

EXHIBIT 2

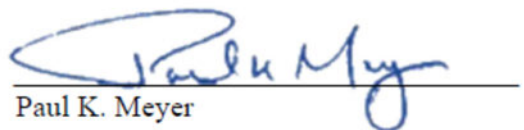
RAI Strategic Holdings, Inc.
and
R.J. Reynolds Vapor Company
v.
Altria Client Services LLC,
Philip Morris USA, Inc.,
and Philip Morris Products S.A.

Civil Action No. 1:20-cv-00393-LO-TC

Amended and Supplemental Opening Expert Report
of Paul K. Meyer

TM Financial Forensics, LLC

April 26, 2021


Paul K. Meyer

December 7, 2020.⁵² And, on July 7, 2020, the FDA authorized marketing of IQOS as a MRTP.⁵³ In contrast, to date, no e-cigarette has received PMTA authorization. Indeed, former FDA Commissioner David Kessler stated that he “wouldn’t bet on” any e-cigarettes surviving the FDA review.⁵⁴

49. I understand that one major impediment to PMTA authorization for e-cigarettes is concern over youth use/abuse of e-cigarettes, a concern was expressed by, for example, the FDA, HHS, and CDC.⁵⁵ In contrast, I understand that IQOS’ characteristics and sales practices position it away from youth use.⁵⁶ For example, IQOS does not come in fruit or candy flavors that are more likely to appeal to youth, and is sold with restrictions that impede access to the product by nonsmokers and youth.⁵⁷ I understand that the FDA did not find youth abuse of IQOS but, instead, observed that “[t]he data from countries where IQOS® is marketed, specifically Italy and Japan, show low uptake by youth and current nonsmokers,” and that “limited options in terms of flavor choice and the price of the IQOS® device may reduce the appeal to youth,” concluding that “[o]verall, the current evidence indicates IQOS® uptake by youth and nonsmokers will be low.”⁵⁸
50. I understand that IQOS was uniquely designed to appeal to smokers not only by delivering nicotine but by approximating as closely as possible the overall sensorial experience of smoking—an experience which, as I discuss throughout this Report, is highly valued by consumers.⁵⁹

⁵² <https://www.fda.gov/tobacco-products/premarket-tobacco-product-applications/premarket-tobacco-product-marketing-orders>; <https://www.fda.gov/media/144701/download>.

⁵³ <https://www.fda.gov/news-events/press-announcements/fda-authorizes-marketing-iqos-tobacco-heating-system-reduced-exposure-information>; deposition of Nicholas Gilley (Reynolds Vice President of Marketing Performance), December 3, 2020: pp. 150, 265.

⁵⁴ “Former FDA chief: ‘I don’t see how’ regulators keep Juul, other e-cigarettes, on the market,” October 25, 2019: 1199_RESP00014222-229 (at 222, 224).

⁵⁵ Based on discussions with Stacy Ehrlich; <https://www.fda.gov/news-events/press-announcements/fda-warns-firms-remove-unauthorized-e-liquid-products-market-first-letters-issued-manufacturers-did>.

⁵⁶ Based on discussions with Stacy Ehrlich.

⁵⁷ *See, e.g.*, “Altria launches Iqos tobacco device in US, and the timing couldn’t be better,” CNBC, October 4, 2019: 1199_RESP50006476-484 (at 479-480).

⁵⁸ PMTA Coversheet: Technical Project Lead Review (TPL), May 15, 2017: 1199_RESP00011697-818 (at 772).

⁵⁹ “Factors that influence smokers’ and ex-smokers’ use of IQOS: a qualitative study of IQOS users and ex-users in the UK,” Tompkins, Charlotte N E, November 23, 2019: <https://tobaccocontrol.bmj.com/content/tobaccocontrol/30/1/16.full.pdf>, p. 20: 1199_RESP00011896-903 (at 900) (“Participants commonly claimed that the overall sensory experience of using IQOS was equivalent to, or better than smoking combustible cigarettes, which accounted for continued use.”).