ORAL ARGUMENT NOT YET SCHEDULED

No. 17-5196

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

NICOPURE LABS, LLC, RIGHT TO BE SMOKE FREE COALITION, *et al.*,

Plaintiffs-Appellants,

v.

FOOD AND DRUG ADMINISTRATION, *et al.*,

Defendants-Appellees.

Appeal from the United States District Court for the
District of Columbia, No. 1:16-cv-00878

BRIEF OF *AMICI CURIAE* CLIVE BATES AND ADDITIONAL PUBLIC HEALTH/TOBACCO POLICY AUTHORITIES IN SUPPORT OF PLAINTIFFS-APPELLANTS AND REVERSAL OF THE DISTRICT COURT DECISION

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CERTIFICATE AS TO PARTIES, RULINGS, AND RELATED CASES

A. Parties and Amici

Pursuant to Circuit Rule 28(a)(1)(A), except for the following, all parties, intervenors, and *amici curiae* appearing before the District Court and in this Court are listed in the Brief for Plaintiffs-Appellants:

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B. Ruling Under Review

U.S. District Court for the District of Columbia, *Nicopure Labs v. FDA*, Nos. 16-0878, 16-1210 (consolidated) (ABJ), Order and Memorandum denying Petitioners' Motions for Summary Judgment and Granting Respondents' Cross Motion for Summary Judgment, 266 F. Supp. 3d 360 (July 21, 2017).

C. Related Cases

There are no related cases.

/s/ Christopher G. Browning, Jr.
CHRISTOPHER G. BROWNING, JR.

CERTIFICATE REGARDING SEPARATE BRIEFING

Pursuant to Circuit Rule 29(d), counsel for *Amici Curiae* Clive Bates and Additional Public Health/Tobacco Policy Authorities (the "*Amici*") state that separate briefing is appropriate. The *Amici* are scholars, researchers, and policy experts who work in the areas of public health, science, and regulation and who have focused on the subject of tobacco harm reduction. As such, their views reflect an expertise and background unique from that of the other *amici curiae* supporting Plaintiffs-Appellants, and their briefing is catered to this expertise. Furthermore, based on communications with other counsel for other *amici curiae*, counsel understands that this brief focuses on points that will not be developed in the briefs of the other *amici curiae* supporting Plaintiffs-Appellants. Accordingly, it would not be practicable for the *Amici* to join such other *amici curiae* in a single brief.

/s/ Christopher G. Browning, Jr.
CHRISTOPHER G. BROWNING, JR.

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page(s)

Cases

Statutes

Regulations

Other Authorities

GLOSSARY OF ABBREVIATIONS

ENDS	electronic nicotine delivery systems
FDA	Food and Drug Administration
MRTP	modified risk tobacco products
National Academies	National Academies of Science, Engineering, and Medicine
RCP	Royal College of Physicians
vaping	the use of e-cigarettes

STATUTES AND REGULATIONS

All applicable statutes and regulations are contained in the Brief for Plaintiffs-Appellants.

STATEMENT OF IDENTITY, INTEREST IN THE CASE, AND SOURCE OF AUTHORITY

The *Amici* are Clive Bates – the lead *amicus*, Director of *The Counterfactual*, and former Director of the United Kingdom's primary anti-smoking non-profit: Action on Smoking in Health – as well as Philip Alcabes (Professor of Public Health at Adelphi University's College of Nursing and Public Health); Scott Ballin (health policy consultant; advisor to the Morven Dialogues on Tobacco, Nicotine, and Alternative Products Harm Reduction at the University of Virginia; and former Vice President for Public Policy and Legislative Counsel at the American Heart Association); Konstantinos Farsalinos, M.D. (Research Scientist at the University of Patras' Onassis Cardiac Surgery Center); William T. Godshall, MPH (Founder and Executive Director of Smokefree Pennsylvania); Jacques Le Houezec (consultant in public health and Président of SOVAPE); Bernd Mayer, Ph.D. (Professor and Chairman of the Department of Pharmacology at the University of Graz); Jeff Nesbit (Executive Director of Climate Nexus and former Associate Commissioner of the Food and Drug Administration); Joel L. Nitzkin, M.D., M.P.H., D.P.A. (Chief Executive Officer of JLN MD Associates and Senior Fellow for Tobacco Policy at the R Street Institute); Riccardo Polosa, M.D., Ph.D. (Full Professor of Internal Medicine at the University of Catania); Sally L. Satel, M.D. (Resident Scholar at the American Enterprise Institute); Michael B. Siegel, M.D. (Professor of Community Health Sciences at the Boston

University School of Public Health); Jeff Stier (Senior Fellow at the Consumer Choice Center); David Sweanor, J.D. (Adjunct Professor at the University of Ottowa's Centre for Health Law, Policy, and Ethics). *See also* Notice ¶¶ 1-2 & app. 1 [Doc. No. 1718070].

