FDA needs to extend the public comment period on PM MRTP for iQOS for 180 days after the FULL application is public

This comment was submitted to Regulations.gov on October 2, 2017; the tracking number is 1k1-8yzw-s3z7. A PDF version of the letter is available here.

I urge other organzations, whether they are planning comments or not, to submit similar letters.

October 2, 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 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:

I am writing on behalf of UCSF TCORS in response to the June 15, 2017 Notice of availability for public comment on the modified risk tobacco product applications (MRTPAs) 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. The Notice states that FDA will accept comments on these three complex applications until December 12, 2017 (180 days from the date the Notice was posted). Additionally, the Notice states that in the event that fewer than 30 days remain in the comment period when the final batch of application documents is posted, FDA will extend the comment period to allow for at least 30 days of public comment from the day the final batch is posted.

FDA is required by section 911(e) of the Family Smoking Prevention and Tobacco Control Act (TCA) to make the MRTPA publicly available, and section 911(g)(4)(E) requires FDA to take into account comments, data, and information submitted by interested persons in making its determination of whether to issue a MRTP marketing order. In violation of these mandates, as of October 2, 2017, FDA has not made essential portions of the MRTPA publicly available, making it impossible or severely difficult for us to prepare a useful public comment. Therefore, we respectfully request that FDA extend the comment period for 180 days after *all* of the application documents have been posted.

As FDA acknowledged in its Notice, the MRTPAs are very large. When we started detailed work on preparing comments, we realized that the applications posted by FDA are still not complete. As of October 2, 2017, 110 days after the MRTPA notice was posted, FDA has still not posted two of the nine modules of the MRTPA, Module 7 (Scientific Studies and Analyses) and Module 9 (References). As the Main Table of Contents reveals, these two modules contain the essential information on the studies and analyses conducted by Philip Morris that purport to provide the scientific evidence used to support its claims that the IQOS products either reduce harm or reduce exposure to harm, and are critically important for scientists to review. We and other interested persons have no way to analyze the merit of Philip Morris's evidence and claims without these essential documents, and

now can only comment on Philip Morris's subjective summaries.

As FDA acknowledges in its Notice about the MRTPA, the MRTPA documents are extremely long and complex, and warrant thoughtful consideration by experts, scientists, academics, and other interested persons. As the docket now stands, such legally mandated examination is impossible because the docket is incomplete, lacking perhaps the most significant sections on Scientific Studies and Analyses and References. Extending the public comment period for only 30 days after the last batch of application documents are posted (likely the longest, most complex, and most significant portions of the applications) would not provide scientists, experts, and other interested persons adequate time to analyze and provide meaningful and useful comments. Therefore we request that FDA do the following:

1. Post all of the application materials listed in the table of contents (including all sections of Modules 7 and 9);
2. Extend the time to comment by 180 days from the date that the complete applications have been made public so that we and other interested persons can have a meaningful opportunity to review and analyze the MRTPA.

Thank you.

Sincerely yours,

Stanton A. Glantz, PhD
Professor of Medicine
Truth Initiative Distinguished Professor in Tobacco Control
Director, Center for Tobacco Control Research and Education
Principal Investigator, UCSF TCORS

cc: Center for Tobacco Products Ombudsman's Office