December 12, 2017

VIA ELECTRONIC FILING

Scott Gottlieb, M.D.
Commissioner
Division of Dockets Management (HFA-305)
Food and Drug Administration (FDA)
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket No. FDA-2017-D-3001; 82 Fed. Reg. 27487

Modified Risk Tobacco Product Applications: Applications for IQOS system with Marlboro Heatsticks, IQOS system with Marlboro Smooth Menthol Heatsticks, and IQOS system with Marlboro Fresh Menthol Heatsticks Submitted by Philip Morris Products S.A.

Dear Dr. Gottlieb,

I am grateful for the opportunity to submit this comment regarding the modified risk tobacco product (MRTP) application by Philip Morris Products S.A. cited above under Section 911(g) of the Federal Food, Drug and Cosmetic Act[1] on behalf of TechFreedom. TechFreedom is a post-partisan think tank dedicated to promoting the progress of technology that improves the human condition. To this end, we seek to advance public policy that makes experimentation, entrepreneurship, and investment possible, and thus unleashes the ultimate resource: human ingenuity.

Congress established the Modified Risk Tobacco Products (MRTP) process specifically to incentivize and encourage manufacturers to develop innovative products that truly reduce the harm caused by cigarette smoking. TechFreedom wholly supports the MRTP process and applauds the agency's innovation-first approach. The U.S. Food and Drug Administration (FDA) and the Center for Tobacco Products (CTP) have set a new course for addressing tobacco harms — as you and CTP Director Mitch Zeller have noted in public

[1] 21 U.S.C. § 387k (2012).

comments, public documents, as well as your recent paper in the New England Journal of Medicine.[2] We welcome this change: the approach of the last fifty years would, according to the U.S. Centers for Disease Control (CDC), mean more than 480,000 Americans continuing to die every year from smoking. This is no longer acceptable: we now have the technology to do better. We also have the data on why people smoke necessary to understand the tradeoffs involved and to predict, with reasonable confidence, that approving technologies like the IQOS system will save lives.

I. Introduction to Modified Risk Tobacco Products (MRTP)

Since the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) was signed into law in 2009,[3] there have been three pathways by which new tobacco-related products (or product claims) can make it to market: (1) Pre-Market Tobacco Authorization (PMTA) for "new" products; (2) Substantial Equivalence (SE) to existing predicate products, and; (3) the Modified Risk Tobacco Products (MRTP) approval process for specific claims about specific products. The application at issue here was submitted by Philip Morris Products S.A. under the MRTP process.

MRTPs are governed by Section 911 of the Federal Food, Drug, and Cosmetic Act (FD&C Act),[4] as amended by the Tobacco Control Act, which defines MRTPs as "tobacco products that are sold or distributed for use to reduce harm or the risk of tobacco-related disease associated with commercially marketed tobacco products."[5] Under Section 911, the FDA may issue an order authorizing the marketing of a product as a MRTP only if the evidence submitted in the application meets the section's requirements, including, among other things, that "the product will or is expected to benefit the health of the population as a whole."[6]

Two statutory findings are key in understanding how Congress intended the MRTP process to be applied. First, Congress found that "[u]nless tobacco products that purport to reduce the risks to the public of tobacco use actually reduce such risks, those products can cause

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[2] *See* Scott Gottlieb, M.D. & Mitchell Zeller, J.D., *A Nicotine-Focused Framework for Public Health*, N. Engl. J. Med. (Sept. 21, 2017), http://www.nejm.org/doi/pdf/10.1056/NEJMp1707409.

[3] Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111-31 (2009) (codified as amended at 21 U.S.C. § 387 (2012)).

[4] *See* 21 U.S.C. § 387k (2012).

[5] *Id.* § 387k(b)(1).

[6] U.S. Food & Drug Admin., Modified Risk Tobacco Products Applications: Draft Guidance for Industry 30 (2012), https://www.fda.gov/downloads/TobaccoProducts/Labeling/RulesRegulationsGuidance/UCM297751.pdf (citing 21 U.S.C. §§ 911(g)(1)(B), (g)(2)(B)(iv)) [hereinafter Draft Guidance].

substantial harm to the public health.…"[7] Second, Congress noted that "[t]he dangers of products sold or distributed as modified risk tobacco products that do not in fact reduce risk are so high that [FDA must] ensur[e] that statements about modified risk tobacco products are complete, accurate, and relate to the overall disease risk of the product."[8]

Given these findings, Congress created the MRTP process so that, as the FDA noted in its 2012 Draft Guidance, "companies [could] take advantage of these provisions by making bold, innovative product changes that substantially reduce, or even eliminate altogether, either the toxicity or addictiveness of tobacco products, or both."[9] The MRTP allows tobacco companies that embrace technological advancement and innovation in order to better the human condition to market tobacco products with claims of either reduced risk or reduced exposure. In doing so, such companies can help guide consumers towards safer tobacco consumption options.