The primary interest of the *Amici* is in public health, science, and regulation, with a focus on tobacco harm reduction – the replacement of high-risk nicotine products like cigarettes with low-risk products like e-cigarettes. The *Amici* are concerned that scientific judgments and regulatory practices adopted in the United States will affect the health of American citizens and, further, will influence and result in *de facto* norms internationally.

All parties and proposed intervenors have consented to the filing of this *amicus* brief. *See* Fed. R. App. P. 29(a)(2).

STATEMENT OF AUTHORSHIP AND FINANCIAL CONTRIBUTIONS

No counsel for a party authored this brief in whole or in part, and no person (other than the Amici or their counsel) contributed money that was intended to fund the preparation or submission of this brief. *See* Fed. R. App. P. 29(a)(4)(E).

ARGUMENT

The *Amici* respectfully submit this brief in support of Plaintiffs-Appellants and their challenge to aspects of the rule Deeming Tobacco Products to Be Subject to the Federal Food, Drug, and Cosmetic Act, 81 Fed. Reg. 28,974 (May 10, 2016) [hereinafter Deeming Rule], promulgated by the Food and Drug Administration (the "FDA").

The *Amici* observe that the use of e-cigarettes ("vaping") is proving highly beneficial to the health of millions of American adults in that it offers a low-risk alternative to cigarette smoking. Smoking prevalence has been falling rapidly and has reached record lows since vaping products were introduced.

However, excessively burdensome or restrictive regulation of e-cigarettes will have unintended consequences, effectively protecting the cigarette market, increasing smoking, and causing harm to health. The Royal College of Physicians (the "RCP") expresses this concern as follows:

> A risk-averse, precautionary approach to e-cigarette regulation can be proposed as a means of minimising the risk of avoidable harm, e.g. exposure to toxins in e-cigarette vapour, renormalisation, gateway progression to smoking, or other real or potential risks.
>
> However, if this approach also makes e-cigarettes less easily accessible, less palatable or acceptable, more expensive, less consumer friendly or pharmacologically less effective, or inhibits

> innovation and development of new and improved products, then it causes harm by perpetuating smoking. Getting this balance right is difficult.

Tobacco Advisory Grp., Royal Coll. of Physicians, NICOTINE WITHOUT SMOKE: TOBACCO HARM REDUCTION 187 (2016) [hereinafter RCP REPORT], *available at* https://tinyurl.com/h5ypa7s (downloadable .pdf at bottom of page).[1]

The *Amici* agree that "*getting this balance right is difficult*," *id.* (emphasis added), but the FDA has failed to account for the likelihood or the risks of harmful unintended consequences arising from its own interventions in the e-cigarette market – what should be a central concern for public health. The costs are likely to overwhelm the claimed benefits, and the failure to account for them undermines the Deeming Rule, as this Court has said that it will not "tolerate rules based on arbitrary and capricious cost-benefit analyses." *See City of Portland v. EPA*, 507 F.3d 706, 713 (D.C. Cir. 2007); *accord Motor Vehicle Mfrs. Ass'n of U.S., Inc. v.*

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[1] The RCP is England's first college of physicians, tracing its origin to a 1518 charter of King Henry VIII and later confirmed by Parliament. An Acte Concerning Physicons, 1523, 14 & 15 Hen. 8, c. 5 (Eng.). Its mission is "to improve the care of individual patients, and the health of the population." RCP REPORT, *supra*, at xi.

