NEW YORK CITY DEPARTMENT OF
HEALTH AND MENTAL HYGIENE
Michelle Morse, MD
Acting Commissioner

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Via Electronic Submission

http://www.regulations.gov

Re: Modified Risk Tobacco Product Application: Renewal Application for IQOS 3.0 System Holder and Charger, Heated Tobacco Product, Submitted by Philip Morris Products S.A. [Docket No. FDA-2021-N-0408]

To Whom It May Concern:

The New York City Department of Health and Mental Hygiene (NYC Health Department) appreciates the opportunity to provide comments to the Food and Drug Administration regarding Renewal of the Modified Risk Granted Orders Issued to Philip Morris Products S.A. for IQOS System Holders and Chargers.

The NYC Health Department believes the statutory standards for granting the exposure Modification Order under section 911(g)(2) of the Federal Food, Drug, and Cosmetic Act were never met during their initial application, and the additional information and data now available, further weakens IQOS's ability to meet the required standard of protecting public health. Now that IQOS is being reintroduced into the United States (U.S.) market, the U.S. Food and Drug Administration (FDA) has an obligation to consider newer data from worldwide studies suggesting that this designation is inappropriate. Likewise, the FDA should take into account evidence demonstrating that Philip Morris International (PMI) used the order to make unauthorized reduced risk claims in multiple other countries.[1] For example, reporting in the *Manila Bulletin*, a widely circulated English language newspaper in the Philippines, said a PMI official "explained the U.S. FDA decision has effectively differentiated IQOS from combustible cigarettes when it comes to health risk"[2] - which is an overt claim of reduced health harm despite the FDA's clear rejection of a reduced risk claim for IQOS. While the exposure modification order did not result in significant adoption of IQOS in the U.S., this was likely due to limited availability, given that IQOS was taken off the market in 2020 due to a patent infringement claim and only recently reintroduced in specific cities in Texas and Florida. In fact, although IQOS was not readily available in New York City (NYC), a 2019 NYC Health Department poll found that 20% of New Yorkers ages 18-24 polled had already heard of the product at that time.[3]

Research from parts of the world where IQOS is more readily available continue to demonstrate that caution is warranted and is outlined in further detail below. This growing body of evidence indicates that Modified Risk Granted order should not be renewed.

The availability of IQOS Does Not Promote Public Health

As the NYC Health Department has noted in previous comments regarding these products, the FDA must take into account several additional factors when evaluating the benefit to health of individuals and of the population as a whole: (1) the likelihood that existing tobacco product users will stop using them completely and switch to using IQOS; (2) the likelihood that persons who do not use tobacco products will start using IQOS; and (3) the

risks and benefits to persons from the use of IQOS compared to the use of medications approved by the FDA to treat nicotine dependence.[4]

(1) Existing Tobacco Users May Not Fully Switch to IQOS, Undermining Potential Reduced Exposure

Evidence suggests that many existing tobacco users who try IQOS will not stop using combustible tobacco products completely and will become dual users. Supporting this concern, a cohort study in Japan found that among non-smokers and former smokers, using heated tobacco products predicted increased likelihood of relapse to or initiation of combustible cigarettes one year later.[5] Similarly, PMI data from Germany found that only half (53%) of IQOS users use IQOS exclusively, while the remainder also smoke cigarettes.[6] Other data from PMI, following people who used IQOS during 2022 in four countries, found that more than one third of people used cigarettes in addition to IQOS and that proportion did not decrease over time in any of the country panels studied.[7] Recent studies from the International Tobacco Control Project (ITC) at Canada's University of Waterloo found that even fewer people in Japan and Korea quit smoking when using IQOS than suggested in PMI data.[8]

Further, a 2019 NYC Health Department poll found that among New Yorkers who had heard of IQOS, 69% of those who smoke every day had tried IQOS, without giving up cigarettes.[9] If dual use of IQOS and traditional cigarettes becomes a norm, it would likely erode any anticipated harm reduction benefits and eliminate PMI's justification for IQOS's modified risk claim.

