The Tobacco Control Act Means to Protect the U.S. From Any New Tobacco Products That Will Not Reduce Health Harms – But FDA Isn’t Cooperating

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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.” At a minimum, that standard requires that FDA determine that the harm-reductions from allowing a new tobacco product on the market (e.g., from smokers switching to the less-harmful new product) will be larger than any increased harms (e.g., from increased youth use or from smokers engaging in dual use instead of quitting). Given the inevitable uncertainties when trying to predict how allowing a new tobacco product’s marketing will affect future consumer behavior and health, the TCA gives FDA considerable discretion as to how it will administer the PMTA procedures to protect the public health. So far, FDA has failed to exercise that discretion appropriately.

Indeed, FDA’s development of its only permissive PMTA orders to date (for Swedish Match snus and Philip Morris IQOS) have been “arbitrary and capricious” under the Administrative Procedures Act and also violate the TCA’s “appropriate for the protection of the public health” standard. FDA PMTA evaluations and orders failed to explain how it was interpreting and applying the remaining gray areas of that standard. Moreover, FDA’s evaluations were not sufficiently comprehensive or rigorous to support a reasonable determination that allowing the products on the market was “appropriate” under any possible viable interpretation of the standard. FDA also failed to include readily available restrictions and requirements on the products and their labeling, marketing, and sale in the final PMTA orders to prevent unnecessary individual and public health harms and risks.

Unfortunately, FDA’s subsequent Final PMTA Guidance regarding e-cigarettes and Proposed PMTA Rule provide no assurance that the agency will avoid these failings in the future. Yet FDA will be facing a wave of new applications to meet the May 2020 court-ordered deadline for all e-cigarettes and certain other tobacco products currently on the U.S. market to apply for PMTA orders. In addition, several applications are already pending at FDA for Modified Risk Tobacco Product (MRTP) orders to allow manufacturers to market the products with reduced-risk claims – and MRTP applications require the exact same kind of careful evaluations and protective final orders that FDA has so far failed to provide in the PMTA context. If FDA does not begin to act more responsibly and comply with applicable legal standards, it could be forced to do so from either members of the tobacco industry legally challenging permissive orders given to their competitors or by public health groups bringing legal actions to strike down any PMTA or MRTP orders that produce unnecessary health harms or risks.

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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 get such 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 increased public health harms from any new types or variants of tobacco products appearing in the U.S. market.

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. 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.\(^4\) 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.\(^5\)

To address this odd situation, FDA’s deeming rule announced that it would exercise its enforcement discretion to allow all these illegal new tobacco 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, and 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.\(^6\) However, in response to a lawsuit by a collection of public


\(^{2}\) Id. and TCA § 905(j) [21 U.S.C. 387e(j)].

\(^{3}\) TCA § 910(c) [21 U.S.C. 387j(e)].


\(^{5}\) See, e.g., id. at 28977-78, 29009-29012.

\(^{6}\) Id. at 29009-29012; FDA, Guidance: Extension of Certain Tobacco Product Compliance Deadlines Related to the Final Deeming Rule (Revised) (March 2019), available at [www.fda.gov/tobacco-products/rules-regulations-and-guidance/guidance](http://www.fda.gov/tobacco-products/rules-regulations-and-guidance/guidance). 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. See, e.g., Campaign for Tobacco-Free Kids, Leading Health Groups Urge FDA to Stop Sales of New, Juul-Like E-Cigarettes Illegally Introduced Without Agency Review (August 7, 2018), available at [www.tobaccofreekids.org/press-](http://www.tobaccofreekids.org/press-)
health groups, in May 2019, a federal District Court order rejected 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.\(^7\) The court subsequently ordered that the SE or PMTA applications must be submitted no later than May 12, 2020, with FDA generally required to rule on the applications within a year after received.\(^8\)

Because of the difficulty in finding a substantially equivalent e-cigarette that was on the U.S. market on February 15, 2007, FDA expects that manufacturers seeking permissive orders to allow their e-cigarettes to be marketed legally in the United States will submit PMTA applications.\(^9\) To date, however, no PMTA or SE application has yet been submitted for any e-cigarette product.\(^10\) While the e-cigarettes have been generally free from any enforcement efforts as the deadline for submitting new product applications nears, FDA has initiated enforcement actions against some e-cigarettes for violating other TCA requirements.\(^11\) In addition, because of increasing youth use of e-cigarettes, in September 2019, FDA announced that it would soon begin exercising its discretion to take enforcement action, before the May 12, 2020 application deadline, against any e-cigarette products on the market without a permissive PMTA or SE order that has any added flavor other than tobacco.\(^12\)

To date, FDA has considered only a small number of PMTAs and granted permissive PMTA orders for only eight similar Swedish Match snus smokeless tobacco products and for a Philip Morris IQOS heated tobacco products system with several different types of IQOS heatsticks.\(^13\)

\(^8\) American Academy of Pediatrics v. FDA, Memorandum and Order (MD, So. Div., July 12, 2019).
\(^9\) See, e.g., FDA, Guidance for Industry, Premarket Tobacco Product Applications for Electronic Nicotine Systems (June 2019), available at www.fda.gov/tobacco-products/rules-regulations-and-guidance/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;” yet it is hard to imagine any way the cigar could be consumed that could reduce public health harms (and many ways it could be consumed to increase harms and risks).


But there could be hundreds of e-cigarette PMTA applications 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.\textsuperscript{14}

It is also possible that some of the e-cigarette products submitting PMTAs will also submit modified-risk-tobacco-product (MRTP) applications to try to obtain FDA permission to make relative-risk or relative-exposure claims about the e-cigarettes in their labeling or advertising. To issue a permissive MRTP order for an e-cigarette, FDA must determine, first, that using the proposed e-cigarette instead of the comparison product (e.g., regular cigarettes) will, as claimed, 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).\textsuperscript{15} Although slightly different text is used, the public health standards that apply to MRTP orders 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.\textsuperscript{16}

No MRTP applications have yet been submitted for any e-cigarettes, and FDA has not yet issued any permissive MRTP orders for any tobacco product. But MRTP applications are already pending with FDA for IQOS, snus and moist-snuff smokeless tobacco products, and very-low-nicotine cigarettes.\textsuperscript{17}


\textsuperscript{15} To issue a permissive MRTP order, FDA must also make some other secondary or related findings. TCA § 911(g) [21 U.S.C. 387k(g)].

\textsuperscript{16} TCA § 911(g) [21 U.S.C. 387k(g)]; TCA § 910(c)(4) [21 U.S.C. 387j(c)(4)]; Eric N. Lindblom, \textit{Key Parameters of the ‘Appropriate for the Protection of the Public Health’ Standard for FDA Regulatory Action Under the U.S. Tobacco Control Act} FOOD & DRUG LAW JOURNAL (under review). 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’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 refers to “risks and benefits” and uses “protect” instead of “promote.” For simplicity’s sake, this paper will refer to the very similar 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.

What Legal Standards Apply to PMTA and MRTP Applications?

When FDA evaluates PMTA or MRTP applications to determine whether issuing an order to allow the proposed tobacco products on the market would be “appropriate for the protection of the public health” (AFPPH), it is clear from the TCA 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); non-health impacts are not directly relevant to such FDA AFPPH determinations. But 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. Any impacts from issuing permissive PMTA or MRTP orders on illicit trade, government or industry costs or 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.

By requiring FDA to focus exclusively on the health harms and risks to the population as a whole when it determines whether a permissive PMTA or MRTP order would be AFPPH, the Act does not put a higher priority on preventing or reducing youth tobacco use health risks and harms and risks than it does on reducing adult health risks or harms. Nor does it allow FDA to put a greater weight on preventing or reducing health harms among any specific sub-population or disadvantaged group. For FDA’s AFPPH determinations, impacts on health disparities or inequities do not matter, only the net impact on the health risks and harms to the population as a whole is relevant.

Despite these constraints 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 are to brand-new youth or adult tobacco product users, those who switch from using other tobacco products, or to those using another tobacco product who adopt the new PMTA or MRTP products. As discussed more fully below, a permissive PMTA or MRTP order that was AFPPH 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 made the order “arbitrary or capricious” under the Administrative Procedures Act. TCA § 912(b) [21 U.S.C. 387l(b)]; 5 U.S.C. 706(2)(A).
product use, or dual users, 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.

To address these challenges, FDA could develop evidence-based, expert estimates of the different possible net public health impacts from issuing an order to let a PMTA or MRTP product onto the market under different possible scenarios. But 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 health harms to persons who would not otherwise suffer any tobacco-related harms or will also create a risk of producing a negative net public health impact. Moreover, even if we assume that the TCA’s ambiguous language would, in some situations, allow a new PMTA or MRTP product on the market even if FDA determined it would produce some new health harms or would 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.

