Murray R. Garnick
Executive Vice President
and General Counsel

August 8, 2018

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

Re: Docket No. FDA–2017–N–4678—Comments on "Modified Risk Tobacco Product Applications: Applications for Six Camel Snus Smokeless Tobacco Products Submitted by R.J. Reynolds Tobacco Company."

Altria Client Services LLC, on behalf of Philip Morris USA Inc., U.S. Smokeless Tobacco Company LLC, and Nu Mark Inc., submits these comments to the above-referenced Modified Risk Tobacco Product applications.[1] Altria expresses no opinion on the merits of Reynolds' applications. We write instead to raise our concern that the modified risk tobacco product provisions of the Tobacco Control Act, as applied to Reynolds' application, may violate the First Amendment by restricting manufacturers' truthful speech regarding the health risks of their products.

FDA now recognizes that there is a scientific consensus that it is the combustion of tobacco and the resulting smoke—not the nicotine—that is the direct cause of most tobacco-related harm. FDA also recognizes that noncombustible tobacco products are lower on the continuum of risk than combustible cigarettes, and, therefore, have an important role to play in reducing that harm.[2] Smokers cannot be expected to switch to less harmful alternatives, however, if they aren't told the truth about them. Yet today, the FDA regulatory system is preventing smokers from being told the full truth about relative risks of different tobacco products. And that imbalance of information is having real and disturbing consequences. Today, there is a widespread *misunderstanding* among smokers as to whether there is a difference in risk among tobacco products. The science is clear and undisputed: smokeless

[1] Philip Morris USA Inc., U.S. Smokeless Tobacco Company LLC, and Nu Mark Inc. are wholly-owned subsidiaries of Altria Group, Inc. Altria Client Services LLC provides certain services, including regulatory affairs, to the Altria family of companies. "We" and "our" collectively refer to Philip Morris USA Inc., U.S. Smokeless Tobacco Company LLC and Nu Mark Inc.

[2] FDA now recognizes that the "nicotine in cigarettes is not directly responsible for the cancer, lung disease, and heart disease that kill hundreds of thousands of Americans each year." Remarks of Commissioner Scott Gottlieb, M.D., FDA, *Protecting American Families: Comprehensive Approach to Nicotine and Tobacco* (July 28, 2017), https://goo.gl/P2iMj3. Accordingly, FDA's goal is to "move addicted smokers down [the] continuum of risk to . . . less harmful products," and away from combustible products like cigarettes. *Id.*

Altria Group, Inc.
6601 W. Broad Street, Richmond, VA 23230
804 614-9540

tobacco products are safer than combustible tobacco products.[3] Yet many smokers are still under the impression that smokeless tobacco products present the *same health risks* as combustible tobacco products.[4] The same is true for e-vapor products.[5] A recent study found that U.S. adults "increasingly believe that e-cigarettes could be as harmful as combustible cigarettes," perhaps because "the nature of the regulatory environment influences perceptions of e-cigarettes."[6]

The Tobacco Control Act, of course, establishes a pathway for manufacturers to communicate accurate reduced risk information to consumers. Under 21 U.S.C. 387k, a manufacturer must request advance FDA authorization to communicate a claim to a consumer, including that a tobacco product presents a lower risk of tobacco-related disease, is less harmful than another product, contains reduced levels of a substance in its smoke, or is free of a substance. To receive authorization to make such a claim, the Act requires an applicant to show any health-related claim "is expected to benefit the health of the population as a whole taking into account both users of tobacco products and *persons who do not currently use tobacco products*." 21 U.S.C. 387k(g)(1)(B). In making this "population effects" determination, the statute directs FDA to take into account a variety of possible, future unintended consequences of communicating a fully substantiated claim, including the possibility that some consumers will switch to the less harmful product rather than quit; that some will use the less harmful tobacco product rather than FDA-approved cessation products; and that "persons who do not use tobacco

