Washington Legal Foundation
Advocate for freedom and justice®
2009 Massachusetts Avenue, NW
Washington, DC 20036
202.588.0302

Critical Legal Issues: WORKING PAPER SERIES

FDA'S FIRST AMENDMENT BLINDSPOT WIDENS WITH OVERZEALOUS INTERPRETATION OF MODIFIED-RISK TOBACCO REGULATION

Joel Kurtzberg, **Adam Mintz**, and **John MacGregor**
Cahill Gordon & Reindel LLP

Washington Legal Foundation
Critical Legal Issues WORKING PAPER Series

Number 218
July 2020

TABLE OF CONTENTS

ABOUT OUR LEGAL STUDIES DIVISION

Since 1986, WLF's Legal Studies Division has served as the preeminent publisher of persuasive, expertly researched, and highly respected legal publications that explore cutting-edge and timely legal issues. These articles do more than inform the legal community and the public about issues vital to the fundamental rights of Americans—they are the very substance that tips the scales in favor of those rights. Legal Studies publications are marketed to an expansive audience, which includes judges, policymakers, government officials, the media, and other key legal audiences.

The Legal Studies Division focuses on matters related to the protection and advancement of economic liberty. Our publications tackle legal and policy questions implicating principles of free enterprise, individual and business civil liberties, limited government, and the rule of law.

WLF's publications target a select legal policy-making audience, with thousands of decision makers and top legal minds relying on our publications for analysis of timely issues. Our authors include the nation's most versed legal professionals, such as expert attorneys at major law firms, judges, law professors, business executives, and senior government officials who contribute on a strictly *pro bono* basis.

Our eight publication formats include the concise COUNSEL'S ADVISORY, succinct LEGAL OPINION LETTER, provocative LEGAL BACKGROUNDER, in-depth WORKING PAPER and CONTEMPORARY LEGAL NOTE, topical CIRCULATING OPINION, informal CONVERSATIONS WITH, balanced ON THE MERITS, and comprehensive MONOGRAPH. Each format presents single-issue advocacy on discrete legal topics.

In addition to WLF's own distribution network, full texts of LEGAL OPINION LETTERS and LEGAL BACKGROUNDERS appear on the LEXIS/NEXIS® online information service under the filename "*WLF*," and every WLF publication since 2002 appears on our website at www.wlf.org. You can also subscribe to receive select publications at www.WLF.org.

To receive information about WLF publications, or to obtain permission to republish this publication, please contact Glenn Lammi, Chief Counsel, Legal Studies Division, Washington Legal Foundation, 2009 Massachusetts Avenue, NW, Washington, DC 20036, (202) 588-0302, glammi@wlf.org.

ABOUT THE AUTHORS

Joel Kurtzberg is a Partner in the New York, NY office of Cahill Gordon & Reindel LLP. Over his more than 20-year career, Mr. Kurtzberg has been at the forefront of First Amendment and commercial speech litigation. Representing pharmaceutical, food, and tobacco companies in advising on and litigating First Amendment issues surrounding FDA regulations, he has secured several high-profile victories for his clients. Joel prevailed on behalf of Amarin Pharma, Inc. in the precedent-setting case that challenged the constitutionality of the FDA's restrictions on off-label promotion by the company of its lead product. Mr. Kurtzberg also led the Cahill litigation team for Lorillard Tobacco Company in successfully bringing a First Amendment challenge to the FDA's proposed graphic warnings on cigarette packaging and advertisements. Recognized by the *Financial Times* and *National Law Journal* as innovative and effective, *Chambers USA*, *Media Law International*, and *Best Lawyers* rank Mr. Kurtzberg among New York's top First Amendment litigators.

Adam S. Mintz is a Counsel with Cahill Gordon & Reindel LLP where he focuses his practice on Litigation matters. He represents global corporations, financial institutions, boards of directors and select individuals in litigation and appeals, as well as before government and regulatory bodies. Mr. Mintz's practice covers securities litigation, antitrust litigation, government investigations including SEC enforcement actions, various internal investigations (including those overseen by audit committees and special committees), regulatory guidance, commercial litigation, class action defense, First Amendment/media litigation and appellate work. Mr. Mintz has been selected to the 2016, 2017, 2018 and 2019 New York Metro Super Lawyers "Rising Stars" list. He joined the firm in 2010 and became a counsel in 2019.

