: “Placing certain marketing restrictions on the newly authorized tobacco products from the outset, such as the media channels through which the firm markets its products, are essential components of limiting youth-exposure, and are thus appropriate for the protection of public health.” *Id.* at 116; *see also id.* at 115 (describing the purpose of marketing requirements and restrictions for new tobacco products). In this way, the Appendix appears to be focusing on showing that it was AFPPH to include the restrictions in the Final Order, rather than explaining that FDA had determined that the orders could not be AFPPH unless they included those restrictions). *See id.* at 115–16. This distinction could be relevant if the requirements were legally challenged on First Amendment grounds. *See* discussion *infra* note 163 and accompanying text.

59. IQOS PMTA Decision Summary, *supra* note 29, at 11.

60. *Id.* at 32.

61. *Id.* (providing a parallel analysis and “does not preclude” a conclusion regarding other potentially harmful constituents produced by IQOS use). FDA’s “does not preclude” findings are a bit odd, given that the TCA requires PMTA applicants to provide evidence that enables FDA to determine that allowing the product on the market is AFPPH, and gives no indication that it is sufficient for the FDA to simply state that such a determination is not precluded based on the application’s evidence and other available evidence FDA finds and considers. TCA, Pub. L. No. 111-31, sec. 101, § 910(c)(2)(a),

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further evaluation or analysis, that eight other chemicals which IQOS users are exposed to at higher levels than conventional cigarette smokers were also identified as potentially genotoxic and/or carcinogenic.⁶² More broadly, FDA states that “the studies conducted by the applicant have not demonstrated evidence of reduction in long-term disease risks,” and “reduced risk has not been demonstrated in the studies submitted by the applicant.”⁶³ Yet FDA concludes that such a reduction is likely because “the currently available evidence indicates that [conventional cigarette] smokers who switch completely to IQOS will have reduced toxic exposures and, consequently, although not demonstrated in the studies in the application, are less likely to be at risk of tobacco-related diseases.”⁶⁴

123 Stat. 1776 (2009) (codified at 21 U.S.C. § 387j(c)(2)(a)(2012)). Moreover, FDA provides no explanation of how large those new health risks would have to be to preclude an AFPPH determination or how FDA determined that the likelihood and size of those health risks were not sufficient to do so.

62. IQOS PMTA Decision Summary, *supra* note 29, at 32–33.

63. *Id.* at 59, 56.

64. *Id.* at 65. This analysis of FDA’s PMTA orders will not question FDA’s expertise or discretion in evaluating and analyzing the research and other information provided by the applicants or other research FDA cites in its decision summaries. But it is worth noting that the IQOS PMTA Decision Summary does not mention several published peer-reviewed studies that were readily available to FDA and can be seen as taking a more negative view of IQOS harms and risks than the Decision Summary presents. *See, e.g.*, Farzad Moazed et al., *Assessment of Industry Data on Pulmonary and Immunosuppressive Effects of IQOS*, 27 Supplement 1 TOBACCO CONTROL at s20–s25 (2018), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6252496>; Gideon St. Helen et al., *IQOS: Examination of Philip Morris International’s Claim of Reduced Exposure*, 27 Supplement 1 TOBACCO CONTROL at s30–s36 (2018), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6252487>; Stanton A. Glantz, *PMI’s Own in Vivo Clinical Data on Biomarkers of Potential Harm in Americans Show that IQOS is Not Detectably Different from Conventional Cigarettes*, 27 Supplement 1 TOBACCO CONTROL s9–s12 (2018), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6202159>; Barbara Davis et al., *iQOS: Evidence of Pyrolysis and Release of a Toxicant From Plastic*, 28 TOBACCO CONTROL 34 (2018), <https://tobaccocontrol.bmj.com/content/28/1/34>. Critiques of the research submitted by Philip Morris in support of its PMTA application, with references to contradictory research, were also provided to FDA in comments submitted to the public docket for Philip Morris’s related application to secure a permissive MRTP order, but none of those comments were mentioned or addressed in the IQOS PMTA Decision Summary. *See, e.g.*, Matthew Springer, Comment Letter on the Food and Drug Administration (FDA) Notice: Modified Risk Tobacco Product Applications: Applications for IQOS System With Marlboro Heatsticks, IQOS System With Marlboro Smooth Menthol Heatsticks, and IQOS System With Marlboro Fresh Menthol Heatsticks Submitted by Philip Morris Products S.A.: Availability (Nov. 20, 2017), www.regulations.gov/document?D=FDA-2017-D-3001-0118 (stating that the Philip Morris application “does not support the conclusion that IQOS will not harm endothelial function” and that independent research “shows that IQOS harms endothelial function as much as conventional cigarettes”). The IQOS PMTA Decision Summary does not mention this comment or the cited research, and only mentions the word “endothelial” once in a passing reference. IQOS PMTA Decision Summary, *supra* note 29, at 58. *See generally* Laura K. Lempert, & Stanton A. Glantz, *Notes on FDA’s Technical Project Lead Review for the IQOS PMTA* 19 (June 17, 2019), https://tobacco.ucsf.edu/sites/tobacco.ucsf.edu/files/wysiwyg/Notes%20on%20FDAs%20Technical%20Project%20Lead%20Review%20for%20the%20IQOS%20PMTA_17Jun2019.docx, and Laura K. Lempert, & Stanton A. Glantz, *Analysis of FDA’s IQOS Marketing Authorisation & its Policy Impacts*, TOBACCO CONTROL (June 29, 2020), <https://tobaccocontrol.bmj.com/content/early/2020/06/29/tobaccocontrol-2019-055585.info> (providing

FDA does not, however, provide any indication as to how likely or large these reductions of disease risk might actually be or what the worst case scenario might be in regard to IQOS health impacts on either smokers who switch (or to brand-new users or dual users).⁶⁵ Moreover, FDA does state that additional research into IQOS health risks and harms is needed or would be helpful “to support the continued marketing of the products as appropriate for the protection of the public health,” thereby acknowledging that future research into IQOS health harms could show that allowing the marketing of IQOS is not AFPPH.⁶⁶ But FDA does not explain why running that risk by allowing IQOS on the market now is AFPPH.

*The data for [conventional cigarette] smokers who use IQOS while continuing to smoke (dual use) is less clear but the available evidence shows no increase in HPHC [harmful or potentially harmful constituent] exposures for those who dual use.*⁶⁷

This conclusion is odd given FDA’s discussion later in the Decision Summary about how inhaling IQOS’s aerosol exposes users to four carcinogens and a number of other potentially harmful constituents not found in cigarette smoke, which means dual users would be exposed to a greater number of HPHCs than exclusive cigarette smokers.⁶⁸ Moreover, FDA discusses research showing that dual users on average reduced their cigarette consumption only slightly (by about 1 cigarette per day) but replaced that with larger amounts of IQOS use (about 2-4 heatsticks per day), and acknowledges that “the health benefits of

critiques of FDA’s evaluation of the science and other evidence in the IQOS PMTA Decision Summary and identifying relevant research FDA did not appear to consider). However, the IQOS PMTA Decision Summary does make several references to FDA staff having conducted an “independent review of the literature” relating to certain specific matters, without listing the reviewed research, which might have included consideration of some of the uncited research contrary to the research and assertions in the Philip Morris application or to FDA’s related findings or conclusions. IQOS PMTA Decision Summary, *supra* note 29, at 56, 58, 60, 93.

65. Throughout the Decision Summary, FDA describes and relies on research done or provided by the applicant, Phillip Morris, without any reference to inherent conflicts of interest, past evaluations of research finding biases in favor of industry positions in industry research and industry-supported research, or past court determinations that Philip Morris and other tobacco companies have intentionally misrepresented or distorted research. *See e.g.*, Clayton Velicer et al., *Tobacco Papers and Tobacco Industry Ties in Regulatory Toxicology and Pharmacology*, 39 J. PUB. HEALTH POL’Y 34 (2018); Tom Lasseter et al., *Scientists Describe Problems in Philip Morris E-Cigarette Experiments*, REUTERS (Dec. 20, 2017), <https://www.reuters.com/investigates/special-report/tobacco-iqos-science>; Elisa K. Tong & Stanton A. Glantz, *Tobacco Industry Efforts Undermining Evidence Linking Secondhand Smoke with Cardiovascular Disease*, 116 CIRCULATION 1845 (2007); *United States v. Philip Morris*, 449 F. Supp. 2d 1, 208, 870–71, 877–78, 885 (D.C. Cir. 2006); Yogi H. Hendlin et al., *Financial Conflicts of Interest and Stance on Tobacco Harm Reduction: A Systematic Review*, 109 AM. J. PUB. HEALTH (2019). *See also infra* note 120.

66. IQOS PMTA Decision Summary, *supra* note 29, at 84.

67. *Id.* at 11.

68. *Id.* at 32.

reducing cigarette consumption instead of quitting completely are unclear.”⁶⁹ FDA stated later that: “Whether this [dual] user population will achieve an exposure reduction when compared to exclusive [conventional cigarette] use, and to what magnitude, is unclear.”⁷⁰ Nevertheless, FDA ultimately concluded that “based on the currently available evidence, dual use is unlikely to pose increased health risks compared to continued exclusive [conventional cigarette] use.”⁷¹

While this conclusion seems odd based on just the research FDA mentions, FDA did not even consider the possibility that the IQOS aerosol, like e-cigarette aerosols, delivers its HPHCs through different types of particles with different particle disposition in the mouth and respiratory tract compared to smoking, which could have different health consequences that create brand new risks to dual users (or complete switchers) that a simple comparison of exposure levels would not reveal.⁷²

At the same time, FDA clearly recognized that future data and research might show that certain types of dual use are sufficiently prevalent and more harmful than exclusive cigarette smoking, and that allowing the continued marketing of IQOS would not be AFPPH.⁷³ Yet FDA did not explain why running that risk by issuing the current permissive PMTA Order is AFPPH, nor did FDA estimate either the likelihood or size of any reasonable worst-case

69. *Id.* at 73, 96. It is also quite clear from existing research that reducing cigarette consumption is a much less effective way to reduce harms and risks compared to quitting all smoking, which does not secure any significant harm reductions at all unless the consumption declines are dramatic and reduce smoking to very low levels. *See, e.g.,* Rachna Begh, *Does Reduced Smoking if You Can't Stop Make Any Difference?* 13 *BMC MED.* 257 (Oct. 12, 2015), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4601132/>; Peter N. Lee, *The Effect of Reducing the Number of Cigarettes Smoked on Risk of Lung Cancer, COPD, Cardiovascular Disease and FEV1-A Review*, 67(3) *REG. TOXICOLOGY & PHARMACOLOGY* 372 (Dec. 2013), <https://www.sciencedirect.com/science/article/pii/S0273230013001402?via%3Dihub>; Allan Hackshaw et al., *Low Cigarette Consumption and Risk of Coronary Heart Disease and Stroke: Meta-Analysis of 141 Cohort Studies in 55 Study Reports*, 360 *BRIT. MED. J.* (Jan. 24, 2018), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5781309>. *See also*, B. Poland, B & F. Teischinger, *Population Modeling of Modified Risk Tobacco Products Accounting for Smoking Reduction and Gradual Transitions of Relative Risk*, 19 *NICOTINE & TOBACCO RES.* 1277 (Nov. 1, 2017), <https://www.ncbi.nlm.nih.gov/pubmed/?term=Population+Modeling+of+Modified+Risk+Tobacco+Products+Accounting+for+Smoking+Reduction+and+Gradual+Transitions>.

70. IQOS PMTA Decision Summary, *supra* note 29, at 56.

71. *Id.* at 96.

72. *See, e.g.,* National Academies of Sciences, Engineering, and Medicine, *Public Health Consequences of E-cigarettes*, *NAT'L ACADS. PRESS* 72 (Kathleen Stratton et al. eds., 2018), <https://www.ncbi.nlm.nih.gov/pubmed/29894118>; *See also* Zachary T. Bitzer et al., *Effects of Solvent and Temperature on Free Radical Formation in Electronic Cigarette Aerosols*, 31 *CHEMICAL RES. TOXICOLOGY* 4 (2018), <https://www.ncbi.nlm.nih.gov/pubmed/29161504>; Ariane Lechasseur et al., *Variations in Coil Temperature/Power and E-Liquid Constituents Change Size and Lung Deposition of Particles Emitted by an Electronic Cigarette*, 7 *PHYSIOLOGICAL REPS.* (2019), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6540444/>.

73. IQOS PMTA Decision Summary, *supra* note 29, at 83–84.

scenario for possible increased user harms or public health harms from dual use, which could either provide the basis for such an explanation or make it harder to develop:

*Dual use of IQOS and [conventional cigarettes] was common in all countries in the pre- and post-market studies. . .*⁷⁴

Rather than support FDA's AFPPH determination, this bullet is purely observational (based on relatively few studies) and could be seen as negative, unless the dual users in other countries are not delaying smoking cessation but clearly moving toward a complete switch. More importantly, FDA made no related estimates or findings in the Decision Summary regarding how much dual use might occur in the United States when IQOS is marketed pursuant to the PMTA Order or about the possible characteristics of that dual use – such as the extent to which it might or might not entail meaningful reductions in cigarette consumption, be a precursor to smoking cessation, or prevent or delay either smoking or total cessation. FDA was clearly aware of the risk that dual use could prevent or reduce cessation.⁷⁵ But FDA did not explicitly discuss that risk anywhere in the Decision Summary, much less present any related findings or estimates or explain how that risk did not interfere with its AFPPH determination. Instead, the Decision Summary summarizes some studies relating to dual use and concludes only that “the findings suggest that some smokers will find IQOS appealing and acceptable enough to initiate use of the product;”⁷⁶ dual use “may account for a substantial portion of IQOS users in a real-world setting” and “appears likely;”⁷⁷ that “[t]he limited data available indicates that a dual-use period is common during the switching period;”⁷⁸ and “[t]here is evidence that U.S. cigarette smokers are interested in IQOS, but limited data for use of IQOS to achieve [conventional cigarette] smoking cessation.”⁷⁹ Despite these imprecise and incomplete findings, the Decision Summary concludes that “IQOS is appropriate for protection of public health, even if there is some dual-use among smokers as they potentially transition to the product.”⁸⁰

The nicotine levels do pose an addiction risk for non-tobacco users who initiate use of these products; however, the risk is no higher than

74. *Id.* at 11.

75. In a section of the Decision Summary focusing on the likelihood of IQOS use by current smokers, FDA briefly described a study designed “to evaluate whether marketing IQOS would have negative effects on smokers who intend to quit, such as causing them to delay their quit attempts.” *Id.* at 71 (including other passing references to dual use delaying or preventing cessation).

76. *Id.* at 71.

77. *Id.* at 56, 73.

78. *Id.* at 83. *See also id.* at 77, 97.

79. IQOS PMTA Decision Summary, *supra* note 29, at 83.

80. *Id.* at 84.

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*for other, currently available, tobacco products and initiation is expected to be low generally.*⁸¹

Even if such an expectation could provide a reasonable basis for an AFPPH determination without further findings regarding the likelihood and size of potential non-user initiation and addiction, the support for this low expectation by FDA is unclear. FDA directly admits that because IQOS is still a relatively new product in other countries, with limited data available only from Japan and Italy, “the extent to which youth will initiate and use IQOS in these markets, or any other market that may start selling IQOS, is unknown.”⁸² In addition, referencing the sudden rapid growth in youth e-cigarette use in the USA after they had already been on the market for several years, FDA states: “Certainly, the potential for rapid uptake of a novel tobacco product among youth exists.”⁸³ Nevertheless, FDA concludes that: “Overall, the current evidence indicates IQOS uptake by youth and nonsmokers will be low.”⁸⁴

This conclusion appears to be based on the fact that IQOS will be available in the USA only in tobacco and menthol flavors (far fewer than the many flavors available for e-cigarettes) and on FDA’s finding that these limited flavor options and the price of IQOS “may reduce IQOS’s appeal to youth.”⁸⁵ However, FDA did not provide any data or analysis regarding the relative prices of IQOS versus e-cigarettes or cigarettes, nor did FDA discuss the unique role menthol flavoring has played in increasing youth smoking and e-cigarette initiation, which could extend to IQOS initiation, as well.⁸⁶ Unlike its analysis for the PMTA Order for the Swedish Match snus, FDA did not consider the possibility that issuing a permissive order for IQOS could also create a “perceived favorable profile” that would increase nonuser initiation and use – and also discourage total cessation and, through dual use, discourage smoking cessation.⁸⁷

81. *Id.* at 11.

82. *Id.* at 76, 97.

83. *Id.* at 76.

84. *Id.*

85. *Id.*

86. *See id.* On the role of menthol in youth initiation, *see, e.g.*, James Nonemaker et al., *Examining the Role of Menthol Cigarettes in Progression to Established Smoking Among Youth*, 98 ADDICTIVE BEHAVIORS 106045, 1–2 (2019); Joanne D’Silva et al., *Differences in Subjective Experiences to First Use of Menthol and Nonmenthol Cigarettes in a National Sample of Young Adult Cigarette Smokers*, 20 NICOTINE & TOBACCO RES. 1062, 1062–63 (2018); Suchitra Krishnan-Sarin et al., *Studying the Interactive Effects of Menthol and Nicotine Among Youth: An Examination Using E-Cigarettes*, 180 DRUG & ALCOHOL DEPENDENCE 193, 193–94 (2017); FDA, *Menthol and Other Flavors in Tobacco Products*, www.fda.gov/tobacco-products/products-ingredients-components/menthol-and-other-flavors-tobacco-products (last visited July 15, 2020).