However, the TCA does incorporate the requirement in the Administrative Procedures Act (APA) that FDA’s regulatory actions, including any FDA clarification and application of the AFPPH standard relating to PMTA and MRTP orders, must not be “arbitrary or capricious, or an abuse of discretion.”23 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.24 In particular, an otherwise AFPPH PMTA or MRTP order could still 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 reducing the likelihood or size of the desired net public health gains).25

These complications are simplified somewhat by the fact that the TCA and APA give FDA enormous 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 uncertainties inherent

25 See, e.g., State of La., ex rel. Guste v. Verity, 853 F.2d 322, 331 (5th Cir. 1988); South Terminal Corp. v. EPA, 504 F2d 646, 655-56, 676 (1st Cir. 1974). See, also, Lindblom, Key Parameters of the “Appropriate for the Protection of the Public Health” Standard, supra note 16.
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.\(^{26}\) Moreover, the APA places very few constraints on how FDA might exercise that discretion, 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.\(^{27}\)

For example, FDA might reasonably determine that to be AFPPH no permissive PMTA or MRTP order may produce a significant risk of producing a non-trivial net increase in public health harms – so long as FDA explained the basis for its decision and showed that it had considered contrary evidence and analysis. Or, alternatively, 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 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 it contradicted common sense and 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.\(^{28}\)

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.\(^{29}\) 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 PMTA orders it has issued to date. As discussed below, FDA typically relies on reciting the text relating to the AFPPH standard in the


\(^{27}\) See, e.g., FERC v. Elec. Power Supply Ass’n, 136 S. Ct. 760 (2016) at 782. Even when an agency fails to fully articulate the reasons for its decision, however, it will not be found “arbitrary or capricious” if the court “can reasonably discern the basis for the agency's action.” Am. Iron and Steel Inst. v. EPA, 526 F.2d 1027, 1047 (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” (citations omitted)). But see, also, Encino Motorcars, LLC v. Navarro, 136 S. Ct. 2117 (2016), quoting Motor Vehicle Mfrs. Ass’n. Inc. v. State Farm Mutual Auto. Ins. Co., 463 U.S. 29, 43 (1983) [“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.”]; Judulang v. Holder, 565 U.S. 42, 53 (2011), quoting Motor Vehicle Mfrs. Ass’n 463 U.S. 29, 43 (1983) (“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.” (internal citations omitted)).

\(^{28}\) See, also, Lindblom, Key Parameters of the “Appropriate for the Protection of the Public Health” Standard, supra note 16.

\(^{29}\) Id.
TCA, assumes without explanation that PMTA products may be allowed on the market even if that creates a risk of producing a net negative impact on the public health, and fails to present or explain any FDA position regarding how much larger or more likely the expected or estimated net public health benefits from allowing a product must be compared to the estimated likelihood and size of any possible net public health harms to make issuing a PMTA order AFPPH.

No matter how FDA (or the courts) ultimately refine or clarify the AFPPH standard in the context of PMTA or MRTP orders, to determine whether issuing a specific permissive order is AFPPH FDA would need to develop viable estimates of the likelihood and size of the different possible net public health impacts it might produce. At a minimum, FDA would need to determine whether, under any reasonably possible worst-case scenario, the availability and marketing of the product might produce a non-trivial negative net public health impact. Assuming that at least some risk of a net public health loss is permitted by the standard, 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.30

Gaps in available research and experience and the inherent difficulties in predicting future industry and consumer behavior 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 limits, 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 impacts on quality adjusted life years (QALYs) was a valid proxy for quantifying public health impacts, and that it was 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. FDA might then develop those estimates (or other estimates of overall public health impacts) 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 which have uncertain values that could not otherwise be reasonably quantified.31

30 It is theoretically possible that the worst-case scenario for some permitted PMTA or MRTP tobacco products would not be negative. But issuing a permissive order for any 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 and use and the new health risks and harms that would be caused by any use of the permitted new product by anyone other than users of more-harmful products who switch completely and would not otherwise have quit or switched.

As discussed below, however, the permissive PMTA orders FDA has issued to date do not indicate that FDA has taken any of these types of actions when making its AFPPH determinations, nor has FDA issued any publicly available proposed or final rules or other materials indicating that it will necessarily do so when issuing future PMTA or MRTP orders or doing the underlying health-impact evaluations.

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 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 MRPT orders that are necessary to evaluate and determine whether permitting the products’ marketing would be AFPPH and not “arbitrary or capricious.”

Until FDA provides these clarifications, and structures its evaluation of manufacturer applications accordingly, its permissive PMTA and MRTP orders will be highly vulnerable to legal challenges that could prompt the courts to strike them down as “arbitrary or capricious” or not AFPPH. As detailed below, a court could readily find that FDA’s analysis and findings in developing its PMTA orders allowing the Swedish Match Snus and Philip Morris IQOS products on the market could not procedurally or substantively sustain FDA’s determinations that the final orders were AFPPH, regardless of how FDA or the courts might interpret the standard.

**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 TCA, and has not explained how it has interpreted and applied the AFPPH standard in any of the permissive PMTA orders it has issued to date. All FDA does, explicitly, in the

32 FDA’s order letters, decision summaries, and other documentation for each of the permissive PMTA orders it has issued – for the eight Swedish Match snus and for the Philip Morris IQOS system with three IQOS heatsticks – are available at the FDA website, Premarket Tobacco Product Marketing Orders, https://www.fda.gov/TobaccoProducts/Labeling/TobaccoProductReviewEvaluation/PremarketTobaccoApplications/ucm472108.htm (last visited Sept. 20, 2019). The decision summary for each of the Swedish Match snus is the same: Office of Science, Center for Tobacco Products, FDA, Premarket Tobacco Application (PMTA) Technical Project Lead (TPL) Review (Nov. 3, 2015)(“Snus Decision Summary”). The letter orders for each of the eight snus products are slightly different: Ashley, D, Director, Office of Science, Center for Tobacco Products, FDA, Marketing Order letter to Swedish Match (Nov. 10, 2015) for FDA Submission Tracking Numbers (STN): PM0000010, 011, 012, 013, 014, 015, 016, 017, respectively (“Snus Final Order”). The decision summary and the order letter for each of the IQOS products is the same: Holman, MR, Director, Office of Science, Center for Tobacco Products, FDA, Marketing Order letter to Philip Morris Products, S.A., FDA Submission Tracking Numbers (STNs): PM0000424-
PMTA decision summaries and orders is restate the TCA text that outlines the AFPPH standard, without either identifying the remaining gray areas or gaps relevant to PMTA determinations or doing anything to clarify or fill them. 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 accordingly, or FDA has 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 determinations and orders.

At the same time, FDA’s publicly released documentation for both the Swedish Match snus and Philip Morris IQOS PMTA orders clearly acknowledge the possibility that the marketing of the new products could or would cause some new individual health harms, could possibly create an overall negative net public health impact, and might end up not being AFPPH. For example, the Snus 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 anticipated that there was a “low likelihood” that the marketing of the snus would increase nonuser uptake and decrease or delay cessation. The IQOS Decision Summary went a bit further, concluding that current evidence indicated that IQOS uptake among youth and nonsmokers would occur, but be low, although “the potential for rapid uptake of a novel tobacco product among youth exists.” Moreover, while the IQOS Final Order included some specific restrictions and requirements to prevent youth use and possibly other harmful uses, FDA clearly saw that the marketing of IQOS, like the marketing of the Swedish Match snus, could still cause more individual and public health harms than FDA anticipated or expected. For example, the IQOS Final 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.”

In both the Snus and IQOS Decision Summaries, FDA states: “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.” Snus Decision Summary at 8; IQOS Decision Summary at 11. Compare to TCA § 910(c)(4) [21 U.S.C. 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 Decision Summary 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.

In both the Snus and IQOS Decision Summaries, FDA states: “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.” Snus Decision Summary at 8; IQOS Decision Summary at 11. Compare to TCA § 910(c)(4) [21 U.S.C. 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 Decision Summary 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.

33 Snus Decision Summary at 36, 7.

35 IQOS Decision Summary at 76. See, also, id. at 79 [“The 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.”].

36 IQOS Final Order at 1. See, also, IQOS Decision Summary at 111, 115, 116, 120. The Decision Summary also states that continuing research into the compounds found at higher levels in IQOS than in

IQOS and Snus Final Orders also required 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.”

Accordingly, FDA was implicitly using an interpretation of the AFPPH standard that, in at least some situations, allows new tobacco products (such as the snus and IQOS products) on the market even if they could create new individual health harms or might produce a negative net impact on the overall public health. But FDA does not provide any explanation or justification for interpreting and applying the AFPPH standard in that way. Nor does FDA further 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.

Even if FDA has reasonably developed the more detailed interpretation of the TCA’s AFPPH standard that is necessary to make valid PMTA evaluations, there is nothing in the public record of its PMTA 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 Procedures 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. 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.

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. Id. at 84.

37 Snus Final Order at 3 or 4; similar text in the IQOS Order Letter at 9. See, also, IQOS Decision Summary at 111, 115, 116, 120. In addition, both Final Orders 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 Final Order at 4; IQOS Final Order at 9.

38 See supra notes 24 and 27. See, also, Teva Pharmaceuticals USA, 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 [i]t did not mention” (internal quotes and citations omitted)); Williams Gas Processing-Gulf Coast Co., L.P. v. F.E.R.C, 475 F.3d 319, 329 (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 State Farm, 46 U.S. 29, 50 (1983)).
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’s PMTA orders for the snus and IQOS clearly create at least some significant risk of producing both new health harms and a non-trivial net harm to the public health, FDA has not revealed any effort, in either case, either to quantify the risks its PMTA orders pose to the public health or to evaluate them against the likelihood and size of the potential net public health gains. Without doing this kind of analysis, FDA could not possibly have done a reasonable evaluation of whether issuing the permissive PMTA orders is AFPPH under any legally viable interpretation of the AFPPH standard that might be applied. For example, if the standard were interpreted to allow a risk of a negative net public health impact so long as it was smaller (or substantially smaller) than the likelihood and size of the expected net public health gains, FDA would need to make some kind of reasonable determination that the risk of a negative net public health impact was, indeed, smaller (or substantially smaller). But FDA’s final orders and decision summaries do not show that FDA has done that.39

In particular, FDA did not describe what the worst-case scenario for the public health might be from allowing either the Swedish Match snus or Philip Morris IQOS products on the market or what its likelihood might be. Nor did FDA determine or clearly state in either case that the likelihood of producing a net public health gain was larger than the risk of a negative net public health impact or that the size of the possible net public health gains were larger than the possible net public health losses. Nor did FDA determine or state that the likelihood and size of the net public health gains was sufficient to justify any possible new health harms caused by the marketing of the new products. Nor did FDA discuss, or even identify, all of the different ways that allowing the marketing of the products might cause brand-new health harms and risks. Instead, in each case, FDA carefully evaluated the quality of the research and other evidence provided by the applicants, but then provided only a vague, oddly passive and incomplete evaluation of what that might mean in terms of possible positive or negative public health impacts from allowing the products’ marketing.