John MacGregor is an Associate with Cahill Gordon & Reindel LLP, where he focuses his practice on matters relating to securities and regulatory enforcement, white collar defense, internal investigations, First Amendment/media litigation, commercial litigation, antitrust litigation, and anti-corruption, compliance and trade sanctions. Mr. MacGregor represents global corporations and financial institutions in litigation and appeals, as well as before government and regulatory bodies in matters concerning criminal inquiries (including the Foreign Corrupt Practices Act), government investigations (including DOJ and SEC enforcement actions), and securities and antitrust matters. He also has experience conducting internal investigations and assisting multinational companies in assessing and enhancing their regulatory compliance programs.

The views expressed herein are those of the authors and not necessarily of the firm or its clients.

EXECUTIVE SUMMARY

The Food and Drug Administration has a complicated relationship with the First Amendment. The agency consistently chafes against arguments that the Constitution limits its regulation of promotional and other types of speech. Over the past three decades, regulated entities have been increasingly successfully challenging FDA actions that prohibit, limit, or compel speech about their products or services. Despite those defeats, FDA has continued its confrontational approach.

One example of that approach is the agency's overzealous implementation of a 2009 tobacco control law's section on modified-risk tobacco products. Two courts have rejected facial First Amendment challenges to the law's limits on risk-related speech. FDA has set an extremely high approval bar, under which it has granted only two applications for reduced-risk promotion. And the agency has taken informal action against purported "switch claims" made about specific e-cigarettes as well as one company's support of a ballot proposition to reverse a city's ban on some tobacco alternatives.

This WORKING PAPER explains that modified-risk tobacco manufacturers could successfully bring *as-applied* First Amendment challenges against FDA actions under the tobacco control law. FDA's chilling of speech on the benefits of switching to tobacco alternatives not only singles out speech based on its content, but it also undermines Congress's goal of improving public health. The agency's inquiry on financial support for ballot proposition impermissibly targets the company's fully protected right to participate in public debates.

The WORKING PAPER also notes that the two court decisions upholding the tobacco control law's provision on modified-risk communication leave open one form of promotion. The law curbs messages "directed to consumers . . . respecting the product." That language, as one court specifically acknowledged, does not limit manufacturers' ability to engage in generic advertising about tobacco alternative products in general.

FDA'S FIRST AMENDMENT BLINDSPOT WIDENS WITH OVERZEALOUS INTERPRETATION OF MODIFIED-RISK TOBACCO REGULATION

INTRODUCTION

In 2009, the Family Smoking Prevention and Tobacco Control Act ("FSPTCA") was signed into law, giving the Food and Drug Administration ("FDA") sweeping authority to regulate the manufacture, distribution, and marketing of tobacco products. Among other things, the FSPTCA contains the modified-risk tobacco product ("MRTP") provision, which allows companies to commercially market "modified-risk" tobacco products—*i.e.*, "tobacco product[s] . . . sold or distributed for use to reduce harm or the risk of tobacco-related disease associated with commercially marketed tobacco products"—only after they obtain advance authorization from the FDA. 21 U.S.C. § 387k(b)(1) and (a).

Under the statutory standard, the FDA may not authorize advertisements of modified-risk tobacco products, even if truthful and not misleading, unless the manufacturer can affirmatively demonstrate to the FDA that the product—as actually used by consumers—will (i) "significantly reduce harm and the risk of tobacco-related disease to individual tobacco users" ***and*** (ii) "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." *Id.* at § 387k(g)(1) (emphasis added).

Thus, to take a simple example, it would violate the MRTP provision for a tobacco manufacturer to tell consumers that "tobacco product x, while not safe, is less harmful than cigarettes," even if that statement were undisputedly true and not misleading, unless the manufacturer could affirmatively demonstrate to the FDA that the product will "significantly reduce harm and the risk of tobacco-related disease to individual tobacco users" ***and*** "benefit the health of the population as a whole." This can be done, for example, by showing that the health benefits gained by having smokers switch to the less-harmful "tobacco product x" outweigh the health costs imposed by having people who do not currently use tobacco products at all start using "tobacco product x."