87. Snus PMTA Decision Summary, *supra note* 45. Although the Snus PMTA Decision Summary does not clearly explain or define “perceived favorable profile,” it refers to the snus becoming more popular with some potential consumers because of the snus receiving a permissive FDA PMTA Order – possibly through press coverage and word of mouth via social media, (despite the TCA provision that prohibits any express or implied statement or representation by manufacturers or sellers directed at

FDA does state that: “The proposed marketing and advertising restrictions will help ensure lower youth exposure and access to the products.”⁸⁸ But it is not clear whether FDA’s expectation of low youth initiation was contingent on the Final Order including those restrictions – which require nicotine addiction warnings, age and ID verification before electronic sales or advertising, and disclosing Philip Morris’s sponsorship of any IQOS promotions done by third-parties on its behalf.⁸⁹ It is clear, however, that FDA believed that the marketing of IQOS might produce a new surge in youth initiation, even with those restrictions in place. Otherwise, the PMTA Order would not have required such extensive post-market reporting and surveillance to “help FDA ensure, on an ongoing basis, that the continued marketing of new tobacco products remains appropriate for the protection of public health.”⁹⁰ But the IQOS PMTA documents do not explain why FDA determined that issuing the PMTA Order was still AFPPH despite FDA’s contradicting conclusion that at least some new youth initiation would occur and considerably higher levels of youth initiation would be possible.⁹¹

In addition, the PMTA documents offer no analysis or findings about the extent to which youth IQOS initiation would prompt IQOS initiation among youth who would otherwise not initiate into any tobacco product use at all (as opposed to preventing or delaying smoking initiation among otherwise smoking youth) or about whether some youth who initially initiate into using IQOS would subsequently initiate into more-harmful conventional cigarette smoking. Nor does FDA specifically evaluate or estimate how harmful regular, long-term IQOS use might be to nonsmoking youth or adults who would not otherwise have initiated into any tobacco-nicotine use at all, even if they did not progress into conventional smoking. Although FDA concludes that using IQOS alone is likely less harmful than smoking, FDA makes no attempt to estimate the new individual or public health harms that would be caused by the marketing of IQOS prompting use by otherwise nonusers.

consumers that misleads them into believing the snus have been approved, deemed safe, or endorsed by FDA or that the snus are safe or less harmful by virtue of the PMTA order or any other regulation or inspection by FDA). TCA, Pub. L. No. 111-31, sec. 103, §301(b)(7)(13), 123 Stat. 1776 (2009) (codified at 21 U.S.C. § 331(tt) (2012)).

88. IQOS PMTA Decision Summary, *supra* note 29, at 12.

89. *See supra* note 58 and accompanying text.

90. IQOS PMTA Decision Summary, *supra* note 29, at 120; *see also id.* at 115; IQOS PMTA Order, *supra* note 45, at 1, 6–7.

91. FDA’s social science review expressed concerns about the lack of information in the Philip Morris applications “about youth under age 18, as well as the lack of a discussion of submitted data’s applicability to youth and the lack of presentation of the data in stratified categories that would allow us to make inferences about youth,” concluding that the applications “do not contain sufficient information to address these concerns from a Social Science perspective.” IQOS PMTA Decision Summary, *supra* note 29, at 83. However, the Technical Project Lead did not agree with the social science conclusions and, referring only to the data from Italy and Japan where IQOS is already legally marketed, stated that: “Overall, the current evidence indicates low IQOS uptake by youth.” *Id.*

Data from Italy and Japan, where IQOS is already marketed: “show low uptake by youth and current nonsmokers. In these countries, the likelihood of uptake is slightly higher in former smokers, but still low. Appropriately, the population most likely to use IQOS are current [conventional cigarette] smokers.”⁹²

This text provides only observations about data in two other countries, and FDA does not link those observations to any related findings or conclusions as to how the marketing of IQOS could affect uptake by youth, current nonsmokers, former smokers, or current smokers in the United States. In addition, the Decision Summary includes no discussion or findings regarding how the marketing of IQOS in the United States might create new health harms by prompting former smokers who would not otherwise relapse into smoking or any other tobacco use to relapse into IQOS use, and possibly subsequently relapse into smoking, as well.⁹³

FDA's Decision Summary acknowledges that IQOS use might be more harmful than e-cigarette use.⁹⁴ But it does not anywhere consider the possibility that the marketing of IQOS might increase individual and public health harms by prompting some users of e-cigarettes or other non-smoked tobacco products to begin using IQOS, either through complete switching or dual use, or by prompting smokers who would have otherwise switched to e-cigarettes to switch to IQOS, instead.⁹⁵ More broadly, FDA's PMTA analysis did not consider whether there was any reason to allow the marketing of IQOS as a potentially harm-reducing smoking substitute given that a diverse range of less-harmful e-cigarettes are already readily available in the U.S.⁹⁶ In particular, the Decision

92. IQOS PMTA Decision Summary, *supra* note 29 at 12.

93. The closest the Decision Summary comes to doing any such evaluation is in its description and critique of a study looking at former smokers' and others' stated likelihood to try IQOS after viewing certain labeling and marketing materials, and in its description of data about former smokers' and others' use of IQOS in Italy and Japan. *Id.* at 68–69, 73–76. But nothing is said about whether the intended or actual IQOS use by former smokers might be instead of continued total cessation, instead of other non-smoked tobacco product use, or instead of relapsing back into smoking, or might be a new pathway to smoking relapse. Going the other way, the Decision Summary also does not consider whether any former smokers who would otherwise relapse into smoking might relapse into using IQOS instead.

94. *Id.* at 22 (describing and citing a study finding that the levels of certain harmful or potentially harmful constituents were “1-2 orders of magnitude higher in [IQOS] compared to e-cigarettes”); *see also id.* at 56 (stating that it would have been useful to have comparisons of the secondhand exposure impacts from IQOS and other tobacco products, such as e-cigarettes).

95. Yet the Decision Summary notes that “[n]umerous studies demonstrate that consumers tend to perceive IQOS as similar to e-cigarettes in terms of risk.” *Id.* at 89. It also describes a study finding that respondent former smokers' and never-smokers' interest in IQOS appeared to be similar or somewhat lower than their interest in e-cigarettes (with nothing said about current smokers' relative interests) *Id.* at 75, 96.

96. On e-cigarettes being less harmful than IQOS, *see supra* note 94 and, e.g., Noel J. Leigh, et al., *Cytotoxic Effects of Heated Tobacco Products (HTP) on Human Bronchial Epithelial Cells*, 27

Summary did not even discuss the issue of whether the marketing of IQOS would prompt any smokers to switch entirely to IQOS who would not otherwise switch completely to e-cigarettes (which is likely the only way IQOS marketing could produce any new health gains).⁹⁷

In addition, FDA did not consider specific ways that Philip Morris or IQOS-selling retailers might, to maximize profits, legally advertise and promote IQOS to increase both harm-reducing and harm-increasing uses of the product within the constraints of the PMTA Order.⁹⁸ This omission seems odd given the long history of both legal and illegal irresponsible marketing by the Philip Morris entities, including reports of irresponsible Philip Morris marketing of IQOS

TOBACCO CONTROL s26 (2018) (providing a study that was not mentioned in the IQOS PMTA Decision Summary).

97. FDA also failed to consider these issues in its evaluation of the Philip Morris application to market IQOS with reduced-risk or reduced-exposure claims and FDA's subsequent MRTP order allowing its marketing with reduced-exposure claims. IQOS MRTP Decision Summary, *supra* note 45; IQOS MRTP Order, *supra* note 24. The closest FDA comes to looking at any of these issues is in the IQOS MRTP Decision Summary, where it references several applicant-submitted studies that considered, among other things, the impact of IQOS labeling and marketing materials on consumers' intent to use various products, including IQOS, combusted cigarettes, e-cigarettes, and any other nicotine-containing products. IQOS MRTP Decision Summary, *supra* note 45 at 46. Yet there is no related discussion relating to e-cigarettes, such as whether any e-cigarette users might switch to IQOS. The Decision Summary elsewhere notes that another study indicated that consumers generally consider IQOS health risks as slightly higher than e-cigarette use, and later mentions that consumers might be more likely to try IQOS if e-cigarettes were not available. *Id.* at 46, 59. But there is no related discussion of whether IQOS would still serve as a constructive smoking alternative given the ready availability of e-cigarettes that are both less harmful than IQOS and generally perceived as less harmful.

98. The IQOS PMTA Decision Summary "Marketing Plan" subsection states that, at the request of FDA, the applicant provided a summary of its plan for marketing IQOS in the U.S. IQOS MRTP Decision Summary, *supra* note 45 at 86–87. But the text describing its main concepts is redacted, and FDA provides no related analysis or comments. *Id.* In the Decision Summary Appendix, FDA discusses research and other findings on how tobacco product advertising and promotions can increase youth, nonuser, and overall use. *Id.* at 111–22. The Appendix does not make any connection between its analysis (done to support the order's electronic advertising and sales restrictions and advertising reporting requirements) and the Decision Summary's findings of likely low harms and risks from allowing the marketing of IQOS. *See also supra* note 58 and accompanying text.

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before FDA issued its IQOS PMTA Order.⁹⁹ None of that is even mentioned in the Decision Summary.¹⁰⁰

It is difficult to understand or justify FDA's failure to consider possible health-harming industry practices relating to IQOS or many of the obvious ways youth and adult nonusers and users of different types of tobacco products might respond to IQOS marketing in harmful ways. Section 910 of the Tobacco Control Act requires FDA to consider all of the possible tobacco product user and nonuser responses to the marketing of IQOS and their potential impacts on the risks and benefits to the health of the population as a whole when making its PMTA AFPPH determinations.¹⁰¹ In addition, existing case law firmly establishes that FDA's PMTA AFPPH determinations, if challenged in court, will be struck down as "arbitrary or capricious" if FDA has not at least considered significant evidence and analysis that was presented to or otherwise known to FDA that could have changed its findings or determinations.¹⁰²

Even if these material omissions were somehow excused, the actual findings FDA did make to support its AFPPH determination are too imprecise and uncertain to provide a legally defensible foundation. As outlined above, FDA bases its determination on findings that: (1) smokers who switch completely to

99. See, e.g., *United States v. Philip Morris USA, Inc.*, 449 F. Supp. 2d 1 at 511-29, 560-61, 580-94, 616-22, 639-43, 645-51, 656-64, 667-72, 682-84, 691-92, 852-53, 907-13 (D. D.C. 2006) [*aff'd* in *United States v. Philip Morris*, 566 F.3d 1095 (D.C. Cir. 2009)]; Campaign for Tobacco-Free Kids, *The Facts about Philip Morris International: Company Is Cause of the Tobacco Problem, Not the Solution*, https://www.tobaccofreekids.org/assets/images/content/PMI_bad_acts.pdf (last visited July 15, 2020); Letter from Matthew L. Myers, President, Campaign for Tobacco-Free Kids, to Mitchell Zeller, Director, FDA Center for Tobacco Products, (Mar. 23, 2018), https://www.tobaccofreekids.org/assets/content/press_office/2018/2018_03_28_IQOS_global_marketing.pdf (last visited July 15, 2020); Letter from Matthew L. Myers, President, Campaign for Tobacco-Free Kids, to Mitchell Zeller, Director, FDA Center for Tobacco Products, (Aug. 13, 2018), https://www.tobaccofreekids.org/assets/content/what_we_do/federal_issues/fda/2018_08_13_IQOS_FDA_Social_Media_Marketing.pdf (last visited July 15, 2020); Sheila Kaplan, *Big Tobacco's Global Reach on Social Media*, N.Y. TIMES (Aug. 24, 2018), <https://www.nytimes.com/2018/08/24/health/tobacco-social-media-smoking.html> (last visited July 15, 2020).

100. Before FDA issued its IQOS PMTA Decision Summary and Order, there were also reports about the electronics in IQOS enabling Philip Morris to collect information about how often and how heavily IQOS consumers use the product, which Philip Morris could use to identify users reducing or quitting consumption to target with special advertising or promotions. See, e.g., Tom Lasseter et al., *Philip Morris device knows a lot about your smoking habit*, REUTERS, (May 15, 2018), <https://www.reuters.com/investigates/special-report/tobacco-iqos-device>. This issue also was not mentioned in the IQOS PMTA Decision Summary, although it is possible that the redacted text in the descriptions of the IQOS products might have mentioned this information collection capacity. See IQOS PMTA Decision Summary, *supra* note 29, at 14-16.

101. TCA, Pub. L. No. 111-31 sec. 101 § 910(c)(4), 123 Stat. 1776 (2009) (codified at 21 U.S.C. § 387j(c)(4) (2012)). See also Lindblom, *supra* note 22, at 541-42.

102. See, e.g., *Nat'l Ass'n of Home Builders v. Defenders of Wildlife*, 551 U.S. 644, 658 (2007) (holding that an agency would be arbitrary or capricious if it "entirely failed to consider an important aspect of the problem"); see also *supra* note 37.

using only IQOS are likely to reduce their risk of tobacco-related disease; (2) some smokers might switch completely to IQOS; (3) more smokers will engage in dual use, but that probably will not increase their health harms compared to just smoking; (4) youth and other nonuser initiation is expected to be low generally; and (5) IQOS use by former smokers, although somewhat more likely than nonuser initiation, will also likely be low.¹⁰³

Even if we overlook the questionable aspects of some of these findings and assume they are all accurate or reasonably determined, these five findings cannot be added together to support a reasonable conclusion that allowing the marketing of IQOS is more likely to produce a net public health gain rather than a net public health loss. To make such a conclusion (arguably the very minimum that might possibly be sufficient to justify an AFPPH determination), FDA would need to go further and also find, at least, that the likelihood and size of all the possible health benefits from IQOS serving as a complete smoking substitute would be larger than the likelihood and size of the possible new health harms from all the different harm-increasing uses of IQOS.¹⁰⁴ But FDA did not make any such statement or finding and did not otherwise weigh the likelihood or size of all the different possible new harms from allowing IQOS on the market against the likelihood or size of the different possible harm reductions.¹⁰⁵

Reading between the lines in the light most favorable to FDA, one might speculate from the publicly available IQOS PMTA decision documents that FDA, based on its review of the Philip Morris application, found that if IQOS were allowed on the market: (1) some smokers who would not otherwise quit smoking or all use would switch entirely to using IQOS and thereby reduce their tobacco-related harms; (2) other smokers engaging in dual use would not increase their harms (and would not have otherwise quit smoking or all use); and

103. See IQOS PMTA Decision Summary, *supra* note 29, at 11–12. The Decision Summary also briefly mentions that complete switching by smokers to using IQOS could also benefit those who would be exposed to secondhand IQOS aerosol instead of secondhand smoke by reducing their HPHC exposure. *Id.* at 92.

104. See *supra* note 46 and accompanying text.

105. Philip Morris's application provided a Population Health Impact Model designed to project the possible positive and negative effects on the population health of the United States from allowing IQOS to be marketed, based on different assumptions about harmfulness and consumer responses. *Id.* at 77–79, 97–98. After stating that it had no concerns with the model's statistical and computational aspects, FDA pointed out some limitations of the model (e.g., considered only cigarettes and IQOS and not the use of other tobacco products and provided only 20-year projections) and rejected some of Philip Morris's assumptions (e.g., that nonsmokers would not use IQOS). *Id.* Rather than require that Philip Morris fix the model's shortcomings and provide projections for a range of different assumptions – so that FDA would be able to evaluate and compare reasonable worst-case, middle-case, and best-case scenarios in terms of possible public health gains versus losses – FDA simply concluded that “the overall analysis of the population model does not provide evidence to support the application.” *Id.*; see also 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 TOBACCO CONTROL s82 (2018).

(3) all the other harm-increasing uses of IQOS by smokers, dual users, former smokers, e-cigarette users, and youth and adult nonusers would likely produce new health harms that were smaller than the likely gains from the complete switching by smokers who would not otherwise quit. But even if that was what FDA actually did behind the scenes, it would still fail to pass legal muster because FDA never stated in the IQOS PMTA Decision Summary or Order that it made all those findings; did not present evidence and analysis that could support all those findings; and did not show that it had considered certain contrary facts, research, and analysis. In addition, FDA did not explain how such a finding that the likely overall new harms from allowing IQOS on the market would likely be smaller than the likely new harm-reductions could, by itself, support an AFPPH determination.¹⁰⁶

Accordingly, both the substance of FDA's AFPPH determination and the process FDA used to do its AFPPH evaluation and make its final determination were "arbitrary or capricious."¹⁰⁷

B. The Missing Analyses and Questionable Assumptions in FDA's Permissive MRTP Order for the Swedish Match Snus

FDA determined that allowing the snus to be marketed with the proposed reduced-risk claim will benefit the health of the population as a whole (despite the possibility that it might produce net public health harms) based on FDA's finding that available evidence indicated that: (1) exclusive use of the snus, although still harmful and addicting, was significantly less harmful than exclusive smoking; (2) at least some smokers might switch exclusively to using snus instead of smoking, with users of other, possibly more harmful smokeless tobacco products even more likely to switch; and (3) the health gains from such switching would likely be larger than any new health harms from nonusers also starting to use the snus, as well.¹⁰⁸

FDA's analysis to support its snus MRTP Order was considerably stronger than the analysis underlying its IQOS PMTA Order, both because of the more extensive and conclusive available evidence regarding snus use being significantly less harmful than smoking and because FDA directly addressed more of the harm-increasing ways the snus might be used. But there were still a number of troubling errors, omissions, and other shortcomings.