"[P]reventing smoking has been a high priority for the RCP since the health harm of smoking was first recognised over 60 years ago." *Id.* "In the more than 50 years since [the RCP's] first report, *Smoking and health*, in 1962, [the RCP] ha[s] argued consistently for more and better policies and services to prevent people from taking up smoking, and help existing smokers to quit." *Id.*

State Farm Mut. Auto. Ins. Co., 463 U.S. 29, 43 (1983) (an agency rule is "arbitrary and capricious if the agency has . . . entirely failed to consider an important aspect of the problem"). Indeed, this Court has said that "[t]he failure of an agency to consider obvious alternatives has led uniformly to reversal." *Brookings Mun. Tel. Co. v. FCC*, 822 F.2d 1153, 1169 (D.C. Cir. 1987) (alteration in original) (quoting *Yakima Valley Cablevision, Inc. v. FCC*, 794 F.2d 737, 746 n.36 (D.C. Cir. 1986)).

For these reasons, as well as those stated by Plaintiffs-Appellants and other supporting *amici curiae*, the Court should rule in favor of Plaintiffs-Appellants.

I. Vaping Is Reducing Smoking in the United States and Providing an Overall Benefit to Public Health.

There is little dispute among experts that vaping is much less harmful than cigarette smoking, though there is some uncertainty about the precise magnitude of the reduction in risk. Authorities have summarized this understanding as follows:

> When nicotine is decoupled from the deadly toxins in inhaled smoke, it is substantially less harmful. Most of the harm is due to the inhalation of combustion products [about 70 human carcinogens and other toxins in particulate matter (sometimes called "tars") and carbon monoxide]. E-cigarette aerosol is very different. E-cigarettes do not contain any tobacco and do not produce carbon monoxide. . . . It is not that e-cigarettes are completely safe, or even the safest nicotine-containing product available, but that they are much safer than smoking.

David B. Abrams et al., *Harm Minimization and Tobacco Control: Reframing Societal Views of Nicotine Use to Rapidly Save Lives*, 39 Ann. Rev. Pub. Health

14.1, 14.5 (forthcoming April 2018) (citations omitted), *advance publication available at* https://tinyurl.com/y7eehbw8.

In January 2018, the National Academies of Science, Engineering, and Medicine (the "National Academies") confirmed this view in its report, *The Public Health Consequences of E-cigarettes*:

- While e-cigarettes are not without health risks, they are likely to be far less harmful than combustible tobacco cigarettes.
- E-cigarettes contain fewer numbers and lower levels of toxic substances than conventional cigarettes[.]
- The long-term health effects of e-cigarettes are not yet clear.

Health & Med. Div., Nat'l Acads. Sci., Eng'g & Med., Public Health Consequences of E-Cigarettes (Jan. 23, 2018), *available at* https://tinyurl.com/y8xluwsx (presentation summary, see slide 44).[2]

It is true that we will not know the long-term health effects of vaping for several decades, but we already have enough information to know beyond any reasonable doubt that they will be far less severe than for equivalent smoking. It would require a novel and implausible theory for dramatically reduced toxic exposures *not* to translate into much lower harm to health and risk of disease.

[2] For an online version of the full report, see Nat'l Acads. Sci., Eng'g & Med., PUBLIC HEALTH CONSEQUENCES OF E-CIGARETTES (2018), *available at* https://tinyurl.com/ya4w37kb (navigable under the "Contents" tab).

The 2016 RCP Report is a major assessment of the public health implication of electronic nicotine delivery systems ("ENDS"), such as e-cigarettes, and the strategy of tobacco harm reduction. In response to widespread public misperception of the relative risks of smoking and vaping, it provided the following carefully formulated statement with qualified quantification of risk:

> Although it is not possible to precisely quantify the long-term health risks associated with e-cigarettes, the available data suggest that they are unlikely to exceed 5% of those associated with smoked tobacco products, and may well be substantially lower than this figure.

RCP REPORT, *supra*, at 87.

However, the FDA has approached the regulation as if the health impacts of ENDS are not fully known, Deeming Tobacco Products to Be Subject to the Federal Food, Drug, and Cosmetic Act, 79 Fed. Reg. 23,142, 23,157 (Apr. 25, 2014) (proposed rule) ("*We do not currently have sufficient data about e-cigarettes to determine what effects they have on the public health.*" (emphasis added)), while citing a selection of studies suggesting presence of some hazardous agents, Deeming Rule, 81 Fed. Reg. at 29,029. The FDA has done this without quantifying the magnitude of any risks that would arise and without providing an overall synthesis based on what is known.