Making that showing has proven to be extraordinarily costly and difficult. In the more than ten years since the passage of the FSPTCA, numerous companies have submitted MRTP applications to the FDA seeking to market their products as less dangerous alternatives to traditional cigarettes. The FDA, however, has granted MRTP status to only two applicants,[1] despite millions of dollars spent by numerous

[1] On October 22, 2019, the FDA authorized Swedish Match to market eight separate snus (a moist powder smokeless tobacco) products as MRTPs. *See FDA grants first-ever modified risk orders to eight smokeless tobacco products*, FOOD AND DRUG ADMINISTRATION (Oct. 22, 2019) (noting that the FDA "announced today that, for the first time, it has authorized the marketing of products through the modified risk tobacco product . . . pathway"). In addition, on July 7, 2020, the FDA authorized Philip Morris to market as MRTPs four separate products used in a tobacco heating system. *See FDA authorizes marketing of IQOS tobacco heating system with "reduced exposure" information*, Food and Drug Administration (July 7, 2020) (noting that the FDA approved "Philip Morris Products S.A.'s 'IQOS Tobacco Heating System' as modified risk tobacco products," which "marks the second set of products ever to be authorized as MRTPs").

applicants to conduct studies intended to satisfy the heavy burden of proof put on them by the MRTP provision. The FDA's aggressive approach has led to a near-total *de facto* ban on truthful and non-misleading advertisements informing the public of the comparative health benefits of MRTPs over cigarettes.

Appellate courts have thus far rejected facial challenges under the First Amendment to the MRTP provision. *See Discount Tobacco City & Lottery, Inc. v. United States*, 674 F.3d 509 (6th Cir. 2012) (rejecting facial First Amendment challenge to MRTP provision by various tobacco companies); *Nicopure Labs v. FDA*, 944 F.3d 267 (D.C. Cir. 2019) (rejecting facial First Amendment challenge to application of the MRTP provision to e-cigarettes under the so-called "deeming rule"). But those cases leave open ***as-applied challenges*** on First Amendment grounds if the FDA applies the MRTP provision to constitutionally protected speech about tobacco products.

In the context of e-cigarettes, the FDA has recently been employing aggressive enforcement tactics in two areas that we think cry out for an as-applied First Amendment challenge. First, the FDA has threatened to take enforcement action under the MRTP provision for those tobacco companies that engage in "switch claims"—defined here to be commercial claims by e-cigarette companies urging smokers to "switch" to e-cigarettes without referencing any comparative health benefits of e-cigarettes over cigarettes. As an example of this, on September 9, 2019, the FDA issued a Warning Letter to e-cigarette company Juul Labs, Inc., alleging that

Juul had improperly marketed its e-cigarette products as MRTPs by urging existing smokers to switch to Juul's products. Many statements identified by the FDA made no reference at all to the comparative health benefits of Juul's products and did not urge non-smokers to use Juul's products. Prohibiting these types of "switch" claims makes no sense and cannot survive First Amendment scrutiny. Surely, the FDA wants e-cigarette companies to target their advertising to existing users of tobacco products, rather than targeting people who do not use tobacco products at all. If switch claims that do not expressly tout comparative health benefits can be said to "imply" such claims—as the FDA's position suggests—then most responsible forms of truthful and non-misleading e-cigarette advertising will be forbidden. That is a result the First Amendment does not allow.