For example, in its discussion of the relative harmfulness of snus, FDA reasonably concluded that dual use of snus with smoking is considerably more harmful than using only snus and noted that it had previously concluded that

106. See *supra* note 39 and accompanying text.

107. See *supra* note 35 and accompanying text; see also *supra* note 55 and accompanying text.

108. See Snus MRTP Decision Summary, *supra* note 45, at 6–7 (providing an executive summary of FDA's determinations).

“there is insufficient information to conclude that smokers who use snus in conjunction with smoking will realize any reductions in risk of tobacco-related disease.”¹⁰⁹ But FDA did not discuss anywhere in the Decision Summary the possibility of dual use by those who previously only smoked, especially without sharp reductions to their prior smoking levels, might increase overall user harms and risks. Nor did FDA mention that smokers who switch completely to snus would not eliminate their smoking harms, given that their past smoking would have already locked in certain current and future smoking-caused harms and risks. FDA also did not discuss the possibility that snus-only use after years of prior smoking might be considerably more harmful than snus use with no former smoking.¹¹⁰ Nor did FDA mention that users of more-harmful smokeless tobacco products who switched to snus would not, for parallel reasons, secure harm reductions equal to the difference between the harmfulness of the snus and the harmfulness of those other smokeless products.

In its analysis of how the marketing of the MRTP snus might affect different harm-increasing or harm-reducing uses of the snus, FDA appropriately considered impacts on smokers, former smokers, and adult and youth nonusers.¹¹¹ But FDA did not consider how the snus marketing might affect the use of IQOS or e-cigarettes by different types of consumers (and did not make any findings about the relative harmfulness of snus, IQOS, and e-cigarettes). The Decision Summary also discussed the possibility that exposure to the reduced-risk claim could increase the risk that youth and young adult nonusers would initiate into using the snus and experience new harms and risks (and the Final Order included some related advertising restrictions).¹¹² But FDA’s analysis did not consider any specific ways that the manufacturer or retail sellers of the snus might supplement the newly permitted reduced-risk claim with other claims or marketing strategies (within the constraints of existing law and the MRTP Order or without) to increase nonuser use or other harm-increasing uses.¹¹³ Nor did

109. *Id.* at 28–29. FDA also states that smokers who switch to dual use “would not experience a reduction in their individual risk.” *Id.* at 29.

110. These facts were especially relevant given FDA’s reliance on the applicant’s study showing that the proposed reduced-risk claim produced a significant increase in stated intentions to purchase the snus only among older smokers (i.e., those likely to have larger accumulated smoking-caused health harms and risks who would likely secure smaller harm reductions from switching completely compared to younger smokers). The applicant’s study provided findings only for smokers 25 years of age or older (small significant increase in stated intent to buy the snus) compared to those 18–24 years of age (no significant increase), and FDA does not appear to have received or required data on whether such stated intentions increased with age among those 25 years or older. *Id.* at 40, 41.

111. *Id.* at 39–43.

112. *See id.* at 42–43; Snus MRTP Order, *supra* note 24, at 13–15.

113. Fortunately, neither Swedish Match nor any major retailers appear to have yet marketed the snus products in the United States in any clearly irresponsible or harm-increasing ways. But failing to consider that possibility in making its evaluation of the possible harms and risks from allowing the snus marketing with a reduced-risk claim remains imprudent and, therefore, “arbitrary and capricious,” especially as, over time, competitive pressures can drastically change a profit-maximizing

FDA mention the possibility, as it had with its underlying PMTA Order for the snus, that the MRTP Order and related press or social media attention might produce an additional “perceived favorable profile” that could further increase nonuser initiation and use,¹¹⁴ or that the snus might become a new youth fad, much like e-cigarettes have. Nor did FDA discuss the possibility that otherwise nonusers who initiated into snus use might move on to smoking or other forms of tobacco use more harmful than using the snus.¹¹⁵

As in its evaluation of the IQOS PMTA, FDA’s evaluation of the snus MRTP application also did not provide any estimates of the likelihood or size of the impacts the MRTP marketing might have on the different possible harm-increasing or harm-reducing uses of the snus, or of what the related health consequences might be from each of those different use changes. Nor did FDA provide any estimates of the worst-case, best-case, or expected net public health gains from issuing the order, or explain how the expected net public health gains justified running the risk of a negative net public health impact (which FDA clearly considered possible).¹¹⁶ The absence of any such estimates makes it difficult to understand how FDA could determine that issuing the order “will significantly reduce harm and the risk of tobacco-related disease to individual tobacco users and 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.”¹¹⁷ Moreover, FDA’s core finding to justify issuing the order appears to be that “the population health benefits gained by cigarette smokers (and potentially other smokeless tobacco users) switching to these products will not be outweighed by the risks of initiating new tobacco use.”¹¹⁸ That equation not only has no estimated quantification but also omits any consideration of other possible health harms from the snus marketing, such as new harms from smokers switching to dual use instead of quitting smoking or switching to exclusive snus use instead of quitting all tobacco-nicotine use.

manufacturer’s marketing behavior. For example, in meetings with FDA Center for Tobacco Product staff in 2011–2012 some manufacturers of e-cigarettes said that they would never sell e-cigarettes with any flavors other than tobacco or menthol (the only flavors permitted for cigarettes). Yet they soon began marketing e-cigarettes with other flavors to try to regain market share from flavor-selling competitors. This information coming from the recollection of the author from his time as Director of the FDA Center for Tobacco Products Office of Policy.

114. See *supra* note 87 and accompanying text. Any such “perceived favorable profile” might also increase other harm-increasing uses, as well as constructive switching to snus; but FDA did not discuss that either.

115. Such use patterns could greatly increase the new harms from issuing the MRTP Order; and FDA’s Decision Summary for the underlying PMTA Order it issued for these same snus stated that switching from smokeless tobacco use to smoking is more common in the United States than switching from smoking to smokeless tobacco use. See Snus PMTA Decision Summary, *supra* note 45, at 29–30.

116. See Snus MRTP Order, *supra* note 24, at 1–2; See Snus MRTP Decision Summary, *supra* note 45, at 13.

117. Snus MRTP Order, *supra* note 24, at 1–2.

118. Snus MRTP Decision Summary, *supra* note 45, at 12.

In addition, FDA's findings about how the marketing of the MRTTP snus might affect consumer behaviors was based almost exclusively on a single quantitative study conducted by the manufacturer that presented the immediate responses of a sample of adult users and non-users to seeing a video delivering the proposed MRTTP claim relating to their understanding, perceptions, and behavioral intentions.¹¹⁹ Basing such an important decision on a single manufacturer study, without any replication or similar results from other non-industry studies seems odd, especially as some journals will not even publish research studies conducted by tobacco companies because of the enormous conflicts of interest involved and past tobacco industry efforts to manipulate or distort research to prevent or delay public health regulation.¹²⁰ FDA does not mention these possible problems, but FDA does note that an actual use study would have provided more useful information about the claims effects on use patterns.¹²¹ Indeed, FDA had previously recommended that the applicant conduct an actual use study to address deficiencies in its original application; But the Decision Summary does not explain why that was not required or not ultimately necessary.¹²²

FDA also noted several deficiencies with the study the applicant did provide. For example; (1) the Decision Summary mentioned that the video in the study was significantly different from the video the applicant proposes to use in its marketing; (2) some parts of the survey instrument appeared to confuse some respondents; (3) the study did not assess perceptions of risk from dual use compared to exclusive smoking; (4) it did not provide information as to how respondents who intended to buy the product expected to use it (e.g., for complete switching, for dual use moving toward quitting smoking or instead of quitting smoking, or as an alternative to quitting all use); (5) it did not provide direct evidence that the proposed claim would encourage complete switching by smokers; (6) it tested the proposed reduced-risk claim only when delivered via a video; and (7) it did not include any evidence regarding responsive perceptions, intentions, or behaviors among youth.¹²³ Although FDA mentions each of these

119. *Id.* at 12–13, 29.

120. See, e.g., Ruth E. Malone, *Changing Tobacco Control's Policy on Tobacco Industry-Funded Research*, 22 *TOBACCO CONTROL* 1 (2013); *A New Policy on Tobacco Papers*, 7 *PLoS MED.* e1000237 (2010); *The New International Journal of Environmental Research and Public Health (IJERPH) Policy Concerning Tobacco Company Funding*, 15 *INT'L J. ENVTL. RES. & PUB. HEALTH* 2831 (2018). See *supra* note 65 and accompanying text.

121. Snus MRTTP Decision Summary, *supra* note 45, at 40, 41, 44.

122. *Id.* at 9, 16.

123. *Id.* at 17–18, 30–37, 40–43. The Decision Summary notes that the study's testing of the reduced-risk claim delivered as part of a comprehensive video with additional information and imagery is "likely more engaging" than other possible formats and could therefore "reflect an upper bound of effectiveness" of the claim in terms of beneficial impact on consumers—except that a broader marketing plan with the reduced-risk claim "could have a larger impact than a single exposure (regardless of impact)." *Id.* at 42. See also *id.* at 29–30. As the Decision Summary also recognizes, however, such a

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problems and there were certainly ways to address them in a timely fashion, FDA did not require any remedial action by the applicant or take any action to develop any of the missing information, itself.

In addition, the study did not provide a range of additional information that would have enabled FDA to make a more informed evaluation and helped to ensure that the reduced-risk claim would, if allowed, work effectively as possible. For example, the study did not provide any data on the study participants' perceptions, intentions, or behaviors before seeing the video with the reduced risk claim, which would have provided more insights into how the reduced-risk claim (and the video factors other than the claim) impacted perceptions and intentions. The study also did not provide any insights into the proposed claim's possible impacts on e-cigarette or IQOS use, did not ask the smoker participants about their perceptions of whether the snus could actually serve as a complete or satisfying smoking substitute (e.g., how important inhaling was to them), and did not evaluate whether the claim had different impacts on different key subpopulations, such as those with less education or weaker English literacy or heavy versus lighter smokers. Moreover, the study did not evaluate whether the claim would have been understood better and produced stronger intentions to use the snus as a complete substitute for smoking if it had referred to the listed risk reductions being secured when the snus were used *as a complete substitute for cigarettes* rather than, as proposed, when used *instead of cigarettes*.¹²⁴ FDA neither discussed any of these shortcomings in the study nor took any action to address them. Instead, FDA accepted the manufacturer's single study, as submitted, as adequate and persuasive.¹²⁵

In addition, some of the study's findings that the Decision Summary listed as supporting FDA's conclusion that granting the order would likely encourage complete switching by some smokers were statistically insignificant.¹²⁶ While listing not-statistically-significant findings is common in research studies, FDA is not a researcher reporting results but a regulatory agency evaluating research to decide whether it would protect the public health to allow an addictive, harmful tobacco product to be marketed with reduced risk claims. Accordingly,

broader reduced-risk marketing campaign could also increase youth use of the snus (and other harm-increasing uses of the snus) beyond what the video-based study suggests. *Id.* at 41, 43.

124. *Id.* at 29. As the Decision Summary notes, during the review of the MRTP application by FDA's Tobacco Products Scientific Advisory Committee (TSPAC), members suggested that the reduced-risk claim should use this alternative "switching completely" phrasing because "instead of" seemed vague. *Id.* at 18. The Decision Summary also acknowledged the potential ambiguities and problems with the "instead of" phrasing and considered whether the applicant's study suggested any significant problems. *Id.* at 29. But FDA did not require the applicant to show that "switching completely" or any other phrasing would not work better than "instead of," and FDA did not otherwise investigate whether any other phrase might work better. *Id.* at 18.

125. *See id.* at 42.

126. *Id.* at 12, 40-42.

it would be prudent for FDA to follow policy of not citing any research findings to support a permissive MRTP order unless they are statistically significant.¹²⁷

The study's statistically significant findings indicated that, despite being exposed to the reduced-risk claim video, significant numbers of consumers inaccurately perceived that they could secure the snus lower disease risk while still smoking numerous cigarettes or, conversely, that exclusively using the snus was just as harmful as exclusively smoking.¹²⁸ The study also found that exposure to the reduced-risk video increased the number of respondents inaccurately thinking that using the snus would be less harmful than using FDA-approved cessation aids and that using the snus would be less harmful than quitting all tobacco-nicotine use.¹²⁹ Yet FDA did not require that the applicant do any tests to determine whether presenting the reduced-risk claim in different ways or providing supplementary information (e.g., through product inserts, onserts, or labeling) might reduce these problems and the related risk that the snus would be used in harm-increasing ways.

More procedurally, the Decision Summary states that FDA considered all comments submitted by interested parties relating to the MRTP application.¹³⁰ But, unlike with the notice-and-comment process for FDA rulemaking, the Decision Summary did not present any summary of the comments received or provide any FDA responses.¹³¹ This lack of transparency makes it difficult to

127. It is also inconsistent for the Decision Summary to cite statistically insignificant increases to stated intentions to purchase the snus by young adult smokers and adult smokeless tobacco users, in response to seeing the reduced-risk claim video, to support FDA's finding that issuing the MRTP Order would produce harm-reducing complete switching while it also dismisses the not statistically significant increases in former smokers stated intentions to purchase the snus as supporting "the conclusion that the claim will not increase interest in the product among unintended groups. . ." *Id.* at 42. On the other hand, it could have been reasonable for the FDA to use the study's findings that seeing the video *reduced* stated intentions to purchase the snus among young and old adult never tobacco users, but not to statistically significant degrees, to support a finding that issuing the order would not *increase* snus use among just those two groups. *See id.*

128. *Id.* at 35, 38.

129. *Id.* at 36.

130. *Id.* at 11. Numerous comments were submitted relating to the Swedish Match Snus MRTP. *See* U.S. Food & Drug Admin., *Modified Risk Tobacco Product Applications: Applications for 10 Products Submitted by Swedish Match North America Inc.; Availability*, www.regulations.gov/document?D=FDA-2014-N-1051-0001 (last visited July 15, 2020). The Decision Summary states that specific comments "are addressed in the Social Science review." Snus MRTP Decision Summary, *supra* note 45, at 19. But the Decision Summary does not summarize any Social Science review of the comments or provide any information about how to access it. *See id.* Nor does any Social Science review appear to be available via FDA's website, as are all its other documents relating to the snus MRTP Order. *See Modified Risk Tobacco Products*, Food & Drug Admin., <https://www.fda.gov/tobacco-products/advertising-and-promotion/modified-risk-tobacco-products#Overview> (last visited July 15, 2020).

131. The TCA requires FDA to seek public comments on MRTP, but not PMTA, applications, and says nothing about FDA seeking comments on proposed MRTP or PMTA orders. *See* TCA, Pub. L. No. 111-31, sec. 101, § 911(e), 123 Stat. 1776 (2009) (codified at 21 U.S.C. § 387k(e) (2012)) (laying out the requirement for MRTP). Although some redactions or other modifications might be necessary to

determine whether FDA adequately considered comments that submitted evidence and analysis contrary to FDA's findings or Order. It also seems odd that FDA would follow a less rigorous notice-and-comment process for allowing new addictive and harmful tobacco products onto the U.S. market, especially with relative-risk claims, than it follows for implementing rules to reduce tobacco use harms more directly and powerfully, with less risk of harmful side effects or harmful net impacts.

Even if FDA adequately considered all the relevant submitted comments, the other omissions and problems with its evaluation of the snus MRTP application do not provide an adequate or "not arbitrary or capricious" basis for FDA's determination that issuing the MRTP Order will "benefit the health of the population as a whole" (or, more generally, be AFPPH).¹³² Although the snus are clearly established as being among the least harmful types of tobacco products (and considerably less harmful and risky than the IQOS products), it is still difficult, if not impossible, to piece together a justification for FDA's final MRTP Order from the evidence and analysis presented in its Decision Summary. Most fundamentally, FDA's core finding that "the health benefits gained by cigarette smokers (and potentially other smokeless tobacco users) switching to [the snus] will not be outweighed by the health harms from nonusers initiating new tobacco use" does not appear to consider a range of possible harm-increasing uses of the snus by smokers, such as snus use by smokers that prevents or delays smoking or total cessation and the possibility that some initiation into snus use by otherwise nonusers would evolve into more harmful tobacco use, such as smoking.¹³³

Even if we assumed that FDA actually meant that it had determined that the health gains from smokers and more-harmful smokeless users who would not otherwise quit smoking or all use switching to exclusively using snus (the only ways snus use can produce health gains) would not be offset by all the different health-harming ways the snus could be used, the Decision Summary does not provide estimates or other evidence about the likelihood and size of all the different possible harm-increasing uses to support that conclusion (even under the most permissive legally viable interpretation of the AFPPH standard that might be applied in this context). It is also clear from the Decision Summary that

protect any confidential and proprietary business information of the applicants that they did not want disclosed, FDA could choose to make submitted PMTA applications and its own proposed final PMTA and MRTP orders available for public comment and provide summaries of the comments and FDA's responses when issuing the final orders. If FDA had any concerns about revealing certain PMTAs before it issued a final order—even after all proprietary business information had been redacted or even the submitting company's name had been redacted—FDA could still seek and receive helpful general public comments on whether and under what conditions certain types (but not specific brands) of new products should or should not be granted permissive PMTA orders.