The Missing Analyses and Questionable Assumptions in FDA’s Permissive PMTA Orders for the Swedish Match Snus:

To justify its PMTA order for the Swedish Match snus, FDA concluded that:

39 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, e.g., supra note 38; California Public Utilities Comm. v. F.E.R.C., 879 F.3d 966, 973, note 5 (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,’” citing 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. F.E.R.C., 373 F.3d 1335, 1345 (DC 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”).
“the totality of evidence provided in the applications support authorization of these products so that current [smokeless tobacco] product users will have additional options for less toxic tobacco products, thereby potentially decreasing the negative health impact from tobacco product use making the marketing of these proposed products appropriate for the protection of public health.”

Underlying this conclusion were FDA’s findings that, although addictive and harmful, the exclusive use of the snus instead of smoking offers a lower risk of developing various diseases, and their exclusive use instead of using other smokeless tobacco products offers the “potential for reductions in oral cancer risk” and could reduce excess cancer risk in general.” While FDA stated that the evidence indicated that smokers switching to exclusively using the snus “is expected to be limited,” it concluded that such switching by current users of other smokeless tobacco products was “more likely.” But FDA provided no estimates of how many smokers or users of other smokeless tobacco products might actually switch completely, or what the related public health impacts might be.

FDA acknowledged that if, because of the marketing of the snus, “nonusers were to initiate or users decrease cessation, there would be negative health consequences,” and FDA also considered the possibility that a permissive PMTA order, by producing a “perceived favorable profile,” might increase snus initiation and use, discourage smokeless cessation, and, through dual use with more toxic tobacco products, discourage transition to using only the less-toxic snus or discourage total cessation. Yet FDA then dismissed these public health risks by stating: “It is anticipated that the marketing of the proposed products, as described in the PMTAs, [sic] there is a low likelihood of nonuser uptake of these products, decreased or delayed cessation, or other significant shifts in user demographics.” However, FDA provided no estimates of what those low likelihoods might be, or what the public health consequences would be if they were realized.

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40 Snus Decision Summary at 7 (emphasis added).
41 Snus Decision Summary at 6. The Decision Summary also states that, looking only at reduced exposure to carcinogenic NNN (N-nitrosornicotine), users of different other types of smokeless tobacco products could decrease their excess cancer risk by 38% to 92% if they switched completely to using the snus (and did not increase consumption), and further reductions in excess cancer risk could occur with the corresponding reductions in exposure to carcinogenic NNK ((4methylnitrosamino)-1-(3-pyridyl)-1-butanone). Id. But FDA does not explain what these percentage reductions to the excess cancer risk of other smokeless tobacco product users means in real terms (i.e., what are the excess cancer risks of other smokeless tobacco product users and what would their excess risk be, given their past use of the other smokeless products, if they switched completely to using the snus, instead).
42 Id. at 7.
43 Id. at 7, 30-31. Although FDA 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 prohibiting any express or implied statement or representation by manufacturers or sellers directed at 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 § 103(b), creating new subsection 21 U.S.C. 331(tt).
44 Snus Decision Summary at 37.
A careful reading of the Snus PMTA Final Order and Decision Summary indicates that FDA concluded that the risks of creating new harms or a negative net impact on the public health were very small given existing youth and adult user and nonuser behaviors relating to snus and other smokeless tobacco products and because the snus appear to be minimally harmful compared to other tobacco products. Given that, FDA subsequently concluded that it made sense and was AFPPH to provide smokeless tobacco users with these new presumably lower-risk options because doing that could, potentially, reduce some smokeless users overall tobacco-related health harms and risks, and the downside risks were small (although FDA never tried to quantify their relative size compared to the possible public health gains). But even if those rather loose and incomplete conclusions were somehow adequate to sustain an AFPPH determination, other FDA findings and omissions call them into question.

For example, FDA’s analysis states that existing research indicates that switching from smokeless tobacco use to smoking is more common in the United States than switching from smoking to smokeless tobacco use.\(^{45}\) That suggests that any increased snus smokeless tobacco use from issuing the permissive orders could prompt more increases to smoking than decreases. In addition, it is clear that snus users who move on to smoking would incur much larger increased health harms and risks than the reduced harms and risks smokers would gain from switching exclusively to snus (because of the harms and risks the smokers have already incurred from their past smoking) and would also incur disproportionately larger new health-harm increases compared to the harm reductions that users of other smokeless tobacco might gain from switching entirely to the snus.\(^{46}\) Accordingly, the net public health impact of allowing the snus on the market just from its possibly prompting more snus users to move on to smoking than it prompts smokers to switch completely to snus could be highly negative on a per capita basis – and could be offset only if a much larger number of current smokeless tobacco users switched to using the snus. Yet FDA does not discuss all these facts or possibilities. Nor does FDA provide any finding, evidenced-based or not, that sufficiently more smokeless tobacco product users would switch to using the presumably less-harmful snus to offset any possible increased harms from the marketing of the snus increasing smoking more than it reduces smoking (or prompting other harm-increasing uses of the snus).\(^{47}\)

Similarly, FDA makes no direct mention of the fact that any smokers who initiated dual use with the new snus who would otherwise have quit all smoking or quit all use would, on average, incur far larger increases in health harms and risks than the harm reductions users of other smokeless tobacco products would likely secure, on average, from switching to using only the snus. Nor does FDA provide any estimates, insights, or conclusions about the relative number of smokers

\(^{45}\) Id. at 29-30. Although FDA notes, or summarizes the applicant as asserting, that studies in Scandinavian countries suggest that users there “will transition to from cigarettes to snus, rather than switching from snus to cigarettes.” Id. at 29.


\(^{47}\) The closest FDA comes to making such an analysis is to note that the limited available data and research indicates that “in the US, switching from ST [smokeless tobacco] use to smoking is more common than switching from smoking to ST use” but “the adoption of snus use in the US is low and therefore, unlikely to lead to use of other tobacco products” and “[t]hus, it is anticipated that the marketing of these products, as described in the PMTAs, is unlikely to lead to significant increases in initiation of tobacco product use.” *Id.* at 30.
who might engage in such dual use compared to the number of other smokeless users who might switch to the snus, or about the related net public health impacts.

FDA reports that the Swedish Match application provided some results and analyses from a Dynamic Population Model that projected possible impacts of allowing the snus on the market on initiation and cessation of snus use and smoking, switching and dual use under different scenarios. Such a model could have enabled FDA to do the kind of comparative risks-versus-benefits analysis, including consideration of worst-case scenarios, necessary to determine if issuing a permissive PMTA order would be AFPPH. But FDA complained that “it is difficult to determine from these population model results what effect, if any, the marketing and sale of the PMTA [sic] would have on tobacco use and health effects in the US,” and added that “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.” FDA did not require that Swedish Match provide any of that additional information or analysis or modeling (and FDA did not do any such modeling on its own). Instead, FDA concluded that improved modeling was not necessary because “given the particular situation that these PMTAs offer epidemiologic data on Swedish snus use and health impact ("The Swedish Experience"), as well as experience from sales of similar Swedish snus products in the US, CTP reviewers can develop a reasonable understanding of potential impact from marketing of the proposed products.”

FDA never fully described or explained that “reasonable understanding” developed by the CTP reviewers. Moreover, this FDA conclusion and its related AFPPH determination were based on the remarkably permissive and risky assumption that the marketing and use of the new snus products would parallel the past marketing and use of those snus and other smokeless tobacco products already on the market. Yet markets and consumer preferences rarely stay constant. Despite acknowledging the possibility of a “perceived favorable profile” effect (which could change existing consumer patterns), FDA concluded that because of the low acceptability and low adoption of snus in the United States in the past, “it does not appear there would be significant shift [sic] in these snus product use by nonusers or current tobacco users” and “it is anticipated that the marketing of these products, as described in the PMTAs, is unlikely to lead to significant increases in initiation of tobacco product use.” Similarly, FDA noted that, while flavored smokeless tobacco products are a potential concern for youth initiation, “uptake of snus products including among youth in the US is low even with such flavors available in currently

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48 Snus Decision Summary at 32.
49 Id.
50 Id. (grammatical errors in the original).
52 Id. at 30-31, 34.
53 Id. at 29, 30. For similar conclusions, see, also, id. at 7, 37.
marketed products and unexpected to dramatically increase with the marketing of the PMTA products at this time.\textsuperscript{54}

In making these conclusions, however, FDA failed to consider the possibility that the marketing of the snus, even if done as described in the PMTA applications, might prompt related press coverage and social media attention that would work to change consumer behavior relating to snus, smokeless, and other tobacco products. For example, nowhere in the snus PMTA decision summary does FDA directly consider the possibility that the snus advertising or press or social media mentions might prompt increasing numbers of smokers to start seeing the snus as the new ideal, invisible way to consume nicotine in smoke-free workplaces, public places, or homes, thereby reducing pressures to quit all smoking and weakening their inclinations to do so. Nor did FDA mention the possibility that using the new snus could become a new fad among youth that they could participate in without their parents or teachers noticing, thereby increasing overall youth addiction to nicotine. In addition, FDA did not consider the possibility that Swedish Match or tobacco product retailers, as profit maximizing businesses, might market the snus more aggressively or irresponsibly than described in the PMTA, which they could readily do without violating any applicable laws or regulations or contradicting the permissive PMTA orders (which placed no new marketing restrictions or requirements on the snus).\textsuperscript{55}

FDA’s failure even to consider these possibilities and other ways that snus marketing and use might increase health harms and risks when making its AFPPH determinations was “arbitrary or capricious.”\textsuperscript{56} Indeed, these possibilities call into question, or even contradict, FDA’s apparent conclusion that the downside health risks were so small that allowing the marketing of the possibly less-harmful snus (without any new restrictions or requirements) was AFPPH just because of the potential health gains if some users of other smokeless tobacco products ended up switching completely to using them, instead.\textsuperscript{57}

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

\textsuperscript{54} Id. at 25. Yet the Snus Final Order clearly anticipated the possibility that their marketing might produce a net public health harm and not be AFPPH. See supra notes 34-37 and accompanying text.