Second, the FDA has also been reportedly investigating potential violations of the MRTP provision that stem from Juul's ***political*** speech. In 2019, Juul donated $18.6 million to a campaign in support of Proposition C, a ballot initiative that sought to overturn San Francisco's ban on the sale and distribution of e-cigarettes.[2] Some of

[2] On September 21, 2019, the San Francisco *Chronicle* reported that the FDA would "investigate whether Juul is illegally claiming that vaping products are safer than cigarettes in political ads for Proposition C . . . without having received the agency's authorization to make such claims." The *Chronicle* cited an email, which has not been made public, from Mitchell Zeller, the director of the FDA's Center for Tobacco Products, to San Francisco Supervisor Shamann Walton in which Zeller indicated that the FDA would review statements made by Juul in support of Proposition C. Although Juul's advertising on behalf of Proposition C was conducted by the Coalition for Responsible Vaping, an entity funded entirely by Juul, according to the *Chronicle*, the FDA is treating these statements as though they were made by Juul. Catherine Ho, *FDA to Investigate Juul over SF Ads Claiming Vaping Is*

these political ads urged voters to vote for Proposition C because e-cigarettes pose less health risks than cigarettes, which have not been banned in San Francisco. According to public reports, the FDA has been investigating whether such political advertisements violate the MRTP provision.

If true, such conduct would not only violate the First Amendment, but would also be inconsistent with representations made by the FDA to the courts in defending a facial challenge to the MRTP provision in *Discount Tobacco City & Lottery*.[3] In that case, to avoid a finding that the MRTP provision was unconstitutional, the government assured both the district court and the US Court of Appeals for the Sixth Circuit that the MRTP provision would never be applied in a manner that would infringe on core political speech or speech about scientific debate.

In addition to bringing as-applied challenges to these examples of governmental overreach, another alternative for tobacco companies, consistent with the case law to date, would be to engage in generic advertising promoting the comparative health benefits of certain tobacco products. In *Discount Tobacco City & Lottery*, the court expressly held that the MRTP provision does not apply to such

---

Safer than Cigarettes, S.F. CHRONICLE, Sept. 21, 2019; Catherine Ho, *Juul Ends Support for Prop. C, SF Measure to Overturn e-Cigarette Sales Ban*, S.F. CHRONICLE, Sept. 30, 2019.

[3] *See Principal Brief of Plaintiffs-Appellants/Cross-Appellees*, 10:5235 (6th Cir. May 28, 2010) at 1 ("The Act is the most sweeping regulation of the speech of a lawful industry in American history and consequently violates the First Amendment in myriad ways."); *Plaintiffs' Memorandum in Support of Motion for Summary Judgment*, 09 Civ. 117 (JHM) (ERG) (W.D. Ky. Nov. 30, 2009) at 15 (arguing that the Act's "prohibitions cannot be reconciled with Plaintiffs' rights secured by the First Amendment").

generic advertising. 674 F.3d at 532. The court noted that the MRTP provision applies only "to consumer-directed claims regarding a manufacturer's specific products" and that there is "no reason to believe that it . . . applies when Plaintiffs limit their speech to discussions of generic product categories like smoke-free tobacco products." *Id.* at 533 (internal quotation marks omitted). Thus, according to the Sixth Circuit, there is nothing prohibiting e-cigarette companies from engaging in truthful and non-misleading generic advertising, including statements about the comparative health benefits of MRTPs, without pre-authorization from the FDA. And nothing in the US Court of Appeals for the D.C. Circuit's decision in *Nicopure Labs* suggests that such generic advertising would be improper either.

I. THE FDA'S INVESTIGATION OF "SWITCH CLAIMS" VIOLATES THE FIRST AMENDMENT

On September 9, 2019, the FDA issued a Warning Letter to Juul, alleging that Juul had marketed its products as MRTPs. In an accompanying press release, the FDA cited examples of statements made by Juul during a presentation to the Cheyenne River Sioux Tribe that the FDA thought ran afoul of the MRTP provision. Among these statements were the following:

- "'[Juul is] a smart, really well thought-out alternative to smoking.' Make the switch."
- "I think [Juul is] an amazing invention . . . . I don't know how we lived without that. The alternative for smokers."

These "switch claims" make no claim at all that Juul's products are comparatively safer than traditional cigarettes or that they can help smokers quit. Nonetheless, the FDA apparently considers them to violate the MRTP provision, presumably because they allegedly ***imply*** that e-cigarettes are a safer alternative to cigarettes. But such an aggressive reading of the MRTP provision goes too far.

