

**ORAL ARGUMENT NOT YET SCHEDULED**  
**No. 17-5196**

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**UNITED STATES COURT OF APPEALS**  
**FOR THE DISTRICT OF COLUMBIA CIRCUIT**

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NICOPURE LABS, LLC & RIGHT TO BE SMOKE FREE COALITION

*Plaintiffs-Appellants,*

v.

FOOD AND DRUG ADMINISTRATION, et al.

*Defendants-Appellees*

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ON APPEAL FROM THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF COLUMBIA

No. 1:16-cv-00878-ABJ (Hon. Amy Berman Jackson)

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**BRIEF OF *AMICUS CURIAE* PUBLIC HEALTH LAW CENTER**  
**IN SUPPORT OF DEFENDANTS-APPELLEES**

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**CERTIFICATE AS TO PARTIES, RULINGS, AND RELATED CASES**

Pursuant to D.C. Circuit Rule 28(a)(1), counsel for *amici curiae* certifies as follows:

**Parties and Amici**

Except for the following, all parties, intervenors, and *amici* appearing to date before the district court and in this Court are listed in the Brief for Appellees, filed May 2, 2018. Public Health Law Center and Public Citizen have filed notice of their intent to file as *amici curiae* in support of Appellees in this Court.

**Ruling Under Review**

References to the rulings at issue appear in the Brief for Appellees.

**Related Cases**

This case has not previously been before this Court or any other court. Counsel is aware of no related cases currently pending in this or any other court.

## **CORPORATE DISCLOSURE STATEMENT**

No party to this filing has a parent corporation, and no publicly held corporation owns 10% or more of the stock of any party to this filing.

The Public Health Law Center is a non-profit corporation organized under 26 U.S.C. § 501(c)(3), affiliated with the Mitchell Hamline School of Law in Saint Paul, Minnesota. The Center is a public interest legal resource center dedicated to improving health through the power of law, grounded in the belief that everyone deserves to be healthy. It works with local, state, national, tribal, and global leaders to help them strengthen public policies that promote health. The Tobacco Control Legal Consortium is the Center's tobacco program. Legal centers affiliated with the Consortium are listed in Appendix A.

**CERTIFICATE OF COUNSEL REGARDING  
SEPARATE BRIEFING & CONSENT TO FILE**

All parties have consented to the filing of this brief. No counsel of any party to this proceeding authored any part of this brief. No party or party's counsel, or any other person – other than *amicus curiae*, its members, or its counsel – contributed money intended to fund the preparation or submission of this brief.

Pursuant to D.C. Circuit Rule 29(d), counsel for the Public Health Law Center certifies that a separate brief is necessary, because the Center's experience and expertise uniquely equip it to inform the Court about the tobacco industry's long history of deception concerning the harm caused by its products and the supposed benefits of its purportedly lower-risk products, the human costs of that deception, and the inadequacy of efforts to protect the public through other methods of regulation than pre-approval of modified risk tobacco product [MRTP] claims.

In addition, the Center's extensive experience and expertise in the drafting and defense of such tobacco control policies as minimum-price laws and prohibitions on discounts positions it to assist the Court in evaluating Nicopure's arguments that purveying free samples is expressive conduct protected by the First Amendment. To the best of the Center's knowledge, its brief will be the only *amicus* brief filed in support of Appellees to address the ban on e-cigarette samples.

The Center has communicated with all other *amici* supporting affirmance of which it is aware in order to avoid duplication of briefing.

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**GLOSSARY**

B&W	Brown & Williamson Tobacco Corporation
BAT	British American Tobacco Company
FAIR	Forum for Academic & Institutional Rights, Inc.
FDA	Food & Drug Administration
JTI	Japan Tobacco International
MRTP	Modified Risk Tobacco Product
MSA	Tobacco Master Settlement Agreement
PM	Philip Morris Companies
R&D	Research & Development
RJR	R.J. Reynolds Tobacco Company

## **IDENTITY & INTEREST OF *AMICUS CURIAE***

The Public Health Law Center is a public interest legal resource center that works to develop, implement, and defend effective public health laws and policies, including those designed to reduce tobacco use. The Center has filed more than fifty briefs as *amicus curiae* in the highest courts in the U.S. and before international bodies, including many briefs filed by its tobacco program, the Tobacco Control Legal Consortium, that have addressed First Amendment challenges brought by the tobacco industry against government regulation.

Having worked for nearly two decades to ensure that the public is informed about the dangers of tobacco use and nicotine addiction, the Center is particularly well-suited to address the public health importance and constitutionality of federal regulations requiring substantiation of health claims by tobacco companies. The Center is also keenly aware of the need for safeguards against youth initiation of tobacco use, including the e-cigarette sampling ban.

## **INTRODUCTION & SUMMARY OF ARGUMENT**

In this lawsuit, e-cigarette manufacturers seek to distance themselves from the tobacco industry and from the regulatory structure that resulted from its decades of deception. But the e-cigarette industry is in fact deeply intertwined with the conventional tobacco industry, not only in terms of ownership and personnel, but also in terms of strategy – from focusing on the delivery of nicotine, a highly



addictive substance; to marketing to youth; to making misleading health claims.

And e-cigarettes are – as the FDA determined – not a wholly new commodity, but simply the latest in a long line of supposedly “safer” tobacco products.

The First Amendment requires of government neither willful blindness to history nor quiescence in the face of a new generation of youth becoming addicted to nicotine. Congress and the FDA, well aware of the historical litany of deception in marketing purportedly safer nicotine products, determined that the public could not be protected from deceptive health claims made for the newest entrant in that line, e-cigarettes, without subjecting them to Modified Risk Tobacco Product [MRTP] review. That commonsense judgment conforms fully with the First Amendment, which contemplates that “the stream of commercial information [should] flow cleanly as well as freely.” *Virginia St. Bd. of Pharm. v. Virginia Citizens Consumer Council, Inc.*, 425 U.S. 748, 772 (1976).

The ban on distributing free samples of tobacco products is likewise constitutionally unproblematic. There is no particularized message in handing out free products – any more than there is in selling them – and therefore “communicative elements” are not sufficiently present “to bring the First Amendment into play.” *Texas v. Johnson*, 491 U.S. 397, 404 (1989). Even if sampling were treated as expressive, it would readily pass muster as an amply

justified and narrowly drawn regulation of expressive conduct. *See United States v. O'Brien*, 391 U.S. 367 (1968).

## ARGUMENT

### I. REQUIRING PRE-APPROVAL OF REDUCED-RISK CLAIMS DOES NOT OFFEND THE FIRST AMENDMENT.

MRTP review is not a “restriction on truthful and non-misleading speech,” as the district court characterized it. *Nicopure Labs, LLC v. FDA*, 266 F. Supp. 3d 360, 419 (D.D.C. 2017).<sup>1</sup> Rather, FDA regulation aims simply to ensure that modified-risk claims *are* truthful and non-misleading.