\textsuperscript{55} See infra notes 107-109 and accompanying text for examples of completely legal ways Swedish Match or retailers could market the snus to increase youth use and increase other harm-increasing uses of the snus.

\textsuperscript{56} See, e.g., Nat’l Ass’n of Home Builders v. Defenders of Wildlife, 551 U.S. 644, 658 (2007) (an agency would be arbitrary or capricious if it “entirely failed to consider an important aspect of the problem”); supra note 27.

\textsuperscript{57} Fortunately, neither Swedish Match nor any major retailers appear to have yet marketed the PMTA snus 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 remains imprudent and, therefore, “arbitrary and capricious,” especially as, over time, competitive pressures can drastically change a profit-maximizing 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). But they later began marketing e-cigarettes with other flavors after they began losing market share to competitors. Recollection of author from his time as Director of the FDA Center for Tobacco Products Office of Policy, 2011-2014.
FDA’s decision summary and PMTA orders allowing the marketing of the Philip Morris IQOS products show that FDA considered the marketing of IQOS to be more risky for the public health than the Swedish Match snus, and FDA even included some marketing and sales restrictions in the final IQOS PMTA orders. But FDA’s analysis, findings, and AFPPH determination for IQOS was still riddled with major errors and omissions that makes FDA’s PMTA review process and the final orders, themselves, “arbitrary or capricious” and fails to support its finding that issuing the orders was AFPPH.

Unlike with the Swedish Match Snus Decision Summary and Orders Letters, the documentation for FDA’s PMTA orders for the Philip Morris IQOS products do 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 the 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

As detailed below, the Executive Summary’s bullets listing what the scientific review of the applications had demonstrated 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. There is also 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

58 IQOS Decision Summary 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 not requiring 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 Final Order at 14-15. However, they are mentioned above only generally in an Executive Summary bullet with no description or detail, the main text of the Decision Summary 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 Decision Summary at 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 108-109. 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, 115. In this way, the Appendix appears to be focusing on showing that it was AFPPH to include the restrictions in the Final Order (not on explaining that FDA had determined that the orders could not be AFPPH unless they included those restrictions). This distinction could be relevant if the requirements were legally challenged on First Amendment grounds. See infra note 122 and accompanying text.
While the decision summary discusses related research and evidence, it does not make this conclusion any more specific or detailed, but does suggest some weaknesses. For example, FDA states that the applicant has 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 has failed to support a conclusion that they do not pose any risk to users. 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.”60 Then FDA notes, without any further evaluation or analysis, that eight other chemicals that IQOS users are exposed to at higher levels than conventional cigarette smokers were also identified as potentially genotoxic and/or carcinogenic.61 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.”62 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.”63

59 These and the other bulleted quotes are from the IQOS Decision Summary at 11-12.

60 IQOS Decision Summary at 32, which also offers a parallel analysis and “does not preclude” 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 does not say that it is sufficient that the application’s evidence, and other available evidence FDA finds and considers, does not preclude such a determination. TCA § 910(c)(2)(A) [21 U.S.C. 387j(c)(2)(A)]. 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.

61 IQOS Decision Summary at 32-33.

62 Id. at 59, 56.

63 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 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(Suppl 1) Tob. Control s20 (epub Aug. 29, 2018); Gideon St. Helen, et al., IQOS: examination of Philip Morris International’s claim of reduced exposure, 27(Suppl 1) Tob. Control s30 (epub Aug. 29, 2018); 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(Suppl 1) Tob. Control s9 (epub Aug. 29, 2018); Barbara Davis, et al., IQOS: evidence of pyrolysis and release of a toxicant from plastic, 28 Tob. Control 34 (epub Dec. 17, 2018). 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., Comment from Matthew Springer, UCSF, Docket Number: FDA-2017-D-3001, posted December 4, 2017, www.regulations.gov/document?D=FDA-2017-D-3001-0118 (last visited Sept. 20, 2019) [stating that the Philip Morris application “does not support the conclusion that IQOS will not
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 brand-new users. 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. 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.”

This conclusion is odd given FDA’s discussion later in the decision summary about how IQOS 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 smokers. 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 notes that “the health benefits of reducing cigarette consumption instead of quitting completely are unclear.”

harm endothelial function” and that independent research “shows that IQOS harms endothelial function as much as conventional cigarettes”). The IQOS Decision Summary does not mention this comment or the cited research, and only mentions the word “endothelial” once in a passing reference. IQOS Decision Summary at 58. For a critique of FDA’s evaluation of the science and other evidence in the IQOS Decision Summary, which identifies other research FDA did not appear to consider, see Laura K. Lempert, & Stanton A. Glantz, Notes on FDA’s Technical Project Lead Review for the IQOS PMTA, https://tobacco.ucsf.edu/sites/tobacco.ucsf.edu/files/wysiwyg/Notes%20on%20FDAs%20Technical%20Project%20Lead%20Review%20for%20the%20IQOS%20PMTA_17Jun2019.docx (last visited Sept. 20, 2019). However, the IQOS 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. Id. at 56, 58, 60, 93.

Throughout the Decision Summary, FDA describes and relies on research done or provided by the applicant, Philip 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 Jnl Public Health Policy 34 (Feb. 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 (last visited Sept. 20, 2019); Ruth E. Malone, Changing Tobacco Control’s policy on tobacco industry-funded research, 22 Tob. Control 1 (2013); Elisa K. Tong & Stanton A. Glantz, SA, Tobacco industry efforts undermining evidence linking secondhand smoke with cardiovascular disease, 116 Circulation 1845 (Oct. 16, 2007); USA v. Philip Morris, 449 F. Supp. 1 (Aug. 17, 2006) at, e.g., 208, 870-71, 877-78, 885.

Id. at 84.

Id. at 32.

Id. at 73. See, also, id. at 96.
In addition, FDA later states: “Whether this [dual] user population will achieve an exposure reduction when compared to exclusive [conventional cigarette] use, and to what magnitude, is unclear.”68 Nevertheless, FDA ultimately concludes that “based on the currently available evidence, dual use is unlikely to pose increased health risks compared to continued exclusive [conventional cigarette] use.”69

At the same time, FDA clearly recognizes that future research might show that certain types of dual use are sufficiently more harmful than exclusive cigarette smoking and prevalent enough that allowing the continued marketing of IQOS would not be AFPPH.70 Yet FDA does not explain why running that risk by issuing the current permissive PMTA order is AFPPH, nor does FDA estimate either the likelihood or size of the worst-case 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. More substantively, FDA did not even mention 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.71

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

This bullet is purely observational (based on relatively few studies), providing no support for FDA’s AFPPH determination, and FDA made no related estimates or findings in the Executive Summary or any other part of the decision summary regarding how much dual use could or is likely to occur in the United States when IQOS is marketed pursuant to the PMTA order or regarding the possible or likely 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.72 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

68 Id. at 56.
69 Id. at 96.
70 Id. at 83-84.
72 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, with other passing references to dual use delaying or preventing cessation at 87, 89.
product;"\textsuperscript{73} dual use “may account for a substantial portion of IQOS users in a real-world setting” and “appears likely;"\textsuperscript{74} “[t]he limited data available indicates that a dual-use period is common during the switching period;”\textsuperscript{75} 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.”\textsuperscript{76} 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.”\textsuperscript{77}

- “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 for other, currently available, tobacco products and initiation is expected to be low generally.”

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 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.”\textsuperscript{78} 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.”\textsuperscript{79} Nevertheless, FDA concludes that: “Overall, the current evidence indicates IQOS uptake by youth and nonsmokers will be low.”\textsuperscript{80}

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 those limited flavor options and the price of IQOS “may reduce IQOS’s appeal to youth.”\textsuperscript{81} However, FDA did not provide any data or analysis regarding the relative prices of IQOS versus e-cigarettes or cigarettes, nor did it discuss the unique role menthol flavoring has played in increasing youth smoking and e-cigarette initiation, which could extend to IQOS initiation, as well.\textsuperscript{82} Nor did FDA consider or discuss, as it did in the Swedish Match

\textsuperscript{73} Id. at 71.
\textsuperscript{74} Id. at 56, 73.
\textsuperscript{75} Id. at 83. See, also, id. at 77, 97.
\textsuperscript{76} Id. at 83.
\textsuperscript{77} Id. at 84.
\textsuperscript{78} Id. at 76.
\textsuperscript{79} Id.
\textsuperscript{80} Id.
\textsuperscript{81} Id.
Snus Decision Summary, the possibility that issuing a permissive order for IQOS could create a “perceived favorable profile” that would increase nonuser initiation and use – and also discourage total cessation and, through dual use, discourage smoking cessation.\footnote{Supra note 43 and accompanying text.}

In a following, final Executive Summary bullet, FDA also states that: “The proposed marketing and advertising restrictions will help ensure lower youth exposure and access to the products.” But it is not clear whether FDA’s expectation of low youth initiation was contingent on the final orders 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.\footnote{Supra note 58.} 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, given the extensive post-market reporting and surveillance the final orders require regarding future IQOS advertising and youth use to “help FDA ensure, on an ongoing basis, that the continued marketing of new tobacco products remains appropriate for the protection of public health.”\footnote{IQOS Decision Summary at 120. See, also, id. at 115; IQOS Order Letter at 1, 6-7.} But the IQOS PMTA documents do not explain why FDA determined that issuing the PMTA orders was AFPPH despite the unspecified low youth initiation FDA expected or despite the considerably higher levels of youth initiation that FDA considered possible.\footnote{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 Decision Summary 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.}

More specifically, the PMTA documents offer no analysis or findings about whether some youth who initially initiate into using IQOS would subsequently initiate into more-harmful conventional cigarette smoking as well, or 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). 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. FDA finds that dual use is likely not more harmful than just smoking and that using IQOS alone is likely less harmful than smoking, but 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.