132. See *supra* note 22 and accompanying text.

133. Snus MRTP Decision Summary, *supra* note 45, at 12.

FDA could have required the applicant to provide much more reliable and comprehensive information to enable FDA to make less uncertain, more fully informed findings about the various possible behavioral impacts and related harms and risks, or FDA could have readily developed such additional information, itself.

For all these reasons FDA's evaluation of the snus MRTP and subsequent determination that issuing the MRTP Order would be AFPPH (i.e., will benefit the health of the population as a whole) was arbitrary or capricious in violation of the Administrative Procedure Act.¹³⁴

In addition, FDA's expectations about the impact of issuing the Order on different harm-increasing snus uses did not adequately consider the possibility that issuing the Order and related publicity, the reduced-risk and other marketing by the applicant, responsive actions by other members of the tobacco industry, or other factors might dramatically change pre-existing use patterns among users and nonusers well beyond what the applicant's single perceptions and intentions study indicated (e.g., to create a new youth and young adult snus-use fad). Had FDA considered such risks more carefully and taken them more seriously, its evaluation of the application would have been less arbitrary and capricious, and FDA might have also made the Final Order more clearly AFPPH and not arbitrary or capricious, as well.

V. FDA HAS FAILED TO INCLUDE READILY AVAILABLE MEASURES IN ITS FINAL PMTA ORDERS THAT WOULD HAVE PREVENTED UNNECESSARY HEALTH HARMS AND REDUCED THE RISK OF PRODUCING A NEGATIVE NET IMPACT ON THE PUBLIC HEALTH

As already mentioned, the FDA decision summaries and orders acknowledged that the marketing of the PMTA Philip Morris IQOS products and the MRTP snus products would cause at least some risk of new youth initiation, could cause much larger amounts of youth use or other harmful uses than expected, and might produce a negative net impact on the public health or otherwise turn out not to be AFPPH.¹³⁵ Yet FDA did not take advantage of all readily available ways to reduce those harms and risks or provide any explanation for not doing so.

FDA did, however, take some partial steps in that direction. Because FDA's research review showed that consumers tend to underestimate the addiction risk from IQOS, which could increase experimentation and initiation among nonusers and decrease cessation among tobacco users, the FDA IQOS PMTA Order specifically required a special nicotine-addiction warning on all IQOS heatstick

134. See *supra* notes 34–37 and accompanying text.

135. See *supra* notes 49–53 and accompanying text.

packages and advertising.¹³⁶ In addition, the Decision Summary Appendix discussed how tobacco product advertising and promotions, both generally and through specific strategies, increase initiation and use among youth and nonusers.¹³⁷ To address that, the IQOS PMTA Order specifically required that Philip Morris's sponsorship be disclosed in any IQOS promotions done by third-parties on its behalf, and that any Philip Morris social media or other electronic advertising or sales of IQOS be done only with rigorous age and ID verification in order to reduce youth exposure, access, and use.¹³⁸ Based on exactly the same concerns and analysis, FDA included the same requirements and restrictions in its subsequent snus MRTP Order.¹³⁹

However, while the age and ID requirements would also reduce exposure to electronic advertising among adults unwilling to go through such verifications, they did not close the door on electronic advertising that could increase harmful IQOS use among adult nonsmokers and adult tobacco product users. Nor did these electronic advertising provisions do anything to protect youth or adult nonusers from the many other forms of advertising and promotions the decision summaries appendices describe as increasing youth and nonuser use. Nor did FDA include any other provisions in the IQOS PMTA Order or the subsequent IQOS MRTP Order or snus MRTP Order to prevent or reduce harm-increasing uses of the products among youth, nonusers, e-cigarette users, or smokers, other than the nicotine warning statements required in the IQOS PMTA Order.¹⁴⁰

136. IQOS PMTA Decision Summary, *supra* note 29, at 87–89; IQOS PMTA Order, *supra* note 45, at 13. *See also* IQOS PMTA Decision Summary, *supra* note 29, at 12, 98. But FDA could have made the mandated warning even stronger by requiring black text on fluorescent yellow background, which would have made it much more eye-catching than the order's requirement of black on white or vice versa. *See, e.g.,* Laura K. Lempert & Stanton A. Glantz, *Implications of Tobacco Industry Research on Packaging Colors for Designing Health Warning Labels*, 18 NICOTINE & TOBACCO. RES. 1910 (2016) (explaining the impacts of color choices used in advertisements and warning labels).

137. IQOS PMTA Decision Summary, *supra* note 29, at 111–20; *See also id.* at 12.

138. IQOS PMTA Order, *supra* note 45, at 14–15.

139. Snus MRTP Decision Summary, *supra* note 45, at 13, 64–77; Snus MRTP Order, *supra* note 24, at 13–14. Without explanation, the subsequent FDA PMTA Order allowing the marketing of the 20th Century Group very-low-nicotine cigarettes did not include any such marketing restrictions. 22nd Century PMTA Order, *supra* note 45. Apparently, FDA determined that it was AFPPH to allow the highly toxic but not addicting cigarettes to be advertised and sold without rigorous age and ID verification to reduce youth exposure and access, despite identifying only adult smokers as the intended users. 22nd Century PMTA Decision Summary, *supra* note 45, at 61. Although all of FDA's analysis supporting its application of adult-only restrictions and sponsorship disclosures in the electronic marketing of IQOS apply equally well to the marketing of the Swedish Match snus or any other harmful and/or addictive tobacco product, FDA also did not retroactively apply them to the snus PMTA Order, which included no advertising or marketing restrictions (perhaps because FDA planned on applying them to the snus through the later MRTP order), and FDA has not initiated any rulemaking to apply the restrictions more broadly.

140. *See* IQOS PMTA Order, *supra* note 45; IQOS MRTP Order, *supra* note 45; Snus MRTP Order, *supra* note 24. Nor did the underlying Snus PMTA Order include any such restrictions or requirements. *See* Snus PMTA Order, *supra* note 45.

In the PMTA Order sent to Philip Morris, FDA observes that “you include representations about your marketing plan for your products in the United States and indicate that you intend to focus marketing on adult cigarette smokers while limiting reach to unintended audiences.”¹⁴¹ But rather than include requirements in the PMTA Order to ensure that Philip Morris would actually do just that, the Order simply says that “FDA *encourages* you to consider measures to limit youth-exposure to any of the products’ labeling advertising, marketing, and/or promotion appearing in print media publications,” and says nothing about any other forms of advertising that might prompt youth use or other use that increases harms.¹⁴² The snus MRTP Order FDA sent to Swedish Match similarly “recommends limiting youth-exposure to any of the tobacco products’ labeling, advertising, marketing, and/or promotion appearing in print media publications” and states that “we strongly recommend that you take measures to limit youth initiation and use of the products, beyond limiting advertising and promotion as required in this order,” without requiring any such efforts by Swedish Match.¹⁴³

As things stand, there is nothing in the IQOS PMTA Order or the Snus PMTA or MRTP Orders or other applicable federal laws or regulations to stop Philip Morris or Swedish Match or retailers from marketing the products in a variety of ways that could reach and attract youth and adult nonusers or encourage harmful use of the products by current tobacco product users. For example, to maximize sales and profits, the companies could market either product as “a cool new way to use tobacco without smoking,” using ads visible to youth and nonusers at retail outlets and other indoor locations or in magazines and other publications. Or IQOS could be advertised as a “a new fun way to ‘smoke’ where smoking is prohibited” or as “more fun than Juul” or “more

141. IQOS PMTA Order, *supra* note 45, at 2.

142. *Id.* (emphasis added). Similarly, the snus IQOS Decision Summary notes that the Swedish Match “proposes to use the claim in advertisements but does not plan to add it to the products’ labels,” and plans to use a reduced-risk video different from the one in the study (which included other features that appear to be unauthorized implied reduced-risk claims or illegal implied FDA approvals), and the FDA appears to have based its evaluation on Swedish Match following suit. Snus MRTP Decision Summary, *supra* note 45, at 10, 17–18, 30 n.4. But the FDA did not put any restriction in the Final Order to ensure that Swedish Match would use the reduced-risk and market the snus as planned and not implement any problematic changes. *See* Snus MRTP Decision Summary, *supra* note 45. Generally speaking, if the application for a PMTA or MRTP order proposes to package, label, market, and sell the applicant product in a certain way, and FDA bases its AFPPH determination on those proposals, it seems quite odd, and arbitrary or capricious, for FDA not to require the applicant, at a minimum, to package, label, market, and sell the product as proposed (or for FDA to put other restrictions and requirements in the final order necessary to ensure the product is packaged, labeled, marketed, and sold in responsible, AFPPH ways in the future).

143. Snus MRTP Order, *supra* note 24, at 14–15. The MRTP Order also requests that Swedish Match annually provide FDA with summaries of “the implementation and effectiveness of any policies and procedures regarding verification of the age and identity of purchasers of the products” and “the implementation and effectiveness of any policies and procedures regarding restrictions on youth access to the products,” but does not require any such reports or require that Swedish Match implement any such policies or procedures. *Id.* at 15.

satisfying than vaping.” Because snus are not subject to many restrictions and requirements that apply only to cigarettes, the Swedish Match snus could also be promoted through outdoor and indoor ads at or near locations where youth congregate or in publications with heavy youth readerships.¹⁴⁴ The snus could also be advertised as “a way to use tobacco where you live, work, or play without anyone being able to tell,” and could be sold in youth-affordable mini packs. In addition, both the snus and IQOS could be advertised in a variety of ways to former smokers who have quit all use as “a way to return to the joys of tobacco without smoking.”¹⁴⁵

While these examples might be unlikely, they are legal and possible, and they show how existing legal constraints are inadequate to ensure responsible marketing by Swedish Match, Philip Morris, or the tobacco industry in general. Moreover, FDA’s own analysis and findings in the IQOS PMTA and Snus MRTP Decision Summary Appendices show that tobacco product advertising encourages youth, nonuser, and overall initiation and use even when done without such obviously troublesome taglines, themes, or targeting.¹⁴⁶ Indeed, the snus MRTP Decision Summary says that to prevent youth use “it is essential that modified risk marketing be targeted to current tobacco users and disseminated in

144. While there is no discussion on point, the IQOS PMTA Discussion Summary and Order assume that the IQOS heatsticks fit under existing “cigarette” definitions in all federal government laws and regulations placing taxes, restrictions, and requirements on cigarettes, and there has been no indication that Philip Morris or any other party will contest that FDA finding. *See, e.g.* IQOS PMTA Decision Summary, *supra* note 29, at 15, 74; IQOS PMTA Order, *supra* note 45, at 13 n.6 (assuming warning label requirements that apply to combustible cigarettes apply to IQOS sticks, too). As cigarettes, IQOS heatsticks cannot, for example, be sold with flavors other than tobacco or menthol or in packs of fewer than 20 or be offered as free samples under federal law. TCA, Pub. L. No. 111-31, sec. 101, § 907(a)(1)(A), 123 Stat. 1776 (2009) (codified at 21 U.S.C. § 387g(a)(1)(A) (2012)); 21 C.F.R. § 1140.16 (2010) (restricting size of packages and offers of free samples). Under the settlement agreements between the states and Philip Morris and most other cigarette companies, which have cigarette definitions that parallel the federal definitions, the IQOS heatsticks, as cigarettes, cannot, for example, be advertised in outdoor ads, except to a limited extent at retail outlets, or in publications with substantial youth readerships. *See* Campaign for Tobacco-Free Kids, *Summary of the Master Settlement Agreement (MSA)* (July 17, 2017), <https://www.tobaccofreekids.org/assets/factsheets/0057.pdf> (describing the allowances and limitations of advertising). But these legal restrictions do not apply to snus. FDA’s publicly available IQOS PMTA documents do not mention the settlement agreement marketing restrictions that apply to the heatsticks as “cigarettes” or how they might reduce the risk of future IQOS marketing that increases youth or nonuser use. FDA does state that “[a]s a cigarette product, [h]eatsticks cannot be marketed with characterizing flavors aside from tobacco or menthol. . . [which] may reduce the appeal to nonusers.” But FDA does not discuss any other federal restrictions or requirements that apply to the heatsticks as “cigarettes.” IQOS PMTA Decision Summary, *supra* note 29, at 74; *See also id.* at 76, 97.

145. Neither Swedish Match nor Philip Morris or any major retailers appear to have yet marketed the IQOS or snus products in the United States in any such irresponsible or harm-increasing ways. But that does not make FDA’s leaving the door open for them to do so any less imprudent and, therefore, arbitrary or capricious.

146. *See* IQOS PMTA Decision Summary, *supra* note 29, at 111–16; Snus MRTP Decision Summary, *supra* note 45, at 65–70

ways to minimize exposure among youth.”¹⁴⁷ It is also quite possible that the companies will market the IQOS and the MRTP snus products quite aggressively to maximize their sales and profits. In fact, the snus MRTP Decision Summary notes that Swedish Match “proposes to include its claim in its advertising using the following platforms: its branded website, print and online advertising, earned media/public relations, direct mail, email, social media, and consumer activation selling events in adult only facilities,” and FDA did not restrict its ability to do so (other than placing age and ID verification requirements for electronic marketing and sales).¹⁴⁸

Had FDA decided to do more to ensure responsible marketing in its PMTA and MRTP Orders and otherwise minimize exposure to the IQOS and snus advertising among youth and others whose use could only be harmful, numerous effective options were readily available. For example, FDA could have allowed the snus on the market only as a substitute for addicted users of more harmful tobacco products, and allowed IQOS as only a substitute for smokers, with corresponding advertising restrictions. For instance, to reduce exposure to the snus or IQOS advertising among those who could only be harmed by using the products, FDA could have prohibited their advertising in publicly visible indoor and outdoor ads or in ads in general-circulation magazines or other publications. Going further, FDA could have restricted the products’ advertising only to communications directed specifically at those who could benefit from using them, such as ads at adult-only outlets specializing in tobacco-product sales (or that sell only the snus or IQOS) and ads in direct communications (e.g., direct mail, email, social media or hand-outs) provided only to pre-verified adults who self-identify as current users of more harmful products or as users who had already switched to the snus or IQOS.¹⁴⁹

147. Snus MRTP Decision Summary, *supra* note 45, at 13. *See id.* at 43, 45, 48, 71–72 (discussing advertising and impacts on youth). *See also* IQOS PMTA Decision Summary, *supra* note 29, at 115–18 (highlighting the importance of the marketing requirements and restrictions). While the decision summaries focus a lot of protecting youth from the snus or IQOS marketing, almost nothing is said about the need to protect nonusers, including former smokers or former users who might relapse into using the IQOS or snus products, from such marketing or the need to ensure that the marketing that reaches smokers or users of other more-harmful products does not encourage harm-increasing uses of the products.

148. Snus MRTP Decision Summary, *supra* note 45, at 18.

149. A different strategy might have been to restrict the various forms of advertising that reach youth and nonusers rather than prohibit them – e.g., by banning images or colors or permitting only black text on white background except when necessary to convey accurate product information. But such an approach would likely be much less effective at protecting against youth use or harm-increasing nonuser use than available measures to minimize any youth or nonuser exposure to the ads in the first place. *See, e.g.,* Wilm Quentin et al., *Advertising Bans as a Means of Tobacco Control Policy: A Systematic Literature Review of Time-Series Analyses*, 52 INT’L J. PUB. HEALTH 295, 305 (2007). Nevertheless, including such advertising restrictions in the snus and IQOS PMTA Orders would have still provided much stronger protections against both individual and net public health harms than the orders FDA issued.