Tobacco companies offering such innovative products can receive an order authorizing the marketing of a product by the FDA only if the evidence submitted in the application meets the requirements of Section 911. That includes, among other things, showing that the product will, or is expected to, improve the health of the population as a whole. Section 911(g) of the FD&C Act describes what applicants must demonstrate to obtain an order from the FDA.[10] In general, FDA shall issue an order under section 911(g)(1) of the FD&C Act (risk modification order) only if it determines the applicant has demonstrated that the product, as it is actually used by consumers, will: (1) significantly reduce harm and the risk of tobacco-related disease to individual tobacco users; *and* (2) benefit the health of the population as a whole, *i.e.*, both users of tobacco products and persons who do not currently use tobacco products.

Critically, under the FDA's current guidance, an order permitting the sale of an MRTP refers to a single, specific product, not an entire class of tobacco products (*e.g.*, all smokeless products).[11] Further, such an order permitting the marketing of an MRTP is not permanent and only set for a fixed period.[12] Should a company marketing an MRTP wish to continue

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[7] Tobacco Control Act, Pub. L. No. 111-31, § 2(37), 123 Stat 1776, 1780 (2009).

[8] *Id.* § 2(40), 123 Stat 1776, 1780.

[9] Draft Guidance at 1-2.

[10] 21 U.S.C. § 387k(g).

[11] U.S. Food & Drug Admin., Modified Risk Tobacco Products (last updated Dec. 8, 2017), https://www.fda.gov/TobaccoProducts/Labeling/TobaccoProductReviewEvaluation/ucm304465.htm.

[12] *Id.*

doing so at the end of the fixed term, a company would have to seek renewal of the order and the FDA would have to determine that the findings continue to be satisfied.[13]

II. IQOS System: Innovation with Public Health Benefits

In his seminal 1976 British Medical Journal article, the late Professor Michael Russell noted that, "people smoke for nicotine, but they die from the tar."[14] Indeed, you echoed this sentiment just this summer: "[n]icotine itself is not responsible for the cancer, the lung disease and heart disease that kill hundreds of thousands of Americans each year."[15] Instead, "[i]t's the other chemical compounds in tobacco and in the smoke created by setting tobacco *on fire* that directly cause illness and death."[16]

Yet, over 35 years later, smoked tobacco is still the primary source of nicotine and by far the largest cause of preventable death and disease.[17] In an effort to stem such preventable deaths and to create a "smoke-free future," Philip Morris International (PMI) has a host of new devices utilizing a "heat-not-burn" (HNB) technology, which will significantly reduce the release of the chemical compounds in the smoke created by the fire by utilizing heating technology. PMI declares that such a "smoke-free future is one where we think we are able as the industry to play our role and offer products that are a better choice for smokers."[18]

In furtherance of its mission to develop such a smoke-free future, PMI has marketed and sold its "heat-not-burn" products abroad for over a year in several countries, including Japan, Switzerland, and the United Kingdom. Yet, despite the health benefits, these potentially life-saving products are currently unavailable to U.S. consumers. To remedy this, PMI submitted a Modified Risk Tobacco Product (MRTP) application to the FDA for its Tobacco Heating System (THS), which is commercially marketed outside of the United States as the IQOS system. IQOS is a tobacco heating system with three main components: a

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[13] *Id.*

[14] M.A.H. Russell, *Low-tar Medium Nicotine Cigarettes: A New Approach To Safer Smoking*, 1430 British Medical Journal 1976; 1431 (1976), http://www.bmj.com/content/bmj/1/6023/1430.full.pdf.

[15] Toni Clarke, *U.S. proposes cigarette nicotine cut, shirt toward e-cigarettes*, REUTERS (July 28, 2017), https://www.reuters.com/article/us-fda-tobacco-regulation/u-s-proposes-cigarette-nicotine-cut-shift-toward-e-cigarettes-idUSKBN1AD1VW.

[16] *Id.* (emphasis added).

[17] Centers for Disease Control, Smoking & Tobacco Use, *Fast Facts, Diseases and Death* (Nov. 16, 2017), https://www.cdc.gov/tobacco/data_statistics/fact_sheets/fast_facts/index.htm.

[18] Lindsey Rupp & Jennifer Kaplan, *Material World: Yes, Big Tobacco Says It's Racing to Create a Smoke-Free Future* BLOOMBERG (June 13, 2017), https://www.bloomberg.com/news/articles/2017-06-13/material-world-yes-big-tobacco-says-it-s-racing-to-create-a-smoke-free-future.

heated tobacco unit, an IQOS holder, and a charger.[19] To use IQOS, a consumer inserts the heated tobacco unit into the IQOS holder, which contains an electronically controlled heater. The IQOS system currently has three different tobacco consumables: Marlboro HeatSticks, Marlboro Smooth Menthol HeatSticks, and Marlboro Fresh Menthol HeatSticks. Like the more familiar e-cigarettes and smokeless tobacco, the IQOS system allows smokers to continue using nicotine but without the smoke responsible for the deaths of half of all lifelong smokers.[20] Unlike traditional e-cigarettes, these new HNB products use traditional leaf tobacco, but instead of burning it, they heat it to produce an inhalable tobacco flavored vapor. This unique aspect of the IQOS system has two main advantages over traditional e-cigarettes.