- \textit{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.”}\footnote{Id. at 12.}
This text provides only observations about data in two other countries and FDA does not link those observations to any related findings or conclusions by FDA as to how the marketing of IQOS would affect uptake by youth, current nonsmokers, former smokers, or current smokers in the United States. Specifically in regard to former-smoker use of IQOS, neither the decision summary nor any other public PMTA documents include any discussion or findings regarding how the marketing of IQOS in the United States might create brand-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. Going the other way, FDA does not consider whether any former smokers who would otherwise relapse into smoking might relapse into using IQOS, instead.

Similarly, FDA’s Decision Summary analysis did 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 instead or through dual use, or by prompting smokers who would otherwise have switched to e-cigarettes to switch to IQOS, instead. 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 potentially even less-harmful e-cigarettes are already readily available in the U.S. market. For example, the decision summary included no discussion or findings as to whether allowing the marketing of IQOS would prompt any smokers to switch entirely to IQOS who would not otherwise switch completely to e-cigarettes.

In addition, FDA did not consider specific ways that Philip Morris (including its U.S. licensees, Altria and Philip Morris USA) 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 and other applicable legal requirements and restrictions. This omission seems odd given the long history of both legal and illegal

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88 The closest FDA comes to doing such an 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 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.

89 But the Decision Summary does describe and cite 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,” and states that it would have been useful to have comparisons of the secondhand exposure impacts from IQOS and other tobacco products, such as e-cigarettes. IQOS Decision Summary at 22, 56. It also notes that “[n]umerous studies demonstrate that consumers tend to perceive IQOS as similar to e-cigarettes in terms of risk” and 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 smokers’ relative interests) Id. at 89, and 75, 96.

90 The IQOS 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. But the text describing its main concepts is redacted, and FDA provides no related analysis or comments. Id. at 86-87. 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 111-122. But 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.
irresponsible marketing by the Philip Morris entities, including reports of irresponsible Philip Morris marketing of IQOS overseas and in the United States before FDA issued its IQOS order. But none of that is even mentioned in the Decision Summary.

It is difficult to understand and impossible to justify FDA’s failure to consider some of the most basic and obvious possible health-harming and health-benefiting industry practices and consumer responses to the marketing of IQOS by youth and adult nonusers and users of different types of tobacco products, much less compare their potential health impacts against each other. Section 910 of the TCA 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. In addition, existing case law firmly establishes that FDA’s PMTA AFPPH determinations, if challenged in court, will be found “arbitrary or capricious” in violation of the Administrative Procedures Act 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.

Even if these material omissions were somehow excused, the findings FDA does base its AFPPH determination on are too imprecise and uncertain to provide a legally defensible foundation. As outlined above, FDA bases its determination that allowing IQOS on the market is AFPPH on findings that: (1) smokers who switch completely to 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; (d) youth and other nonuser initiation is expected to be low generally; and (4) IQOS use by former smokers, although somewhat more likely than nonuser initiation, will also likely be low. Even if we overlooked the questionable aspects of some of these findings and


92 There have also been reports, before FDA issued its IQOS PMTA order, 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 (last visited Sept. 20, 2019). This issue also was not mentioned in the IQOS Decision Summary, although it is possible that the redacted text in the descriptions of the IQOS products might have referenced this information collection capacity. IQOS Decision Summary at 14-16.

93 TCA § 910(c)(4) [21 U.S.C. 387j(c)(4)]. See, also, Lindblom, Key Parameters of the “Appropriate for the Protection of the Public Health” Standard, supra note 16.

94 See supra note 56.

95 The decisions 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. IQOS Decision Summary at 92.
assumed they were all accurate or reasonably determined (and that no other material factors needed to be considered), these four 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 also to 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. 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.

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: (a) some smokers who would not otherwise quit smoking or all use would switch entirely to using IQOS and thereby reduce their tobacco-related harms; (b) other smokers engaging in dual use would not increase their harms (and would not have otherwise quit smoking or all use); and (c) 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 Decision Summary or Final 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.

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.”

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96 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. 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). But 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.” IQOS Decision Summary at 77-79, 97-98, with quote at 79 and 98. 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(Suppl 1) Tob. Control 27(Suppl 1) s82 (Nov. 2018).

97 See supra note 92.

98 See supra notes 23, and accompanying text, and 35.
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 discussed, FDA anticipated that the marketing of the Swedish Match Snus and Philip Morris IQOS products would cause at least some low risk or low amounts of new youth initiation, could cause larger amounts of new health harms than expected, and might turn out not to be AFPPH. Yet FDA did not identify all the different ways the products’ use might cause new health harms and risks or try to consider all the major factors, such as different industry marketing strategies, that might prompt more youth and other consumers to respond to the marketing of the PMTA products in harm-increasing ways. Nor is there any evidence in the public PMTA decision documents that FDA made any serious attempt to include in the final orders all readily available, viable provisions that would blunt those factors or mitigate their negative behavioral and public health impacts.

All that FDA did in this regard with the Swedish Match snus was to recognize that a positive FDA PMTA order allowing them on the market might create a “perceived favorable profile” that could increase dual use with cigarettes and discourage transition to exclusive use of less toxic tobacco products and cessation and otherwise affect initiation and uptake. But FDA ultimately dismissed any related concerns and included no provisions in the Snus Final Order to prevent or address any possible “perceived favorable profile” or its possible negative impacts on consumer behavior. Nor did the Final Order include any other requirements or restrictions directed at preventing or reducing harm-increasing uses of the snus, either directly or by preventing or restricting marketing practices that could promote such harm-increasing uses.

For IQOS, FDA did not even mention the possibility that issuing a positive PMTA order could produce a “perceived favorable profile” (by that or any name), despite that risk being much higher with IQOS than with the Swedish Match snus. But the FDA Final Order did specifically require a special nicotine-addiction warning on all IQOS heatstick packages and advertising, based on FDA’s review of research showing that consumers tend to underestimate the addiction risk from IQOS, which could increase initiation and decrease cessation among tobacco users. In addition, the Decision Summary Appendix discussed how tobacco product

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99 See, e.g., supra notes 34-37, 65, 70, 78-79, 85 and accompanying text. There are also repeated statements in the IQOS Final Order and Discussion Summary that the marketing of IQOS might not continue to be AFPPH. See, e.g., IQOS Final Order at 1, 2; IQOS Decision Summary at 115-16, 120. The Snus Final Order has some similar text at 3-4.

100 Snus Decision Summary at 30-31, 34.

101 The higher risk from IQOS comes not only from it being, unlike the Swedish Match snus a brand-new product never before sold in the United States but from it offering a way to inhale tobacco without smoking that has already been actively discussed by the media in the United States and worldwide as a less-harmful smoking alternative. In addition, IQOS has already secured much higher use levels than snus generally does in those countries where IQOS has already been marketed, and Philip Morris and its licensees are likely to promote IQOS in the United States much more actively than Swedish Match has promoted its snus.

102 IQOS Decision Summary at 87-89; IQOS Final Order at 13-14. See, also, IQOS Decision Summary at 12, 98. But FDA could have easily made this requirement even stronger by requiring the warning to be black text on fluorescent yellow background (instead of requiring black on white or vice versa), which would have made it much more eye-catching. See, e.g., Laura K. Lempert & Stanton A. Glantz,
advertising and promotions, both generally and through specific strategies, increase initiation and use among youth and nonusers.\textsuperscript{103} To address that, the IQOS Final 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.\textsuperscript{104} 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 described in the Decision Summary Appendix as increasing youth and nonuser use. Nor did FDA include any other provisions in the Final Order to prevent or reduce harmful IQOS use among youth, nonusers, e-cigarette users, or smokers.

In the IQOS Final 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.”\textsuperscript{105} But rather than include requirements in the PMTA order to ensure that Philip Morris would actually do just that, the Final 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.\textsuperscript{106}

As things stand, there is nothing in the IQOS or Snus Final 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 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.\textsuperscript{107}

\textit{Implications of tobacco industry research on packaging colors for designing health warning labels}, 18 Nicotine & Tob. Research 1910 (2016).
\textsuperscript{103} IQOS Decision Summary at 111-120 (Appendix), 12.
\textsuperscript{104} IQOS Final Order at 14-15.
\textsuperscript{105} Id. at 2.
\textsuperscript{106} Id. (emphasis added).
\textsuperscript{107} FDA and others are assuming that the IQOS heatsticks fit under existing “cigarette” definitions in various government laws and regulations and in the settlement agreements between the states and Philip Morris and most other cigarette companies. To date, there is no indication that Philip Morris will challenge that assumption. As long as the IQOS heatsticks are considered cigarettes, they 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 § 907(a)(1)(A) [21 U.S.C. 387g(a)(1)(A)]; 21 Code of Federal Regulations Part 1140. Under the settlement agreements, 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
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. They could also be advertised on social media and through other electronic means without the age and ID verification that FDA required in the IQOS Final Order.\footnote{108} 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.”