There is an abundance of evidence demonstrating that e-cigarettes decrease smoking and do not induce additional smoking. *See generally* Inquiry into the Use and Marketing of Electronic Cigarettes and Personal Vaporisers in Australia by the

H.R. Standing Committee on Health, Aged Care and Sport, Submission 336 (Oct. 19, 2017), *available at* https://tinyurl.com/yaelcydg (submission of Clive Bates and Colin Mendelsohn titled, "Do vapour products reduce or increase smoking?"). The U.S. data are consistent with low-risk vaping's displacement of high-risk cigarette smoking, with a resulting gain for public health. As a 2017 analysis concluded,

> [t]he substantial increase in e-cigarette use among US adult smokers was associated with a statistically significant increase in the smoking cessation rate at the population level. These findings need to be weighed carefully in regulatory policy making regarding e-cigarettes and in planning tobacco control interventions.

Shu-Hong Zhu et al., *E-cigarette Use and Associated Changes in Population Smoking Cessation: Evidence from US Current Population Surveys*, 358 BMJ 3262, at 1 (2017), *available at* https://tinyurl.com/y8m5ndnp (pincite corresponding pagination in hyperlink).

There are three further reasons to be confident that e-cigarettes' overall impact on the U.S. population is very likely to be positive, and great care should be taken not to diminish these benefits with excessively burdensome or restrictive regulation.

First, adult smoking prevalence has fallen rapidly as vaping has increased. The National Health Interview Survey shows that U.S. adult smoking prevalence has fallen rapidly from 18.9% in 2011 to a record low of 14.4% in the six months from January through June of 2017. Tainya C. Clarke et al., Nat'l Ctr.

Health Statistics, EARLY RELEASE OF SELECTED ESTIMATES BASED ON DATA FROM THE JANUARY–JUNE 2017 NATIONAL HEALTH INTERVIEW SURVEY 55 (2017), *available at* https://tinyurl.com/y9544c7e.

Second, adolescent smoking has also been falling rapidly. The Center for Disease Control's National Youth Tobacco Survey shows that between 2011 and 2016, current use of cigarettes by high school students fell from 15.8% to 8.0%, and use of cigars and pipes also fell. Ahmed Jamal et al., *Tobacco Use Among Middle and High School Students — United States, 2011–2016*, 66 Morbidity & Mortality Wkly. Rep. 597, 601 (2017), *available at* https://tinyurl.com/y9p7tw2f.

As for the often-voiced concern that e-cigarettes are a "gateway" to smoking, this is grounded in a confusion between *causation* and *association*. Lynn T. Kozlowski & Kenneth E. Warner, *Adolescents and E-cigarettes: Objects of Concern May Appear Larger Than They Are*, 174 Drug & Alcohol Dependence 209, at 2-3 (2017), *available at* https://tinyurl.com/ybyquu3z (pincite corresponding pagination in hyperlink). Although many studies show strong associations between vaping and smoking, this should be expected. The same factors that cause people to smoke are likely to incline them to vape because vaping is a similar activity that substitutes for smoking (though much less harmful). These strong *associations* do not mean that the vaping causes the smoking. Indeed, the sharp decline in teenage smoking contradicts this notion.

And, even though the National Academies have stated that "[t]here is substantial evidence that e-cigarette use increases risk of ever using combustible tobacco cigarettes among youth and young adults," Nat'l Acads. Sci., Eng'g & Med., PUBLIC HEALTH CONSEQUENCES OF E-CIGARETTES, *supra* note 2, at 416 (emphasis omitted), this has not translated into increases in smoking. In fact, the opposite effect – a rapid *decline* in adolescent smoking – has occurred, as the National Academies themselves observe:

> Overall, the population-based data broadly show opposing trends in e-cigarette and cigarette use prevalence across time among U.S. youth in recent years and thus do not provide confirmatory evidence of the epidemiologic person-level positive associations of vaping and smoking.

Id. at 414.

Third, adolescent vaping is occasional, experimental, and without nicotine. Though concern has been expressed about vaping in teenage populations, this concern should be qualified by two further factors.