Any contention by Nicopure that its truthful, non-misleading speech is being restrained is premature at best. No MRTP applications for e-cigarettes have been denied so far. It is likewise premature to surmise that “the burden of proof is so high that ... it is unlikely” that the FDA will ever approve an MRTP claim, Nicopure Br. at 8, a prediction based on the fact that *one* MRTP application for a tobacco product has been rejected. *Id.* at 18.

For now, the only ground Nicopure could have for a First Amendment challenge is that the pre-approval process itself offends the First Amendment. That challenge fails.

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<sup>1</sup> *But see id.* at 421 (“this provision does not ban truthful statements ...; it simply requires that they be substantiated”).

The First Amendment does not rule out pre-approval of commercial speech claims. *See Cent. Hudson Gas & Elec. Corp. v. Public Svce. Comm'n*, 447 U.S. 557, 571 & n.13 (1980) (suggesting “a system of previewing advertising campaigns” as a *less* speech-restrictive alternative to banning certain commercial speech). In particular, pre-approval is appropriate when significant threats to public safety are plausibly at stake, or when pre-approval is necessary to prevent consumer deception. *See Discount Tobacco City & Lottery, Inc. v. United States*, 674 F.3d 509, 534-37 (6th Cir. 2012) (upholding premarket review of MRTPs, based on government interest in protecting public from deceptive health claims). Both factors are present here.

**A. Pre-Approval of Health Claims Protects Public Health.**

Pre-approval for safety is an accepted part of the regulatory landscape for potentially hazardous products. *See, e.g.*, 7 U.S.C. § 136j(a)(1)(B) (prohibiting claims in connection with the distribution or sale of pesticides that differ substantially from pre-approved claims); 21 U.S.C. § 343(r)(3)(B) (requiring FDA determination that claims are supported by scientific evidence before health-related claims on food and dietary supplement labels are authorized); 21 C.F.R. § 202.1(e)(6)(i) (prohibiting any “representation or suggestion, not approved ..., that a drug is better, more effective, useful ..., [or] safer ... than has been demonstrated by substantial evidence”).

E-cigarettes too are potentially hazardous, and the Surgeon General concluded that “the potential short- and long- term health consequences of inhalation of [e-liquid aerosols], including solvents, flavorants, and toxicants, still require further investigation.”<sup>2</sup> Preliminary data at a minimum indicate that heating e-cigarettes produces formaldehyde and other carcinogens.<sup>3</sup> Some e-liquids and aerosols contain toxic heavy metals (not found in conventional cigarettes) associated with adverse respiratory consequences.<sup>4</sup> Particular flavors can have adverse health effects when inhaled.<sup>5</sup> Nicotine, found in 99% of e-liquids sold in the United States,<sup>6</sup> is associated with increased susceptibility to various diseases, lasting adverse consequences for adolescent brain development, and increased premature and still births, as well as being as addictive as heroin.<sup>7</sup> And claims of reduced harm compared to smoking must be weighed against extensive evidence emerging that e-cigarette use is more likely to increase the probability of initiating smoking and to decrease the probability of quitting than *vice versa*.

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<sup>2</sup> *E-Cigarette Use Among Youth and Young Adults: A Report of the Surgeon General* 117 (2016), [https://e-cigarettes.surgeongeneral.gov/documents/2016\\_sgr\\_full\\_report\\_non-508.pdf](https://e-cigarettes.surgeongeneral.gov/documents/2016_sgr_full_report_non-508.pdf).

<sup>3</sup> *Id.* at 118.

<sup>4</sup> *Id.* at 119.

<sup>5</sup> *Id.* at 115-16.

<sup>6</sup> Kristy Marynak, *Sales of Nicotine-Containing Electronic Cigarette Products: United States, 2015*, 107 AM. J. PUB. HEALTH 702 (2017).

<sup>7</sup> *Surgeon General, supra* note 2, at 113.

**B. Pre-Approval of Health Claims Is Necessitated by the Tobacco Industry's Historical and Ongoing Deceptive Conduct.**

Noting that Congress enacted the MRTP review process largely in response to deceptive marketing of “light” cigarettes as safer than other cigarettes, Nicopure argues that the MRTP regime should not extend to e-cigarettes, based on two implied premises: (1) tobacco companies’ fraudulent marketing of “light” cigarettes was a unique episode, *see* Nicopure Br. at 20; and (2) the e-cigarette industry is a distinct industry, whose credibility is not tainted by the cigarette industry’s history of deception. *See id.* at 52.<sup>8</sup>

Both premises are false. Deceptive modified risk claims for “light” cigarettes were far from an isolated episode. And e-cigarettes are a product of very much the same industry as conventional cigarettes and other tobacco products.

**1. The tobacco industry has lied for decades about the hazards posed by its products.**

From no later than 1953 until at least 2000, tobacco companies “mounted a coordinated, well-financed, sophisticated public relations campaign to attack and distort the scientific evidence demonstrating the relationship between smoking and disease,” *United States v. Philip Morris USA, Inc.*, 449 F.Supp.2d 1, 208 (D.D.C.

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<sup>8</sup> *See also* NJOY, *Amicus* Br. at 29 (“There is no evidence that e-cigarette manufacturers have engaged in a pattern of coordinated deception akin to the conduct [of] combustible-cigarette manufacturers”); State of Iowa, *Amicus* Br. at 24 (“This is a different industry” from Big Tobacco).

2006), *aff'd in relevant part*, 566 F.3d 1095 (D.C. Cir. 2009), while “at the same time ..., they internally acknowledged as fact that smoking causes disease and other health hazards.” *Philip Morris*, 566 F.3d at 1106.

Similarly, while cigarette companies “researched and recognized, decades before the scientific community did, that nicotine is an addictive drug,” *Philip Morris*, 449 F. Supp. 2d at 208, they “publicly denied and distorted the truth about the addictive nature of their products, [and] suppressed research revealing the addictiveness of nicotine.” *Philip Morris*, 566 F.3d at 1107. Meanwhile, tobacco companies deliberately “engineered their products around creating and sustaining ... addiction.” *Id.*

The tobacco industry conspired to assuage public concerns about health risks by creating entities that “conducted the manufacturers’ joint public relations through false and misleading press releases and publications, ... and funded ‘special projects’ to produce favorable research results and witnesses specifically for use in litigation and for support of industry public statements.” *Id.* Meanwhile, the industry did everything it could to suppress and discredit genuine research, *see, e.g., Philip Morris*, 449 F. Supp. 2d at 114-15, 182-84. Purportedly independent – but actually industry-paid – scientists also repeatedly testified at congressional hearings and stated publicly that there was no scientific evidence that cigarettes are addictive. *Id.* at 282-85.

