UNITED STATES INTERNATIONAL TRADE COMMISSION
WASHINGTON, DC

In the Matter of **CERTAIN TOBACCO HEATING ARTICLES AND COMPONENTS THEREOF**	**Investigation No. 337-TA-3447**

PHILIP MORRIS PRODUCTS SA'S COMMENTS TO COMPLAINANTS' PUBLIC INTEREST STATEMENT

Philip Morris Products, S.A.
Exhibit 1040

Philip Morris Products SA ("PMP") respectfully submits that implementation of the remedy requested by Complainants would have impermissible, deleterious effects on the public interest. In a major health initiative, FDA introduced a Plan that includes as a key component the availability of a wide range of less harmful alternatives to cigarettes.[1] PMP asserts that one such alternative should be its IQOS heat not burn ("HNB") system, for which, after more than 2 years of rigorous science-based review, FDA cleared for domestic sale through the Premarket Tobacco Application ("PMTA") process. FDA has stated that a PMTA applicant "must demonstrate to the agency, among other things, that marketing of the new tobacco product would be appropriate for the protection of the public health. That standard requires the FDA to consider the risks and benefits to the population as a whole, including users and non-users of tobacco products."[2] ***Crucially, no other HNB or e-vapor device has been PMTA-authorized in more than 10 years since the controlling statute was enacted***.[3] Given the diverse number of devices needed to fulfill FDA's Plan, and the utter absence of effective, authorized substitutes within the category, denying 34.2 million American smokers access to IQOS would not serve the public interest.[4] Further, denying continued IQOS access to those who already have switched could send people back to combustible cigarettes (the most deadly form of tobacco use), which also would not serve the public interest. To avoid this entirely preventable public health injury, the ITC should decline institution (or delegate public interest to the ALJ).[5]

IQOS HELPS TO ACHIEVE FDA GOALS AND PROTECT THE PUBLIC INTEREST

FDA's Plan "is founded on the principle" that nicotine is not directly responsible for smoking-

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[1] *Strategic Policy Roadmap*, FDA (Jan. 2018), https://www.fda.gov/media/110587/download ("Plan").
[2] *FDA permits sale of IQOS Tobacco Heating System through premarket tobacco product application pathway*, FDA (Apr. 30, 2019), https://www.fda.gov/news-events/press-announcements/fda-permits-sale-iqos-tobacco-heating-system-through-premarket-tobacco-product-application-pathway ("FDA Apr. PA"); *see Why FDA authorized the marketing of the IQOS heated tobacco product as "appropriate for the protection of the public health,"* FDA (Oct. 10, 2019), https://www.fda.gov/science-research/fda-grand-rounds/why-fda-authorized-marketing-iqos-heated-tobacco-product-appropriate-protection-public-health.
[3] *FDA finalizes enforcement policy on unauthorized flavored cartridge-based e-cigarettes that appeal to children, including fruit and mint*, FDA (Jan. 2, 2020), https://www.fda.gov/news-events/press-announcements/fda-finalizes-enforcement-policy-unauthorized-flavored-cartridge-based-e-cigarettes-appeal-children ("FDA Jan. PA").
[4] *Cigarette Smoking Among U.S. Adults Hits All-Time Low*, CDC (Nov. 14, 2019), https://www/cdc.gov/media/releases/2019/p1114-smoking-low.html; *contra* Complainants' Pub. Interest Statement at 5.
[5] 19 C.F.R. § 210.50(b)(l).

related diseases.[6] "It is the other chemical compounds in tobacco, and in the smoke created by setting tobacco on fire, that directly and primarily cause" the negative effects of smoking.[7] The UK's Royal College of Physicians agrees that if nicotine could be delivered without smoke, "most if not all of the harm of smoking" could be avoided.[8] Accordingly, FDA began to "take a fresh look at products that can deliver satisfying levels of nicotine to adults who want access to it without burning tobacco."[9] As Professor David Abrams and others concluded, IQOS is among the types of products FDA's Plan needs to succeed.[10] While cigarettes burn above 600°C and produces smoke with harmful chemicals, IQOS heats tobacco to much lower temperatures with no combustion or smoke, reducing such chemical levels by up to 95%.[11]