First, much of the use captured in the high school-level statistics is occasional and experimental: almost half (45.4%) of those counted as e-cigarette users vaped on only two days or fewer in the survey month, Linda J. Neff et al., *Frequency of Tobacco Use Among Middle and High School Students — United States, 2014*, 64 Morbidity & Mortality Wkly. Rep. 1061, 1062 (2015), *available at* https://tinyurl.com/yc5m4g4o, and most regular or daily adolescent vaping is

concentrated in those who smoke: "Few never tobacco users had used e-cigarettes on 10 or more days in the past month (absolute percent < 0.1%)", Andrea C. Villanti et al., *Frequency of Youth E-cigarette and Tobacco Use Patterns in the United States: Measurement Precision is Critical to Inform Public Health*, 19 Nicotine & Tobacco Res. 1345 (2016), *available through* https://tinyurl.com/ya546m7y.

Second, most teenage vaping does not involve nicotine. One survey showed that, of the twelfth-graders who used e-cigarettes in the last thirty days, only 22% of them had used nicotine-based liquids the last time they used an e-cigarette. *Monitoring the Future Figures 2015*, NAT'L INST. DRUG ABUSE, *available at* https://tinyurl.com/y8ugfhje (last updated Dec. 2015) (slide titled "Substance Vaporized the Last Time e-Cigarette Used").

II. The FDA Claims Five Main Benefits of the Deeming Rule, but These Are Weak or Unsubstantiated and Are More Likely to Turn Out to Be Costs.

Given the potential benefits of vaping, the Deeming Rule is not an adequate and proportional response. The FDA claims five benefits of the Deeming Rule, *see generally* Food & Drug Admin., Dep't Health & Human Servs., DEEMING TOBACCO PRODUCTS TO BE SUBJECT TO THE FOOD, DRUG, AND COSMETIC ACT: FINAL REGULATORY IMPACT ANALYSIS, FINAL REGULATORY FLEXIBILITY ANALYSIS, UNFUNDED MANDATES REFORM ACT ANALYSIS 67 (2016) [hereinafter

DEEMING RULE: FINAL ANALYSES], *available at* https://tinyurl.com/ya3afalz; however, they do not withstand scrutiny.

Claim 1: "[P]remarket review . . . will result in fewer harmful or addictive products from reaching the market than would be the case in the absence of the rule[.]" *Id.*

Response 1: The FDA cannot claim this as a benefit. In reality, the excessive burdens and restrictions of the premarket review and modified risk tobacco product ("MRTP") approval processes are too great for all but the largest manufacturers. Thus, premarket review will result in *far fewer of the much safer alternatives* to cigarettes reaching the market. The very-harmful and very-addictive products that dominate the market – cigarettes – are unaffected by the Deeming Rule. For that matter, they are largely unaffected by the Tobacco Control Act – due to the grandfathering of all cigarette products on the market as of February 15, 2007. *See* 21 U.S.C. § 387j(a)(2)(A)(i)(I). The FDA's approach distorts the market in favor of cigarettes – the most dangerous tobacco products – and at the expense of substantially less-harmful alternatives such as e-cigarettes.

Claim 2: "[Y]outh access restrictions and prohibitions on free samples . . . can be expected to constrain youth access to tobacco products and curb rising uptake." DEEMING RULE: FINAL ANALYSES, *supra*, at 67.

Response 2: The FDA's intervention provides no additional benefit because the States and the District of Columbia have already implemented age restrictions, some even with higher age limits of nineteen or twenty-one. Further, the free samples available to adults in adult vape shop settings have no bearing on youth access or uptake. Thus, a ban on free samples and trials represents an impediment to adult free choice and may prevent adults from switching from smoking to vaping, thereby causing a health detriment.

Claim 3: "[H]ealth warning statements . . . will help consumers understand and appreciate the risks of using tobacco products." *Id.*

Response 3: The health warning envisaged in the Deeming Rule is "*WARNING: This product contains nicotine. Nicotine is an addictive chemical.*" Deeming Rule, 81 Fed. Reg. at 28,988. While it is important that consumers are informed about the presence of nicotine, the FDA conspicuously *does not* provide the most important risk information to consumers – the relative risks of smoking and vaping. And the FDA goes even further in preventing manufacturers making such claims through the excessive burdens of the MRTP application process.