FDA also could have required the products to be sold with additional labeling and information that would reduce the risk that any youth or nonusers exposed to the products or their advertising would begin using them, and also reduce the likelihood that users of more-harmful tobacco products would use the new products in ways that increased, rather than reduced, their tobacco-related harms and risks (e.g., by preventing or delaying smoking or total cessation). For example, FDA might have revised the new nicotine-addiction warning it required for IQOS to also state that the product is meant only as a complete substitute for smoking and any other use will increase harms or risks to the user's health; and FDA could have required a parallel notice on all of the Swedish Match snus packaging and ads stating that it is meant only as a complete substitute for other smoked, otherwise inhaled, or smokeless tobacco product use.¹⁵⁰ In addition, FDA could have required that both products be sold with package inserts that: (1) provide instructions for how to use the product in harm-reducing ways (including reducing nonuser exposure to IQOS); (2) describe the addictiveness, harms, and risks from any other uses; explain the greater health benefits from total cessation; and (3) inform users how they can obtain cessation assistance.¹⁵¹

By requiring such inserts or warnings for the snus, FDA could have also directly addressed the many harmful misunderstandings consumers have about snus, including those that viewing the snus relative risk claim video increased, which FDA discussed in its snus MRTP Decision Summary but did nothing about (e.g., that many consumers inaccurately think that using the snus is less harmful than FDA-approved nicotine replacement therapies or complete cessation or, conversely, is just as harmful as smoking, or that dual use secures the same benefits as using only snus instead of smoking).¹⁵² It is also clear from the IQOS PMTA Decision Summary that FDA was aware of research indicating

150. Requiring such warnings for IQOS would have simply been requiring a stronger version of text Philip Morris was already using in an IQOS brochure provided to study participants, which stated that "the product is intended for smokers who want to continue using tobacco and is not intended for use by non-smokers." IQOS PMTA Decision Summary, *supra* note 29, at 74.

151. For the Swedish Match snus PMTA, the Decision Summary included a statement recommending "appropriate instructions for use." Snus PMTA Decision Summary, *supra* note 45, at 34. But FDA's concern appears to have been only with making sure consumers understood that the snus should be consumed in a different way than traditional U.S. smokeless tobacco products (e.g., different mouth placement and expectoration), and the Final Order made no mention of instructions for use. *Id.* at 31, 39. The Philip Morris IQOS application provided an IQOS Tobacco Heating System User Guide and IQOS Quick Start Guide, which Philip Morris presumably intended to include with the IQOS device sold to consumers. IQOS PMTA Decision Summary, *supra* note 29, at 85–86. FDA describes these materials as instructing users only on how to operate, clean, and maintain the IQOS system. *Id.* at 85. FDA concluded that some "additional support" Philip Morris intended to provide (details redacted) and the instructions in the guides "should resolve most consumer issues related to the issue." *Id.* at 86. But the Final Order did not require Philip Morris to provide that support or those instructions and, as with the snus, FDA did not consider requiring more detailed instructions regarding how to use the product to reduce tobacco-related harms and risks, what uses would increase harms and risks, instead, and what other options are available to users who want to reduce harms and risks even further.

152. *See supra* notes 128–129 and accompanying text.

that IQOS could be more harmful and risky to users than using e-cigarettes, but that consumers tended to view the two different products as being similarly risky.¹⁵³ Accordingly, FDA could have required that IQOS have label warnings or product inserts that informed consumers that switching to IQOS from e-cigarettes could increase user harms and risks.

Another approach would have been for FDA to include provisions in the PMTA and MRTP Orders to address all the specific harmful tobacco product labeling and advertising features or tactics identified in the Decision Summary Appendices, rather than just list certain ways that companies receiving PMTA or MRTP orders “should” constrain their marketing to protect against youth use.¹⁵⁴ For example, both Decision Summaries state that “firms receiving marketing authorization for a new tobacco product should seek to reduce the youth-appeal of the tobacco product’s labeling, advertising, marketing, and promotional materials, including avoiding the use of imagery and themes known to resonate with youth, such as aspirational content depicting tobacco use as ‘cool,’ attractive, rebellious, and/or risky, or as a means to make one more popular, desirable, or independent.”¹⁵⁵ But rather than just encourage such youth-protective marketing, FDA could have required it, and instead of merely identifying harmful marketing tactics, FDA could have prohibited them.¹⁵⁶

153. See IQOS PMTA Decision Summary, *supra* note 29, at 22, 88–89.

154. See *id.* at 116; Snus MRTP Decision Summary, *supra* note 45, at 70. Similarly, rather than just requiring in the Final Order that Philip Morris and Swedish Match maintain records and report on any policies, procedures, or actions it might implement “regarding restrictions on youth access to the products” and to restrict youth-access and to “limit youth-exposure to the products’ labeling, advertising, marketing, and/or promotion,” FDA could have required Philip Morris to develop such policies, procedures, and actions, follow them, and ensure that any retailers selling IQOS followed the policies and procedures, as well. IQOS PMTA Order, *supra* note 45, at 6–7, 10–12; Snus MRTP Order, *supra* note 24, at 10–13.

155. IQOS PMTA Decision Summary, *supra* note 29, at 116; Snus MRTP Decision Summary, *supra* note 45, at 70.

156. See IQOS PMTA Order, *supra* note 45, at 6–7, 10–12; Snus MRTP Order, *supra* note 24. Similarly, the PMTA and MRTP Orders require Philip Morris and Swedish Match to provide FDA with copies of all new advertising, marketing, and/or promotional materials at least 30 days prior to their publication for FDA’s review and comment, but “not for pre-approval.” IQOS PMTA Order, *supra* note 45, at 12–13; Snus MRTP Order, *supra* note 24, at 11. To better protect the public health, FDA could have instead required the submission of any materially changed or new advertising and/or promotional materials for pre-approval prior to any publication, at least whenever they included any new claims about the IQOS or snus products or any other new descriptors or other new text or imagery that, based on existing research on product marketing and consumer behavior, might reasonably be seen as creating a new risk of attracting youth or promoting any harm-increasing uses of the product. See, e.g., Sabeeh A. Bai et al., “Organic,” “Natural,” and “Additive-Free” Cigarettes: Comparing the Effects of Advertising Claims and Disclaimers on Perceptions of Harm, 21 NICOTINE TOBACCO RES. 933 (2019); Tatiana Basáñez et al., *Vaping Associated with Healthy Food Words: A Content Analysis of Twitter*, 8 ADDICTIVE BEHAV. REP. 147 (2018). Or, FDA could have required that before being used any materially changed or new labeling and ads must be submitted to FDA or to independent research facilities for testing to ensure against their misleading consumers in ways that could increase product-related harms. See, e.g., David M. Gardner & Nancy H. Leonard, *Research in Deceptive and Corrective*

Similarly, FDA notes that applicants could limit their tobacco products' youth appeal by "focusing marketing content on instructional demonstrations and product comparisons and avoiding bright, bold, cheerful designs and colors, which can influence youths' product choices because these characteristics affect their perception of the products, draw attention to them, and influence purchase decisions."¹⁵⁷ But FDA did not take the logical next step to require Philip Morris and Swedish Match to follow that approach.

In addition, the decision summaries observe that tobacco product promotional items, celebrity endorsements, and links to cultural icons have been found to increase youth use,¹⁵⁸ and could have prohibited their use in any marketing of IQOS or the Swedish Match snus. Similarly, the decision summaries cite research finding that youth exposure to product displays and advertising at point of sale, and to advertising in print, on television, or in movies increases the risk of tobacco product use among youth and nonusers,¹⁵⁹ and FDA could have prohibited or restricted any such advertising for the snus or IQOS that would directly reach numerous youth or nonusers, or even restricted their sale and in-store advertising to adult-only tobacco-product sales outlets.¹⁶⁰

FDA's failure to even consider these or other available ways to reduce the risk that its PMTA or MRTP orders would cause new individual health harms or produce a negative net public health impact was "arbitrary or capricious" in violation of the Administrative Procedure Act.¹⁶¹ There also does not appear to

Advertising: Progress to Date and Impact on Public Policy, 12 CURRENT ISSUES & RES. ADVERT. 75 (1990); J. Edward Russo et al., *Identifying Misleading Advertising*, 8 J. CONSUMER RES. 119 (1981).

157. IQOS PMTA Decision Summary, *supra* note 29, at 116; Snus MRTP Decision Summary, *supra* note 45, at 70. The Decision Summaries also state that the products' "labeling, advertising, marketing, and promotional materials *should* be clearly tailored to appeal to adults by using personalization strategies that make the content relevant and meaningful to adult recipients . . . without making them look highly appealing or aspirational to other non-targeted populations, such as youth." *Id.* (emphasis added). Additionally, FDA could have included specific restrictions and requirements to help ensure that all future labeling, advertising, marketing, and promotional materials for the IQOS and snus products did that.

158. IQOS PMTA Decision Summary, *supra* note 29, at 113; Snus MRTP Decision Summary, *supra* note 45, at 66–67, 72–73.

159. IQOS PMTA Decision Summary, *supra* note 29, at 112–14; Snus MRTP Decision Summary, *supra* note 45, at 65–68.

160. FDA has considered such adult-only sales restrictions in other tobacco product contexts. Prior to releasing its decision allowing IQOS on the market, FDA proposed an enforcement strategy focusing on enforcement against e-cigarettes on the market without permissive PMTA orders unless they restricted the sale of their flavored brands (other than tobacco and menthol flavored) to adult-only stores or adult-only areas in youth-accessible stores. U.S. FOOD & DRUG ADMIN., MODIFICATIONS TO COMPLIANCE POLICY FOR CERTAIN DEEMED TOBACCO PRODUCTS: GUIDANCE FOR INDUSTRY (2019), <https://www.fda.gov/media/121384/download>. Without any clear explanation, however, that restriction was not included in the final version of that guidance. *See generally* U.S. FOOD & DRUG ADMIN., *Guidance Document*, *supra* note 16.

161. *See supra* notes 35–36, 102 and accompanying text. In fact, the FDA Decision Summaries for the IQOS PMTA and the snus MRTP each state: "In this context, FDA should consider including detailed marketing restrictions and requirements, in addition to other requirements for any product

be any reasonable public health justification FDA could have provided either for not considering them or for not including at least some of them in the final orders. Indeed, it would have been appropriate for the protection of the public health for FDA to have done so, both generally and as that phrase is defined in the statute.

The Tobacco Control Act gives FDA extensive authority to include product and marketing restrictions and requirements in PMTA or MRTP orders, so long as they will prevent new health harms and risks, reduce existing health harms and risks, or otherwise be AFPPH.¹⁶² Accordingly, if FDA reasonably determines that adding restrictions or requirements into a PMTA or MRTP order is AFPPH, the only significant legal impediment is the First Amendment. But its protections against excessive corporate speech restrictions or unreasonable compelled corporate speech would not apply to any non-speech restrictions or requirements FDA included in the orders. Nor would the First Amendment apply to any speech-related restrictions or requirements FDA reasonably determined were necessary to make allowing the products on the market permissible as AFPPH.¹⁶³ In addition, speech-related restrictions in PMTA orders that were not necessary for an AFPPH determination would still be constitutionally valid if they promoted the substantial government interest of preventing and reducing individual or public health harms and risks and still left the manufacturers with reasonable ways to communicate with their legal customers.¹⁶⁴ Moreover, if

receiving a PMTA or MRTP authorization.” IQOS PMTA Decision Summary, *supra* note 29, at 119; Snus MRTP Decision Summary, *supra* note 45, at 73. Yet the Decision Summaries provide no evidence that FDA did that in any reasonable or comprehensive way in either case.

162. TCA, Pub. L. No. 111-31, sec. 101 §§ 910(c)(1)(B), 911(h)(5), 911(h)(1-2), 123 Stat. 1776 (codified 21 U.S.C. §§ 387j(c)(1)(B), 387k(h)(1), (2), (5) (2009)). *See also*, Lindblom, *supra* note 22, at 531-32, 550-51. However, the TCA also leaves FDA free to reject inadequate PMTA or MRTP applications and proposed orders rather than make any effort to fix them by inserting new restrictions and requirements to make them AFPPH, and FDA has no obligation to consider any information or analysis that might support the application or its proposed order other than what the application, itself, offers. TCA, sec. 101 §§ 910(c)(2), 911(g)(1-3)(A) (codified at 21 U.S.C. §§ 387j(c)(2), 387k(g)(1), (2), (3)(A) (2009)).

163. If the courts could strike down a commercial speech restriction or requirement that FDA had reasonably determined was necessary to include in the PMTA or MRTP order to enable FDA to find that issuing it was AFPPH, FDA would have to withdraw the order as no longer AFPPH, preventing any marketing of the subject product. But any speech restrictions or requirements necessary to make the marketing of a product AFPPH would be no more extensive than necessary to achieve the substantial government interest in issuing AFPPH tobacco control rules and would, therefore, under existing First Amendment law, be constitutionally permitted. *See Lorillard Tobacco Co. v. Reilly*, 533 U.S. 525, 553-65 (2001) (discussing the First Amendment’s relationship with commercial speech and the tobacco industry).

164. *See Lorillard Tobacco Co. v. Reilly*, 533 U.S. 525, 553-65 (2001) (finding that a regulation of speech cannot hinder an entity from proposing a commercial transaction or prevent the potential consumer the opportunity to gather relevant information on the products). *See also* Disc. Tobacco City & Lottery, Inc. v. United States, 674 F.3d 509, 537-48 (6th Cir. 2011) (rejecting First Amendment challenges to the MRTP pre-market order process and to a range of speech-related restrictions and requirements placed on cigarettes by the TCA, and suggesting how a TCA requirement that certain cigarette ads be only black text on white background could be restructured to be constitutionally

FDA had allowed the products on the market only as substitute products for smokers and other users of more-harmful tobacco products, making them the products' only legal customers, that would have sharply reduced the scope of the companies' related First Amendment protections, as they would have no constitutional right to advertise to illegal customers, including non-smokers and youth.¹⁶⁵ FDA could have also avoided possible First Amendment compelled-speech problems with any required warnings or product inserts or onserts, even if they were not necessary for FDA's AFPPH determination, by ensuring that they were clearly marked as coming from FDA, not the companies, and were designed to convey accurate product-related information relevant to potential or actual users (as opposed to explicitly discouraging their use by legal customers or engaging in scare tactics or other emotional manipulation).¹⁶⁶

Because it might be seen as impeding rather than advancing the TCA's goal of reducing tobacco-related public health harms (the relevant substantial government interest for constitutional analysis), both the First Amendment and the AFPPH standard might invalidate a speech-related restriction or requirement placed in a PMTA or MRTP order to reduce related health harms and risks if it were clear that the restriction or requirement would also disproportionately reduce the likelihood and size of the expected net public health gains from the order.¹⁶⁷ But FDA could avoid those risks simply by including in the orders only the many available restrictions and requirements (such as those described above) that, based on available information and analysis, FDA reasonably determined would reduce the health harms and risks from allowing the product's marketing without reducing the expected net public health gains to any significant extent.

Despite being able to get around First Amendment constraints, FDA might argue that including strong additional restrictions and requirements in the PMTA orders did not make sense or was unfair because it would be regulating less-harmful tobacco products much more rigorously than more harmful tobacco products, including cigarettes. But, as discussed above, FDA has already included restrictions and requirements on the marketing of IQOS and the Swedish Match snus that are more strict than existing restrictions on the

permitted). For a more detailed analysis of related case law in the parallel situation of FDA PMTA orders for applicant e-cigarettes, see Eric N. Lindblom, *Effectively Regulating E-Cigarettes and Their Advertising—and the First Amendment*, 70 FOOD & DRUG L. J. 57, 81–91 (2015).

165. See, e.g., *Lorillard Tobacco Co.*, 533 U.S. at 571; *Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n of New York*, 447 U.S. 557, 564 (1980); Lindblom, *supra* note 164.

166. See, e.g., Eric N. Lindblom et al., *FDA-Required Tobacco Product Inserts & Onserts – and the First Amendment*, 72 FOOD & DRUG L. J. 1, 11–22 (2017).

167. It is also possible, however, that avoiding the production of brand-new health harms and risks to persons who would not otherwise be harmed or put at risk by including such a restriction or requirement in the final orders could be AFPPH (depending on how FDA and the courts interpret the remaining gray areas of the standard) and could be seen as promoting a separate substantial government interest in not causing brand-new harms or risks to innocent people, so long as the final order still produced some significant net public health gain. See, e.g., Lindblom, *supra* note 164.

marketing of more-harmful smoked tobacco products.¹⁶⁸ Indeed, the AFPPH standard cares only about whether issuing the order will produce a beneficial net public health impact. If new restrictions or requirements added into the order will prevent or reduce new health harms and risks from the product's marketing or increase the likelihood or size of related harm reductions, the fact that they are more strict than those other existing laws or regulations place on more harmful tobacco products is irrelevant. In addition, there is nothing stopping FDA (other than possible political obstacles within the Administration) from concurrently issuing a proposed rule to place parallel requirements and restrictions on some or all other tobacco products when it issues a PMTA order. For example, FDA could have used all of the evidence and analysis provided in the decision summaries to support the PMTA and MRTP orders' requirement that any electronic advertising or sales of the IQOS or snus products be done with rigorous age and ID verification to support a concurrent or subsequent proposed rule to subject all other tobacco products to that same requirement.¹⁶⁹ However, it could not be AFPPH to allow a new PMTA or MRTP product to be marketed in avoidable harm-increasing ways while FDA goes through the typically long process of developing, implementing, and enforcing a final rule that would apply both to the PMTA and MRTP products and other harmful and addictive tobacco products, rather than including measures in the final PMTA or MRTP orders to prevent and reduce such harmful marketing of the PMTA and MRTP products from the start¹⁷⁰

Although not mentioned in the Decision Summaries, it is also possible that FDA believed that including any additional, legally permissible restrictions and requirements in the PMTA or MRTP Orders was unnecessary or not worth doing because the new individual or public health harms or risks created by the marketing of the Swedish Match snus or Philip Morris IQOS were low or unlikely and post-market surveillance could identify any unexpected higher

168. See *supra* note 139 and accompanying text.

169. IQOS PMTA Decision Summary, *supra* note 29, at 111–20; Snus MRTP Decision Summary, *supra* note 45, at 64–75 (providing the analyses that FDA could have used to support such a requirement).