The indignation expressed by Nicopure and its *amici* over supposed impediments to public health posed by e-cigarette regulators carries echoes of past cigarette industry proclamations. *See, e.g., id.* at 195 (1972 Tobacco Institute press release responded to Surgeon General’s Report: “the number one health problem is not cigarette smoking, but ... the extent to which public health officials may ... mislead the American public”).

**2. The tobacco industry has perpetuated deception about allegedly safer products for decades.**

“Light” cigarettes represent merely one episode in the tobacco industry’s campaign to keep old customers and attract new ones by responding to revelations of health harms with allegedly less harmful alternatives.

Filtered cigarettes. Filtered cigarettes were promoted as an alternative to quitting, even though tobacco companies already knew that filters rarely provided actual health benefits.<sup>9</sup> Industry documents privately referred to filters as “an effective advertising gimmick.”<sup>10</sup>

Light cigarettes. Despite knowing “for decades that ... low tar cigarettes do not offer a meaningful reduction of risk,” tobacco companies “engaged in massive, sustained, and highly sophisticated marketing and promotional campaigns to

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<sup>9</sup> R.W. Pollay & T. Dewhirst, *The Dark Side of Marketing Seemingly “Light” Cigarettes*, 11 TOBACCO CONTROL (Supp. I) i18, i18-i20 (2002).

<sup>10</sup> *Id.* at i19 (quoting memo from industry attorneys).

portray their light brands as less harmful.” *Philip Morris*, 566 F.3d at 1124 (quoting district court). For example, “as part of [a] scheme to defraud smokers, [they] withheld and suppressed their extensive knowledge” of the phenomenon whereby addicted smokers compensate for weaker cigarettes by unconsciously taking larger puffs. *Id.* at 1125 (quoting district court). Regulators and researchers were decades behind cigarette companies in understanding this phenomenon. *Philip Morris*, 449 F. Supp. 2d at 461.

The purpose of marketing “light” cigarettes was to dissuade smokers from quitting. Internal industry memos explicitly noted, for example, “Quitters may be discouraged from quitting, or at least kept in the market longer.” *Philip Morris*, 449 F. Supp. 2d at 496 (quoting Brown & Williamson [B&W] memo).

To this day Philip Morris [PM] hires consultants to testify in court, contrary to scientific consensus, that light cigarettes are safer.<sup>11</sup> And tobacco companies continue to circumvent label restrictions on descriptors such as “light” by using color coded packaging.<sup>12</sup>

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<sup>11</sup> David Heath, *Philip Morris Uses Chemical Industry Consultants to Perpetuate ‘Light Cigarette’ Myth*, CTR. PUB. INTEGRITY (May 4, 2016), <https://www.publicintegrity.org/2016/05/04/19618/philip-morris-uses-chemical-industry-consultants-perpetuate-light-cigarette-myth>.

<sup>12</sup> Lauren Lempert & Stanton Glantz, *Packaging Colour Research by Tobacco Companies*, 26 TOBACCO CONTROL 307, 307 (2017); Duff Wilson, *Coded to Obey Law, Lights Become Marlboro Gold*, N.Y. TIMES (Feb. 19, 2010), <http://www.nytimes.com/2010/02/19/business/19smoke.html>.



Heated cigarettes. R.J. Reynolds [RJR] has been held liable for unsubstantiated magazine advertisements claiming that Eclipse, a product that allegedly heated tobacco instead of burning it, “may present less risk of cancer, chronic bronchitis, and possibly emphysema.” *Vermont v. R.J. Reynolds Tobacco Co.*, No. S1087-05 (Vt. Super. Mar. 10, 2010). In reality, Eclipse produces tar levels similar to those of light cigarettes.<sup>13</sup> Nevertheless, in a 2004 study, 91% of smokers who were read claims made by RJR about Eclipse afterwards believed that Eclipse was safer than conventional cigarettes, while 24% believed Eclipse was *completely* safe.<sup>14</sup>

Snus. In recent years, tobacco companies introduced “snus,” a spitless moist snuff, as a less harmful alternative to smoking. But as actually used – and intended by the companies – smokeless products allow smokers to maintain their nicotine addiction when smoking is prohibited.<sup>15</sup> As an internal RJR memo put it: “There is a need to clearly position the product as a *situational* substitute for cigarettes, rather than a replacement.”<sup>16</sup> Far from reducing smoking, smokeless tobacco often

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<sup>13</sup> Linda Pederson & David Nelson, *Literature Review and Summary of Perceptions, Attitudes, Beliefs, and Marketing of Potentially Reduced Exposure Products*, 9 NICOTINE & TOBACCO RESEARCH 525, 532 (2007).

<sup>14</sup> *Id.* at 530.

<sup>15</sup> Carrie Carpenter et al., *Developing Smokeless Tobacco Products for Smokers: An Examination of Tobacco Industry Documents*, 18 TOBACCO CONTROL 54, 57 (2009).

<sup>16</sup> Quoted in *id.* at 56.

leads younger users to start smoking.<sup>17</sup> As with other products, tobacco companies fostered addiction by manipulating smokeless tobacco for optimal nicotine delivery, and by marketing flavored smokeless products to non-users and then “graduating” them to successively stronger products.<sup>18</sup>

**3. The tobacco industry deliberately marketed to youth and lied about it.**

Tobacco industry deception extends to its predatory youth marketing. The trial court in *Philip Morris* found “overwhelming evidence” that tobacco companies market to young people, including those below the legal age of eighteen. 449 F. Supp. 2d at 691. They “intensively researched and tracked young people’s attitudes, preferences, and habits,” and used their resulting “knowledge of young people to create highly sophisticated and appealing marketing campaigns targeted to lure them into starting smoking and later becoming nicotine addicts.” *Id.*

Publicly, the companies and trade organizations “denied, over and over, with great self-righteousness, that they ... marketed to youth,” *id.* at 692, stating, for example, “We do everything possible to discourage teenage smoking.” *Id.* at 679. RJR even claimed that it would not have launched the notorious Joe Camel cartoon

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<sup>17</sup> Keith Haddock et al., *Evidence That Smokeless Tobacco Use Is a Gateway for Smoking Initiation in Young Adult Males*, 32 PREVENTIVE MED. 262 (2001).

<sup>18</sup> Gregory Connolly, *The Marketing of Nicotine Addiction by One Oral Snuff Manufacturer*, 4 TOBACCO CONTROL 73, 73-78 (1995) (citing industry documents).

campaign, which quintupled Camel's share of the 14-17-year-old market from 2.4% to 13.3%., *id.* at 635, "if we thought its appeal was to anyone other than" adult smokers. *Id.* at 689.