Claim 4: "[P]rohibitions against false or misleading claims and unsubstantiated MRTP claims lead to better-informed consumers and help prevent the use of misleading campaigns targeted to youth populations." DEEMING RULE: FINAL ANALYSES, *supra*, at 67.

Response 4: Surveys of adult consumers show that perceptions of the relative risks of e-cigarettes and smoking are highly misaligned with expert assessment. That ultimately increases harm by diminishing the perceived health gains of switching.

The National Cancer Institute surveyed perceptions of risk in 2017 and found only 5.2% of American adults correctly identified electronic cigarettes as "much less harmful" than cigarettes. *Health Information National Trends Survey: Compared to Smoking Cigarettes, Would You Say that Electronic Cigarettes Are . . .* , NAT'L CANCER INST., *available at* https://tinyurl.com/y7bvssug. However, 55.6% thought that e-cigarettes were just as harmful or even more harmful – a view that no experts believe is remotely close to reality.

Consumers form their perceptions of the relative riskiness of smoking and vaping from many sources other than the FDA, including consumer organizations, academics, public health agencies, and the media. Much of this commentary is unreliable and contested, subject to minimal accountability, and beyond the FDA's jurisdiction. The burdens of the FDA's approval process for making MRTP claims mean that few companies (and, so far, none) will be able to address the misinformation circulating about their products. Therefore, the FDA's regulatory approach has the effect of allowing widespread misperceptions to go unchallenged.

Claim 5: "[O]ther institutional changes, such as FDA monitoring of product developments and changes and required ingredient listings . . . will enable FDA to propose more informed regulations appropriate for the protection of the public health." DEEMING RULE: FINAL ANALYSES, *supra*, at 67.

Response 5: There is value in the FDA's collection of product information, provided that the FDA uses this information to create a system with a proportionate framework for risk management and innovation. However, the FDA's highly burdensome premarket review process is required for every new e-cigarette innovation. In this way, since August 8, 2016, the Deeming Rule has created a *de facto* ban on new innovations that would improve the safety of devices themselves and would make it easier or more appealing for smokers to switch. In contrast to the approach taken by the FDA, for instance, the European Union has established a notification system, as well as a number of standards covering product design, labeling, and marketing. Council Directive 14/40, art. 20, 2014 O.J. (L 127) 1, 25 (EU), *available at* https://tinyurl.com/y8e79nec. This approach provides proportionate protection to Europeans but so far has not had severe adverse effects on the European market. Meanwhile, the FDA's Deeming Rule serves as an unjustified barrier to innovations that would benefit consumers.

III. Because Vaping Substitutes for Smoking, It Offers Important Public Health Gains that Could Be Jeopardized by the Unintended Consequences of Excessively Burdensome or Restrictive Regulation.

The central challenge of regulating e-cigarettes is to be aware of, and to account for, the unintended consequences of the regulation itself. There is a long list of harmful unintended consequences that can arise from poorly designed regulation. Letter from Sarah Jakes, New Nicotine Alliance, & Clive Bates, Dir., Counterfactual, to Alette Addison, Healthier Lives Div., Dep't of Health (U.K.) app. 1 at 9-10 (Apr. 29, 2016), *available at* https://tinyurl.com/ycrnr44m. Indeed, there is already evidence that superficially attractive regulation of e-cigarettes can have the effect of perpetuating smoking,[3] ultimately doing more harm than good. There are three particularly harmful unintended consequences of the Deeming Rule, which the *Amici* wish to draw attention to herein.

First, the extreme burdens of the premarket tobacco application required for e-cigarette products will inhibit the uptake and development of

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[3] *E.g.*, Michael T. Cooper & Michael F. Pesko, *The Effect of E-cigarette Indoor Vaping Restrictions on Adult Prenatal Smoking and Birth Outcomes*, 56 J. Health Econ. 178 (2017), *abstract available at* https://tinyurl.com/y9n8kbe2; Michael F. Pesko et al., *The Influence of Electronic Cigarette Age Purchasing Restrictions on Adolescent Tobacco and Marijuana Use*, 87 Preventive Med. 207 (2016), *abstract available at* https://tinyurl.com/yaovl2la; Abigail S. Friedman, *How Does Electronic Cigarette Access Affect Adolescent Smoking?*, 44 J. Health Econ. 300 (2015), *abstract available at* https://tinyurl.com/y8w4jpt2.

low-risk alternatives to cigarettes. The FDA is projecting regulatory burdens so great that most e-cigarette manufacturers will exit the market, even on the FDA's optimistic assumptions about time and cost. The experience of e-cigarette manufacturers suggests that the premarket review process is likely to far exceed the high costs estimated by the FDA in its Regulatory Impact Analysis,[4] and the number of products affected far exceeds the number anticipated by the FDA.[5] The FDA has increased the burden by being opaque about the requirements for a successful premarket tobacco application, thus compounding high costs with high regulatory risk.