First, this gives the user a taste and experience closer to smoking than other products currently on the market. That, in turn, makes it more likely that traditional smokers will make the switch to the less harmful alternative and, ultimately, quit smoking altogether. According to one independent study, fully 70% of U.S. users of e-cigarettes who had been smoking prior to switching from traditional cigarettes reported having stopped smoking following their e-cigarette use.[21] Similarly, 96% of the former smoking e-cigarette users reported being less interested in smoking following their use of e-cigarettes.[22] These studies are in line with PMI's own study, which found that since IQOS was launched in the UK last December, about 70% of people that use it are able to give up conventional cigarettes.[23]

However, despite these reported benefits, only about 22% of all U.S. smokers have made the switch to healthier alternatives, suggesting that a large majority of the estimated 36.5 million current smokers in the U.S. do not view e-cigarettes as an attractive alternative. According to one study, the principle reason for smokers not wanting to switch was

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[19] Product Review, Philip Morris Int'l, IQOS: Our Tobacco Heating System (Dec. 12, 2017, 3:03pm), https://www.pmi.com/smoke-free-products/iqos-our-tobacco-heating-system.

[20] World Health Organization, Tobacco Fact Sheet, (May 2017), http://www.who.int/mediacentre/factsheets/fs339/en/.

[21] Russell, C., Nides M. & McKeganey, N., *Patterns of cigarette smoking and e-cigarette use among 20,676 adult frequent e-cigarette users in the United States*, Centre for Substance Use Research Report (2017), https://www.coresta.org/abstracts/patterns-and-perceptions-e-cigarette-use-and-cigarette-smoking-among-20972-adults-united.

[22] *Id.*

[23] Reuters Staff, *Tobacco group Philip Morris sees iQOS as key to smokeless future in UK* REUTERS(June 30, 2017), https://www.reuters.com/article/us-philipmorris-britain/tobacco-group-philip-morris-sees-iqos-as-key-to-smokeless-future-in-uk-idUSKBN19L1DU.

because, in their view, e-cigarettes were less pleasurable than traditional cigarettes.[24] This is the appeal of PMI's IQOS system: giving the user a taste and experience closer to smoking than other products could entice those stubborn smokers to switch to healthier alternatives. Also appealing to current smokers is the fact that the IQOS system delivers nicotine levels comparable to traditional cigarettes.[25] Evidence shows that this is true, as Indeed, PMI reports that over 2 million adult smokers have switched fully from cigarettes to the IQOS system.[26]

Second, and most critically, by heating rather than burning the tobacco the IQOS system dramatically reduces the harmful chemicals ingested. In traditional cigarettes, the lit end can reach 1600˚ Fahrenheit; at such extreme temperatures, the breakdown of tobacco leaf also causes the release of what the FDA calls "harmful or potentially harmful constituents" (HPHCs) — the likely causes of smoking-related diseases.[27] The IQOS system avoids the combustion altogether by heating the tobacco at a much lower temperature, which keeps many of the chemical reactions that release the HPHCs from occurring.[28] This reduces the release of HPHCs and thus reduces the incidence of smoking-related diseases.[29]

If the purpose of the MRTP process is, as the FDA itself states, to urge companies to "make[] bold, innovative product changes that substantially reduce, or even eliminate altogether, either the toxicity or addictiveness of tobacco products, or both"[30] it seems clear that PMI's IQOS system should receive such a designation. The IQOS system not only "significantly reduces exposure to 15 harmful toxicants in adult smokers who switched to THS to a degree approaching that of cessation over the study period," but, due its delivery of nicotine levels comparable to cigarettes and use of real tobacco, is more likely to induce conventional smokers to make the potentially lifesaving switch to the non-burning IQOS system.[31] These dual benefits make IQOS the ideal candidate to receive MRTP designation, particularly given the FDA's own recognition that "the inhalation of nicotine (i.e. nicotine

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[24] McKeganey N. & Dickson T., *Why Don't More Smokers Switch to Using E-Cigarettes: The Views of Confirmed Smokers*, International Journal of Environmental Research and Public Health, 2-12 (2017), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5486333/pdf/ijerph-14-00647.pdf.

[25] Philip Morris Int'l, Summary of Modified Risk Tobacco Product Application 5 (May, 2017), http://pmiscienceusa.com/wp-content/uploads/Brief-Summary-of-PMIs-MRTP-Application-May-2017.pdf [hereinafter MRTP Summary].

[26] MRTP Summary at 1.

[27] *Id.* at 2 (citing Department of Health and Human Services, Surgeon General's Report: How Tobacco Smoke Causes Disease: The Biology and Behavioral Basis for Smoking-Attributable Disease (2010)).

[28] *Id.*

[29] *Id*.

[30] Draft Guidance at 1-2.

