The IQOS MRTP applications fail to demonstrate reduced harm to individuals or benefit to the public health

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IQOS not shown to reduce harm to individuals as compared to cigarettes

- PMI's clinical studies do not find significantly lower biomarkers of potential harm than conventional cigarettes (Tab 1)
- IQOS harms endothelial function (Tab 2)
- Full range of HPHCs not considered, including HPHCs in sidestream emissions (Tab 4)
- IQOS may expose users to toxins different from cigarettes (Tab 4)
- Risks of immunosuppression, pulmonary toxicity, and hepatotoxicity created by IQOS emissions not adequately evaluated (Tabs 5 and 6)
- Health risks not compared to e-cigarettes (Tab 3)

IQOS not shown to benefit the population as a whole

- Applications do not consider effects on youth, adolescents, or other non-users (Tabs 3 and 7)
- Applications do not address recent experience with e-cigarettes and dual use (Tabs 3 and 7)
- Proposed labeling and warnings will mislead consumers, especially youth (Tab 8)
- Modified exposure claims likely to be misunderstood as modified risk claims (Tab 10)

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MRTP process unfair and biased toward industry

- TPSAC and public need 180 days to consider complete application
  - Key application materials not posted until November 28, 2017
  - New amendments posted on January 12, 2018
- TPSAC should take no action until:
  - MRTP application is complete and final
  - Public given 180 days to comment on final application
  - TPSAC given time to consider complete application and public comments

FDA should not issue a new tobacco product order for IQOS

- All these problems apply to the PMTA, as well as the MRTPA, for IQOS
- Approval of IQOS is not “appropriate for the protection of the public health” as required by TCA sections 910(c)(4) and 911(g)