In actuality, knowing that over 80% of smokers start smoking before they turn eighteen, *id.* at 562, the industry predicated its business model on the need to attract "replacement smokers" for the more than 480,000 who die every year of smoking-caused diseases. *Id.* at 561-62. In the words of the president of Liggett's corporate parent, "[I]f the tobacco companies really stopped marketing to children, the tobacco companies would be out of business in 25 to 30 years because they will not have enough customers." *Id.* at 562.

#### **4. The "vaping" industry is not distinct from the tobacco industry.**

The efforts of Nicopure and its *amici* to distance e-cigarette manufacturers from this sordid history are unpersuasive. "Vaping" no more represents an industry distinct from the cigarette industry than do pipe tobacco, chewing tobacco, or for that matter, "light" cigarettes.

Two thirds of the U.S. e-cigarette market by dollars for the year ending January 27, 2018 was controlled by four of the world's largest cigarette companies.<sup>19</sup> More than 57% was controlled by companies that are successors to

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<sup>19</sup> See Wells Fargo Securities Equity Research, *Nielsen: Tobacco 'All Channel' Data 1/27*, at 8 Ex.10 (Feb. 6, 2018) (BAT, Altria, Imperial Tobacco, Japan Tobacco), <https://11bxcx1bcuig1rfxaq3rd6w9-wpengine.netdna-ssl.com/wp->

the racketeering defendants in *Phillip Morris*, 449 F.Supp.2d 1, and/or to parties to the Tobacco Master Settlement Agreement (MSA).<sup>20</sup>

Juul Labs, responsible for most other U.S. e-cigarette sales,<sup>21</sup> is also closely tied to the cigarette industry. Juul was spun off in 2017 from Pax Labs,<sup>22</sup> formerly Ploom, Inc.<sup>23</sup> From 2011 to 2015, Ploom partnered with Japan Tobacco International [JTI], one of the world's largest sellers of cigarettes, to market forerunner products to Juul.<sup>24</sup> Juul's co-founder said afterward, "We remain close

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content/uploads/2018/02/Nielsen-Tobacco-All-Channel-Report-Period-Ending-1.27.18.pdf.

<sup>20</sup> *Id.* BAT (29.8% e-cigarette market share) is successor to RJR, B&W, and Lorillard, all of which were racketeering defendants and MSA parties. Altria (14.9%) is successor to PM, racketeering defendant and MSA party. Imperial Tobacco (12.7%) is successor to MSA party Commonwealth Brands. The *Philip Morris* court found that Imperial, though not a defendant, participated in joint efforts to conceal cigarettes' health harms and addictiveness. 499 F. Supp. 2d at 42-43, 130-32.

<sup>21</sup> Wells Fargo, *supra* n.19 (26.5%).

<sup>22</sup> Ari Levy, *E-Cigarette Maker Juul is Raising \$150 Million After Spinning Out of Vaping Company*, CNBC (Dec. 19, 2017), [https://www.cnbc.com/2017/12/19/juul-labs-raising-150-million-in-debt-after-spinning-out-of-pax.html?utm\\_source=newsletter&utm\\_medium=email&utm\\_campaign=newsletter\\_axiosprorata&stream=top-stories](https://www.cnbc.com/2017/12/19/juul-labs-raising-150-million-in-debt-after-spinning-out-of-pax.html?utm_source=newsletter&utm_medium=email&utm_campaign=newsletter_axiosprorata&stream=top-stories).

<sup>23</sup> Will Yakowicz, *This Silicon Valley Company Just Raised \$47 Million to Smoke Cigarette Makers*, INC. (June 10, 2015), <https://www.inc.com/will-yakowicz/pax-labs-vaporizer-company-raises-47-million.html>.

<sup>24</sup> *Id.*; JT International, *Innovative Partnership for Ploom and Japan Tobacco International* (Dec. 8, 2011), <https://www.prnewswire.com/news-releases/innovative-partnership-for-ploom-and-japan-tobacco-international-135233543.html>.

to JTI,” and holds open the possibility of future partnerships with Big Tobacco.<sup>25</sup>

Juul and Big Tobacco together account for 93% of U.S. e-cigarette sales.<sup>26</sup>

Other independent e-cigarette companies are prominently staffed by Big Tobacco veterans. The executive vice-president of *amicus* NJOY, the next largest independent e-cigarette seller,<sup>27</sup> worked for PM for 24 years,<sup>28</sup> where he was involved in market research on high school smokers, *Philip Morris*, 449 F. Supp. 2d at 587; NJOY’s senior vice-president from 2010 to 2016 was a sales and marketing executive for Altria for sixteen years;<sup>29</sup> and its “master flavorist” spent his career in the tobacco industry.<sup>30</sup> Nicopure employs a general counsel who previously held senior positions at PM and Lorillard,<sup>31</sup> and a vice-president who worked for PM for 26 years.<sup>32</sup>

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<sup>25</sup> Freddie Dawson, *Pax Labs Looking at International Expansion*, FORBES (Feb. 31, 2015), <https://www.forbes.com/sites/freddiedawson/2015/07/31/pax-labs-looking-at-international-expansion>.

<sup>26</sup> Wells Fargo, *supra* n. 19.

<sup>27</sup> *Id.*

<sup>28</sup> Matt Richtel, *The E-Cigarette Industry, Waiting to Exhale*, N.Y. TIMES (Oct. 26, 2013) (Roy Anise), <https://www.nytimes.com/2013/10/27/business/the-e-cigarette-industry-waiting-to-exhale.html>.

<sup>29</sup> LinkedIn, *Vito Maurici*, <https://www.linkedin.com/in/vitomaurici>.

<sup>30</sup> Benjamin Wallace, *Smoke Without Fire*, NEW YORK (April 28, 2013), <http://nymag.com/news/features/e-cigarettes-2013-5/index2.html>.

<sup>31</sup> Nicopure Labs, *Nicopure Family* (Patricia Kovacevic), <https://www.nicopure.com/about-us/nicopure-family>.

<sup>32</sup> Jerome Harlay, *Nicopure’s New Vice President George Farah*, VAPING POST (Oct. 19, 2016), <https://www.vapingpost.com/2016/10/19/nicopures-new-vice-president-george-farah>.

Finally, the “vaping industry” essentially sells the same product that the tobacco industry has always sold. As a 1991 internal RJR memo admitted, “We are basically in the nicotine business.” *Philip Morris*, 449 F. Supp. 2d at 323; *see also id.* at 208 (tobacco companies “recognized ... that cigarettes are [nicotine] delivery devices”). Similarly, “Juul is in the nicotine business.”<sup>33</sup> 99% of e-cigarette products sold in the U.S. contain nicotine;<sup>34</sup> a key aspect of the e-cigarette business model is working to enhance nicotine delivery so that it resembles the nicotine experience of conventional cigarettes.<sup>35</sup>

**5. E-cigarette marketing resembles marketing for other tobacco products.**

The Surgeon General recently concluded, “[M]any of the marketing techniques used by e-cigarette companies are similar to those used by the tobacco industry for conventional cigarettes.”<sup>36</sup> The industry is replicating tactics documented in the racketeering trial: misleading the public about hazards of their products and their efficacy in aiding smoking cessation; marketing to youth while denying doing so; generating industry-friendly research; and manipulating nicotine levels.