These advertisements suggest that Juul's e-cigarettes are a ***better*** alternative to cigarettes, but that is not—and cannot be—the same as saying that they are a ***safer*** alternative. That difference matters. The MRTP provision arguably attaches to statements about the latter, but cannot possibly apply to statements about the former.

The FDA's reading of the MRTP provision by applying it to these types of "switch claims" runs afoul of the First Amendment. It also makes no sense. The FDA presumably wants e-cigarette companies to direct their advertising to existing users of tobacco products—as opposed to directing them at people who do not use tobacco products at all. As such, "switch claims" that do not highlight comparisons about health and safety are an essential tool for tobacco companies to get their message out responsibly. The FDA's use of the MRTP provision to discourage such speech cannot survive First Amendment scrutiny under any standard of review.

From the government's apparent perspective, the only way for a company to encourage the use of e-cigarettes and other tobacco alternatives over traditional

cigarettes is to go through the FDA's burdensome MRTP authorization process. But that process, which can take years and cost tens of millions of dollars, has been nearly impossible to complete in practice. Since the FSPTCA was enacted, the FDA has granted MRTP status to only two applicants.[4] Despite clear science demonstrating that, on balance, e-cigarettes and other products are safer than traditional cigarettes, the government has effectively used the MRTP provision to censor any effort by e-cigarette companies to urge smokers to switch to e-cigarettes.

In applying the MRTP provision to switch claims that do not even suggest that e-cigarettes are safer than cigarettes, the FDA seeks to regulate core commercial speech—*i.e.*, speech that does "no more than propose a commercial transaction," *Virginia State Board of Pharmacy v. Virginia Citizens Consumer Council, Inc.*, 425 U.S. 748, 762 (1976). As the Supreme Court has made clear, a "consumer's concern for the free flow of commercial speech often may be far keener than his concern for urgent political dialogue," *Bates v. State Bar of Ariz.*, 433 U.S. 350, 364 (1977), and "heightened scrutiny" is appropriate in commercial speech cases driven by concerns about content because "[t]hat reality has great relevance in the fields of medicine and public health, where information can save lives." *Sorrell v. IMS Health Inc.*, 564 U.S. 552, 566 (2011).

[4] *See* FOOD AND DRUG ADMINISTRATION, *supra* note 1.

Under recent Supreme Court case law, the FDA's approach to enforcement of the MRTP provision should be subject to strict scrutiny because it is both content- and viewpoint-based. *See, e.g.*, *National Institute of Family and Life Advocates v. Becerra*, 138 S. Ct. 2361 (2018) (holding that content-based restrictions on speech are presumptively invalid and subject to strict scrutiny); *Reed v. Town of Gilbert, Arizona*, 135 S. Ct. 2218 (2015) (same). There is no doubt that, under these cases, the MRTP provision is "content based." It applies only to speech that promotes a certain message—namely, that which urges consumers to switch to a modified-risk tobacco product because it is safer or less dangerous than traditional cigarettes. *See Reed*, 135 S. Ct. at 2226-27 ("Government regulation of speech is content based if a law applies to particular speech because of the topic discussed or the idea or message expressed" and such regulations "are presumptively unconstitutional and may be justified only if the government proves that they are narrowly tailored to serve compelling state interests").[5]

But even if the traditional intermediate scrutiny test from *Central Hudson Gas & Electric Corp. v. Public Service Commission of New York*, 447 U.S. 557 (1980), were applied, this aggressive interpretation would fail to pass constitutional muster.

[5] Oddly enough, because the MRTP provision is content-based and applies only to claims about comparative health advantages of certain tobacco products over cigarettes, the FDA's position leads to the absurd result that the FDA can take action against tobacco companies urging cigarette smokers to switch to e-cigarettes (which experts agree likely reduces many health risks) but not against tobacco companies urging e-cigarette users to switch to cigarettes (which experts agree would increase health risks).