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 Decision Summary Appendix show that tobacco product advertising encourages youth, nonuser, and overall initiation and use even when done without such obviously troublesome taglines, themes, or targeting.\footnote{109}

Had FDA decided to do more to ensure responsible marketing in its PMTA orders and otherwise minimize exposure to the advertising for IQOS and the Swedish Match snus among those whose use could only be harmful, numerous effective options were readily available. For the Swedish Match snus, for example, FDA could have at least included restrictions and requirements that parallel the existing, more-strict measures that apply to cigarettes but not snus, and placed the same restrictions on social media or other electronic marketing and sales of the snus that it put on IQOS to protect youth. FDA could have also 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 example, 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

\begin{footnotesize}
\footnote{108} Although all of FDA’s analysis supporting its application of adult-only restrictions on the electronic marketing of IQOS and apply equally well to the marketing of the Swedish Match snus (and any other tobacco product), FDA has not yet added them into the PMTA order allowing the Swedish Match snus on the market or initiated any rulemaking to apply the restrictions more broadly. Same situation exists with the IQOS Final Order requirement that any marketing or promotions done on Philip Morris’s behalf by third parties must disclose Philip Morris’s sponsorship.

\footnote{109} See, e.g., IQOS Decision Summary at 111-116. As noted above, neither Swedish Match nor any major retailers appear to have yet marketed the PMTA snus in any clearly irresponsible or harm-increasing ways. But that does not excuse FDA’s leaving the door open for them to do so.
\end{footnotesize}
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 tobacco product use. In addition, FDA could have required that both products be sold with package inserts that provide instructions for how to use the product in harm-reducing ways (including reducing nonuser exposure); describe the addictiveness, harms, and risks from any other uses; explain the greater health benefits from total cessation; and inform users how they can obtain cessation assistance.

Another approach would have been for FDA to include provisions in its PMTA orders that would have at least directly addressed the harmful tobacco product labeling and advertising features or tactics identified in its IQOS Decision Summary and its Appendix, rather than just list certain ways that companies receiving PMTA orders “should” constrain their marketing to

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110 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 Jnl Public Health 295 (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.

111 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 Decision Summary at 73-74.

112 For the Swedish Match snus, the FDA Decision Summary included a statement recommending “appropriate instructions for use.” Snus Decision Summary 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. Id. at 85-86. But FDA describes those materials as instructing users only on how to operate, clean, and maintain the IQOS system. 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. 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.
protect against youth use. For example, FDA states 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.” But rather than just encourage such youth-protective marketing, FDA could have required it. 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.” But FDA did not take the logical next step to require Philip Morris to follow that approach.

In addition, FDA observes that tobacco product promotional items, celebrity endorsements, and links to cultural icons have been found to increase youth use; and could have prohibited their use in any marketing of IQOS or the Swedish Match snus. Similarly, FDA cites 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 consumer behavior, might reasonably be seen as creating a new risk of attracting youth or promoting any harm-increasing uses of the product. IQOS Final Order at 6-7, 10-11, 12.

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In addition, FDA observes that tobacco product promotional items, celebrity endorsements, and links to cultural icons have been found to increase youth use; and could have prohibited their use in any marketing of IQOS or the Swedish Match snus. Similarly, FDA cites 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 consumer behavior, might reasonably be seen as creating a new risk of attracting youth or promoting any harm-increasing uses of the product. IQOS Final Order at 6-7, 10-11, 12.

For research regarding terms and phrases that mislead consumers regarding harmfulness and relative risk, see, e.g., Sabeeh A. Baig, et al., “Organic,” “Natural,” and “Additive-Free” Cigarettes: Comparing the Effects of Advertising Claims and Disclaimers on Perceptions of Harm, 21 Nicotine Tob. Research 933 (2019); Tatiana Basáñez, et al., Vaping associated with healthy food words: A content analysis of Twitter, Addictive Behaviors Rpts 147 (2018). Or FDA could have required that before being used all 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 Advertising: Progress to Date and Impact on Public Policy, 12 Current Issues & Research in Advertising 75 (1990); J. Edward Russo, et al., Identifying Misleading Advertising, 8 Jnl of Consumer Research 119 (Sept. 1981).

FDA also states that PMTA 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). And FDA could have included specific restrictions and requirements to help ensure that all future labeling, advertising, marketing, and promotional materials for IQOS did that.

Id. at 113.
nonusers; 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. It is also clear from the Decision Summary that FDA was aware of research indicating 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. Accordingly, FDA could have required that IQOS be marketed and sold with label warnings or product inserts or onset statements that switching to IQOS from e-cigarettes could increase user harms.

FDA’s failure to even consider these or other available ways to reduce the risk that its PMTA orders for the snus or IQOS would cause new individual health harms or produce a negative net public health impact was “arbitrary or capricious” in violation of the Administrative Procedures Act. Moreover, if FDA had considered these possible measures to reduce health harms and risks, there does not appear to be any reasonable justification FDA could have provided for not including at least some of them in the final snus and IQOS PMTA orders.

The Tobacco Control Act gives FDA extensive authorities to include product and marketing restrictions and requirements in PMTA orders, so long as they will prevent new health harms and risks, reduce existing health harms and risks, or otherwise be AFPPH. Accordingly, if FDA reasonably determines that adding restrictions or requirements into a PMTA order is AFPPH, the only possible 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 provisions FDA included in the PMTA 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 AFPPH and, therefore, permissible under the TCA. In addition, speech-related restrictions in PMTA orders that were not necessary for

117 Id. at 112, 113, 114.
118 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 that would focus FDA’s enforcement against e-cigarettes on the market without permissive PMTA orders on those e-cigarettes that did not restrict the sale of their flavored brands (other than tobacco and menthol flavored) to adult-only stores or adult-only areas in youth-accessible stores. FDA, Modifications to Compliance Policy for Certain Deemed Tobacco Products, Draft Guidance (March 2019), https://www.fda.gov/media/121384/download.
119 See IQOS Decision Summary at 22, 89.
120 See, e.g., supra notes 25, 56, and accompanying text.
121 § 910(c)(1)(B) [21 U.S.C. 387j(c)(1)(B)]. FDA also has similarly broad authorities to include new restrictions and requirements in MRTP permissive orders. § 911(h)(5) & (h)(1)&(2) [21 U.S.C. 387k(h)(5) & (h)(1)&(2)]. However, the Tobacco Control Act 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. § 910(c)(2) [21 U.S.C. 387j(c)(2)]; § 911(g)(1)&(2)&(3)(A) [21 U.S.C. 387k(g)(1)&(2)&(3)(A)].
122 If the courts could strike down a speech restriction or requirement that was necessary to include in the PMTA order so that FDA could allow the new tobacco product on the market as AFPPH, FDA would then be required by the TCA to withdraw its PMTA order and not allow the now-not-AFPPH product to be marketed at all – which would contradict both the TCA’s goal of protecting the public health and the core principles of 1st Amendment corporate-speech case law, which allow restrictions necessary to
an AFPPH determination would still be constitutionally valid if they promote 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. 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).

Both the First Amendment and the APA’s “not arbitrary or capricious” standard might invalidate a speech-related restriction or requirement placed in a PMTA order to reduce health harms and risks if it were clear that the restriction or requirement would also be disproportionately reducing the likelihood and size of the expected net public health gains from allowing the product on the market. But FDA could avoid those risks simply by including only those measures 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.

promote such substantial government interests. See e.g., Lorillard Tobacco Co. v. Reilly, 533 U.S. 525 (2001). See, also, Disc. Tobacco City & Lottery, Inc. v. United States, 674 F.3d 509, 531-537 (6th Cir. 2012)[upholding the MRTP pre-market order process, as described in the TCA, against tobacco industry 1st Amendment challenges]. So far, the courts have not ruled on any 1st Amendment challenges to the PMTA process established by the TCA.

See e.g., Lorillard Tobacco Co. v. Reilly, 533 U.S. 525, 553-565 (2001). See, also, Disc. Tobacco City & Lottery, Inc. v. United States, 674 F.3d 509, 537-548 (6th Cir. 2011)[rejecting 1st Amendment challenges to a range of speech-related restrictions and requirements placed on cigarettes by the TCA, and suggesting how a requirement that certain cigarette ads be only black text on white background could be constitutionally structured]. 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 and Drug L. J. 57 (2015) at 81-91.


Going further, FDA could also legally include restrictions and requirements that it determined would prevent or reduce youth initiation and use even if they also disproportionately reduced the number of adult users of more harmful tobacco products who would switch completely (and would not have otherwise quit) if FDA provided a reasonable explanation for interpreting the AFPPH standard (and the government’s related substantial interest in reducing public health harms relating to tobacco) as placing a higher priority on protecting youth from harmful addiction and use than on reducing harms among existing adult tobacco users. FDA has stated that it has a statutory mandate to protect youth from the dangers of tobacco use. See, e.g., IQOS Decision Summary at 111, 120. But FDA has not explained where the TCA creates that mandate or the extent to which it might outweigh any related duty to reduce tobacco-related harms among adults or overall tobacco use harms. Nor has FDA provided any reasoned interpretation of the AFPPH standard that places a greater priority on preventing and reducing harms to youth compared to harms to adults; and the TCA does not appear to create, or prohibit, any such priority.
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 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 IQOS Decision Summary to support the Final Order’s requirement than any electronic advertising or sales of the product be done with rigorous age and ID verification to support a concurrent proposed rule to subject all other tobacco products to that same requirement. More importantly, however, all that matters in determining what FDA must, may, or may not put in a final PMTA order is whether the restriction or requirement is necessary to make the order AFPPH, will make the order more AFPPH, or will make it less AFPPH or not AFPPH at all. If the added order provision 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 it is more strict than existing regulations placed on more harmful tobacco products is irrelevant. Moreover, it could not be AFPPH to allow a new product to be marketed in harm-increasing ways while FDA goes through the typically long process of developing, implementing, and enforcing a final rule rather than including measures in the final PMTA order to prevent and reduce such marketing from the start.