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<sup>33</sup> Levy, *supra* note 22.

<sup>34</sup> Marynak, *supra* note 6.

<sup>35</sup> Richtel, *supra* note 28.

<sup>36</sup> Surgeon General, *supra* note 2, at 172.

Unfounded health claims. Public health researchers have found, “E-cigarette websites frequently contain unfounded health claims.”<sup>37</sup> A 2014 study found health-related claims on 77% of e-cigarette manufacturer websites, including modified risk claims on 70.5%.<sup>38</sup>

Some of those claims are demonstrably false – for example, that smokers won’t inhale any of the harmful constituents of cigarettes,<sup>39</sup> or that second-hand emissions contain only harmless water vapor.<sup>40</sup> Products claiming to be nicotine-free often do contain nicotine, some at high levels.<sup>41</sup>

Even when not literally false, such health claims tend to mislead.

Adolescents exposed to e-cigarette advertisements are less likely to believe that e-

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<sup>37</sup> Rachel Grana & Pamela Ling, “Smoking Revolution”: A Content Analysis of Electronic Cigarette Retail Websites, 46 AM. J. PREVENTIVE MED. 395, 401 (2014).

<sup>38</sup> Elizabeth Klein *et al.*, *Online E-Cigarette Marketing Claims: A Systematic Content and Legal Analysis*, 2 TOBACCO REGULATORY SCI. 252, 252, 256 (2016).

<sup>39</sup> See Surgeon General, *supra* note 2, at 118, 124 (e-cigarette aerosols contain known carcinogens found in cigarettes); *id.* at 99-107 (discussing hazards of nicotine inhaled from e-cigarettes).

<sup>40</sup> Rachel Grana *et al.*, *E-Cigarettes: A Scientific Review*, 129 CIRCULATION 1972, 1983 (2014) (“it is clear that e-cigarette emissions are not merely ‘harmless water vapor,’ as is frequently claimed”); Klein *et al.*, *supra* note 38, at 259 (numerous studies have found toxins in emissions).

<sup>41</sup> Michael Trehy *et al.*, *Analysis of Electronic Cigarette Cartridges, Refill Solutions, and Smoke for Nicotine and Nicotine Related Impurities*, 34 J. LIQUID CHROMATOGRAPHY & RELATED TECHNOLOGIES 1442, 1453, 1457 (2011).

cigarettes are harmful at all.<sup>42</sup> Young adults exposed to advertising are significantly more likely to believe that e-cigarettes never contain nicotine.<sup>43</sup>

Notwithstanding e-cigarette companies' public professions, a Juul R&D engineer told a reporter – in an apparently off-script moment: “Anything about health is not on our mind.”<sup>44</sup>

Misleading smoking cessation claims. 64% of surveyed e-cigarette websites made claims related to cessation.<sup>45</sup> In reality, evidence “points to ... no proven cessation benefits, and rapidly increasing youth initiation with e-cigarettes.”<sup>46</sup> A meta-analysis of 38 well-designed studies concluded that e-cigarette use is associated with a significantly *lower* rate of smokers quitting.<sup>47</sup>

Like other cigarette alternatives purported to aid cessation, e-cigarettes are actually marketed to maintain nicotine addiction in smoke-free spaces, as proclaimed by such e-cigarette company names as “Smoke Anywhere”<sup>48</sup> and

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<sup>42</sup> Surgeon General, *supra* note 2, at 171.

<sup>43</sup> *Id.*

<sup>44</sup> Quoted in Nitasha Tiku, *Startup Behind the Lambo of Vaporizers Just Launched an Intelligent E-cigarette*, THE VERGE (Apr. 21, 2015), <https://www.theverge.com/2015/4/21/8458629/pax-labs-e-cigarette-juul>.

<sup>45</sup> Grana & Ling, *supra* note 37, at 395.

<sup>46</sup> Grana *et al.*, *supra* note 40, at 1983.

<sup>47</sup> Sara Kalkhoran & Stanton Glantz, *E-Cigarettes and Smoking Cessation in Real-World and Clinical Settings: A Systematic Review and Meta-Analysis*, 4(2) THE LANCET 116 (2016).

<sup>48</sup> <http://www.smokeanywhere.com>.



“NEwhere,”<sup>49</sup> and advertising copy such as “Take back your freedom to smoke anywhere.”<sup>50</sup> 71% of e-cigarette websites analyzed in one study explicitly promoted e-cigarettes as a way of circumventing no-smoking policies.<sup>51</sup> Users themselves commonly cite smoke-free laws as a reason for using e-cigarettes, which “may reinforce dual use patterns and delay or deter quitting.”<sup>52</sup>

Juul’s R&D engineer admitted, “We don’t think a lot about addiction here because we’re not trying to design a cessation product at all.”<sup>53</sup>

Industry-funded science. The e-cigarette industry is continuing the tobacco industry’s tactic of funding industry-friendly research. A review of studies of e-cigarette health effects found author conflicts of interest in 34%,<sup>54</sup> and concluded that “[c]onflict of interest seems to influence the conclusions of these papers.”<sup>55</sup> British American Tobacco [BAT]-sponsored research, for example, found low rates of toxic emissions for its own e-cigarettes,<sup>56</sup> and that its aerosol, unlike

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<sup>49</sup> <https://www.newwhere.com>.

<sup>50</sup> *Id.* at 162 Fig. J.

<sup>51</sup> Grana & Ling, *supra* note 37, at 395.

<sup>52</sup> Grana *et al.*, *supra* note 40, at 1983.

<sup>53</sup> Quoted in Tiku, *supra* note 44.

<sup>54</sup> Charlotta Pisinger & Martin Dossing, *A Systematic Review of Health Effects of Electronic Cigarettes*, 69 PREVENTIVE MED. 248, 250 (2014).

<sup>55</sup> *Id.* at 255.