(2) Youth and Adults Who Have Never Smoked May Start with IQOS, Especially Given IQOS Marketing in the US to Date

Heated tobacco products (HTPs) like IQOS pose more risk for youth uptake than cigarettes or other combustible tobacco products, due to their novelty, product design, and marketing (high tech, clean, lower harm, etc.), which are all similar to e-cigarettes.[10,11,12] Like e-cigarettes, IQOS may be used by youth (and adults) who never would have smoked conventional tobacco products, leading to an overall increase in the segment of the population with a nicotine addiction.[13,14] In fact, there is evidence from around the globe substantiating this concern. One study found that almost half (46%) of Italians who have tried IQOS products had never previously smoked cigarettes.[15] In Greece, prevalence of use is highest in younger adults (21%), the majority of whom started using them before age 25, compared to adults aged 40 and above (11%).[16] In Japan, while younger people are less likely to use tobacco overall, they are more likely to use HTPs than other age groups.[17] A study analyzing data from 11 European countries among those ages 15 and older found that the 15–24 year-old age group was most likely to have tried HTPs, compared to other age groups.[18] And in South Korea, adolescents began using HTPs at a rate three times higher than the rate at which they had previously adopted e-cigarette use.[19]

In NYC, among those who had heard of IQOS, nearly half (48%) of 25-44-year-olds reported having tried the product.[20] Although IQOS has had limited availability in the U.S., the product was launched in Atlanta in 2019. There, the product was marketed as 'clean' and 'high-tech,' and marketing included promotion of $1 'personal IQOS trials' in stores, technical assistance, and chances to socialize with IQOS representatives.[21] The effect of that marketing is clear: in 2020, although IQOS was not available in NYC, nearly one in five New Yorkers had heard of the product.[22] The recent IQOS relaunch in Texas and Florida again offers pop-up stores, mobile units, and flagship stores featuring modern, minimalistic décor, similar to technology retailers.[23,24] These marketing strategies position IQOS as a high-tech product, which may appeal to youth and young adults who have never used tobacco products.

(3) IQOS Is Not a Proven Cessation Device

It is not known how these devices perform relative to FDA-approved tobacco treatment medications and other evidence-based cessation approaches. A 2022 Cochrane review of 13 randomized control trials and time series studies attempting to evaluate this issue found that all studies were industry funded, that none reported on smoking cessation outcomes, and there was insufficient evidence to assess for adverse events.[25] In China, secondary analysis of a randomized clinical trial evaluating the effectiveness of brief advice and referral for smoking cessation found that using heated tobacco product was not associated with cigarette abstinence at 6 months in a community-based cohort of smoking adults with intentions to quit or reduce smoking.[26]

These new analyses reveal that the use case presented by PMI—adults who smoke completely switching to IQOS to stop smoking—is not what happens in the real world. Given these findings and the dearth of data available on population level effects, the Modified Risk Granted Orders should not be renewed.

IQOS May Pose Additional Harm For the Population As a Whole, Due to Secondhand Exposures and Impacts on Smoke-Free Policies

There is evidence to suggest that IQOS exposes others in the vicinity of use to the deleterious effects of secondhand and side stream toxic aerosols. A systematic review of studies analyzing IQOS emissions found that while IQOS emits lower levels of some substances compared to cigarettes, it has greater emissions of other harmful and potentially harmful constituents (HPHC), some of which are not included on the list of HPHCs considered by the FDA.[27] These emissions include volatile organic compounds and fine particulate matter, exposing those nearby to potentially harmful effects. [28,29,30] In fact, a national survey in Japan found that nearly half of non-tobacco users who were exposed to secondhand aerosol from HTPs reported symptoms, including asthma attacks and chest pain. [31,32] HTPs also produce aldehydes, nanoparticle and particulate matter[33] in quantities that negatively affect indoor air quality.[34,35] The systematic review also found that while PMI-funded studies reported immediate returns to baseline air quality, independent studies concluded that HPHCs lingered in the air after IQOS use.[36]

Moreover, because smoke-free air laws in many jurisdictions were drafted to cover conventional, combustible tobacco products, IQOS use is not covered by some existing smoke-free air laws. This is because many smoke-free air laws define "smoking" narrowly and require material to be burned or combusted.[37] A 2019 study from Japan demonstrated that heated tobacco products, like IQOS, were being used in smoke-free locations, including workplaces and restaurants.[38] A more recent study found that people who use HTPs were more likely to use the products in their homes (52% daily and 78% more than once a month) than people who smoked cigarettes (38% and 58%).[39] Such use erodes existing protections and changes norms surrounding smoke-free spaces.

Conclusion

For these reasons, and because there is insufficient evidence to indicate it has reduced harm to either individuals or at the population level, the **Modified Risk Granted Orders should not be renewed.** In addition, the FDA should provide aggressive oversight and enforcement of IQOS marketing. Thank you for allowing public comment on this critically important issue.

Sincerely,

[redacted]

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Acting Commissioner
New York City Department of
Health and Mental Hygiene

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