[31] MRTP Summary at 5.

without the products of combustion) is of less risk to the user than the inhalation of nicotine delivered by smoke from combusted tobacco products."[32]

III. The FDA Should Partner with the FTC to Regulate Tobacco-Related Technology & Marketing

While the FDA should certainly approve PMI's MRTP application, it should—as required by the Tobacco Control Act—also partner with the Federal Trade Commission (FTC) to police consumer protection concerns that may arise regarding the IQOS system, and especially marketing claims made about it, should the FDA grant MRTP approval.[33] As Congress intended under the 2009 Tobacco Control Act, the FDA should retain regulatory control over the tobacco and tobacco-related aspects of such devices, while being sure to not diminish the FTC's "authority … to enforce the laws under its jurisdiction with respect to the advertising, sale, or distribution of tobacco products."[34] For example, products such as the IQOS system utilize both traditional tobacco leaf and innovative technologies. The FDA might regulate the chemical components (*e.g.*, additives) and wholly new technologies, while the FTC could regulate mere updates to that already-approved technology (*e.g.*, software updates and minor modifications regarding, say, aesthetics or ergonomics) and marketing claims regarding its benefits. In doing so, the FDA must be careful *not* to interpret the Tobacco Control Act to completely preempt the FTC's policing of marketing claims about MRTP products.[35]

This dual-enforcement system would combine the FDA's expertise in health products with the FTC's expertise in preventing deceptive marketing practices and overseeing technological advancements. The FTC is perfectly capable of policing marketing claims about updates in the technological aspects of MRTP products. The agency, as we have said, is the *de facto* Federal *Technology* Commission, the primary agency responsible for grappling with technological change.[36] And the Commission has decades of experience policing marketing claims about tobacco, dating back to the 1960s,[37] and continuing with

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[32] Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act, 81 Fed. Reg. 28974, 29033 (May 10, 2016), https://www.gpo.gov/fdsys/pkg/FR-2016-05-10/pdf/2016-10685.pdf.

[33] 21 U.S.C. § 387n.

[34] 21 U.S.C. § 387n(a)(1); *see also* 21 U.S.C. § 387a (discussing FDA's authority generally).

[35] 21 U.S.C. § 387a ("Tobacco products, including modified risk tobacco products … shall be regulated by the Secretary under this subchapter.").

[36] Press Release, TechFreedom, Now in its 100th Year, the FTC has become the Federal Technology Commission (Sept. 26, 2013), *available at* http://techfreedom.org/now-in-its-100th-year-the-ftc-has-become-the/.

[37] *See, e.g.*, JOHN. E. CALFEE, FED. TRADE COMM'N, CIGARETTE ADVERTISING, HEALTH INFORMATION AND REGULATION BEFORE 1970 (1985),

settlements currently in effect, as discussed below. Further, this system would preserve valuable resources at the FDA, better allowing it to focus on its primary mission of "protecting the public health by ensuring the safety, efficacy, and security of human and veterinary drugs, biological products, medical devices."[38]

A. Partnering with the FTC Will Advance the FDA's Own Mission

For the same reasons that the FDA should approve PMI's MRTP application, the FDA should work closely with the FTC to police the development and advertising of such technologically innovative products: the IQOS system will undoubtedly provide significant health benefits to smoking Americans who make the switch. Yet the delays and costs associated with companies having to once again navigate the FDA's lengthy approval process for minor modifications or simply due to passage of an arbitrary period of time will continue to deprive Americans of such benefits. Consumers suffer both if they must wait for a product to be approved that can reduce the harm of an activity (like tobacco consumption) that they would continue to engage in anyway, and especially if the increased costs resulting from the expensive approval process makes the products altogether unaffordable.[39] The latter is particularly important because of the socio-economic divide between smokers and non-smokers. According to the CDC, among the nation's less educated population—those with a high-school-equivalency diploma—the smoking rates remain over 40%, while just 15% of adults overall still smoke.[40]

Indeed, streamlining the approval process for these devices by allowing the FTC to assist in their regulation would better enable the FDA to advance its own mission:

> [FDA] is responsible for protecting the public health by ensuring the safety, efficacy, and security of human and veterinary drugs, biological products, medical devices; and by ensuring the safety of our nation's food supply, cosmetics, and products that emit radiation.

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https://www.ftc.gov/sites/default/files/documents/reports/cigarette-advertising-health-information-and-regulation-1970/wp134.pdf.

[38] FED. DRUG ADMIN., Statement of FDA Mission (April 4, 2017), https://www.fda.gov/AboutFDA/WhatWeDo/.

[39] R. Gupta et al, *The FDA Unapproved Drugs Initiative: an observational study of the consequences for drug prices and shortages in the United States*, J Manag. Care Spec Pharm. 2017; 23(10):1066-1076 (2017), https://www.ncbi.nlm.nih.gov/pubmed/28944731 (noting that a recent examination of all prescription drugs targeted by the FDA's 2006 Unapproved Drug Initiative between 2006 and 2015 demonstrated that the price of these drugs increased by a median of 37% after FDA UDI regulatory action or approval).

[40] Fast Facts & Fact Sheets, Centers for Disease Control & Prevention, *Current Cigarette Smoking Among Adults in the United States* (last updated Dec. 1, 2016), https://www.cdc.gov/tobacco/data_statistics/fact_sheets/adult_data/cig_smoking/index.htm.

> FDA also has responsibility for regulating the manufacturing, marketing and distribution of tobacco products to **protect the public health** and to **reduce tobacco use by minors.**
>
> FDA is responsible for advancing the public health by **helping to speed innovations**….[41]

Partnering with the FTC would further the FDA's mission of better protecting public health and helping to speed development of, and access to, innovation in several key ways.