---

[3] Tobacco Advisory Group, *Protecting Smokers, Saving Lives: The Case for a Tobacco and Nicotine Regulatory Authority* 5 (Royal College of Physicians of London ed., 2002) ("[T]he consumption of non-combustible tobacco is of the order of 10-1,000 times less hazardous than smoking, depending on the product."); World Health Organization, *The Scientific Basis of Tobacco Product Regulation*, WHO Technical Rep. Series 951, 2008 at 10 ("Users of smokeless tobacco products generally have lower risks for tobacco-related morbidity and mortality than users of combustible tobacco products such as cigarettes."); Scientific Committee on Emerging and Newly Identified Health Risks, *Health Effects of Smokeless Tobacco Products* 114 (2008) ("Overall therefore, in relation to the risks of the above major smoking-related diseases, and with the exception of use in pregnancy, [smokeless tobacco products] are clearly less hazardous, and in relation to respiratory and cardiovascular disease substantially less hazardous, than cigarette smoking."); Life Sciences Research Office, Inc., *Differentiating the Health Risks of Categories of Tobacco Products* 5 (Kara D. Lewis ed., 2008) ("Studies have consistently reported that cigarette smoking significantly increases the risk of [lung cancer]. Most studies reported that [smokeless tobacco] users do not have an increased risk of [lung cancer] compared with non-smokers."); Mitchell Zeller et al., *The Strategic Dialogue on Tobacco Harm Reduction: A Vision and Blueprint for Action in the US*, 18 Tobacco Control 324 (2009) ("Cigarette smoking is undoubtedly a more hazardous nicotine delivery system than various forms of non-combustible tobacco products for those who continue to use tobacco, which in turn are more hazardous than pharmaceutical nicotine products.").

[4] Alexander Persoskie et al., *Criterion Validity of Measures of Perceived Relative Harm of E-Cigarettes and Smokeless Tobacco Compared to Cigarettes*, 67 Addictive Behavs. 100, 100-05 (2017) (analyzing data showing that "[o]n direct measures, 26% of adults rated e-cigarettes as less harmful than cigarettes," and using behavioral data to confirm that "[d]irect measures appear to provide valid information about individuals' harm beliefs").

[5] *See* Timothy R. Huerta et al., *Trends in E-Cigarette Awareness and Perceived Harmfulness in the U.S.*, 52 Am. J. Preventive Med. 339, 339 (2017) ("Perception that e-cigarettes were less harmful than regular cigarettes declined from 50.7% in 2012 to 43.1% in 2014."); Ann McNeill et al., *E-Cigarettes: An Evidence Update*, Pub. Health Eng., Aug. 2015, at 6, 11, 57-62, https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/457102/Ecigarettes_an_evidence_update_A_report_commissioned_by_Public_Health_England_FINAL.pdf ("There has been an overall shift towards the inaccurate perception of [e-cigarettes] being as harmful as cigarettes over the last year in contrast to the current expert estimate that using [e-cigarettes] is around 95% safer than smoking.").

[6] Ban A. Majeed et al., *Changing Perceptions of Harm of E-Cigarettes Among U.S. Adults*, 2012-2015, 52 Am. J. Preventive Med. 331, 332, 335-36 (2017).

products will start using the tobacco product that is the subject of the application." 21 U.S.C. 387k(g)(4)(A)-D).

In a variety of ways, however, this statutory scheme raises immediate, serious, and—in light of recent Supreme Court decisions—rather obvious First Amendment issues. We write here to focus on just two in particular, both of which, we believe, the Agency has an obligation to avoid or substantially mitigate in how it processes these and other MRTP applications for noncombustible products, and how quickly it does so.