"No new product of this kind, including any e-cigarette [aka e-vapor product], has gone through as much scientific analysis as IQOS."[12] PMP invested over $7.2 billion in R&D, conducted 8 IQOS clinical studies, and published over 340 peer-reviewed materials on smoke-free products.[13] IQOS is in 53 markets, with nearly 60 billion IQOS Heatsticks sold in 2019.[14] In granting the IQOS PMTA, FDA observed:

> [T]hrough the FDA's scientific evaluation of the company's applications, peer-reviewed published literature and other sources, the agency found that the aerosol produced by the IQOS Tobacco Heating System contains fewer toxic chemicals than cigarette smoke, and many of the toxins identified are present at lower levels than in cigarette smoke. For example, the carbon monoxide exposure from IQOS aerosol is comparable to environmental exposure, and levels of acrolein and formaldehyde are 89% to 95% and 66%

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[6] Scott Gottlieb, *Public Hr'g on Eliminating Youth Use of Elec. Cigarette & Other Tobacco Prod. Use*, FDA, at 11 (Jan. 18, 2019), https://www.fda.gov/media/120342/download.
[7] Plan at 3.
[8] *Ministry of Health v. Philip Morris*, CRI-2017-085-1107, Op. ¶ 33 (Dist. Ct. Wellington NZ Mar. 12, 2018), https://www.pmiscience.com/resources/docs/default-source/NCDC-vs-Morris/new-zealand_moh-_v-pm-new-zealand-limited_march-2018.pdf ("NZ Case").
[9] Plan at 3.
[10] *See, e.g.*, Med./Ed. Ltr., FDA, at 5 (Dec. 14, 2017), https://www.fda.gov/media/110535/download.
[11] NZ Case, Gilchrist Br. ¶ 40, https://www.pmiscience.com/resources/docs/default-source/NCDC-vs-Morris/nz_brief-of-evidence-of-moira-gilchrist_february-2018.pdf; *see* FDA Apr. PA.
[12] NZ Case, Gilchrist Br. ¶ 64.
[13] *Our Science*, PMI (last visited Apr. 14, 2020), https://www.pmi.com/our-science; *Designing a Smoke-Free Future*, PMI, at 42-43 (July 2019), https://www.pmiscience.com/resources/docs/default-source/default-document-library/pmi-science-booklet---2019.pdf?sfvrsn=cbacdd06_4; *PMTA Tech. Project Lead Review*, FDA, at 65, 93, (Apr. 29, 2019), https://www.fda.gov/media/124247/download ("PMTA Rep.").
[14] *2020 First Quarter Highlights*, PMI, at 18 (Apr. 21, 2020), https://philipmorrisinternational.gcs-web.com/static-files/aee8cf52-5beb-4c30-928a-949ce7631959 ("PMI PA"); *Consumer Analyst Group of New York Conference*, PMI, at 12, 45 (Feb. 19 2020), https://philipmorrisinternational.gcsweb.com/static-files/147f7fd1-3302-42dd-b305-8b786c1eeef5 ("PMI Rep.").

to 91% lower than from combustible cigarettes, respectively.[15]

FDA concluded that reduced exposure to such chemicals as compared to combustible cigarettes "will likely result in reduced health risks for CC smokers who switch completely to IQOS," and "is beneficial for those who would be secondarily exposed to the aerosol as compared to environmental tobacco smoke."[16]

In its review of IQOS, FDA also evaluated "the ability to migrate currently addicted adult smokers onto less harmful products, and the ability to prevent youth initiation."[17] FDA found that "IQOS delivers nicotine in levels close to combustible cigarettes, suggesting a likelihood that IQOS users may be able to completely transition away from combustible cigarettes and use IQOS exclusively."[18] It further found that available data "indicate that few non-tobacco users would be likely to choose to start using IQOS, including youth."[19] (Per the premarket order, FDA also will monitor IQOS marketing to prevent youth access.)