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 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 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 orders would be enough to ensure responsible marketing and low levels of new youth initiation or other harm-increasing uses. Fundamental problems with FDA’s findings or expectations of low risks or low harms have already been described. But even if we put that aside, FDA’s reliance on post-market surveillance and possibly withdrawing or amending the final orders to address unanticipated new harms that emerge is still both procedurally and substantively flawed.

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

See Lindblom, *Key Parameters of the “Appropriate for the Protection of the Public Health” Standard,* supra note 16.

127 IQOS Decision Summary at 111-120.

128 It would be similarly irrelevant and unreasonable for FDA to allow a PMTA tobacco product on the market despite finding that it would create unnecessary individual and public health harms and risks based on an asserted preference to rely on its own public education campaigns to prevent and reduce those harms and risks rather than include restrictions or requirements in the final orders to prevent and reduce them.
the likelihood and size of the expected net public health gains or would increase them. Nor could it be AFPPH to allow new health harms to occur and only then take action to prevent or reduce them rather than 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 an even more questionable strategy 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.\(^\text{129}\) FDA’s record for enforcing against specific tobacco product manufacturers or brands if they violate the Tobacco Control Act, other provisions of the Food, Drug & Cosmetic Act, or related rules is also weak, and typically done, when done at all, quite slowly, only after a lengthy process of warning letters, responses, and consultations, and opportunities for the manufacturer to implement corrective actions.\(^\text{130}\) The extent to which this lack of FDA alacrity in

\(^{129}\) For example, despite having extensive powers and authorities to do so since 2009, 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 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 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), available at www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-meetings-industry-related-agencies-ongoing-policy (last visited Sept. 20, 2019).

\(^{130}\) For example, while FDA has issued tens of thousands of warning letters to tobacco product retailers, it has sent relatively few to manufacturers or importers, and even fewer relating to major brands, with very few FDA announcements of either positive resolutions or follow-up FDA enforcement actions. See FDA Website, “Warning Letters,” www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/compliance-actions-and-activities/warning-letters, and “Press Announcements,” www.fda.gov/news-events/fda-newsroom/press-announcements (last visited Sept. 20, 2019). 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, Tob. Control (Epub. Aug. 30, 2019); American Cancer Society, et al., Letter to Dr. Janet Woodcock, Director, Center for Drug Evaluation & Research, FDA (Oct. 14, 2015) [providing evidence of e-cigarettes being marketed with therapeutic claims without required prior FDA approval]; Action on Smoking and Health, et al., Letter to Mr. Mitchell Zeller, Director, Center for Tobacco Products, FDA (Feb. 26, 2016) [urging enforcement against major tobacco companies introducing new tobacco products into the market without required pre-review and permission from FDA]; Matthew M. Myers, President, Campaign for Tobacco-Free Kids, Letter to Ann Simoneau, Director, Office of Compliance and Enforcement, Center for Tobacco Products, FDA (May 26, 2016) [noting that 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 had not prompted any remedial changes or FDA enforcement action]; American Academy of Pediatrics, et al., Letter to Dr. Scott Gottlieb, Commissioner, FDA (Aug. 7, 2018) [urging enforcement against e-cigarettes being marketed in violation of the TCA and the FDA deeming rule]. These and other letters from public health groups providing evidence of violations by tobacco product manufacturers and urging related FDA enforcement against them are available at Campaign for Tobacco-Free Kids, website, 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 Sept. 20, 2019). 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:
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 one of the permitted new PMTA product’s marketing had turned out to be not AFPPH and quickly decided to withdraw the original PMTA order, the statute 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 order to appeal any FDA decision to withdraw the order, which could produce further delays.\(^{131}\) If the withdrawal of the PMTA order meant to stop the sale of the product or require changes to the product, its packaging, labeling, it is also likely that FDA would allow retailers, distributors, and manufacturers to exhaust existing inventories, first.\(^{132}\) In addition, any illegal marketing or sales of the products after the PMTA order was revoked or amended would 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.

Moreover, 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 the snus is causing greater harms than expected or is not AFPPH. For example, the IQOS Final Order requires Philip Morris 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.”\(^{133}\) But there is no mention of requiring any recordkeeping or reports about polices 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 Final Order does require Philip Morris to keep records relating to the sale, distribution, or other disposition of IQOS, including any information about purchasers “previous or current use of other tobacco products (i.e., dual use),” to keep records of all clinical or nonclinical studies done by Philip Morris pertaining to IQOS, including consumer evaluation research studies, and to report annually on any significant findings in new publications, including any new scientific

\(^{131}\) TCA § 910(d)(1)&(2) [21 U.S.C. 387j(d)(1)&(2)]. The statute says nothing about FDA amending a previously issued PMTA order allowing a product on the market. But 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.

\(^{132}\) For example, FDA’s proposed rule requiring graphic health warnings for cigarette packages would only prohibit manufactures 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. FDA, Proposed Rule, Tobacco Products; Required Warnings for Cigarette Packages and Advertisements 84 Federal Register 42754 (Aug. 15, 2019) at 42785.

\(^{133}\) IQOS Final Order at 6-7, 9-13.
data (published or otherwise) “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 adults.”134 But it does not require that Philip Morris actually initiate any data collection or research relating to IQOS 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 IQOS marketing is promoting more harm-increasing use of IQOS than harm-reducing use.

The post-market surveillance requirements for the Swedish Match Snus are similar but even weaker than for IQOS.135 For example, unlike with IQOS, the record keeping requirements do not specifically require keeping any records relating to policies and procedures pertaining to youth access to the products or to the products’ labeling, advertising or promotion, and no related reports on those policies and procedures are required. In addition, no quarterly reports are required, as FDA requires for IQOS, nor is Swedish Match required to provide as much information regarding its advertising or to provide FDA with copies of any new labeling, advertising, marketing, and/or promotional materials 30 days prior to their use. More fundamentally, as with IQOS, FDA did not require adequate new data collection, research, and reporting relating to the Snus or IQOS to ensure that the agency would promptly be alerted to any unexpected harms from the product’s use or to any unanticipated harm-increasing uses of the products that would show that the PMTA orders must be amended or revoked to adequately protect the public health.136

Moreover, if FDA intended to rely on the possibility that the PMTA Final Order would be rescinded to ensure that Snus and IQOS would be marketed responsibly and that Swedish Match and Philip Morris would take actions to ensure that the marketing of their respective products would produce larger public health gains than losses, FDA could have made that a more certain, specific, and effective threat. For example, FDA could have stated that the PMTA 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 PMTA 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.

But 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. Instead, FDA could have prevented all or some of them from ever occurring in the first place without significantly reducing (and possibly reducing) the net public health gains from issuing the orders. Taking a

134 Id. at 6 and 10.
135 Snus Final Order at 3-5.
136 It is possible that FDA was relying on some other sources of data and research to provide such prompt notice of unexpected harms or harm-increasing uses. But that is not mentioned anywhere in the decision summaries or final orders.
stitch in time to save nine is a solid public health principle, and FDA’s failure to do so by including effective restrictions and requirements to prevent unnecessary harm-increasing uses of the snus and IQOS products was both not AFPPH and “arbitrary and capricious.”

**FDA’s Subsequent 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 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. 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 evaluations might be more comprehensive than those done for the Swedish Match snus and Philip Morris IQOS products.

As it has before, FDA acknowledges in the Proposed Rule that its PMTA 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. 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 “[g]enerally, 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 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.” 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

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137 See *supra* note 25 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 to consider those 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* note 56. See, also, *supra* note 24.


139 See, e.g., *Id.* at 50581, 50620, 50621, 50623. The PMTA Final Guidance does not discuss this issue.

140 *Id.* at 50618.
population as a whole.” 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. But FDA provides no clarification as to how certain or positive those understandings or expectations need to be to support an AFPPH determination.

In addition, neither the Proposed Rule nor the Final Guidance say anything about whether allowing the marketing of a new tobacco product expected to produce a net positive effect on the health of the population as a whole could still be not AFPPH because it would also produce new individual or public health harms or risks that could be prevented or reduced by readily available product changes or by including additional restrictions or requirements in the PMTA order relating to the product’s packaging, labeling, marketing, or sale.

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 permissive PMTA order could be AFPPH if it allowed the marketing of a new 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.” 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 marketing as minimally harmful and risky as possible, without interfering with its ability to secure 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; and the text of the proposed rule, itself, only reiterates FDA’s authority under the TCA to include such

141 Id. (emphasis added).
142 Id. at 50621.
143 Supra note 25 and accompanying text.
144 Proposed Rule at 50580. See, also, id. at 50655, proposed new 21 CFR § 1114.31(b)(2) (allowing FDA to include restrictions in the PMTA order that the applicant proposed “to help FDA” make an AFPPH finding); Final Guidance at 15 (applicant “may propose specific restrictions on sale and distribution that can help support a showing that permitting the marketing of the product would be APHP”). The Proposed Rule also states: “Consistent with its mission to protect the public health, FDA seeks to limit youth exposure to the 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 Rule at 50580. 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 50581.
restrictions in the final PMTA orders. 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.”

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.

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. Implementing all readily available steps to minimize the risks and harms from PMTA products would help to reduce the size and scope of these uncertainties, as would implementing all product, labeling, and marketing restrictions and requirements that would help prevent or discourage harm-increasing consumer uses while still allowing for or encouraging harm-reducing uses. But the Proposed Rule and Final Guidance do not discuss these uncertainty problems, do not require applicants to take any of these actions or propose any such measures to shrink the size or scope of these troublesome uncertainties, and do not provide any clear guidance on what else applicants must or should do to address them. Nor do the FDA documents provide any clear insights as to how FDA will address or accommodate 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.

145 Id. at 50655, proposed new 21 CFR § 1114.31(b)(1). See, also, id. at 50581 (“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)).