Further, because every product and variation needs its own premarket tobacco application, most companies will need to undertake dozens to hundreds of

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[4] The FDA gives average first time premarket tobacco application costs of $131,643 for each e-liquid and $466,563 for each device. DEEMING RULE: FINAL ANALYSES, *supra*, at 87-88, 89, 90, 92. According to its Chief Executive, Nicopure anticipates that premarket tobacco applications will cost much more, with each e-liquid premarket tobacco application costing at least $5 million, and each vaporizer (or vaporizer component) premarket tobacco application costing at least $3 million. Dkt. # 20-2 at 8 (Decl. of Jeff Stamler ¶ 22).

[5] The FDA estimated a baseline total of 20,856 to 26,056 affected products excluding e-liquid mixtures and a further 19,900 to 79,800 e-liquid mixtures. DEEMING RULE: FINAL ANALYSES, *supra*, at 78. However, by October 1, 2017, 1.9 million vapor products had been registered: 64,042 Vapor Products and 1,847,556 E-Liquids. This data was available through this database: *Establishment Registration & Tobacco Product Listing*, FOOD & DRUG ADMIN., *available at* https://tinyurl.com/ya89qwao. After November 2017, the database search facilities no longer allowed aggregation of total product registrations.

applications in parallel simply to continue trading with even a fraction of their existing product ranges. The effect on consumers will be a dramatic collapse in the available choices of products, including the removal of many products that individual consumers rely on as alternatives to smoking. The onerous burdens and high costs of any product modification will also place a strong brake on innovation.

These effects will diminish the appeal of e-cigarettes relative to cigarettes and, therefore, serve to perpetuate smoking. The same burdens have not been applied to cigarette products, which trade much more freely through waivers, exemptions, and enforcement discretion. In practice, the regulatory regime inverts the normal principle of proportionality: the least risky products are subject to, by far, the greatest burdens.

Second, the process of communicating relative risk through the use of the MRTP application process will deny smokers truthful and potentially life-saving information. The FDA has created a major regulatory barrier to truthful communication to consumers, meaning that only very few have the resources to file the MRTP application – even if their claims are just as valid for the products of other companies.

MRTP applications are becoming voluminous. The Swedish Match snus application exceeded 100,000 pages. Press Release, Swedish Match, Swedish

Match Submits a Modified Risk Tobacco Product (MRTP) Application (June 11, 2014), *available at* https://tinyurl.com/y7mf6p93. The Philip Morris International iQOS MRTP application was two million pages, including case report forms. William Wan, *Big Tobacco's New Cigarette Is Sleek, Smokeless – but Is It Any Better for You?*, Wash. Post, Aug. 11, 2017, *available at* https://tinyurl.com/yb3wubvy. For the thirty-five MRTP applications filed since 2011, no MRTP orders have been granted so far. *Modified Risk Tobacco Products*, FOOD & DRUG ADMIN., *available at* https://tinyurl.com/yc96zfkn (see under heading of "Summary of MRTP Application Actions," as of May 24, 2017). And it is far from clear that this process will ever work.

At the same time, the FDA has failed to make any material efforts to communicate the relative risks of e-cigarettes as opposed to cigarettes. The FDA exhibits strong risk-aversion and imposes high and shifting evidentiary hurdles when it comes to approving manufacturers' MRTP claims. At the same time, the FDA shows little awareness or concern for the harms that may arise from the FDA decisions that *incorrectly reject* truthful claims and therefore *do not* provide consumers with valid information on products that are much less risky than smoking.

Third, denying adults the right to sample new and unfamiliar products creates a barrier to smokers switching to lower-risk products like e-cigarettes.