IQOS data from outside the United States support FDA's findings. As of Q1 2020, the company had over 14 million IQOS users worldwide, with conversion rates of approximately 73%.[20] In Japan, for example, a recent study by the American Cancer Society found that "[c]igarette sales beg[a]n to substantially decline at the time of the introduction of IQOS."[21] Youth uptake in non-U.S. markets also has proven to be low. One study cited by FDA reported that only 0.9% of youth had ever tried IQOS.[22]

THERE ARE NO ADEQUATE SUBSTITUTES FOR IQOS

There are no adequate replacements for the effective and popular IQOS. As for e-vapor products, ***none has received PMTA authorization***.[23] Controversies over such products also present real barriers to their receiving PMTA authorization and serving as viable IQOS alternatives. For example, there is ongoing

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[15] FDA Apr. PA.
[16] PMTA Rep. at 92.
[17] *FDA's Gottlieb Reaffirms Efforts to Stave Off New Youth Smokers*, BLOOMBERG (Nov. 26, 2018), https://www.bloomberg.com/news/articles/2018-11-26/fda-s-gottlieb-reaffirms-efforts-to-stave-off-new-youth-smokers; *see* FDA Apr. PA.
[18] FDA Apr. PA.
[19] *Id*; PMTA Rep. at 97.
[20] PMI PA at 1.
[21] Michal Stoklosa et. al, *Effect of IQOS introduction on cigarette sales*, BMJ, at 1 (Apr. 29, 2019), *available at* https://tobaccocontrol.bmj.com/content/early/2019/06/11/tobaccocontrol-2019-054998.
[22] PMTA Rep. at 97; *see id.* at 12, 83.
[23] FDA Jan. PA.

scrutiny of youth uptake of e-vaping. HHS Secretary Alex Azar declared that "[t]he United States has never seen an epidemic of substance use arise as quickly as our current epidemic of youth use of e-cigarettes."[24] Thus, HHS "is taking a comprehensive, aggressive approach" to the situation.[25] Even Reynolds American, Inc.'s CEO testified in a February House Committee hearing about the perils of youth vaping.[26] Further, there is a September 2020 deadline by which companies must submit PMTAs for any e-vapor devices they want to keep on the U.S. market. This deadline presents legal and logistical challenges, as it is uncertain whether it will stand and, if so, which companies will comply.[27] Further still, Complainants tout e-vapor products as substitutes, but FDA has warned that such products "are considered illegally marketed and are subject to enforcement."[28] Although Complainants submitted three PMTAs for certain Vuse e-vapor products (Solo, Vibe, and Ciro), these applications were filed recently (October 2019 and April 2020), and may take years to vet, with no guarantee of authorization.[29] Moreover, Solo is the oldest, most basic Vuse design that is in no way interchangeable with the more sophisticated IQOS.[30] In any event, ***all*** e-vapor products are inadequate IQOS replacements from a public health perspective; they have lower switch rates (≈25% v. 73%), and "many smokers do not appear to regard them as a satisfactory substitute for smoking."[31]

As for other HNBs, ***no other such device besides IQOS has been PMTA-authorized***.[32] Without successful completion of this lengthy process, a new HNB cannot be an IQOS alternative. Although Complainants' older Eclipse HNB can be sold domestically, that product was authorized for sale via a

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[24] *Id.*
[25] *Id.*
[26] *Vaping in America*, HOUSE COMMITTEE ON ENERGY AND COMMERCE, Hr'g Tr. (Feb. 5, 2020), https://docs.house.gov/meetings/IF/IF02/20200205/110462/HHRG-116-IF02-Transcript-20200205.pdf.
[27] Emily Field, *E-Cigarette Deadline Extended Amid COVID-19 Pandemic*, LAW360 Art. (Apr. 6, 2020) https://www.law360.com/articles/1260730/e-cigarette-deadline-extended-amid-covid-19-pandemic; Jim McDonald, *First Vape PMTA Has Been Submitted to the FDA*, VAPING 360, https://vaping360.com/vape-news/85364/the-first-vape-pmta-has-been-submitted-to-the-fda/ (Oct. 14, 2019) ("Vaping 360 Art.").
[28] FDA Jan. PA.
[29] *Id.*; *Reynolds Submits Second And Third Complete Premarket Tobacco Product Applications*, PR NEWSWIRE (Apr. 15, 2020), https://www.prnewswire.com/news-releases/reynolds-submits-second-and-third-complete-premarket-tobacco-product-applications-301041151.html; Vaping 360 Art.
[30] Vaping 360 Art.
[31] *See* PMI PA at 1; PMI Rep. at 11; NZ Case, Gilchrist Br. ¶¶ 26.
[32] *See* PMI Rep. at 46.

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