1. The Public's Health Would Be Better Protected by Leveraging the FTC's Expertise

First, the FDA's mission of "protecting public health" would be best served by partnering with the FTC and leveraging its expertise in providing the public and lawmakers with informative resources. The FDA's MRTP review process requires tobacco companies such as PMI to provide immense amounts of data to "demonstrate that such products . . . meet a series of rigorous criteria, and will benefit the health of the population as a whole."[42] Yet the average consumer will likely either be unaware that such information exists, or lack the time or knowledge to properly review this data. The FTC has a long and proud history of developing consumer information publications—on everything from buying a used car to avoiding scams—that are simultaneously detailed and digestible by the average consumer.[43] Smokers who have switched, or are considering switching, to new technologies such as the IQOS system would certainly benefit from a report that provides more information than simply that the product is "modified risk" (essentially the current outcome of the MRTP process). Such a report could go further, and provide detailed, yet digestible, information explaining exactly how the IQOS system reduces the formation of HPHCs that are associated with traditional combustible cigarettes, thus reducing the toxicity that leads to smoking related disease. And such a report could provide consumers a comparative analysis of MRTP products currently available to them, outlining their costs, known benefits, and drawbacks.

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[41] FED. DRUG ADMIN., Statement of FDA Mission (April 4, 2017), https://www.fda.gov/AboutFDA/WhatWeDo/ (emphasis added).

[42] Tobacco Control Act, Pub. L. No. 111-31, § 2(36), 123 Stat 1776, 1779 (2009).

[43] *See, e.g.,* FED. TRADE COMM'N, *Start with Security: A Guide for Businesses, Lessons Learned From FTC Cases* (June 2015), https://www.bulkorder.ftc.gov/system/files/publications/pdf0205-startwithsecurity.pdf; FED. TRADE COMM'N, *Buying a Used Car* (Aug. 2016), https://www.bulkorder.ftc.gov/system/files/publications/pdf-1026_buying-a-used-car.pdf; Bridget Small, *Consumer Information: FTC publications: free and at your fingertips*, FED. TRADE COMM'N BLOG (Oct. 27, 2014), https://www.consumer.ftc.gov/blog/2014/10/ftc-publications-free-and-your-fingertips (noting that the FTC offers almost "200 free publications for consumers and businesses").

Additionally, the FDA's mission of "protecting public health" would be better served by partnering with the FTC and leveraging its unique competition advocacy expertise to ensure governmental actors are truly acting in consumers' best interests. Since 1974, the FTC has aggressively used its competition advocacy program as a means of leveraging the Commission's "expertise in competition, economics, and consumer protection to persuade governmental actors at all levels of the political system and in all branches of government to design policies that further competition and consumer choice."[44]

Through letters from the FTC staff or the full Commission to interested regulators, formal comments, and amicus curiae briefs, among other communications, the this program "helps solve consumers' collective action problem by acting within the political system to advocate for regulations that do not restrict competition unless there is a compelling consumer protection rationale for imposing such costs on citizens."[45] Because consumers will be generally disadvantaged relative to businesses in securing favorable regulations due to relatively high organizational and transaction costs, leveraging this unique FTC expertise would help ensure the FDA continues to strike the right balance in protecting public health — including, but not limited to, deciding between delay and decision, between approval and denial of MRTP applications, deciding when a new MRTP determination is required for similar products, or how long the MRTP term should be.

2. Innovation Would Be Expedited Through FTC Partnership by Reducing Approval Time and Costs

Partnering with the FTC would help to further the FDA's mission of "helping to speed innovations" by ensuring genuine harm reducing technologies are approved and offered to consumers as quickly and inexpensively as possible. The FTC's case-by-case approach is far better suited to fast-changing industries—from broadband to Uber to tobacco companies that utilize innovative technologies to reduce the health risks associated with smoking—than a system based on licensing, such as the MRTP process. This is true for two reasons: (1) blanket regulations fail to predict technological innovations and tend to favor big business, and (2) requiring companies to reapply for MRTP designation for mere updates or simply because an arbitrary period of time has lapsed deprives consumers of the benefits of these products and raises costs that are ultimately born by consumers.

As history has shown, the FDA, like other traditional regulatory agencies, will try to write rules based on what they imagine innovative technologies will, or should, look like. Per

[44] James C. Cooper, Paul A. Pautler & Todd J. Zywicki, *Theory and Practice of Competition Advocacy at the FTC*, 72 ANTITRUST L.J. 1091, 1091 (2005).

[45] *Id*. at 1092.

Moore's Law, digital technology evolves exponentially, with computer processing power doubling approximately every 18 months.[46] Even the most astute agency cannot be expected to predict what the next generation of technology will look like. The FTC by contrast recognizes that technology evolves exponentially, and that new technologies such as the IQOS system can "disrupt markets and create a boon for consumers."[47] As such, the FTC has long looked to "public choice and regulatory economics," which leverages economic tools rather than heavy-handed, one-size-fits-all regulations, as a means of protecting consumers.[48] In doing so, the FTC is able to use its full panoply of tools—including Section 5 enforcement and competition advocacy—to promote innovation through competition rather than regulations. This enables innovative technologies to flourish, while also protecting consumers from deceptive or unfair practices.