<sup>56</sup> Jennifer Margham *et al.*, *Chemical Composition of Aerosol from an E-Cigarette*, 29 CHEM. RES. TOXICOL. 1662 (2016) (BAT R&D).

cigarette smoke, does not significantly suppress immune defense genes.<sup>57</sup> Both conclusions diverge from those of independently funded studies.<sup>58</sup>

The Public Health England conclusion that “vapor products are 95% less harmful than cigarettes,” cited in *Nicopure Br.* at 6, was based on a single academic study<sup>59</sup> whose authors included a consultant to an e-cigarette distributor, a consultant to “manufacturers of smoking cessation products,” and a consultant to “most companies with an interest in tobacco dependence treatments.”<sup>60</sup>

Manipulating nicotine levels. As with conventional cigarettes, tobacco companies’ product development prominently includes manipulation of nicotine levels to “satisfy a smoker’s cravings”: they have “rushed to increase nicotine levels in their vapor devices” to “pack the ... punch” of smoking.<sup>61</sup> But, public

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<sup>57</sup> Linsey Haswell, *et al.*, *Reduced Biological Effect of E-Cigarette Aerosol Compared to Cigarette Smoke Evaluated in Vitro Using Normalized Nicotine Dose and RNA-Seq-Based Toxicogenomics*, 7 NATURE 888 (2017) (BAT R&D)

<sup>58</sup> *E.g.* Mohamad Sleiman *et al.*, *Emissions from Electronic Cigarettes: Key Parameters Affecting the Release of Harmful Chemicals*, 50 ENVIRON. SCI. TECHNOL. 9644 (2016); Elizabeth Martin *et al.*, *E-Cigarette Use Results in Suppression of Immune and Inflammatory-Response Genes in Nasal Epithelial Cells Similar to Cigarette Smoke*, 311 AM. J. PHYSIOL. LUNG CELL MOL. PHYSIOL. L135 (2016).

<sup>59</sup> Editorial, *E-cigarettes: Public Health England’s Evidence-Based Confusion*, 386 THE LANCET 829 (2015) (95% figure was derived from “a paper by David Nutt and colleagues published in *European Addiction Research*”).

<sup>60</sup> David Nutt *et al.*, *Estimating the Harms of Nicotine-Containing Products Using the MDCA Approach*, 20 EUR. ADDICT. RES. 218, 224 (2014).

<sup>61</sup> Barry Meier, “Race to Deliver Nicotine’s Punch, With Less Risk”, N.Y. TIMES (Dec. 24, 2014), <https://www.nytimes.com/2014/12/25/business/race-to-deliver-nicotines-punch-with-less-risk.html>.

health professionals point out, that means nicotine levels that create and sustain addiction.<sup>62</sup>

Marketing to Youth. Although industry executives may claim, “We do not want teens using JUUL,”<sup>63</sup> there is ample evidence that e-cigarettes are deliberately marketed to minors. One study found four times as many e-cigarette advertisements in high youth readership magazines as in high adult readership magazines.<sup>64</sup> Much like conventional cigarettes before the practice was banned, e-cigarette brands sponsor spectator events with significant youth audiences, often distributing free samples.<sup>65</sup> Some e-cigarette ads even feature “back to school” sales.<sup>66</sup> Regulators recently admonished thirteen companies selling e-liquids in packaging designed to resemble snacks and juice boxes popular with children.<sup>67</sup>

See sample illustration, Appendix B.

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<sup>62</sup> *Id.*

<sup>63</sup> Caroline Kee, *Everything You Need to Know About the JUUL, Including the Health Effects*, BUZZFEED (Feb. 5, 2018), <https://www.buzzfeed.com/carolinekee/juul-ecigarette-vape-health-effects?>

<sup>64</sup> Surgeon General, *supra* note 2, at 159 (citing U.S. Congress study).

<sup>65</sup> *Id.* at 159-63.

<sup>66</sup> Kate Keller, *Ads for E-Cigarettes Today Hearken Back to the Banned Tricks of Big Tobacco*, SMITHSONIAN.COM (April 11, 2018), <https://www.smithsonianmag.com/history/electronic-cigarettes-millennial-appeal-ushers-next-generation-nicotine-addicts-180968747>.

<sup>67</sup> Lesley Fair, *FTC-FDA Warning Letters Ask: Is It a Kids’ Treat – Or a Tobacco Product?* (May 1, 2018), <https://www.ftc.gov/news-events/blogs/business-blog/2018/05/ftc-fda-warning-letters-ask-it-kids-treat-or-tobacco-product?>

After NJOY's CEO criticized other e-cigarette manufacturers for using flavors "to attract children," declining market share led NJOY to introduce such flavors as "Butter Crumble" and "Black and Blue Berry." The same CEO then cited research showing that flavors "provide no additional appeal to youth." The research was funded by NJOY.<sup>68</sup> In an independent survey, by contrast, 31% of middle and high school e-cigarette users cited flavors as a reason for use.<sup>69</sup>

Deceptive marketing is especially problematic when directed at youth – e-cigarette use has one of the lowest levels of perceived risk by adolescents for regular use of any drug, including alcohol.<sup>70</sup> More than a third of surveyed middle and high school students who had used e-cigarettes in the past 30 days believed that using e-cigarettes some days but not every day causes *no* harm.<sup>71</sup> In a survey of 15-24-year-olds, only 37% of those who had used Juul products in the past month realized that they always contain nicotine.<sup>72</sup>

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<sup>68</sup> Matt Richtel, *E-Cigarette Makers Are in an Arms Race for Exotic Vapor Flavors*, N.Y. TIMES (July 15, 2014), <https://www.nytimes.com/2014/07/16/business/e-cigarette-makers-are-in-an-arms-race-for-exotic-vapor-flavors.html>.

<sup>69</sup> James Tsai *et al.*, *Reasons for Electronic Cigarette Use Among Middle and High School Students – Nat'l Youth Tobacco Survey, 2016*. 67 MORBIDITY & MORTALITY WKLY REP. 196, 196 (2018)

<sup>70</sup> Lloyd D. Johnston *et al.*, *Monitoring the Future: National Survey Results on Drug Use 1975-2017*, at 43 (2018), <http://www.monitoringthefuture.org/pubs/monographs/mtf-overview2017.pdf>.

<sup>71</sup> Surgeon General, *supra* note 2, at 73 T2.12a.

<sup>72</sup> Jeffrey Willet, *et al.*, *Recognition, Use and Perceptions of JUUL Among Youth and Young Adults*, TOBACCO CONTROL (2018),

**6. The history of tobacco industry deception justifies regulation.**

The foregoing history makes clear why limiting regulation of health claims to such cigarette descriptors as “light” would be inadequate. From claims that smoking has health *benefits*, see *Philip Morris*, 449 F. Supp. 2d at 431-32, to denials of the hazards of smoking, to an endless progression of purportedly reduced-risk products, industry deception is a moving target.

Government “may choose to regulate ... advertising in one industry but not in others, because the risk of fraud ... is in its view greater there.” *Sorrell v. IMS Health Inc.*, 564 U.S. 552, 579 (2011). The past 65 years – up to the present day – provide ample evidence that the risk of fraudulent reduced-harm claims is especially high in the tobacco industry. “Where the record indicates that a particular form or method of advertising has in fact been deceptive ... or when experience has proved that in fact such advertising is subject to abuse, [government] may impose appropriate restrictions.” *In re R.M.J.*, 455 U.S. 191, 202-03 (1982).