For many smokers, vaping is a novelty. New products are appearing all the time, and the vaping experience is highly personalized. In encouraging smokers to switch, it is important that they find products that they like, that they understand, and that work for them. In addition, the higher-quality products (those most likely to help smokers quit) can require up-front cash outlay, so smokers need confidence that their money will not be wasted on unsatisfactory products. Trial of products (with some coaching, most naturally in a vape shop) is an important aspect in successfully switching, and to deny smokers access to this service will mean that fewer switch from smoking to vaping.

IV. The FDA Has Failed to Consider the Likelihood that Its Own Interventions Will Have Harmful Unintended Consequences.

The FDA made the following claim in the Deeming Rule:

> Whether ENDS generally may eventually be shown to have a net benefit on or harm to public health at the population level—and there have not yet been long-term studies conducted to support either claim at this time—*regulation* of ENDS will still benefit public health.

Deeming Rule, 81 Fed. Reg. at 28,984.

The FDA cannot simply assume that its regulation will benefit public health. In so assuming, the FDA has sidestepped the most important concern with the Deeming Rule, namely that *the rule itself* will have serious harmful effects insofar as it fundamentally alters the market structure to favor cigarettes over e-cigarettes. The cost-benefit analysis for the Deeming Rule makes no allowance for the

possibility that the rule itself will have a net harmful effect by perpetuating smoking in the manner envisaged by the RCP but ignored by the FDA.

The cost-benefit analysis for the Deeming Rule is extremely sensitive to changes in smoking prevalence. That is because smoking is so harmful, because the value attributed to life-years gained or lost is so high, and because it affects the millions in America who smoke, vape, or do both. Even a small increase in smoking prevalence resulting from excessively burdensome or restrictive regulation is devastating to the cost-benefit case for the Deeming Rule, yet that possibility has not even been contemplated by the FDA, let alone assessed or modeled.

Thus, the FDA's is the very sort of analysis that this Court should not "tolerate." *See City of Portland*, 507 F.3d at 713; *accord Motor Vehicle Mfrs. Ass'n of U.S., Inc.*, 463 U.S. at 43.

CONCLUSION

The FDA's regulation of e-cigarettes will achieve relatively minor benefits compared to the likelihood of harmful unintended consequences. The FDA's intervention may cause harm to health through numerous mechanisms, including, but not limited to:

- denying consumers potentially life-saving information about risk;
- obstructing consumers' uptake of lower-risk products by denying adults the opportunity to sample unfamiliar products;

- greatly reducing the diversity of products in the e-cigarette market and removing products that consumers use as alternatives to smoking, through the excessively burdensome premarket review process; and

- slowing the pace of innovation in safer alternatives to cigarettes, including innovation in safety, use, and consumer acceptability.

The FDA has made no serious attempt to assess or mitigate these consequences, and they are likely to do harm to human health.

The FDA's cost-benefit analysis and its justification for the deeming rule was fundamentally flawed: understating costs and risks, while overstating benefits. The Deeming Rule should not have been issued on this basis.

Respectfully submitted, this 20th day of February, 2018.

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CERTIFICATE OF COMPLIANCE

This brief complies with the type-volume limitation of Fed. R. App. P. 29(a)(5) & 32(a)(7)(B) because it contains 5236 words (including headings, footnotes, and quotations), excluding the parts of the brief exempted by Fed. R. App. P. 32(f) and by D.C. Cir. R. 32(e)(1).

This brief also complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and with the type-style requirements of Fed. R. App. P. 32(a)(6) because it was prepared using Microsoft Word 2016 in 14-point Times New Roman font, a proportially spaced typeface.

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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the BRIEF OF *AMICI CURIAE* CLIVE BATES AND ADDITIONAL PUBLIC HEALTH/TOBACCO POLICY AUTHORITIES IN SUPPORT OF PLAINTIFFS-APPELLANTS AND REVERSAL OF THE DISTRICT COURT DECISION was served on this day, via the Court's electronic filing system on all counsel of record and that eight copies of the brief were dispatched for delivery to the clerk by First-Class Mail, postage prepaid, within two business days addressed as follows:

United States Court of Appeals for the D.C. Circuit
ATTN: Office of the Clerk of Court
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This 20th day of February, 2018.

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