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December 12, 2017

Mr. Mitchell Zeller
Director, Center for Tobacco Products
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Re: 82 FR 27487, Docket no. FDA-2017-D-3001-3002 for Modified Risk Tobacco Product Applications: Applications for IQOS System With Marlboro Heatsticks, IQOS System With Marlboro Smooth Menthol Heatsticks, and IQOS System With Marlboro Fresh Menthol Heatsticks Submitted by Philip Morris Products S.A.; Availability

Dear Mr. Zeller:

We are writing to complain about the public comment process for the above-referenced docket on Philip Morris's modified risk tobacco product applications (MRTPA) for IQOS.

The initial June 15, 2017 Notice of Availability for public comment stated that FDA would accept comments on these extremely complex and lengthy applications until today, December 12, 2017 (180 days from the date the Notice was posted). However, FDA failed to make publicly available significant portions of the applications, including the Module 7 Scientific Studies and Analyses. On October 2, 2017, we requested that FDA extend the time period to comment by 180 days from the date that the complete applications have been made public.

On November 21, 2017, FDA issued a notice stating that once all the MRTPA documents – "including amendments" – are posted, FDA intended to issue a notice in the Federal Register announcing when the comment period would close, which would be no earlier than 30 days from the date the last batch of application documents – "including amendments" – is posted. Additional application documents were posted on November 28, 2017.

On December 8, 2017, FDA issued a Special Announcement entitled, "Clarification: No Deadline Set for Public Comments on Philip Morris Products S.A. MRTP Applications" which stated that "at this time, **there is no deadline for public comments** on these applications." However, the deadline set for comments to TPSAC members was not changed (written comments should be received by FDA by 4:00 p.m. on January 4, 2018).

FDA's announcement did little to "clarify" the situation. Instead, this announcement introduced even more confusion for the public and scientists, like us, who seek to carefully analyze the

complete applications and make meaningful comments to help inform FDA's decision on this very important matter.

We understand that FDA is engaged in continual discussions with Philip Morris about its MRTPA, and therefore expect that there will be amendments to the applications. The FDA's decision has created a situation in which the public has no way of knowing what or when amendments, if any, will be made. In addition, by doing so, FDA effectively turned the nominal 180 day comment period (which was reasonable in light of the magnitude and complexity of Philip Morris' application) into a 30-day comment period for the public to analyze new amendments that could be significant.

Given the complexity of the application and how the many parts relate to each other, it might not be easy to determine how changes in one part of the application affect the interpretation of other parts. One could also imagine a situation in which Philip Morris submitted amendments in a way that obscured these important linkages.

This situation puts the public in an even more difficult situation than the FDA did after posting application materials on November 28, 2017 with a 30-day deadline.

In effect the FDA has established short deadlines for the public who wish to comment on the applications, but not for the applicant who submitted the application. The deadline for public comment is not only inadequate to allow thorough examination and thoughtful consideration of the millions of pages of the application materials, but is also fundamentally unfair. Indeed, by permitting Philip Morris to continually amend its application (perhaps in response to comments and analyses we and others have already posted to the docket), FDA effectively accommodates the industry while limiting the ability of the public to participate in the process.

The scientists and experts at UCSF and our colleagues at Stanford and Georgia State University have worked hard and tried the best we could to examine the exceptionally complex application materials, and managed to submit 10 thorough public comments by today, December 12, the original deadline. We identified many serious problems with the applications, including demonstrating that Philip Morris' own data does not support several of its statements.

The FDA has granted Philip Morris an open invitation to amend its applications *ad infinitum*, and we, the public, are simply not in a position to continually track the changes that Philip Morris makes and continually adjust our comments. As a result, the current FDA policy has potentially compromised the value of the 10 comments we have submitted. The other alternative for us or other members of the public who have not yet completed their comments is to wait until the application is posted in full before beginning work on the public comments. The practical effect of doing so would be to cut the effective comment period to 30 days.

To be fair, the public should be given equal consideration to Philip Morris (or any future applicant) and allowed 180 days to submit comments from the date Philip Morris (or any future applicant) has certified that the applications are complete and final and the FDA has posted the compete application.