Population Effects

First, any censorship of truthful and accurate information based on "population effects" clearly runs afoul of the First Amendment. Once a claim is proven accurate, FDA cannot disfavor certain speakers (manufacturers) or certain content (comparative health claims) in deciding whether to allow the information to be spoken. That kind of thumb-on-the-scale censorship merits "strict" judicial scrutiny that can be met only with a law "narrowly tailored" to advance a "compelling" government interest.[7] Strict scrutiny is so exacting it is often "fatal" to a law's constitutionality.[8] Speech restrictions are especially problematic when they result in the suppression of accurate information in the realm of public health: just last month, the Supreme Court reiterated that it will readily strike down speech restrictions, especially "in the fields of . . . public health, where information can save lives."[9]

Censorship intended to stop people from making "bad" decisions is precisely the kind of speech restriction the First Amendment forbids.[10] It is never a valid government interest to deprive consumers of truthful information in order to prevent "bad" choices they or others might make.[11] The U.S. Supreme Court has long "rejected the notion that the Government has an interest in preventing the dissemination of truthful commercial information in order to prevent

---

[7] *See Sorrell*, 564 U.S. at 564-66, 571-72; *see also NIFLA*, 138 S. Ct. at 2371; *Matal v. Tam*, 137 S. Ct. 1744 (2017); *Reed v. Town of Gilbert*, 135 S. Ct. 2218 (2015); *Cigar Ass'n of Am. v. U.S. Food & Drug Admin.*, 2018 WL 3304627, at *1 (D.D.C. July 5, 2018) (citing *NIFLA* and granting injunction pending appeal that enjoins FDA from enforcing health warnings requirements for cigars and pipe tobacco).

[8] *See Adarand Constructors, Inc. v. Pena*, 515 U.S. 200, 237 (1995) (plurality opinion).

[9] *Nat'l Inst. of Family & Life Advocates v. Becerra* ("*NIFLA*"), 138 S. Ct. 2361, 2374 (2018) (quoting *Sorrell v. IMS Health Inc.*, 564 U.S. 552, 566 (2011)).

[10] *Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n of N.Y.*, 447 U.S. 557, 566 (1980).

[11] In the commercial speech arena, the Supreme Court adheres to the cardinal principle that "the offensive assumption that the public will respond 'irrationally' to the truth" and the strategy of "keep[ing] people in the dark for what the government perceives to be their own good," will not sustain a ban on truthful statements regarding a product. *44 Liquormart, Inc. v. Rhode Island*, 517 U.S. 484, 503 (1996) (citation omitted). The government is simply not allowed to act out of fear that "people would make bad decisions if given truthful information." *Thompson v. W. States Med. Ctr.*, 535 U.S. 357, 359 (2002). Instead of a "highly paternalistic approach" based on such fear, FDA must "assume that [] information is not in itself harmful, that people will perceive their own best interests if only they are well enough informed, and that the best means to that end is to *open* the channels of communication rather than to *close* them." *Va. Bd. of Pharmacy v. Va. Citizens Consumer Council, Inc.*, 425 U.S. 748, 770 (1976) (emphases added). As the Supreme Court has held, the choice "between the dangers of suppressing information, and the dangers of its misuse if it is freely available" is one "that the First Amendment makes for us." *Id.*

members of the public from making bad decisions with the information."[12] This anti-paternalism principle is so robust that the Supreme Court has invalidated every commercial speech restriction under *Central Hudson* over the last 20 years except one involving attorney advertising.[13] While the government may have an interest in reducing tobacco use, depriving consumers of truthful information relevant to them about comparative health claims undermines that interest and innumerable less restrictive and more direct means of achieving that goal exist other than suppressing truthful speech.[14]

Given these concerns, and certainly in the context of MRTP applications for noncombustible tobacco products, the Agency should conform its application of the MRTP statute to these constitutional requirements. The science is overwhelming that noncombustible products, including snus, present significantly lower risk of disease and illness compared to combustible cigarettes.[15] In our MRTP application for our moist smokeless tobacco products, we relied in part on decades of epidemiological evidence gathered and maintained by the Centers for Disease Control. All of this data demonstrates scientifically the intuitive point that if most tobacco related harm is caused by inhalation of cigarette smoke, consumption of tobacco without smoke inhalation will result in significant risk reductions for smokers who switch. The Agency must recognize that smokers have a right to know this information, and must allow a substantiated claim to be made unless there is a compelling reason to withhold it.