146 Id. at 50596. See, also, Final Guidance at 19 (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). 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. Proposed Rule at 50580, 50607. See, also, Final Guidance at 25-26.

147 See, id. at 29-33; Proposed Rule at 50644. 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 50579.

148 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., Id. at 50599, 50602, 50603, 50604, 50605, 50606, 50607, 50615. 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
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 continue to market them responsibly thereafter (without requiring that they do so).\(^\text{149}\) Rather than prevent all clearly harmful marketing in the first place, the Proposed Rule, like the Swedish Match snus and Philip Morris IQOS final orders, appears 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.\(^\text{150}\) 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 are implemented.\(^\text{151}\)

More constructively, the Proposed Rule and Final 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

\(^{149}\) Id. at 50580-581, 50581-582, 50643, proposed new 21 CFR § 1114.7(f)(2).

\(^{150}\) Id. at 50581, 50620, 50623, 50655, proposed new 21 CFR § 1114.31(b)(3), 50656, proposed new 21 CFR § 1114.41.

\(^{151}\) See, e.g., supra at text associated with notes 107-108 and at notes 129-132 and associated 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 § 910(a) & (c), § 905(j) [21 U.S.C. 387(a) & (c), 387e(j)]. But 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 (D.C.D.C. 2016).
impact on the public health,\textsuperscript{152} 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.”\textsuperscript{153} Even more specifically, the Proposed Rule states that the PMTA summary must contain a discussion of the “health 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.”\textsuperscript{154} 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.\textsuperscript{155}

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.”\textsuperscript{156}

\textsuperscript{152} Supra notes 140, 141.

\textsuperscript{153} Proposed Rule at 50610.

\textsuperscript{154} \textit{Id.} at 50583. For 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, see \textit{id.} at 50605-606. Similarly, the Final Guidance recommends that applicants provide a summary that describes “the likelihood” that nonusers will initiate or reinitiate 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 Guidance at 24, with related text at 37, 38. However, while the Final Guidances’ 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.

\textsuperscript{155} As described above, 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.

\textsuperscript{156} Proposed Rule at 50584 (emphasis added).
It is troubling, however, that FDA does not take the logical next step of also requiring applicants to develop these kinds of quantitative 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). Nor does anything in the Proposed Rule or Final Guidance suggest that FDA will do any such modeling or estimates on its own.

Conclusion

It is quite possible that an FDA PMTA order allowing the Swedish Match snus or the Philip Morris IQOS products (or some future PMTA or MRTP products) onto the U.S. market could be AFPPH and not “arbitrary or capricious.” But the PMTA orders FDA actually issued obviously were not, for both procedural and substantive reasons. So why did FDA present such sloppy, vague, and incomplete analyses of the Swedish Match and Phillip Morris applications and issue such overly permissive, under-protective PMTA 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 who either do the PMTA analyses or review and approve them were certainly fully aware of all the different ways the marketing of new tobacco products can increase individual and public health harms and risks. Yet all such impacts were not discussed, or even mentioned, for either the Swedish Match snus or Philip Morris IQOS products. In addition, many of them 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 do any such modeling relating to the snus and IQOS 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. CTP leadership and staff were also well aware of many different possible, legally viable restrictions and requirements that can 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 placed no such provisions in its final PMTA order for the snus and included only partial, inadequate provisions in the IQOS final order.

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157 See, e.g., supra note 31 and accompanying text. See, also, infra note 159 and accompanying text, supra text accompanying note 30, notes 48-50 and accompany text, and note 96 and accompanying text.

158 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 Guidance at 51. The Proposed Rule makes no mention of modeling at all.

Given FDA’s knowledge and expertise, the most disturbing possible explanation for its failings with the Swedish Match and Philip Morris PMTA orders would be if non-public-health concerns came into play, such as political pressure from the White House to allow the products on the market with minimal restrictions or requirements, or a desire by government lawyers to avoid threatened legal challenges from Swedish Match or Philip Morris 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 would weaken industry arguments against a future FDA rule to sharply reduce smoking (e.g., by reducing nicotine levels in cigarettes) and make it easier for FDA to get permission from the White House and OMB, at long last, to issue such a rule.\footnote{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), and had consequently 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 that analysis, even if accurate, and its resulting Hail-Mary-pass approach to tobacco control to justify its AFPPH PMTA determinations.}

It could also be that FDA has not yet been 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 to the PMTAs, FDA’s analysis must necessarily be somewhat vague and conclusory.

In addition, FDA might have realized that any reasonable interpretation and rigorous application of the AFPPH standard to PMTA products would make it more difficult to allow any new products on the market, yet the Tobacco Control Act clearly anticipates that some new products will get through (and FDA might have wanted to allow the marketing of the snus and IQOS products for strategic or political reasons).\footnote{Another possible strategic reason for allowing the Swedish Match snus on the market would be to prevent any manufacturers of PMTA products FDA did not allow on the market from being able to argue in court that FDA was using an interpretation of the AFPPH standard that would not permit any new products, which would clearly contradict the statute.} Similarly, FDA might have realized that even without a clearly articulated AFPPH standard, any comprehensive and transparent evaluation of the likelihood and size of the new health harms and risks created by allowing the new products on the market compared to the likelihood and size of the new harm and risk reductions would also make allowing the snus or IQOS products on the market much more difficult.

However, it is quite possible that FDA could have still legally allowed the snus and IQOS products on the market – despite doing a comprehensive evaluation following a clearly articulated, legally viable AFPPH standard – if FDA had been willing and able to include sufficient restrictions and requirements in the final PMTA orders 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 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 White House and OMB did not support or permit FDA efforts to include more comprehensive new restrictions or requirements in the Swedish Match or Philip

160, 161
Morris PMTA 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.

Less political explanations are also possible for FDA’s inadequate evaluation of the PMTA applications and excessively weak final orders. But having inadequate resources or being pressed for time cannot be used as an excuse. The statute provides FDA 180 days to review PMTA applications and issue final orders, but 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 provided by the applicant.\textsuperscript{162} FDA’s Center for Tobacco Products also 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.\textsuperscript{163}

Another largely procedural problem, however, could have been in play. 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 decision summaries 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 PMTA order. The IQOS Decision Summary, for example, 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.\textsuperscript{164} In addition, very little is done to raise and carefully consider important issues or questions not presented by the application, itself.\textsuperscript{165} 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

\textsuperscript{162} The initial Swedish Match application was submitted on March 11, 2015, with eleven listed subsequent amendments, and FDA issuing its final order on November 10, 2015. Snus Decision Summary at 1, 3; Snus Final Order at 1. The initial Philip Morris application was submitted on May 15, 2017, with twelve listed subsequent amendments, and FDA issuing its final order on April 30, 2019. IQOS Decision Summary at 1, 2; Snus Final Order at 1.

\textsuperscript{163} See, e.g., FDA, Fiscal Year 2019 Justification of Estimates for Appropriations Committees (February 2019) (showing 886 full-time equivalent Center for Tobacco Product employees in FY 2018), available at https://www.fda.gov/about-fda/budgets/2019-budget-summary; TCA § 919(b) [21 U.S.C. 387s(a)] (showing industry users fees of $712 million per year for FY 2019 and future years).

\textsuperscript{164} See e.g., IQOS Decision Summary at 56, 58, 93, 94; and 11, 32, 65, 76, 83-84, 95, 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.

\textsuperscript{165} For example, early text in the IQOS 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 Decision Summary 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. Moreover, key issues pertaining to the PMTA application raised in submitted MRTA comments were not discussed in the Decision Summary. See, e.g., Comment from O’Neill Institute for Nat’l & Global Health Law, Georgetown University Law Center, Docket No. FDA-2017-D-3001-0202 (posted May 30, 2018) (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).
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, FDA seems to look only at the application’s information, assertions, and analysis to see if it reveals any clear reason to deny the application.\footnote{166}

FDA’s errors and omissions in its PMTA orders for the Swedish Match snus and Philip Morris IQOS, and its parallel failures to clarify what manufacturers must establish in their future PMTA applications, is enormously troubling given the large number of of applications from e-cigarette manufacturers that will likely be submitted to meet the court-established May 12, 2020 deadline for PMTA applications. In addition, FDA already has several pending MRTP applications that present the exact same kinds of challenges for FDA but can present even higher risks of increasing harm-increasing use.\footnote{167} If FDA handles those PMTA and MRTP applications similarly to how it handled the Swedish Match and Philip Morris PMTAs, 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 (including the FDA staff who evaluate the applications) that 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 its 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.\footnote{168}

2. Propose any restrictions or requirements on the product or its labeling, 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.

\footnote{166 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.” § 911(c)(2) [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.}

\footnote{167 As noted above, however, FDA might face more strict constraints against issuing permissive MRTP orders compared to issuing permissive PMTA orders. See supra note 16.}

\footnote{168 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.
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 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.\(^{169}\)

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.

Applying these criteria, FDA should also recall and reevaluate the unsupported and inadequate PMTA orders it has already issued for the Swedish Match snus and Philip Morris IQOS products, providing the manufacturers with a reasonable opportunity to amend or supplement their applications, accordingly.

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 by FDA. The absence of legal challenges to date might be due to competitors not wanting to bring lawsuits that could make it more difficult for them to obtain PMTA orders for their own products in the future.

\(^{169}\) 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.
or increase the likelihood that FDA would include more restrictions and requirements in any future permissive PMTA orders they were able to secure.

Why no public health organizations have brought legal challenges yet is less clear. Perhaps, like FDA, they see the Swedish Match snus PMTA order as simply not raising big enough individual or public health risks to worry about or spend much time on. But IQOS is a much more risky and potentially transformative product, and future MRTP orders or PMTA orders allowing e-cigarettes legally on the market would also present much larger health threats that are more likely to be realized. 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 evaluations and orders to date. But now they do.

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