Even when a particular party’s advertising is “not in fact misleading,” it may still be prohibited if it exemplifies a trend “which enhances the opportunity for misleading practices.” *Friedman v. Rogers*, 440 U.S. 1, 15 (1979); see also

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<http://tobaccocontrol.bmj.com/content/early/2018/04/07/tobaccocontrol-2018-054273>.

*Milavetz, Gallop & Milavetz, P.A. v. United States*, 559 U.S. 229, 251 (2010)

(“Evidence ... demonstrating a [misleading] pattern of advertisements” is sufficient to establish the likelihood of deception).

Given the history of tobacco marketing, and the frequency with which reduced-risk claims are interpreted – especially by youth – to mean little or no risk, it is not far-fetched to characterize the entire category of modified harm claims for tobacco products as “more likely to deceive the public than to inform it.” *Cent. Hudson*, 447 U.S. at 563. Accordingly, such claims could probably be banned outright. *Id.* Here they are subjected only to “a system of previewing advertising,” a “more limited regulation of ... commercial expression.” *Id.* at 571 & n.13.

Alternatively, if reduced-risk claims are judged to be only “potentially misleading,” *In re R.M.J.*, 455 U.S. at 203, then the ceaselessly shifting nature of tobacco industry deception makes clear, at the fourth prong of *Central Hudson* review, that the government interest in protecting the public from deception with deadly consequences could *not* be “served as well by a ... restriction” on the speech of the tobacco industry that is “more limited.” *Cent. Hudson*, 447 U.S. at 564.

## **II. DISTRIBUTING FREE SAMPLES OF AN ADDICTIVE, TOXIC PRODUCT IS NOT EXPRESSIVE CONDUCT PROTECTED BY THE FIRST AMENDMENT.**

Providing free samples is not protected expressive conduct. *See City of Dallas v. Stanglin*, 490 U.S. 19, 25 (1989) (“It is possible to find some kernel of expression in almost every activity a person undertakes [but]... such a kernel is not sufficient to bring the activity within the protection of the First Amendment.”) In order “to avoid creating a rule that all conduct is inherently expressive,” the Supreme Court has established that “the person desiring to engage in assertedly expressive conduct [must] demonstrate that the First Amendment even applies.” *Clark v. Cmty. for Creative Non-Violence*, 468 U.S. 288, 293 n.5 (1984). That is a burden Nicopure cannot meet.

### **A. Distributing Samples Does Not Convey a Particularized, Understood Message.**

The First Amendment is implicated only “when an intent to convey a particularized message [is] present” and “the likelihood [is] great that the message would be understood by those who viewed it.” *United States Telecom Ass’n v. F.C.C.*, 825 F.3d 674, 741 (D.C. Cir. 2016) (quoting *Spence v. Washington*, 418 U.S. 405, 410-11 (1974)). The best that Nicopure can offer is that “[i]nformation regarding the product’s quality and characteristics will ... be conveyed.” Nicopure Br., at 38; *see also id.* at 37 (sampling “helps customers find the flavors that work

best for them” and “get a feel for personal vaporizers”). None of this comes close to a particularized message.

If a customer learns something from sampling an e-cigarette, it is through direct experience, not communication. Indeed, the experience that is supposed to be informative is singularly ineffable: “This product tastes like *this*.”

Even that slender learning has nothing to do with distributing free samples. The same learning would be gained by using an e-cigarette that was bought, stolen or borrowed. “[O]bjects themselves do not actually communicate – people do.” *Mastrovincenzo v. City of New York*, 435 F.3d 78, 91 (2d Cir. 2006); *see also Nordyke v. King*, 319 F.3d 1185, 1189 (9th Cir. 2003) (“The question in *Johnson* was whether flag burning was speech, not whether a flag was speech.... Someone has to do something with the symbol before it can be speech”).

If simply enabling someone to experience something constituted expression, no regulation of commerce would be immune from First Amendment review. Any regulation of whether, where, or when a given product may be sold impinges on consumers’ ability to experience that product; regulation of the travel industry, *see, e.g.*, Cal. Bus. & Prof. Code §§ 17550.1-17550.30, likewise impinges on consumers’ ability to acquire new information through direct experience.

Nor is it evidence of the “communitive [*sic*] aspect of sampling” that consumers’ behavior may be influenced by trying e-cigarettes. *Nicopure Br.* at 39-



40. The effectiveness of a marketing tactic is not evidence that it is expressive. Prices – or for that matter, toothpaste flavoring – also influence consumer behavior, but it does not follow that minimum price laws – or wintergreen – require First Amendment review.

**B. Distributing Samples Does Not Fall Within the Narrow Categories of Conduct That Have Been Found Expressive.**

The Supreme Court has “rejected the view that an apparently limitless variety of conduct can be labeled ‘speech’ whenever the person engaging in the conduct intends thereby to express an idea.” *Johnson*, 491 U.S. at 404. Still less is conduct protected when, as with e-cigarette samples, *no* idea is expressed. Rather, the First Amendment applies “only to conduct that is inherently expressive,” *Rumsfeld v. Forum for Acad. & Inst. Rights, Inc.* [*FAIR*], 547 U.S. 47, 66 (2006), or to “conduct with a *significant* expressive element.” *Arcara v. Cloud Books, Inc.*, 478 U.S. 697, 706 (1986) (emphasis added).

Accordingly, courts have rejected claims of protected expressive conduct advanced on behalf of a campus ban on military recruiting, *FAIR*, 547 U.S. at 66; nudity, *City of Erie v. Pap’s A.M.*, 529 U.S. 277, 289 (2000); recreational dancing, *Stanglin*, 490 U.S. at 25; sexual activity, *Arcara*, 478 U.S. at 705; commercial travel, *Walsh v. Brady*, 927 F.2d 1229, 1237 (D.C. Cir. 1991); serving alcohol, *Talk of the Town v. Las Vegas*, 343 F.3d 1063, 1069-70 (9th Cir. 2003); and gun

possession, *Nordyke*, 319 F.3d at 1190, to name just a few. Distributing e-cigarette samples is no more expressive.

When courts have found that conduct *is* expressive, it has been when “[t]he expressive, overtly political nature of th[e] conduct was both intentional and overwhelmingly apparent.” *Johnson*, 491 U.S. at 406.

Ordinary commerce represents a paradigmatic sphere of *non-expressive* conduct. “[R]estrictions on protected expression are distinct from restrictions on economic activity.” *IMS Health*, 564 U.S. at 567. “[S]elling items that have a predominantly utilitarian, not an expressive, purpose” is not protected expression. *Hunt v. City of Los Angeles*, 638 F.3d 703, 716 (9th Cir. 2011). If selling e-cigarettes is not protected expression, then neither is the same act minus payment.

Indeed, providing samples that may addict the recipient smacks even more of conduct than sampling in general. Creating addiction is conduct, not expression.