The FDA's position violates the central principles of commercial speech jurisprudence because it is, at its core, a paternalistic attempt to shield the public from speech about e-cigarettes that the government believes will harm consumers. The government and other critics of MRTPs justify such regulation on the grounds that, even if the science shows that e-cigarettes and other tobacco alternatives are safer than cigarettes, society as a whole is better off if we convince individuals to get off tobacco and tobacco alternatives entirely. *See, e.g.*, Sally Satel, *The Vaping Overreaction*, THE ATLANTIC, Oct. 23, 2019 (noting that "many policy makers and members of the public do not grasp the benefits of nicotine harm reduction, because they simply won't admit or don't believe that e-cigarettes are less risky for smokers"). The critics, therefore, argue that advertisements encouraging the use of tobacco alternatives should be restricted to the rarest of circumstances.

But the First Amendment precludes the government from restricting speech for such paternalistic reasons. The premise of the First Amendment is that a free society depends on a fully functioning marketplace of ideas. So long as participants in that marketplace are engaged in truthful and non-misleading speech, the government should not and cannot tip the scales in favor of a particular viewpoint absent the most compelling of circumstances. The government's justification for stifling any suggestion that traditional smokers should switch to tobacco alternatives—even without saying that they should do so because such products are healthier or safer

than traditional cigarettes—does not come close to meeting that standard.

In fact, the FDA's reading of the MRTP provision is entirely inconsistent with the stated intent of the law, which is to "benefit the health of the population as a whole." 21 U.S.C. § 387k(g)(1). Juul's statements do no more than urge existing smokers to switch to Juul's products. They do not in any way promote the use of Juul's products by non-smokers or tout the relative health benefits of Juul's products. And because existing smokers are precisely the people who would benefit from Juul's products—which are generally believed to be less harmful than traditional cigarettes—limiting Juul's ability to market its products to this group will have an affirmatively detrimental effect on public health. Such an approach would fail to satisfy any level of First Amendment scrutiny because it would not "directly advance" an important governmental interest, *Central Hudson*, 447 U.S. at 564-66, let alone be "narrowly tailored" to further a compelling governmental interest, *Becerra*, 138 S. Ct. at 2371.

II. THE GOVERNMENT IS REPORTEDLY USING THE FSPTCA TO TARGET POLITICAL SPEECH IN SUPPORT OF MODIFIED-RISK TOBACCO PRODUCTS

A. The FDA Reportedly Attempted to Silence Political Speech

The FDA has also targeted core political speech in its efforts to enforce the MRTP provision. Throughout 2019, Juul donated millions of dollars to the Coalition for Responsible Vaping, a campaign supporting Proposition C. During the campaign,

the Coalition published numerous advertisements focusing on reversing the e-cigarette ban rather than marketing Juul's products to consumers. The ads included language such as the following:

- "By taking e-cigarettes off the shelves, you're basically going to force a lot of ex-smokers to go back to smoking."
- "Doctors and health professionals agree: vaping helps adults get off cigarettes."
- "Recent studies show that vaping is a less harmful alternative."[6]

In response to the FDA's September 9, 2019 letter alleging that Juul marketed its products as MRTPs, on September 17, 2019, San Francisco Supervisor Shamann Walton sent the FDA a letter urging the agency to expand its investigation to cover statements Juul made in support of Proposition C. *See* Letter from Supervisor Shamann Walton to FDA (Sept. 17, 2019). According to press reports, shortly after it received this letter, the FDA confirmed that it would broaden the scope of its investigation to include statements Juul funded in support of Proposition C. *See* Catherine Ho, *FDA to Investigate Juul over SF Ads Claiming Vaping Is Safer than Cigarettes*, S.F. CHRONICLE, Sept. 21, 2019. In the shadow of this threat, Juul quickly withdrew its financial support of Proposition C, which ultimately failed to pass by an overwhelming margin. *See* Catherine Ho, *Juul Ends Support for Prop. C, SF Measure to Overturn e-Cigarette Sales Ban*, S.F. CHRONICLE, Sept. 30, 2019.

[6] Stanton A. Glantz, *FDA to Investigate Juul over SF Ads Claiming Vaping is Safer than Cigarettes*, UCSF CENTER FOR TOBACCO CONTROL RESEARCH AND EDUCATION, Sept. 21, 2019.