170. It would also be counterproductive (and irrelevant for qualifying an order as AFPPH) for FDA to allow a PMTA or MRTP tobacco product on the market, after finding that it would create unnecessary individual and public health harms and risks, based on an asserted FDA preference to rely on its own concurrent or future public education campaigns to prevent and reduce those harms and risks rather than include restrictions or requirements in the final orders that would prevent and reduce them earlier or more effectively and certainly. Taking on that burden to counteract harm-increasing product marketing that could simply have been prevented in the first place and using limited FDA tobacco control resources for those purposes, simply does not make sense. It is also unlikely that FDA could develop, implement, and sustain a counter-marketing public education campaign that would work as effectively as placing marketing restrictions and requirements in the order. Moreover, it would be much more AFPPH for FDA both to include the restrictions and requirements in the PMTA and MRTP orders and develop and run the complementary public education campaigns, which would work to reduce tobacco use and its harms even more quickly and powerfully, rather than just do the latter.

amounts of youth initiation or other harm-increasing uses, at which point FDA could take remedial action to stop or reduce those harms and risks. Or perhaps, FDA believed that post-market surveillance and the threat of revoking the PMTA or MRTP Orders would be enough to ensure responsible marketing and low levels of new youth initiation or other harm-increasing uses. As already described above, there are some fundamental problems with FDA's findings or expectations of low risks or low harms from the marketing of the IQOS products and the MRTP snus.¹⁷¹ But, even if we put that aside, any FDA reliance on post-market surveillance and possibly withdrawing or amending the final orders to address unanticipated new harms that might emerge is still both procedurally and substantively flawed as well as legally impermissible.

Most fundamentally, it could not be AFPPH, under any viable interpretation of the standard, to create any new health harms or risks by allowing the marketing of the snus or IQOS products if their likelihood and size could easily be reduced effectively through including additional, readily available restrictions or requirements in the PMTA orders – especially if that would not reduce or increase the likelihood and size of the expected net public health gains. Nor could it be AFPPH to allow new health harms to occur and only afterwards take action to prevent or reduce them rather than implement readily available measures to prevent or reduce the likelihood and size of the possible new harms from the start.

Closing the barn door only after the horses have bolted is even more problematic considering how long it typically takes FDA to initiate effective preventive or remedial tobacco control action, if it does so at all, even when faced with a health emergency or crisis or a public health disaster.¹⁷² FDA's record for enforcement against specific tobacco product manufacturers or brands if they violate the TCA, other provisions of the Food, Drug & Cosmetic Act, or related rules is also weak. Enforcement is typically done, when done at all, quite slowly, only after a lengthy process of warning letters, responses, consultations, and opportunities for the manufacturer to implement corrective actions.¹⁷³ The extent

171. See *supra* notes 93–102, 112–134 and accompanying text.

172. For example, despite having extensive powers and authorities to do so since 2009, the FDA has yet to implement a substantive rule to reduce the close to half a million premature deaths that occur each year from smoking in the United States. Nor has the FDA yet issued a rule, even in just proposed form, to address the sharp increase in youth e-cigarette use that FDA labeled an “epidemic” and a “crisis” in the Fall of 2018. See, e.g., FDA Statement, U.S. Food & Drug Admin., *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* (Oct. 31, 2018), www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-meetings-industry-related-agencys-ongoing-policy (last visited July 15, 2020).

173. For instance, while the FDA has issued tens of thousands of warning letters to tobacco product retailers, often with related press announcements, it has sent relatively few to manufacturers or importers, and even fewer relating to major brands, with very few FDA press announcements of either positive resolutions or follow-up FDA enforcement actions. See *Warning Letters*, U.S. FOOD & DRUG

to which this lack of FDA clarity in taking effective enforcement or other regulatory action is from internal FDA factors or from lack of support or impediments from the White House, the Office of Management and Budget, or other federal agencies is not clear. But it is clear that FDA does not have a strong record for taking quick remedial action in the tobacco control context.

Even if FDA did promptly notice that the marketing of a new PMTA or MRTP product had turned out to be not AFPPH and quickly decided to withdraw the original order, the statute does not provide for quick remedial action. For withdrawing a PMTA order, the TCA requires “due notice and opportunity for informal hearing” and, “where appropriate, advice on scientific matters from the Tobacco Products Scientific Advisory Committee,” and allows the holder of the PMTA or order to appeal any FDA decision to withdraw the order, which could produce further delays; withdrawing an MRTP order also requires an opportunity for an informal hearing; and other TCA provisions and other laws and rules provide manufacturers with other due process and appeal rights.¹⁷⁴ If the withdrawal of the PMTA or MRTP order meant to stop the sale of the product or

ADMIN., www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/compliance-actions-and-activities/warning-letters; *Press Announcements*, U.S. FOOD & DRUG ADMIN., www.fda.gov/news-events/fda-newsroom/press-announcements (last visited July 15, 2020). Yet there is strong evidence that major manufacturers and major brands have been violating the TCA or related rules. See, e.g., Erik K. Soule et al., *Major Online Retailers Selling Electronic Cigarettes as Smoking Cessation Products in the USA*, TOBACCO CONTROL (Aug. 30, 2019) and Letter from Am. Cancer Soc’y et al. to Dr. Janet Woodcock, Dir., Ctr. for Drug Evaluation & Research, U.S. Food & Drug Admin. (Oct. 14, 2015) (regarding e-cigarettes being marketed with therapeutic claims without required prior FDA approval); Letter from Action on Smoking and Health to Mr. Mitchell Zeller, Dir., Ctr. for Tobacco Prods., U.S. Food & Drug Admin. (Feb. 26, 2016) (explaining major tobacco companies introducing new tobacco products into the market without required FDA pre-market review and permissive new product orders); Letter from Matthew M. Myers, President, Campaign for Tobacco Free Kids to Ann Simoneau, Dir., Office of Compliance and Enf’t, Ctr. for Tobacco Prods., U.S. Food & Drug Admin. (May 26, 2016) (regarding FDA warning letter sent to Reynolds American, Inc. and its subsidiary Santa Fe Natural Tobacco Co. for the marketing of Natural American Spirit brand cigarettes in violation of the TCA’s modified risk provisions not having prompted any remedial changes or FDA enforcement action); Letter from Am. Acad. of Pediatrics et al., to Dr. Scott Gottlieb, Comm’r, U.S. Food & Drug Admin. (Aug. 7, 2018) (regarding e-cigarettes being marketed in violation of the TCA and the FDA Deeming Rule). See also *Comments Submitted to the FDA by the Campaign for Tobacco-Free Kids and Partners*, www.tobaccofreekids.org/what-we-do/us/fda/comments-letters (last visited July 15, 2020) (providing records of these and other letters from public health groups that present evidence of violations by tobacco product manufacturers). FDA’s 2015 warning letter regarding Natural American Spirit brand cigarettes being marketed with illegal reduced-risk claims ultimately produced a settlement agreement between FDA and the manufacturer in 2017, but the agreement has been criticized for permitting the continuing use of terms and phrases in the brand’s advertising that violate the TCA. See, e.g., Stefanie K. Gratale et al., *Regulating Language, Not Inference: An Examination of the Potential Effectiveness of Natural American Spirit Advertising Restrictions*, 28 TOBACCO CONTROL 43 (2019).

174. TCA, sec. 101 § 910(d)(1–2) (codified at 21 U.S.C. § 387j(d)(1–2)); TCA, sec. 101 § 911(j) (codified at 21 U.S.C. § 387k(j)). See also TCA, sec. 101 § 912(a) (codified at 21 U.S.C. § 387(a)); 21 C.F.R. 10.75. The TCA says nothing about FDA amending a previously issued PMTA order allowing a product on the market. But the FDA could, presumably, withdraw an issued order, following the required procedures, while notifying the manufacturer that a new, revised version of the order would be issued concurrently with the initial order’s withdrawal.

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require changes to the product, its packaging, or labeling, it is also likely that FDA would allow retailers, distributors, and manufacturers to exhaust existing inventories, first.¹⁷⁵ In addition, any continuing illegal marketing or sales of the products after the PMTA order was revoked or amended would likely be addressed through FDA's normal system of warning letters and related procedures before the products were actually pulled off the market, further adding to the time before the unexpected or unanticipated health harms would be effectively addressed.¹⁷⁶

Adding to these inevitable delays, the post-market surveillance and reporting FDA has required from Philip Morris and Swedish Match is inadequate for enabling FDA to determine quickly whether the actual marketing of IQOS or snus products is causing greater harms than expected or is not AFPPH. For example, the PMTA and MRTP Orders require Philip Morris and Swedish Match to establish and maintain records and make reports about policies and procedures and advertising and marketing plans pertaining to "regarding restrictions on youth access to the products" and efforts to "restrict youth-access and limit youth-exposure to the products' labeling, advertising, marketing, and/or promotion."¹⁷⁷ But there is no mention of requiring any recordkeeping or reports about policies or actions pertaining to restricting access to products or reducing exposure to labeling, advertising and promotion among *non-youth* who would be harmed by using IQOS, to otherwise prevent use of IQOS by those who can only be harmed, or to ensure that smokers use IQOS in ways that reduce rather than increase harms and risks.

The orders do require the companies to: (1) keep records relating to the sale, distribution, or other disposition of the products, including any information about purchasers "previous or current use of other tobacco products (i.e., dual use);" (2) keep records of all clinical or nonclinical studies done by the companies pertaining to the products, including consumer evaluation research studies; and (3) report annually on any significant findings in new publications, including any new scientific data (published or otherwise), including, for IQOS, "on the likelihood of product use by current users of tobacco products within the same tobacco product category, current users of tobacco products in other tobacco product categories, former users of any tobacco product, and youth and young

175. For example, the FDA's Proposed Rule requiring graphic health warnings for cigarette packages would only prohibit manufacturers from introducing non-complying packs into the U.S. market after a specific future date, with distributors and retailers allowed to exhaust their inventories of noncomplying cigarettes after that. Tobacco Products; Required Warnings for Cigarette Packages and Advertisements, 84 Fed. Reg. 42754, 42784–85. (Aug. 15, 2019) (to be codified at 21 C.F.R. pt. 1141).

176. See U.S. FOOD & DRUG ADMIN., REGULATORY PROCEDURES MANUAL (2019), https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/compliance-manuals/regulatory-procedures-manual#_top.

177. IQOS PMTA Order, *supra* note 45, at 6–7, 9–13; Snus MRTP Order, *supra* note 24, at 10–13, 15, 17.

adults” and, for the snus, “regarding the MRTPs and consumer perception, behavior, or health.”¹⁷⁸ But they do not require that Philip Morris or Swedish Match actually initiate any data collection or research relating to the products and any related health harms and risks to exclusive users or dual users, either generally or in comparison to smoking or other forms of tobacco-nicotine use, or relating to whether the products’ marketing is promoting more harm-increasing uses than harm-reducing uses. As a result, there are no requirements in the orders to ensure that FDA would be promptly be alerted to any and all unexpected product users or harms from the products’ use that would show that the orders must be amended or revoked to adequately protect the public health.¹⁷⁹

Moreover, if FDA intended to rely on the possibility that the PMTA or MRTP Orders would be rescinded to ensure that Philip Morris and Swedish Match would market the IQOS and snus products responsibly and that take additional action to ensure that their marketing would produce larger public health gains than losses, FDA could have made that rescission a more certain, specific, and effective threat. For example, FDA could have stated that the orders would automatically be revoked if certain surveys or data sources showed that significantly more youth than adults were using the products or that significantly more nonusers than existing users of more harmful tobacco products were initiating into regular use. Or, FDA could have stated that it would quickly revoke the orders if it became clear that the marketing or the products was preventing or delaying total cessation or smoking cessation more than it was increasing total switching from smoking or other more harmful tobacco use by those who would not otherwise quit, or was prompting more otherwise non-using youth to initiate into regular use of the products than youth who would otherwise have been smokers or used other more-harmful tobacco products.

However, even with much more comprehensive post-market surveillance requirements and clearly stated standards or triggers for revoking the PMTA Orders, any related revocation or amendment of the PMTA Orders to stop or reduce any unexpected harms would still be unnecessarily allowing new harms to occur before doing anything about them. By including readily available restrictions and requirements in the orders, FDA could have prevented all or some of these harms and risks from ever occurring in the first place without significantly reducing (and often increasing) the net public health gains from issuing the orders. Taking a stitch in time to save nine is a solid public health principle, and FDA’s failure to do so by including effective restrictions and

178. IQOS PMTA Order, *supra* note 45, at 6, 10; Snus MRTP Order, *supra* note 24, at 8, 10–11, 16.

179. See IQOS PMTA Order, *supra* note 45; Snus MRTP Order, *supra* note 24. It is possible that the FDA plans also to rely on some other sources of data and research to provide prompt notice of unexpected harms or harm-increasing uses. But that is not mentioned anywhere in the decision summaries or final orders.

requirements to prevent unnecessary harm-increasing uses of the snus and IQOS products was both not AFPPH and “arbitrary and capricious.”¹⁸⁰

VI. FDA'S GUIDANCE AND PROPOSED RULE RELATING TO PMTAS NEITHER CLARIFY THE REMAINING GRAY AREAS OF THE AFPPH STANDARD NOR SUGGEST THAT FUTURE FDA PMTA EVALUATIONS AND ORDERS WILL BE AFPPH OR NOT ARBITRARY OR CAPRICIOUS

Since issuing its PMTA Orders for the IQOS and snus products, FDA has issued a Final Guidance for Industry relating to securing PMTA orders for e-cigarettes and, on September 25, 2019, published a much more detailed Proposed Rule pertaining to PMTA applications and orders.¹⁸¹ Neither provides any assurance that FDA's future PMTA orders allowing new tobacco products on the market will be AFPPH or “not arbitrary or capricious,” or that the underlying PMTA evaluations will not be “arbitrary or capricious. But they do, at least, suggest that future FDA PMTA and MRTP evaluations might be more comprehensive than those done for the Swedish Match snus and Philip Morris IQOS products.

As in its PMTA and MRTP Orders, FDA acknowledges in the proposed rule that its AFPPH determinations could turn out to be inaccurate, implicitly adopting an interpretation of the AFPPH standard that permits the marketing of products that create risks of producing a net harm to the public health.¹⁸² But the Proposed Rule does not explain or justify that interpretation, and provides scant guidance as to how much more likely or larger the expected net gain from issuing a permissive PMTA order must be to justify running a risk of a negative net public health impact. In this regard, the Proposed Rule does say that:

Generally, FDA intends to consider the marketing of a new tobacco product to be [AFPPH] where a PMTA contains sufficient valid scientific evidence to demonstrate that the potential risks and benefits

180. See *supra* note 36 and accompanying text. Even if failing to include readily available measures in the final PMTA orders that would reduce acknowledged or obvious health risks and harms caused by allowing the products on the market could somehow be AFPPH and not “arbitrary or capricious,” FDA's failure even to consider those obvious and readily available health-protecting measures and provide a reasonable explanation for how allowing the products on the market without them was AFPPH would still be “arbitrary and capricious.” See *supra* notes 102, 35 and accompanying text.

181. See Final PMTA Guidance, *supra* note 12; Premarket Tobacco Product Applications and Recordkeeping Requirements, 84 Fed. Reg. 50,556 (Sept. 25, 2019) (to be codified at 21 C.F.R. pts. 1100, 1107, 1114) [hereinafter Proposed PMTA Rule]. Guidance documents are typically non-binding statements of current agency policies or practices, including recommendations for what subject entities could or should do to comply with underlying laws or regulations. While the documentation for proposed and final rules can also include non-binding agency policy statements, the text of the rule itself, when put into final form and implemented, establishes legally binding requirements and restrictions.

182. See Proposed PMTA Rule, 84 Fed. Reg. at 50,581, 50,620–21, 50,623. The PMTA Final Guidance does not discuss this issue.

of the marketing of the new tobacco product would have a net positive effect on the health of the population as a whole,” which “requires a balancing of product-specific potential risks and benefits.”¹⁸³

It also states that a PMTA product would receive a no marketing order if “the product is not likely to have a net benefit to the population as a whole.”¹⁸⁴ But FDA provides no clarification as to how that balancing will be done or what “not likely” means. A later section of the Proposed Rule indicates that, after reviewing the PMTA applications, FDA will make its AFPPH determinations based on its understanding of the health risks from the products use and on how it expects consumers to respond to its marketing.¹⁸⁵ Yet FDA provides no clarification as to how certain or positive those understandings or expectations need to be to support an AFPPH determination (or how the risk of producing a negative net public health impact factors in).

This continued FDA failure to clarify how it will interpret and apply the AFPPH standard in the PMTA context is discouraging. Until the FDA staff have a clear, reasonable interpretation of the standard to apply, it will remain difficult, if not impossible, for them to review and evaluate PMTA applications or structure permissive PMTA orders in a “not arbitrary or capricious” manner.