Blanket regulations also generally have the effect of favoring incumbent industry participants who have the resources to hire lawyers and lobbyists to continuously navigate the regulatory process. Economist and author Timothy P. Carney succinctly explained this dynamic:

> If regulation is costly, why would big business favor it? Precisely ***because*** it is costly.
>
> Regulation adds to the basic cost of doing business, thus heightening barriers to entry and reducing the number of competitors. Thinning out the competition allows surviving firms to charge higher prices to customers and demand lower prices from suppliers. Overall regulation adds to overhead and is a net boon to those who can afford it — big business.
>
> Put another way, regulation can stultify the market. If you're already at the top, stultification is better than the robust dynamism of the free market.[49]

Thus, in the context of potentially disruptive forms of competition through new technologies, regulatory efforts that create blanket rules should be viewed with skepticism,

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[46] *See* MIT Technology Review, Moore's Law and the Origin of Life (April 15, 2013), https://www.technologyreview.com/s/513781/moores-law-and-the-origin-of-life/.

[47] Joshua Wright, Commissioner, Fed. Trade Comm'n, Keynote Address at the Big Ideas About Information Lecture at Clemson University: Regulation in High-Tech Markets: Public Choice, Regulatory Capture, and the FTC 1, 15 (April 2, 2015), https://www.ftc.gov/system/files/documents/public_statements/634631/150402clemson.pdf.

[48] *Id*. at 13-15 ("For many years, the FTC has used its mantle to comment on legislation and regulation that may restrain competition in a way that harms consumers. This advocacy program has been a priority at the Commission since the early 1980s with broad support among commissioners of all political stripes."); *see also* James C. Cooper et al., *Competition Advocacy at the FTC*, 72 ANTITRUST L.J. 1091 (2005).

[49] TIMOTHY P. CARNEY, THE BIG RIPOFF: HOW BIG BUSINESS AND BIG GOVERNMENT STEAL YOUR MONEY p.III (2006).

even when created "in the public interest."[50] It is precisely for these reasons why the FTC's flexible, case-by-case approach, should be leveraged as a tool to assist the FDA in regulating innovative smoking technologies, particularly where companies are merely updating or improving technologies that have already been granted MRTP status.

Once again using the IQOS system as an example, one can imagine that updates and technological advancements will continue to be developed over the life of the product, allowing the system to remove even more toxins, thus providing greater health benefits. According to PMI's CEO André Calantzopoulos, the company has already spent more than $3 billion in developing new and healthier nicotine-delivering devices and plans to spend even more.[51] Indeed, PMI's investment in innovative technologies is not limited to merely reducing the toxins produced by tobacco products, but also in reducing the environmental impact of producing such devices. This commitment to health and environmental innovation is particularly demonstrated by the development of a $111 million, environmentally progressive research center called "the Cube."[52] Given PMI's immense investment in research and development, such updates and technological advancements are inevitable. Understanding this in conjunction with the costs and time associated with gaining FDA approval, how quickly, and how cheaply, consumers' can access these beneficial products will greatly depend on whether and to what extent the FDA will, on top of FTC policing, require tobacco companies to go through the MRTP process all over again for relatively minor changes to their products.

Thus, if tobacco companies must reapply for MRTP designation due to an arbitrary time limit such as is currently required, or simply because it slightly modifies the product, the costs and time delays inherent in the FDA's lengthy approval process will continue to deprive Americans of such benefits. For example, should the FDA approve the system as an MRTP in the first instance, allowing the FTC to police updates to the system would ensure that consumers do not have to wait another year or more simply to enjoy these added health benefits. This is particularly important given that at least 3.7 million adult consumers have already stopped smoking and switched to the IQOS system in the 32

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[50] *Id*. at 7-8.

[51] Lindsey Rupp & Jennifer Kaplan, *Material World: Yes, Big Tobacco Says It's Racing to Create a Smoke-Free Future* BLOOMBERG (June 13, 2017), https://www.bloomberg.com/news/articles/2017-06-13/material-world-yes-big-tobacco-says-it-s-racing-to-create-a-smoke-free-future.

[52] *Id.*

countries in which it is available today.[53] Such a delay is particularly unnecessary given the existing literature and studies supporting the benefits of the IQOS system, and e-cigarettes generally, and companies' incentives to continuously maintain such research.[54] As other FDA approval processes show, approval requirements rarely result in additional clinical research or motivates companies to undergo new studies of old products. Using the FDA's 2006 Unapproved Drugs Initiative (UDI) as an example, one study showed that nearly 90% of those drug products that received FDA approval between 2006 and 2015 "were supported by literature reviews or bioequivalence studies, not new clinical trial evidence."[55]

Further, consumers suffer doubly if the increased costs resulting from the expensive approval process make the products altogether unaffordable. Again, using UDI to illustrate, another study showed that FDA approval resulted in significant increases in the wholesale costs of drugs to consumers. For example, following FDA approval, the average wholesale price of intravenous vasopressin increased from $4.27 to $138.40 per vial in November 2016, a 3141% increase.[56] Understanding, that the vast majority of American smokers are less-educated and less able to afford expensive technology (as noted above), requiring companies to reapply for MRTP status either due to an arbitrary time limit or for minor updates will ultimately raise the costs and likely make these products unavailable to those who need them most.