Nicopure’s principal authority for the proposition that offering free samples implicates expressive conduct is unpersuasive. The court reasoned in *Discount Tobacco* that a prohibition on distributing cigarette samples targeted “the ‘communicative impact’” of cigarette sampling, because it did not apply to all consumer products. 674 F.3d at 539. But if this analysis were correct, it would subject to First Amendment review *any* regulation of commerce that does not apply to all products, including minimum price laws, targeted taxes, and

restrictions on where or when alcohol may be sold. That is not the law. First Amendment principles of speaker neutrality “cannot be construed to divest the states of their ability to devise specific rules for businesses in different fields.” *Wine & Spirits Retailers, Inc. v. Rhode Island*, 481 F.3d 1, 7 (1st Cir. 2007); *see also Nat’l Lime Ass’n v. EPA.*, 627 F.2d 416, 448 (D.C. Cir. 1980) (“[t]hat different industries may be subject to different standards ... is clear”).

There is nothing so “inherently expressive,” *FAIR*, 547 U.S. at 66, about providing free e-cigarette samples as to make it an exception to the rule that “[m]ost human conduct, especially in the commercial realm, is not expressive.” *State v. Chepilko*, 965 A.2d 190, 198 (N.J. Super. App. Div. 2009).

**C. Even If Distributing E-Cigarette Samples Had an Expressive Component, a Prohibition Would Not Offend the First Amendment.**

Even if the sampling ban warranted First Amendment review, it would not be subject to *Central Hudson* review, under which Nicopure erroneously analyzes it.<sup>73</sup> That standard applies to restrictions on commercial *speech*. *O’Brien* provides the standard for reviewing restrictions on expressive conduct. *See, e.g., Lorillard Tobacco Co. v. Reilly*, 533 U.S. 525, 569 (2001) (applying *O’Brien* test *arguendo* to regulations of tobacco displays and finding no First Amendment violation even if the regulations did implicate expression).

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<sup>73</sup> Admittedly, the Sixth Circuit made the same mistake in *Discount Tobacco*, 674 F.3d at 539; the error was ultimately harmless – the court upheld the ban. *Id.*

Review under *O'Brien* is relatively deferential. *See Johnson*, 491 U.S. at 407 (“*O'Brien*’s relatively lenient standard”); *United Video, Inc. v. F.C.C.*, 890 F.2d 1173, 1190 (D.C. Cir. 1989) (“the relaxed first amendment scrutiny of *United States v. O’Brien*”).<sup>74</sup>

Under this standard, ... statutes need not be narrowly tailored to the government’s interests or be the least restrictive means of achieving those interests. [S]tatutes need only satisfy the less stringent standard of promoting an important or substantial government interest in a manner that would be achieved less effectively absent the regulation.

*FAIR*, 547 U.S. at 67.

Here, the government has a “substantial, and even compelling” interest, *Lorillard*, 533 U.S. at 564, in preventing youth gaining access to a highly addictive product. *See Discount Tobacco*, 674 F.3d at 541 (citing “extensive documentation that free samples ... are an ‘easily accessible source of [tobacco] products to young people”). The restriction is directed not at suppressing expression but at preventing youth use of products that may cause life-long addiction. Any incidental restriction on e-cigarette companies’ expression “embodies a narrow fit between the harm articulated and the restriction employed,” *id.* at 541 – the only

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<sup>74</sup> Arguably, the standard for reviewing restrictions on expressive conduct should be even more lenient in commercial contexts (if expressive commercial conduct is not an oxymoron), in keeping with the “lesser protection” the Constitution accords commercial speech, *Cent. Hudson*, 447 U.S. at 562-63, reflected in less stringent review in commercial contexts for speech restrictions, *Cent. Hudson*, 447 U.S. 557, and required disclosures, *Zauderer v. Office of Disciplinary Counsel*, 471 U.S. 626 (1985).

way to prevent youth access to free samples is to prevent free sampling. Finally, the ban “leaves open ample channels of communication.” *Lorillard*, 533 U.S. at 569. E-cigarette companies have proven themselves adept at using multifarious media to market their products.

The prohibition on free samples should not invoke First Amendment review at all, but if it does, the restriction readily survives.

### CONCLUSION

Because neither pre-approval of health claims for hazardous products nor provision of free samples offends the First Amendment, the decision of the district court upholding those provisions of the Tobacco Control Act, as deemed to apply to e-cigarettes, should be affirmed.

DATED: May 9, 2018

Respectfully submitted,

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## CERTIFICATE OF COMPLIANCE

I hereby certify that, according to the word processing program used to prepare it, this brief, excluding the parts exempted by Fed. R. App. P. 32(f), contains 6490 words.

This document complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the type-style requirements of Fed. R. App. P. 32(a)(6). It has been prepared in a 14-point proportionally spaced typeface (Times New Roman), using Microsoft Word for Mac v. 15.39.

DATED: May 9, 2018

/s/ Thomas Bennigson  
Thomas Bennigson

**CERTIFICATE OF SERVICE**

I hereby certify that on May 9, 2018, I caused to be filed electronically via the Court's CM/ECF System, and thereby served on all counsel, a true and correct copy of this Brief of *Amicus Curiae* Public Health Law Center in support of Defendants-Appellees.

/s/ Thomas Bennigson  
Thomas Bennigson

## APPENDIX A

### **Tobacco Control Legal Consortium**

The Tobacco Control Legal Consortium is a program of the Public Health Law Center, Inc., located at Mitchell Hamline School of Law in St. Paul, Minnesota.

#### Affiliated Legal Centers

ChangeLab Solutions  
Oakland, California

Legal Resource Center for Public Health Policy  
University of Maryland School of Law  
Baltimore, Maryland

Public Health Advocacy Institute  
Northeastern University School of Law  
Boston, Massachusetts

Public Health and Tobacco Policy Center  
Boston, MA

Smoke-Free Environments Law Project  
Center for Social Gerontology  
Ann Arbor, Michigan

Tobacco Control Policy and Legal Resource Center  
New Jersey GASP  
Summit, New Jersey



## APPENDIX B

### E-Liquid Packaging



The product on the left is a nicotine-laced liquid for e-cigarettes that can be fatal to kids who ingest as little as a teaspoon. The e-liquid label calls the product a “JUICE BOX,” mimics shelf-stable beverage packaging, and even has an image of one of those little sippy straws on the side of the box. Open it up and it’s apple-scented.<sup>1</sup>

<sup>1</sup> Image and text from Lesley Fair, *FTC-FDA Warning Letters Ask: Is It a Kids’ Treat – Or a Tobacco Product?* (May 1, 2018), <https://www.ftc.gov/news-events/blogs/business-blog/2018/05/ftc-fda-warning-letters-ask-it-kids-treat-or-tobacco-product?>