It is also highly unlikely that a PMTA or MRTP order could be AFPPH if it allowed the marketing of a tobacco product without requiring readily available product changes or labeling or marketing restrictions that would reduce related health harms and risks without disproportionately reducing the expected net public health gain – and such an order would, in any case, be “arbitrary or capricious.”¹⁸⁶ Yet nothing in the Proposed Rule or Final Guidance states that FDA must reject applications that have not taken advantage of readily available measures to make the new tobacco product and its packaging, labeling, and marketing as minimally harmful and risky as possible, without interfering with the product’s ability to serve as a less-harmful alternative to other tobacco use and secure related net public health gains. Nor is there any text that strongly suggests that FDA will do so. Instead, the Proposed Rule states that applicants “may choose” to propose restrictions on the distribution, advertising, promotion, or sale of the new tobacco product “to help support” a showing that its marketing would be AFPPH;¹⁸⁷ and the text of the Proposed Rule, itself, only reiterates

183. *Id.* at 50,618.

184. *Id.*

185. *Id.* at 50,603.

186. *See supra* note 36 and accompanying text.

187. Proposed PMTA Rule, 84 Fed. Reg. at 50,580. *See also id.* at 50,655 (proposing new 21 C.F.R. § 1114.31(b)(2), which allows FDA to include restrictions in the PMTA order that the applicant proposed “to help FDA” make an AFPPH finding); Final PMTA Guidance, *supra* note 12, at 12 (stating that applicant “may propose specific restrictions on sale and distribution that can help support a showing that permitting the marketing of the product would be APPH”). The Proposed Rule also states: “Consistent with its mission to protect the public health, FDA seeks to limit youth exposure to the

FDA's authority under the TCA to include such restrictions in the final PMTA orders.¹⁸⁸

As for requiring applicants to make their new tobacco products less harmful or risky, the Proposed Rule requires applicants only to identify the measures they have taken to reduce or eliminate those risks associated with the design of the tobacco product and packaging “not normally associated with the use of the tobacco product.”¹⁸⁹ Similarly, the Proposed Rule focuses on how the product's labeling (including inserts, onserts, instructions, and warnings) should not be false or misleading and should work to ensure consumers operate the product correctly, but says nothing about how the labeling should promote harm-reducing use and discourage harm-increasing uses.¹⁹⁰ Although both documents discuss how applicants must and should provide certain information regarding the product's components, ingredients, additives, and constituents, including information regarding purity or contamination, neither recommends or requires any action by applicants to minimize contamination or to eliminate any unnecessary additives that make the product more harmful or potentially harmful.¹⁹¹

As previously discussed, two of the major difficulties with making AFPPH determinations are the considerable uncertainties relating to the long-term harmfulness or comparative harmfulness of new products to different types of users, and the inescapable difficulties in predicting future industry and consumer behaviors relating to the new product that could increase or reduce health harms. But the size and scope of the most problematic aspects of these uncertainties

labeling, advertising, marketing, or promotion of a new tobacco product in order to limit uptake of the new tobacco product by nonusers of tobacco products, especially youth.” Proposed PMTA Rule, 84 Fed. Reg. at 50,580. But the closest FDA comes to requiring applicants to propose or incorporate requirements and restrictions to prevent such unnecessary marketing to youth is when the Proposed Rule states that in certain situations FDA may be unable to determine that allowing the marketing of the new tobacco product is AFPPH if the applicant does not propose to address youth access to the product and exposure to its marketing and related youth initiation (e.g., by selling the product solely in adult-only establishments or using age-verification controls for digital advertising). *Id.* at 50,581.

188. Proposed PMTA Rule, 84 Fed. Reg. at 50,655. *See also id.* at 50,581 (stating that “where FDA determines that restrictions on the sales and distribution of the new tobacco product (including access to, and the advertising and promotion of, the tobacco product) would be APPH, FDA *can* impose such restrictions under the terms of a marketing order”) (emphasis added).

189. *Id.* at 50,596. *See also* Final PMTA Guidance, *supra* note 12, at 16 (recommending measures to prevent harms from exposure to the applicant e-cigarette's nicotine liquids by children and others, separate from inhalation during the product's use).

190. Proposed PMTA Rule, 84 Fed. Reg. at 50,580, 50,607. *See also* Final PMTA Guidance, *supra* note 12, at 22–23.

191. *See* Final PMTA Guidance, *supra* note 12, at 26–30; Proposed PMTA Rule, 84 Fed. Reg. at 50,644. Indeed, FDA implies that, in regard to harmfulness to users, it is enough for a new product to qualify as AFPPH if it “delivers significantly lower levels of a specific HPHCs to users than the tobacco products they are currently consuming, which studies indicate may result in decreased morbidity and mortality,” even if it could be made less harmful and risky without reducing its use as a less-harmful substitute for other tobacco product use. *Id.* at 50,579.

would be sharply reduced if applicants were required to take all readily available steps to make the products as minimally harmful as possible (without interfering with their ability to serve as effective less-harmful substitutes for more harmful tobacco use) and if the final order included all effective product, labeling, marketing, and sales restrictions and requirements that would help prevent or discourage harm-increasing consumer uses while still allowing for or encouraging harm-reducing uses. However, the Proposed Rule and Final Guidance: (1) do not discuss these uncertainty problems, (2) do not require applicants to take any of these actions, (3) do not otherwise propose any measures to shrink the size or scope of these troublesome uncertainties by reducing the underlying risks, and (4) do not provide any clear guidance on what else applicants must or should do to reduce the likelihood and size of the uncertain health risks that could be caused allowing the PMTA product's marketing. Nor do the FDA documents provide any clear insights as to how FDA will shrink or otherwise substantively address these uncertainties when making its AFPPH determinations, given that it is not requiring that the PMTA products be made as minimally harmful as possible nor mandating or planning that PMTA orders include all effective restrictions and requirements that will reduce unnecessary health harms or risks. Instead, FDA simply provides requirements or guidance about what kind of research and data should be provided.¹⁹²

The Proposed Rule also indicates that FDA will continue to make its AFPPH determinations based on an assumption that applicants will market the PMTA products as proposed in the application in the short-term and then

192. For example, in a number of places, the Proposed Rule states that in some cases there may be gaps in the existing scientific information relating to certain topics that the applicant might need to fill by conducting its own investigations to make it possible to demonstrate that allowing the marketing of the product would be AFPPH. *See, e.g.*, Proposed PMTA Rule, 84 Fed. Reg. at 50,556, at 50,599, 50,602–07, 50,615. But FDA provides little guidance as to when the “full reports of all information . . . published or known to, or which should reasonably be known to, the applicant” required by the proposed rule for each of the various application topic and sub-topic areas would be sufficient to demonstrate that the product's marketing would be AFPPH or when the applicant would need to develop additional data or research. *Id.* at 50,650 (proposing new 21 C.F.R. § 1114.7(k)). The Proposed Rule says only that the applicant would need to conduct its own investigations if there were no information available on the specific topic or subtopic, and that the provided reports of all available information, including any done by the applicant, must be sufficient for FDA to “be able to determine the potential risks and benefits to the population as a whole.” *See id.* at 50,605–07. *See also id.* at 50,602, 50,618–19. In regard to predicting how consumers will actually respond to the future marketing of the new product, FDA does say that if it “is unable to determine the impact that the labeling, advertising, marketing, and promotion of the new tobacco product may have on consumer *perceptions and use intentions*, FDA intends to issue a no marketing order for the new tobacco product.” *Id.* at 50,606 (emphasis added). That suggests that when actual consumer use data is not available, FDA will be relying primarily on pre-application studies of consumer perceptions and use intentions (e.g., when presented with possible future labeling or advertising) to develop its estimates of how consumer will actually behave in the future. *See also id.* at 50,582, 50,606, 50,610, 50,616, 50,651 (proposing new 21 C.F.R. § 1114.7(k)(iv)), 50,655 (proposing new 21 C.F.R. § 1114.27(b)(ii)(G)). But FDA does not explain how it will develop its estimates of future consumer behaviors based on the perception and intended use studies and other relevant information.

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continue to market them responsibly thereafter (without requiring that they do so).¹⁹³ Rather than prevent all clearly harmful marketing in the first place, the Proposed Rule, like the Swedish Match snus MRTP and Philip Morris IQOS PMTA Orders, appear to rely primarily on FDA requiring successful applicants to provide periodic reports of marketing data and information and in some cases require advance notice of marketing changes (but not prior FDA permission) to prevent the companies from marketing in legal but irresponsible ways.¹⁹⁴ This indirect constraint, with FDA able to take legal action to stop irresponsible advertising only after it has caused related harms, is much less effective than either restricting harmful forms of advertising in the first place or requiring prior FDA permission before any major labeling or advertising changes may be implemented.¹⁹⁵

More constructively, the Proposed PMTA Rule and Final PMTA Guidance do indicate that FDA might evaluate future applications in a more comprehensive way than it evaluated the Swedish Match and Philip Morris PMTAs by actually considering more of the health impacts from all the different potential harm-increasing uses and harm-reducing uses of proposed new PMTA products. Besides making it clear that whether or not the marketing of a new product is AFPPH will depend on its *net* impact on the public health,¹⁹⁶ FDA states that the Proposed Rule would require PMTA's to contain an "in-depth analysis and discussion" of the effect the marketing of the new product will have on the health of the population as a whole "by integrating all of the information (both qualitative and quantitative as available) regarding the product, its potential effects on health, as well as tobacco use behavior, including likelihood of cessation and initiation, to provide an overall assessment of the potential effect that the marketing of the tobacco product may have on overall tobacco-related morbidity and mortality."¹⁹⁷ Even more specifically, the Proposed Rule states that the PMTA summary must contain a discussion of the:

193. *Id.* at 50,580–82, 50,643 (proposing new 21 C.F.R. §1114.7(f)(2)).

194. *Id.* at 50,581, 50,620, 50,623, 50,655–56 (proposing new 21 C.F.R. § 1114.31(b)(3), § 1114.41).

195. *See supra* notes 118–22, 145–50 and accompanying text. Under the TCA, a manufacturer must obtain a new permissive SE or PMTA new product order before marketing a substantially changed version of a tobacco product that has been legally on the market (unless the substantial change does not raise new or different questions of public health, such as threatening to increase youth use or reduce user cessation). TCA, Pub. L. No. 111-31, sec. 101 § 907(a), § 907(c), § 905(j) 123 Stat. 1776 (2009) (codified at 21 U.S.C. § 387j(a), § 387j(c), § 387e(j) (2012)). A U.S. district court has ruled that only substantial changes to an existing tobacco product's physical characteristics, as opposed to changes to its labeling (or, presumably, to its packaging or advertising), can trigger the TCA's requirement that manufacturers must obtain a permissive new-product order, even if the latter changes raise different questions of public health. *Philip Morris v. FDA*, 202 F. Supp. 3d 31, 51 (D.D.C. 2016).

196. *See supra* notes 183–184 and accompanying text.

197. Proposed PMTA Rule, 84 Fed. Reg. at 50,610.

[H]ealth risks of the tobacco product to both users and nonusers of the product and whether the tobacco product presents less health risk than other tobacco products . . . [t]he impact the product and its marketing will have on the likelihood of changes in tobacco use behavior of tobacco product users, including cessation, switching (i.e., to a different tobacco product), and poly use (i.e., using the new tobacco product in conjunction with one or more other tobacco products) . . . [and] on the likelihood of tobacco use initiation by tobacco products nonusers, especially youth and young adults, including among never users and former users, and the likelihood of poly use and switching behaviors.¹⁹⁸

Presumably, FDA would not specifically require this information if it were not going to consider all of it when making its future PMTA AFPPH determinations.¹⁹⁹

Going further, the Proposed Rule “recommends” (but does not require) that PMTA applications “include estimates of the effect that the new tobacco product may have on the health of the population as a whole, such as effects on tobacco use initiation switching and cessation, and reductions in premature mortality, or increases in life-years lived” and states that applicants “may” assess the net public health impact by “weighing” the potential reductions in disease risks from users of more harmful products switching to the new product against the potential increases in disease risks from nonusers using the new product (and, although unsaid by FDA, presumably from other harm-increasing uses of the product, as well) and “*should* provide quantitative assessments in the concluding discussion whenever possible.”²⁰⁰

It is troubling, however, that the Proposed Rule does not take the logical next step of also requiring applicants to develop these kinds of quantitative

198. *Id.* at 50,583. *See also id.* at 50,605–06 (providing additional text showing FDA’s awareness of all the many consumer behaviors that could impact the net public health impact from allowing the marketing of a PMTA tobacco product). Similarly, the Final PMTA Guidance recommends that applicants provide a summary that describes “the likelihood” that nonusers will initiate or reinstate tobacco use through the new product, that users of the new product will move on to potentially more harmful tobacco use or engage in dual use, or that current users will use the new product instead of quitting all tobacco use or using an FDA-approved cessation product. Final PMTA Guidance, *supra* note 12, at 24, 37–38. However, while the Final PMTA Guidance documents list of possible different health impacts on different types of consumers goes further than those considered in the Snus and IQOS Decision Summaries, it still leaves out some relevant responses (e.g., users of less-harmful tobacco products switching to the new product, youth or adults initiating into using the new product instead of into using a more-harmful or less-harmful product, or uses of the new product that do not prevent but delay total cessation or cessation of more-harmful product use). The Guidance also does not explain how the consumer behavior likelihoods presented in the application should or could be translated into likelihoods of harms and benefits and any final determinations of net public health impacts.

199. As previously described, however, FDA’s Swedish Match Snus and Philip Morris IQOS PMTA Decision Summaries did not mention or discuss all of these possible impacts from allowing those products’ marketing.

200. Proposed PMTA Rule, 84 Fed. Reg. at 50,583–84 (emphasis added).

estimates through the types of modeling described previously to estimate best- and worst-case scenarios, which are likely necessary for any “not arbitrary or capricious” AFPPH determinations (i.e., to determine in a reasonable way that the potential new public health gains from allowing the PMTA product’s marketing sufficiently outweigh the possible new public health harms).²⁰¹ FDA clearly understands the benefits of such modeling, which it has supported for its own uses.²⁰² In addition, the Decision Summaries for the IQOS and Swedish Match snus PMTA Orders and the snus MRTP Order critiqued some similar models provided in the applications for projecting future impacts from the marketing of the products and, especially for the PMTA models, described how they could have been made much more useful to FDA.²⁰³ Yet the Proposed PMTA Rule or Final PMTA Guidance do not require any such modeling by applicants, nor do they suggest that FDA will do any such modeling or estimates on its own.²⁰⁴

VII. CONCLUSION

It is quite possible that FDA orders allowing the Philip Morris IQOS or Swedish Match snus products (or other tobacco products) onto the U.S. market or to be marketed with MRTP claims could be AFPPH and “not arbitrary or capricious.” But the PMTA and MRTP orders FDA has actually issued were “arbitrary and capricious” and were not AFPPH for both procedural and substantive reasons.²⁰⁵ So why did FDA present such sloppy, vague, and incomplete analyses and issue such overly permissive, under-protective orders? Given the lack of any reassurance in the Final PMTA Guidance or Proposed PMTA Rule that FDA will correct these inadequacies in the future, trying to answer this question becomes even more relevant and important.

The leadership and staff at FDA’s Center for Tobacco Products (CTP) who either do the PMTA and MRTP analyses or review and approve them were

201. See *supra* notes 42, 40, 105 and accompanying text.

202. See, e.g., Apelberg et al., *supra* note 42.

203. Snus PMTA Decision Summary, *supra* note 45, at 32 (“it would have been useful if the applicant had provided a clearer description of the model and its use . . . [and] had provided additional information to aid in the interpretation of model analyses and results . . . in order to facilitate an evaluation of the plausibility and relevance of these scenarios for the U.S. population”); Snus MRTP Decision Summary, *supra* note 45, at 43.

204. The Guidance’s only reference to any modeling of the possible consumer behaviors in response to the marketing of the PMTA product is a passing reference to how FDA has received meeting requests related to marketing applications pertaining to a range of topics, including such modeling, which in many cases has resulted in the submission of more complete applications. Final PMTA Guidance, *supra* note 12, at 51. The proposed PMTA rule makes no mention of modeling at all.

205. As noted earlier, while released after this paper was in near-final form, it appears that FDA’s 22nd Century PMTA Order and IQOS PMTA Order, and their underlying Decision Summaries have the same flaws that have been detailed in this article relating to the Snus MRTP Order (and the underlying Snus PMTA Order) and the IQOS PMTA Order.

certainly fully aware of all the different ways the marketing of new tobacco products would increase individual and public health harms and risks. Yet the decision summaries and orders did not discuss or even mention all such impacts. In addition, many of the CTP personnel certainly knew how modeling can be done, despite inevitable uncertainties, to provide insightful, evidence-based best-case and worst-case projections of future public health impacts based on expert-based estimates or ranges or estimates of how harmful different ways of using the product might turn out to be and the range of different ways consumers might respond to their marketing. Yet, despite doing such modeling in other areas, FDA did not require or apparently do any such modeling relating to the IQOS or snus applications to develop an adequate understanding of the relative likelihood and size of the possible individual and public health harms and risks versus harm and risk reductions from the products' marketing. The CTP leadership and staff were also well aware of many different possible, legally viable restrictions and requirements that could be placed on tobacco products or their labeling, marketing, or sale to prevent and reduce exposure and use by youth and nonusers and otherwise discourage harm-increasing product use and encourage harm-reducing use. Yet FDA included only partial, inadequate provisions in the final Swedish Match and IQOS PMTA and MRTP Orders.