If the FDA's mission is truly to help speed innovations and protect the public's health, preventing or delaying potentially millions of consumers' access to such beneficial

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[53] Nick Rolli, V.P. Investor Relations & Financial Communications, Altria Group, *Philip Morris International, Inc., 2017 Third-Quarter Results Conference Call,* 8 PMI (Oct. 19, 2017) (script), https://www.pmi.com/investor-relations/overview/event-details/?eventId=5246145.

[54] *See, e.g.,* Institute of Medicine of the National Academies, Clearing the Smoke: Assessing the Science Base for Tobacco Harm Reduction (2001), https://www.nap.edu/catalog/10029/clearing-the-smoke-assessing-the-science-base-for-tobacco-harm (noting, as Dr. Ernst Wynder, a leading epidemiologist and pioneer in smoking and health research, stated in 1979 "…it is important to appreciate that a virtually harmless [tobacco product used] by only 1% of May 2017 3 the population will have a lesser impact on the reduction of tobacco-related diseases than a somewhat more harmful [product used] by 80% of the total smoking population."); Schaller J-P, Keller D, et al, Evaluation of the Tobacco Heating System 2.2. Part 2: Chemical composition, genotoxicity, cytotoxicity, and physical properties of the aerosol, 81 Suppl 2:S27-S47. (2016), https://www.ncbi.nlm.nih.gov/pubmed/27720919 (recognizing the levels of these HPHCs, excluding nicotine, were on average 90% lower than those measured in the smoke from the 3R4F reference cigarette).

[55] R. Gupta et al, *The FDA Unapproved Drugs Initiative: an observational study of the consequences for drug prices and shortages in the United States*, J Manag. Care Spec Pharm. 2017; 23(10):1066-1076 (2017), https://www.ncbi.nlm.nih.gov/pubmed/28944731.

[56] Aaron Hakin, MS, et al, *High Costs of FDA Approval for Formerly Unapproved Marketed Drugs*, JOURNAL OF THE AMERICAN MEDICAL ASSOCIATION (Dec. 12, 2017), https://jamanetwork.com/journals/jama/fullarticle/2663287.

technologies is surely intolerable. Partnering with the FTC could minimize this problem. Specifically, the FDA should remove the arbitrary timeframes, thereby allowing companies that receive MRTP designation to maintain such designation so long as the product is not substantially altered. Further, the FDA should allow the FTC to use its enforcement power under Section 5 of the FTC Act (discussed below) to enforce the propriety of marketing statements about such products and any non-substantial modifications made.

B. Partnering with the FTC Would Not Relieve Tobacco Companies of Federal Oversight

Relying on the FTC to police health claims by companies that sell devices such as the IQOS would not allow them to escape regulation. In fact, the FTC has a long history of insisting upon scientific evidence as the basis for marketing them. Section 5 of the FTC Act confers broad authority to investigate "unfair and deceptive acts and practices in or affecting commerce."[57] The FTC has increasingly used this broad authority aggressively in the context of false or misleading marketing claims, initiating investigations pertaining to a wide variety of "unfair" or "deceptive" practices.

Particularly illustrative of both the FTC's ability and willingness to bring enforcement actions against tobacco companies that make false and deceptive claims are the dual actions brought against Santa Fe Natural Tobacco Company, Inc. and Alternative Cigarettes, Inc. in 2000.[58] As the FTC summarized the settlements at the time:

> Santa Fe and Alternative Cigarettes represented that because their tobacco cigarettes contain no additives, they are less hazardous than otherwise comparable cigarettes that contain additives. They did this through a variety of statements, including Alternative Cigarettes' assertion that "Native Americans smoked all-natural tobacco without the ills that are associated with smoking today." The [FTC's] complaints allege that the two companies did not have a reasonable basis for the representations at the time they were made. Among other reasons, the FTC alleged, the smoke from the Pure, Gold and Natural American Spirit cigarettes, like the smoke from all cigarettes, contains numerous carcinogens and toxins, including tar and carbon monoxide.[59]

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[57] 15 U.S.C. § 45 (2012).

[58] *See* FED. TRADE COMM'N, *FTC Accepts Settlements of Charges that "Alternative" Cigarette Ads Are Deceptive* (April 27, 2000), https://www.ftc.gov/news-events/press-releases/2000/04/ftc-accepts-settlements-charges-alternative-cigarette-ads-are.

[59] Press Release, Federal Trade Commission, Settlements Require Companies to Disclose that Herbal Cigarettes Are Dangerous and that "No Additives" Does Not Mean a Safer Smoke (2000), https://www.ftc.gov/news-events/press-releases/2000/04/ftc-accepts-settlements-charges-alternative-cigarette-ads-are.

As in negligence actions, should the FTC believe such companies are making false or deceptive claims, both sides would bring in scientific experts to determine the validity of such claims based on evidence.

