EXHIBIT 1
FILED UNDER SEAL

CONTAINS CONFIDENTIAL BUSINESS INFORMATION
SUBJECT TO PROTECTIVE ORDER

UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA
ALEXANDRIA DIVISION

RAI STRATEGIC HOLDINGS, INC. and R.J. REYNOLDS VAPOR COMPANY, Plaintiffs and Counterclaim Defendants, v. ALTRIA CLIENT SERVICES LLC; PHILIP MORRIS USA INC.; and PHILIP MORRIS PRODUCTS S.A., Defendants and Counterclaim Plaintiffs.	Civil Action No. 1:20-cv-393

AMENDED AND SUPPLEMENTED OPENING EXPERT REPORT

OF STACY EHRLICH

Stacy Ehrlich — April 26, 2021

B. Any Advantage VUSE E-Cigarettes Can Gain for PMTA Review Is Valuable, Given the High Authorization Hurdles Such Products Face

127. E-cigarettes face a number of hurdles to PMTA authorization – hurdles that ultimately could frustrate the ability of any e-cigarette to receive such authorization. FDA's ENDS Guidance states that "[i]f . . . there is significant initiation by youth, minimal quitting, or significant dual use of combust[ed] and non-combust[ed] products, then the public health impact could be negative."[195] [redacted][196] Accordingly, any advantage the VUSE e-cigarette PMTAs can gain is particularly valuable in this high-stakes situation.

1. Epidemic Youth Use Is a Hurdle to an E-Cigarette PMTA

128. One of the primary hurdles that e-cigarette PMTAs face is the "epidemic" youth use of e-cigarettes.[197] Former U.S. Health and Human Services Secretary, Alexander Azar, reflected that "[t]he United States has never seen an epidemic of substance use arise as quickly as our current youth use of e-cigarettes."[198] As of September 2020, there were 3.6 million U.S. youth using these products – with more than 8 in 10 using flavors.[199] Regular use of e-cigarettes among high school students (*i.e.* those that use at least 20 out of the last 30 days) increased from 20% in

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[195] 1199_RESP00014118-1199_RESP00014169 at 1199_RESP00014135 (citing 79 Fed. Reg. 23141, 23147 (2016).

[196] [redacted]

[197] 1199_RESP00010611-1199_RESP00010614; *see* 1199_RESP00011826-1199_RESP00011831; *Pediatrics*, 399 F. Supp. 3d at 485.

[198] 1199_RESP00010611-1199_RESP00010614; *see* 1199_RESP00011826-1199_RESP00011831.

[199] 1199_RESP00015126-1199_RESP00015128 at 1199_RESP00015127; *Youth Tobacco Use: Results from the National Youth Tobacco Survey*, FDA (Dec. 22, 2020), https://www.fda.gov/tobacco-products/youth-and-tobacco/youth-tobacco-use-results-national-youth-tobacco-survey.

131. In addition to FDA, other governmental bodies have expressed concern over youth use of e-cigarettes. For example, last April, Members of Congress launched the Congressional Caucus to End the Youth Vaping Epidemic "to discuss needed solutions to better protect American youth from the dangers of vaping and nicotine addiction."[212] Reynolds American, Inc.'s CEO acknowledged before a Congressional committee in February 2020 that "[t]he increasing youth vaping over the past two years and serious health issues from illicit products are now at the heart of a national discussion."[213]

132. The FTC also included Reynolds in an inquiry regarding sales, advertising, and promotional methods for e-cigarettes.[214] The FTC ordered Reynolds to produce, among other things, annual data on the sales and giveaways of its e-cigarettes; annual amounts spent on advertising and promoting e-cigarettes; and information about e-cigarette placement, the websites and social media accounts used to advertise or sell e-cigarettes, affiliate programs, influencer marketing, and college campus programs.[215] FDA, too, closely scrutinizes sales, advertising, and promotional methods for e-cigarettes as part of its PMTA review.[216] Accordingly, any FTC findings from its study are likely to be of interest to FDA and could impact whether the VUSE e-cigarettes will receive PMTA authorization.

133. Because of the levels of youth use of e-cigarettes reported, e-cigarette manufacturers have come under increasing scrutiny. Even before Reynolds filed its VUSE

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[212] 1199_RESP50000411-1199_RESP50000412.

[213] 1199_RESP00010932-1199_RESP00011048 at 1199_RESP00010958.

[214] *See* 1199_RESP00014485-1199_RESP00014486.

[215] *Id.*

[216] 1199_RESP00010622-1199_RESP00010625.

PMTAs, FDA decided in 2018 to "reevaluat[e] its current compliance policy with respect to VUSE brand products and similar products."[217] As FDA explained:

> During the summer of 2018, FDA conducted an enforcement blitz of retailers nationwide, which resulted in more than 1,100 Warning Letters and approximately 130 civil monetary penalties being issued to retailers for underage sale of e-cigarettes. Those cases included the illegal sale of VUSE products to minors. This is unacceptable, both legally and as a matter of public health.[218]

134. [redacted][219]

135. [redacted][220][redacted][221]

[217] *Id.* at 1199_RESP00010622.

[218] *Id.* at 1199_RESP00010623.

[219] [redacted]

[220] [redacted]

[221] [redacted]

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