Also of particular concern, FDA set the deadline for submitting comments to TPSAC for January 4, 2018. This date is almost certainly before all the MRTPA materials (including amendments) will have been posted, and necessarily before the public will have a chance to analyze them and offer

meaningful comments to be considered by TPSAC and FDA at the TPSAC meeting scheduled for January 24-25, 2018.

In addition, to the extent that TPSAC discusses the substance of Philip Morris' still-open application, the FDA will have effectively converted TPSAC into an advisory committee to assist Philip Morris in refining its application prior to TPSAC's formal consideration of the complete application.

These deadlines make a mockery of both the MRTP public comment process as well as the TPSAC process, which are mandated by law in sections 911(e) and (f) of the Family Smoking Prevention and Tobacco Control Act. Neither the public nor TPSAC has been given the *complete* MRTP application materials, and neither the public nor TPSAC has been given enough time to examine the applications and make thoughtful comments or recommendations.

We therefore request that FDA:

1. Set a specific deadline by which all MRTPA materials, including amendments, shall be submitted and made publicly available;

2. Extend the time for public comment to 180 days from the date that the applications are *complete and final* and made publicly available (i.e., all amendments have been posted); and

3. Remove the Philip Morris MRTP applications from the January TPSAC meeting agenda and schedule another TPSAC meeting to a time no sooner than 180 days from the date the applications are final so TPSAC will have a sufficient amount of time to review Philip Morris' application together with the public comments on the complete and final application

Absent such changes, FDA has established a process that is biased against the public interest and in favor of industry.

Respectfully,

Stanton A. Glantz, PhD
Professor of Medicine
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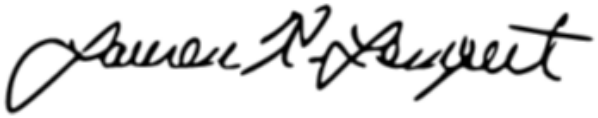

Lauren K. Lempert, JD, MPH
Law and Policy Specialist
Center for Tobacco Control Research and Education

attachment: List of public comments submitted by UCSF concerning Philip Morris's MRTP applications for IQOS.

Public Comments Submitted on Philip Morris International MRTP application for IQOS

1. PMI's Own Data on Biomarkers of Potential Harm in Americans Show that IQOS is Not Detectably Different from Conventional Cigarettes

2. The evidence PMI presents in its MRTP application for IQOS is misleading and does not support the conclusion that IQOS will not harm endothelial function; independent research done in a more relevant physiological model shows that IQOS harms endothelial function as much as conventional cigarettes

3. Philip Morris's Population Health Impact Model Based on Questionable Assumptions and Insufficient Health Impact Measures Does Not Adequately Support its MRTP Application

4. Because PMI application did not report the full range of HPHCs in IQOS aerosol, characterize HPHCs in sidestream emissions, include a non-targeted analysis of chemicals in emissions, or conduct clinical studies to describe exposure to toxicants during dual use with other tobacco products, FDA must deny PMI's application

5. IQOS emissions create risks of immunosuppression and pulmonary toxicity, so FDA should not issue an order permitting IQOS to be labeled or marketed with reduced risk claims

6. PMI's MRTP application for IQOS does not adequately evaluate potential for liver totoxicity risk

7. PMI's MRTP Application for IQOS Does Not Consider IQOS's Appeal to Youth or Adolescents, or the Likelihood that Youth and Adolescents will Initiate Tobacco Use with IQOS or Use IQOS with Other Tobacco Products

8. The evidence cited in PMI's MRTP Application indicates that the proposed labeling and warnings for IQOS will mislead consumers, particularly youth, about the product

9. Detailed analysis of the Executive Summary (Section 2.7) submitted by Philip Morris International in support of its MRTP application for IQOS

10. Because PMI has not demonstrated that IQOS is associated with lower risks, FDA should not permit modified exposure claims, because such claims are likely to be misunderstood as modified risk claims