C. Partnering with the FTC is Consistent with Case Law and in the Best Interests of the Public

In upholding the FDA's MRTP requirement on First Amendment grounds, the Sixth Circuit, in *Discount Tobacco v. U.S.*, recognized that the "low tar" claims made by the tobacco industry were often misleading, and "[e]vidence in the congressional record demonstrating a pattern of [potentially deceptive] advertisements ... [may be] adequate to establish ... the likelihood of deception," which satisfied the government's declared interest in the regulation.[60] But this analysis — upholding the MRTP process against First Amendment challenges — does not control how FDA should apply the MRTP process, or what role it should leave to the FTC. Indeed, there are multiple reasons why relinquishing regulatory authority over such claims to the FTC is in the best interest of the public and the FDA's mission.

First, before enactment of the 2009 Tobacco Control Act, "the advertising and promotion of cigarettes was largely exempt from [FDA] regulation due to preemptive provisions of the Federal Cigarette Labeling and Advertising Act."[61] But the capacious language of the Tobacco Control Act, which grants the FDA and FTC dual enforcement authority over certain aspects of tobacco promotion, ensures that the FDA will not leave a vacuum in consumer protection by relying on the FTC to police certain aspects of MRTP technologies.

Second, the potential benefits of providing a healthier alternative to smoking far outweighs the risk of false or misleading advertising. As the Surgeon General correctly noted, the claims that low tar brands were less harmful than conventional cigarettes were false "and [and b]y making these false claims, [the major tobacco manufacturers] have given smokers an acceptable alternative to quitting smoking, as well as an excuse for not quitting."[62] However, unlike the substantiated claims that "low tar" cigarettes were safer, significant research shows that the IQOS system does in fact provide health benefits and does, in fact,

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[60] *Disc. Tobacco City & Lottery, Inc. v. United States*, 674 F.3d 509, 535 (6th Cir. 2012).

[61] Fact Sheet 5: Tobacco Control Legal Consortium, *Tobacco Product Marketing Restrictions,* Public Health Law Center (July 2009), http://www.publichealthlawcenter.org/sites/default/files/fda-5.pdf.

[62] *Disc. Tobacco City & Lottery, Inc. v. United States*, 674 F.3d 509, 535 (6th Cir. 2012) (quoting *United States Surgeon General Report, The Health Consequences of Smoking,* 25 (2004) (concluding that "[s]moking cigarettes with lower machine-measured yields of tar and nicotine provides no clear benefit to health")).

lead to less smokers inhaling toxins.[63] Thus, even if claims by companies that sell similar devices were overstated (they aren't), the use of these devices would still be far healthier than traditional cigarettes, leaving consumers better off (even if not *as much* better off as expected). In this way, the FDA's lengthy approval process is denying Americans these benefits, and allowing the FTC to police such claims would mean that Americans would receive these benefits *and* that the companies would be held liable for overstating the benefits. Win, win.

Third, while there is "ample caselaw … to support the conclusion that tobacco manufacturers have historically 'marketed and promoted their low tar brands to smokers … as less harmful than full flavor cigarettes despite either lacking evidence to substantiate their claims or knowing them to be false,"[64] there is no such evidence supporting the conclusion that similar companies have made such false claims about innovative electronic-based smoking devices. This is important, as the IQOS system—while using traditional tobacco and providing a user with a similar *experience*—is actually a vastly different product in the respect that matters for regulatory purposes: health effects. Saying a cigarette is healthier than another cigarette is in no way the same as claiming an entirely new and technologically dissimilar device is healthier. Thus, previous misleading claims regarding traditional cigarettes should in no way serve as evidence, or even an indicator, as to whether tobacco companies will do the same with entirely different devices such as the IQOS system.

IV. Conclusion

The FDA should grant PMI's MRTP application expeditiously, and formalize a partnership with the FTC, such as through a Memorandum of Understanding, by which the two agencies will coordinate on policing MRTP technologies. Doing so is not only required by the Tobacco Control Act, but would also further the FDA's mission of "protecting public health" and "helping speed innovation" by combining the FDA's expertise in health products with the FTC's expertise in preventing deceptive marketing practices and overseeing technological advancements. The FDA should focus its resources on processing MRTP applications, while relying on the FTC to police other consumer protection issues related to

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[63] *See, e.g.,* ROYAL COLLEGE OF PHYSICIANS, NICOTINE WITHOUT SMOKE: TOBACCO HARM REDUCTION (2016), https://www.rcplondon.ac.uk/projects/outputs/nicotine-without-smoke-tobacco-harm-reduction-0 (noting that it is widely recognized that "most of the harm caused by smoking arises not from nicotine but from other components of tobacco smoke"); DEP'T OF HEALTH AND HUMAN SERV'S, SURGEON GENERAL'S REPORT: HOW TOBACCO SMOKE CAUSES DISEASE: THE BIOLOGY AND BEHAVIORAL BASIS FOR SMOKING-ATTRIBUTABLE DISEASE (2010), https://www.ncbi.nlm.nih.gov/books/NBK53017/ (recognizing that smoking-related harm and disease are directly caused by the long-term exposure to the toxicants found in smoke from combusted tobacco).

[64] *Id.*

FDA-approved MRTP technologies, and to educate consumers about the relative risks and benefits of such technologies compared to other tobacco products.

Sincerely,

/s/

Graham Owens
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TechFreedom