This is precisely the type of government interference the FDA assured the Sixth Circuit would not occur in its defense of the MRTP provision's constitutionality in *Discount Tobacco*. In that case, the tobacco companies had produced evidence that scientists retained by the tobacco companies were afraid to appear on television and engage in scientific debate about the comparative safety of various tobacco products for fear of violating the MRTP provision. In response, the government represented that it had not "even remotely suggested" that the MRTP provision would prevent companies from "engag[ing] in scientific debate." Relying on that argument, the Sixth Circuit rejected the tobacco companies' facial challenge, while taking great pains to emphasize that tobacco companies' "ability to make direct comments on public issues remains untouched" and that "there is no basis in the record to believe that the Act will be interpreted or applied to infringe significantly on noncommercial speech rights." *Discount Tobacco*, 674 F.3d at 533 (internal quotation marks omitted).

B. Advertisements in Support of Proposition C Constitute Core Political Speech

The FDA's reported expansion of its investigation to include the coalition's advertisements supporting Proposition C presents a fact pattern reminiscent of the *Nike* v. *Kasky* dispute from the early 2000s. *Kasky v. Nike*, 45 P.3d 243 (Cal. 2002), *cert. granted sub nom. Nike v. Kasky*, 537 U.S. 1099, *and cert. dismissed*, 539 U.S. 654 (2003). There, protesters publicly accused Nike of unfair labor practices—*e.g.*, using a "sweatshop" and "slavery" to make its sneakers—and engineered a boycott of Nike's

products. When Nike tried to respond with public statements of its own denying that it had engaged in such practices, the California Supreme Court held that the protestors' speech was subject to greater protection than Nike's responses because the former was core political speech (subject to strict scrutiny), while the latter was commercial speech (subject only to intermediate scrutiny). *Kasky*, 45 P.3d at 262 (holding that, even if a speaker has a "secondary purpose to influence lenders, investors, or lawmakers," the speech is still commercial if it is "primarily intended to reach consumers and to influence them to buy the speaker's products"). The U.S. Supreme Court granted *certiorari* to address this issue but later dismissed the petition as "improvidently granted," leaving open this important First Amendment question as to whether speech by a product's manufacturer responding to public criticism of that product constitutes political or commercial speech.

The advertisements in support of Proposition C present the identical issue. Made in a political campaign, in which opponents were free to—and did[7]—frequently point out the health risks of using e-cigarettes, the coalition's responses about the comparative health risks of using e-cigarettes instead of cigarettes constituted

[7] *See, e.g.*, Editorial Board, *SF Voters Should Reject Vaping Company Juul's Prop. C*, S.F. CHRONICLE, Sept. 19, 2019 ("Prop. C represents the effort of the dominant brand of a highly addictive and undoubtedly unhealthy product to dictate the terms of how it should be regulated."); Catherine Ho, *"Say No to Juul": Pelosi Slams SF Vaping Ballot Measure*, S.F. CHRONICLE, Aug. 22, 2019 (noting that Speaker Pelosi characterized Proposition C as a "brazen special-interest attempt to addict our children to cigarettes" and urged San Francisco voters to reject the ballot initiative because "[w]ith all the unknown short-term and long-term consequences of e-cigarettes, we cannot let corporate special interests buy themselves this proposition").

political speech, not commercial speech, and are at the core of what the First Amendment protects. If commercial speech paradigmatically consists of speech that does "no more than propose a commercial transaction," *Virginia State Board of Pharmacy*, 425 U.S. at 762, then the speech in support of Proposition C was not commercial. It urged viewers to take political action about a ballot proposition that impacted e-cigarettes and provided scientific and political arguments in favor of the ballot proposition. That actual and potential consumers also viewed these political advertisements did not make the speech lose its political character. At the very least, it was so "inextricably intertwined with otherwise fully protected speech" that it still should have been governed by the "test for fully protected expression." *Riley v. National Federation of the Blind of N.C., Inc.*, 487 U.S. 781, 796 (1988).