Timing of Authorizations

Second, the absence of clear, binding, and expeditious deadlines governing the FDA's review of MRTP claims presents its own independent and serious First Amendment problem. Because the preclearance requirement operates as a prior restraint, the First Amendment requires adequate procedural and substantive safeguards to ensure that protected speech is not suppressed. Such prior restraint is permissible only where (1) the government meets its burden of proving the speech is not protected by the First Amendment; (2) the period of suppression is the shortest period necessary to review an application and a decision is made by a deadline specified in

---

[12] *Thompson v. Western States Medical Center*, 535 U.S. 357 (2002).

[13] *See* 1 Law of Lawyer Advertising § 2:17, nn.3-4 (2018). The Court upheld limited speech restrictions on attorney solicitation in *Florida Bar v. Went For It, Inc.,* 515 U.S. 618, 634 (1995). Otherwise, in the 40 years since *Central Hudson*, the Court has consistently invalidated laws that burden commercial speech, often by stating that the Court need not resolve whether a higher standard of scrutiny applies because the law fails *Central Hudson* in all events. *E.g.*, *Tam*, 137 S. Ct. 1744 (2017) (striking Lanham Act's disparagement clause); *Sorrell*, 564 U.S. 552 (2011) (striking Vermont statute limiting sale of prescriber information to pharmaceutical companies); *W. States Med. Ctr.*, 535 U.S. 357 (2002) (striking federal law prohibiting advertising of compounded drugs); *Lorillard*, 533 U.S. 525 (2001) (striking state law prohibiting tobacco advertising); *Greater New Orleans Broad. Ass'n, Inc. v. United States*, 527 U.S. 173 (1999) (striking federal law prohibiting casino advertising); *44 Liquormart*, 517 U.S. 484 (1996) (striking state law prohibiting alcohol price advertising); *Edenfield v. Fane*, 507 U.S. 761 (1993) (striking state law prohibiting CPA solicitation).

[14] *Discount Tobacco City & Lottery, Inc. v. United States,* 674 F.3d 509 (6th Cir. 2012), does not change these conclusions. That lawsuit—brought years before FDA had even exerted its full authority under the Act to all tobacco products—included a facial challenge to the MRTP provisions in the statute. In denying that challenge, the court left undecided whether those provisions could withstand First Amendment scrutiny in an as-applied context.

[15] *See supra* note 3.

advance; and (3) judicial review is promptly available.[16] Any prior restraint scheme must also employ "narrow, objective, and definite standards to guide the licensing authority."[17]

At minimum, the foregoing standard requires that FDA announce a deadline for completing review of MRTP applications and complete its review by that deadline. The deadline must be short. Notably, the Supreme Court has held that even a 57-day delay in reviewing an application is unconstitutional.[18] The need for expedition is especially acute where, as here, an MRTP application is for noncombustible tobacco products—which FDA agrees are lower on the risk continuum than combustible products because once an applicant demonstrates the claim is true and non-misleading with respect to the consumer to whom it is directed, that should be the end of the matter and FDA should approve the application.

Conclusion

The evidence is overwhelming that for smokers who switch, smokeless tobacco products generally offer significantly lower risk of tobacco-related harm, including all of the harms caused by the inhalation of smoke from combustion of tobacco.[19] When an MRTP applicant wants to make a truthful, non-misleading health claim about a smokeless tobacco product, FDA must promptly approve it. The Agency should prioritize the dissemination of accurate, non-misleading information about smokeless tobacco products not only because the First Amendment requires it, but also because it will help advance the Agency's own stated goal of reducing harm through the advancement of reduced-risk products.

We appreciate the opportunity to submit these comments. As always, we would be happy to discuss further the views expressed in these and other Altria comments.

Sincerely,

Murray R. Garnick

[16] *Se. Promotions, Ltd. v. Conrad*, 420 U.S. 546, 560 (1975).
[17] *Forsyth Cty. v. Nationalist Movement*, 505 U.S. 123, 131 (1992).
[18] *See Teitel Film Corp. v. Cusak*, 390 U.S. 139, 141-42 (1968) (per curiam).
[19] *See supra* note 3.