Given the considerable knowledge and expertise of CTP staff, the most disturbing possible explanation for FDA's failings with the PMTA and MRTP Final Orders would be if non-public-health concerns came into play, such as White House pressure to allow the products on the market with minimal restrictions or requirements for ideological or political reasons, or a desire by government lawyers to avoid threatened legal challenges from Philip Morris or Swedish Match if their applications were not successful or the final orders were too restrictive. Or perhaps FDA thought that having the snus and, especially, IQOS on the market as smoking substitutes with MRTP claims (despite no clearly articulated justification for doing so) would weaken industry arguments against a future FDA rule to sharply reduce smoking and would make it easier for FDA to get permission from the White House and the Office of Management & Budget (OMB), at long last, to issue such a rule (e.g., by reducing nicotine levels in cigarettes).

Or perhaps, FDA believed that it would not be able to implement any strong new anti-smoking rules in the foreseeable future (e.g., because of political and bureaucratic constraints and the many years that can be required to get through the rulemaking and clearance processes, overcome inevitable tobacco industry legal challenges, and finally implement and enforce the rule).²⁰⁶ Seeing that path

206. Indeed, despite having extensive tobacco control authorities since 2009, FDA has yet to implement a substantive tobacco control rule that would significantly reduce tobacco use or its harms in the United States because of political and bureaucratic obstacles and either a lack of support or direct opposition from the Administration.

blocked or overly long, perhaps FDA decided that its best chance for tobacco control progress was to allow on the market any reasonable less-harmful tobacco products that did not seem especially attractive to youth and hope that market competition between the less-harmful products and smoked tobacco products would secure new public health gains, despite the large downside risks. But FDA could hardly explain any such politically strategic analysis, even if accurate, to justify its AFPPH determinations.

It could also be that strategic, political, or bureaucratic factors, or good-faith disagreements among FDA's public health experts, have prevented FDA from being able to determine exactly how it wants to interpret and apply the remaining gray areas of the AFPPH standard and, without a clearly articulated standard to apply, FDA's PMTA and MRTP analyses had to be somewhat vague and conclusory.

Along these lines, FDA might also have realized that developing any reasonable interpretation of the protective AFPPH standard in the PMTA and MRTP contexts and rigorously applying it would make it much more difficult for FDA to allow any new products on the market or permit any reduced-risk or reduced-exposure claims. But if FDA did not readily allow any new products or claims that could make it more difficult for FDA to implement its preferred tobacco control strategies, increase political or bureaucratic interference, intensify attacks by the tobacco industry and its allies, and possibly prompt Congressional action to try to weaken the Act's standards and authorities. Similarly, FDA might have realized that, even without a clearly articulated AFPPH standard, any comprehensive and transparent evaluation of the likelihood and size of all the new health harms and risks created by allowing the new products or MRTP claims compared to the likelihood and size of the new harm and risk reductions from the orders would also make allowing the products or claims much more difficult – producing the same strategic and political problems.

However, even if FDA had clearly articulated and rigorously applied a legally viable AFPPH standard and done a comprehensive, not-arbitrary-or-capricious evaluation of the applications, it is quite likely that it could have still issued legally valid PMTA and MRTP orders for the IQOS and snus products. But to do that, FDA would have had to include sufficient restrictions and requirements in each final order to prevent or reduce unnecessary new health harms and risks and minimize the likelihood and size of any possible net public health loss (at least to the extent that could be done without disproportionately reducing the likelihood or size of the net public health gain). But political or bureaucratic pressures or obstacles might have interfered with FDA's willingness or ability to do that. For example, it is possible that the generally anti-regulation Trump White House and OMB did not support or permit FDA efforts to include more comprehensive new restrictions or requirements in the

PMTA or MRTP orders, especially as putting such restrictions and requirements on these less-harmful products would indicate that new regulations should be implemented to place the same or stronger restrictions or requirements on more-harmful tobacco products, as well.²⁰⁷

Less political explanations are also possible for FDA's inadequate evaluation of the Swedish Match and IQOS PMTA and MRTP applications and its excessively weak Final Orders. But having inadequate resources or being pressed for time cannot be used as an excuse. FDA's Center for Tobacco Products has hundreds of qualified staff members to help review and evaluate the applications or do related research and analysis, and the agency receives generous funding to support its efforts to regulate tobacco products through firmly established mandatory industry user fees.²⁰⁸ Nor are there serious time constraints that might explain rushed and incomplete FDA evaluations or orders. Although the TCA says that FDA must review PMTA applications and issue final orders within 180 days, the clock does not start until FDA considers the application complete and FDA can also restart the clock whenever the applications are amended or new information is requested or provided by the applicant.²⁰⁹ And, the TCA sets no deadline for how quickly FDA must consider MRTP applications.²¹⁰

Another largely procedural problem, however, could have been in play that would explain much of FDA's shortcomings. Although not articulated in the order documentation or elsewhere, it appears that the staff in the Office of Science at FDA's Center for Tobacco Products who do the work that is described in the PMTA and MRTP decision summaries have chosen or been told to focus primarily on evaluating just the information and analysis provided in the applications to see if that application-focused evaluation produces any reason *not* to issue a favorable order. The IQOS PMTA Decision Summary, for example,

207. See, e.g., *id.*; Exec. Order No. 13771, Reducing Regulation and Controlling Regulatory Costs, 82 Fed. Reg. 9339 (Jan. 30, 2017); Exec. Order No. 13777, Enforcing the Regulatory Reform Agenda, 82 Fed. Reg. 12285 (Feb. 24, 2017) (providing examples of the Trump Administration's generally anti-regulation approach); See, e.g., *supra* note 16; Emily Baumgaertner, *The FDA Tried to Ban Flavors Years Before the Vaping Outbreak – Top Obama Officials Rejected the Plan*, L.A. TIMES (Oct. 1, 2019), <https://www.latimes.com/politics/story/2019-10-01/vaping-flavors-obama-white-house-fda>; Katie Thomas & Sheila Kaplan, *E-Cigarettes Went Unchecked in 10 Years of Federal Inaction*, N.Y. TIMES (Oct. 14, 2019), <https://www.nytimes.com/2019/10/14/health/vaping-e-cigarettes-fda.html>.

208. See U.S. FOOD & DRUG ADMIN., JUSTIFICATION OF ESTIMATES FOR APPROPRIATIONS COMMITTEES 211 (2019) (showing 886 full-time equivalent Center for Tobacco Product employees in FY 2018). See *id.* at 23; TCA, Pub. L. No. 111-31, sec. 101 § 919(b) 123 Stat. 1776 (2009) (codified at 21 U.S.C. 387s(a) (2012)) (establishing industry users fees of \$712 million per year for FY 2019 and future years).

209. TCA, sec. 101 § 910(c)(1) (codified at 21 U.S.C. 387j(c)(1)). For example, the initial Philip Morris PMTA application was submitted on May 15, 2017, with twelve listed subsequent amendments, and FDA issuing its final order on April 30, 2019 (more than 700 days later). IQOS PMTA Decision Summary, *supra* note 29, at 1, 2; IQOS PMTA Order, *supra* note 45, at 1.

210. See TCA, sec. 101 §911 (codified at 21 U.S.C. 387k).

mentions some independent literature reviews done by FDA and makes various findings based on available evidence or information, but they always pertain to issues or questions raised by the application.²¹¹ In addition, very little is done in any of the decision summaries to raise and carefully consider important issues or questions not presented by the application, itself (even if they have been raised in formal comments submitted to FDA by interested parties).²¹² In this way, FDA's review procedure appears to allow the application to curtail the scope of FDA's AFPPH analysis. Rather than require the application to provide all the information, analysis, modeling, and proposed restrictions and requirements on the product and its marketing and sale necessary to provide for an adequate AFPPH evaluation and to show that granting a PMTA order could be AFPPH—and look to externally available evidence and analysis if it does not—FDA seems to look primarily at the information, assertions, and analysis the application has chosen to provide (with some requests for additional related information by FDA) to see if the application, itself, reveals any clear reason it should be denied.²¹³

FDA's errors and omissions in its PMTA and MRTP Orders for the Swedish Match snus and Philip Morris IQOS products, and its parallel failures to clarify what manufacturers must establish in their future PMTA applications, is enormously troubling given the large number of applications from e-cigarette and other tobacco product manufacturers that will likely be submitted to meet

211. See, e.g., IQOS PMTA Decision Summary, *supra* note 29, at 11, 32, 56, 58, 65, 76, 83–84, 93–96, 98. But some references to the available evidence appear to apply only to evidence supplied by the applicant. See, e.g., *id.* at 11, 32, 84. In addition, other FDA findings or conclusions appear based only on the applicant-provided information. See, e.g., *id.* at 61, 94.

212. For example, early text in the IQOS PMTA Decision Summary states that: “All relevant information submitted to the agency, including information from the MRTPAs, the TPSAC meeting on the MRTPAs and the public comments to the MRTPAs, to the extent relevant to the PMTAs, has been considered in review of these applications.” IQOS PMTA Decision Summary, *supra* note 29, at 14. But FDA does not anywhere mention any general FDA application-review procedure, practice, or attempt to identify and consider relevant issues or questions not raised by the applicant. See *id.* Moreover, key issues pertaining to the PMTA application raised in submitted MRTP comments were not discussed in the Decision Summary. See, e.g., Comment Letter from Eric Lindblom, Dir., Tobacco Control and Food & Drug Law, O’Neill Inst. for Nat’l & Glob. Health Law, Georgetown Univ. Law Ctr., to U.S. Food & Drug Admin. Ctr. for Tobacco Products (May 30, 2018), <https://www.regulations.gov/document?D=FDA-2017-D-3001-0202> (raising issues regarding the potential new health harms and risks from users of e-cigarettes moving to IQOS and the need for any permissive order to include certain restrictions and requirements to prevent unnecessary individual and public health harms and risks). See also *supra* notes 107–08, 130–131 and accompanying text.

213. Such an odd approach could come from a tragic misreading of the TCA’s text which states that FDA shall deny an application for a PMTA order “if, upon the basis of the information submitted to [FDA] as part of the application and any other information before [FDA] with respect to such tobacco product, [FDA] finds that—(A) there is a lack of a showing that permitting such tobacco product to be marketed would be appropriate for the protection of the public health.” TCA, sec. 101 § 911(c)(2) (codified at 21 U.S.C. 387j(c)(2)). But that text clearly means to put the burden of proof on the applicant, not to restrict FDA’s review to only those facts, assertions, and analyses the application presents.

the court-established September 2020 deadline for all e-cigarettes and other post-deeming tobacco products currently on the market to submit PMTA applications if they want to continue being sold.²¹⁴ In addition, FDA already has several pending MRTP applications that present the exact same kinds of challenges for FDA.²¹⁵ If FDA handles these PMTA and MRTP applications similarly to how it handled the Philip Morris and Swedish Match PMTA and MRTP applications, the agency will again fail to protect the public health.

To be fair to the industry, comply with the requirements of the TCA and the APA, and work effectively to protect and promote the public health, FDA needs to eliminate the remaining ambiguities about what the AFPPH standard requires PMTA and MRTP applications to establish. Regardless of how FDA clarifies that standard (or if it does not), FDA should clearly announce to the industry and other interested parties (with related instructions to the FDA staff who evaluate the applications) that PMTA and MRTP applications, to be successful, must at a minimum:

1. Establish that the product is significantly less harmful and risky to users than at least some other tobacco products currently on the market (or at least that it is quite likely that it is less harmful, with little or no risk that it might turn out to be more harmful) – and also show that all available steps have been taken to make the product as minimally harmful and risky as possible without interfering with its ability to serve as a substitute for more harmful tobacco product use.²¹⁶
2. Propose any restrictions or requirements on the product or its labeling, packaging, marketing, sale, or use that are necessary to eliminate or minimize any risk or producing a net harm to the public health or that will otherwise prevent or reduce any new harms from the marketing of the product that are not necessary to secure larger net public health gains.²¹⁷
3. Provide convincing evidence and analysis that the likelihood and size of all the different ways the marketing of the subject product with those restrictions and requirements could increase health harms and

214. See *supra* notes 11–12 and accompanying text.

215. *Modified Risk Orders*, U.S. FOOD & DRUG ADMIN., *supra* note 24.

216. For example, the applicant would have to justify including any additive in the new tobacco product unnecessary for its delivery of nicotine to users that is a harmful or potentially harmful constituent (or creates any such constituent during the product's use) by showing that including the additive would be highly likely to increase harm-reducing uses of the product, thereby securing related health gains that were significantly larger than any new health harms the additive might cause by prompting harm-increasing uses of the product.

217. For examples of possible restrictions or requirements that applicants might propose (or FDA might mandate), see *supra* notes 149–160 and accompanying text.

risks are significantly (or substantially) smaller than the likelihood and size of the reduced harms and risks from the product being used as a complete substitute for smoking or other more-harmful tobacco product use.²¹⁸

These criteria would ensure that FDA's review of PMTA and MRTP applications would be much more comprehensive and effective than its review of the Swedish Match snus and Philip Morris IQOS applications. They would also work regardless of how FDA might (or might not) clarify the AFPPH standard. But they might be made somewhat more specific depending on how FDA clarified the standard (e.g., by indicating roughly how much smaller the estimated risk and size of possible negative net public health impacts must be than the estimated likelihood and size of the expected net public health gains).

To expedite matters, keep the burden of proof on the applicants, and reduce its own review burdens, FDA could also make it clear that it will not only evaluate applications based primarily on these three criteria but will immediately reject any applications that do not at least exhibit a good-faith effort to comply with them (rather than provide the applicants with opportunities to amend or supplement their applications or exercise FDA's own authority to fix deficient applications by including restrictions or requirements in the order that the applicant did not propose). In addition, FDA could publish a list of those restrictions or requirements it has determined or believes are necessary components of any PMTA or MRTP because they will prevent and reduce harm-increasing uses of the product while still allowing for or supporting harm-reducing uses.²¹⁹

Applying these criteria, FDA should also recall and reevaluate the inadequately supported and insufficiently protective PMTA and MRTP orders it has already issued, providing the manufacturers with a reasonable opportunity to amend or supplement their applications, accordingly.

218. Going further, FDA could require applicants to provide their best-case, worst-case, and most-likely estimates, with supporting evidence and analysis, of: (a) the product's harmfulness when used by otherwise nonusers or by smokers (or other more harmful tobacco product users) using the product through either dual use or as a complete substitute; and (b) all the various ways youth and adult nonusers and users of other tobacco products might respond to the product's marketing that could increase or reduce health harms and risks. That would make it much easier for FDA to develop its own expert, application-based high, low, and most likely estimates of those impacts, which it could then use as inputs for either informal or more detailed modeling to develop projections of the possible worst, best, and most-likely net public health impacts from allowing the product's marketing – thereby making it possible for FDA to make “not arbitrary or capricious” AFPPH determinations.

219. See Eric N. Lindblom, *How Would an Ethically Responsible FDA Evaluate PMTA and MRTP Applications and Issue Related Orders* 75 FOOD & DRUG L.J. 1, 1–38 (2020) (providing a detailed analysis of how FDA might interpret and apply the AFPPH standard in the context of PMTA and MRTP applications and how it might structure any permissive PMTA or MRTP applications to best promote and protect the public health, with a special focus on e-cigarette PMTA or MRPT applications).

Unless or until FDA takes such steps to provide a sufficient basis for determining that issuing a PMTA or MRTP is AFPPH, its orders allowing new tobacco products on the market will risk being legally challenged and overturned by the courts. Legal challenges could come not only from members of the public health community (who have successfully challenged other FDA tobacco control actions and inactions) but from manufacturers or importers of products that must compete against the tobacco products inappropriately allowed on the market or allowed to make MRTP claims by FDA. The absence of industry legal challenges to date might be due, in part, to competitors not wanting to bring lawsuits that could make it more difficult for them to obtain PMTA or MRTP orders for their own products in the future or that could increase the likelihood that FDA would include more restrictions and requirements in any future permissive PMTA or MRTP orders they might be able to secure for their products.

Why no public health organizations have yet brought legal challenges is less clear. Perhaps, like FDA, they see the Swedish Match Snus PMTA and MRTP Orders as simply not raising big enough individual or public health risks to worry about or to allocate scarce resources to oppose. Or some might think that having IQOS on the market as a smoking-alternative with the MRTP claims could be beneficial despite the risks of harm-increasing uses, as well. But future MRTP PMTA orders allowing e-cigarettes legally on the market or allowing them to be marketed with MRTP claims could present much larger and likely health threats which are more likely to be realized if FDA does not structure its orders appropriately. It is also possible that the public health groups have not previously had a detailed analysis of the procedural and substantive shortcomings of the FDA's permissive PMTA and MRTP evaluations and orders to date that unnecessarily threaten the public health. But now they do.