The FDA's reported investigation of the coalition's political speech is also inconsistent with recent cases involving the FDA's regulation of off-label promotion of pharmaceuticals. Courts have held that FDA regulations imposing criminal penalties on companies that engage in the truthful and non-misleading marketing of off-label uses of their products without FDA pre-authorization violate the First Amendment. *See United States v. Caronia*, 703 F.3d 149 (2d Cir. 2012) (vacating a pharmaceutical sales representative's conviction for conspiring to introduce a misbranded drug into interstate commerce when the conviction was based on truthful and non-misleading statements the sales representative made while promoting the drug for off-label use);

Amarin Pharma, Inc. v. United States Food & Drug Administration, 119 F. Supp. 3d 196 (S.D.N.Y. 2015) (holding that the FDA could not bring a misbranding action against a pharmaceutical company for truthful and non-misleading promotion of an off-label use of a drug).[8]

Much of the coalition's speech in support of Proposition C did nothing more than respond to criticism concerning the health risks associated with e-cigarettes. The responses included truthful and non-misleading statements such as "[b]y taking e-cigarettes off the shelves, you're basically going to force a lot of ex-smokers to go back to smoking." But, much like the cases involving off-label promotion of pharmaceuticals, the government seems to think that statements such as these are too dangerous for the public to hear unless the speaker first obtains government permission. This position has been roundly rejected by courts in that context and should also be rejected here.

The D.C. Circuit's decision in *Nicopure Labs*, holding that "the First Amendment does not bar the FDA from preventing the sale of e-cigarettes [when marketed] as safer than existing tobacco products until their manufacturers have shown that they actually are safer as claimed," 944 F.3d at 272, is inconsistent with the off-label promotion cases as well. If the FDA cannot restrict truthful and non-misleading speech about off-label uses of drugs by requiring pre-authorization of any such

[8] Full disclosure: Joel Kurtzberg represented Amarin in this case.

speech, it should not be able to do the same with truthful and non-misleading claims about the comparative health benefits of various tobacco products.

III. UNDER *DISCOUNT TOBACCO*, E-CIGARETTE COMPANIES MAY ADVERTISE THEIR PRODUCTS GENERICALLY

Even with the FDA's overly aggressive enforcement of the MRTP provision, tobacco companies have other avenues to truthfully and non-misleadingly promote their products. In a little-quoted but important provision of the Sixth Circuit's decision in *Discount Tobacco*, the court expressly held that the MRTP provision does not apply to generic advertising about categories of tobacco products that do not reference specific products. As the court explained as part of its effort to avoid a First Amendment problem:

> [T]he [MRTP provision] only applies to products where (1) the labeling or advertising of the specific product makes particular health claims, (2) the labeling or advertising of the product uses key words, or (3) the "tobacco product manufacturer of which has taken any action ***directed to consumers*** through the media or otherwise . . . ***respecting the product***." 21 U.S.C. § 387k(b)(2)(A). Because the restriction applies to consumer-directed claims regarding a manufacturer's specific products, there is no reason to believe that it touches upon Plaintiffs' non-commercial speech . . . or that the [MRTP provision] applies 'when Plaintiffs limit their speech to discussions of generic product categories like smoke-free tobacco products.'

Discount Tobacco, 674 F.3d at 533 (emphasis in original). In light of this ruling, there would be no violation of the MRTP provision if a consortium of e-cigarette companies pooled money to encourage users of traditional cigarettes to switch to e-cigarettes and other MRTPs, including through the use of truthful and non-misleading

statements about their comparative health benefits.

The FDA is aware of this part of the *Discount Tobacco* holding; in fact, the FDA has relied on it when responding to First Amendment objections to the deeming rule—which allows the FDA to deem e-cigarettes containing nicotine to meet the statutory definition of a "tobacco product." In that context, the FDA has argued that the deeming rule survives First Amendment scrutiny because, as *Discount Tobacco* held, it applies only to "consumer-directed claims regarding a manufacturer's specific products." 81 Fed. Reg. at 28987.

While the FDA might not agree, the implication of that holding of *Discount Tobacco* is that modified-risk tobacco companies may speak generically about switching from traditional cigarettes to e-cigarettes, without running afoul of the MRTP provision. Significantly, the D.C. Circuit's decision in *Nicopure Labs* does not suggest otherwise.

