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

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| NICOPURE LABS, LLC<br>Plaintiff,<br>vs.<br>FOOD AND DRUG ADMINISTRATION,<br>*et al.*<br>Defendants. | C.A. NO. 1:16-cv-0878-ABJ |

**BRIEF OF *AMICI CURIAE* THE NATIONAL CENTER FOR PUBLIC POLICY RESARCH AND TECHFREEDOM IN SUPPORT OF PLAINTIFF**

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## INTRODUCTION

The National Center for Public Policy Research and TechFreedom (jointly "Amici"), nonprofit organizations focusing on balancing regulation and consumer interests, respectfully submit this *amicus curiae* brief in support of Plaintiff NicoPure Labs, LLC's ("NicoPure") challenge to the Food and Drug Administration's regulation of electronic vaping devices and e-liquids in the Deeming Rule, 81 Fed. Reg. 28,973 (May 10, 2016) ["Deeming Rule"].

The Deeming Rule's regulation of e-cigarettes raises serious issues of national significance beyond the scope of this lawsuit. This brief provides an overview of the effect of the Deeming Rule on consumers, in support of the Plaintiff's contention that the FDA has failed to properly analyze and weigh the costs and benefits of the Deeming Rule. *See* Plaintiff's Memorandum of Points and Authorities in Support of NicoPure Labs, LLC's Motion for Summary Judgment, at 26–32 ["Plaintiff's Memorandum"]. The Plaintiff's argument rightly

focuses on the Deeming Rule's effect on e-cigarette companies such as those similarly situated to the Plaintiff. This brief supplements the Plaintiff's argument by providing a more detailed perspective on the Deeming Rule's effect on consumers.

E-cigarettes have offered users of traditional tobacco products an alternative that presents significantly reduced risks of cancer and other dangers associated with the use of traditional tobacco products. As described throughout the Plaintiff's Memorandum, the Deeming Rule will have an extraordinarily burdensome effect on the e-cigarette industry and may push many e-cigarette companies to increase prices to meet the high cost of regulation, force them to stop selling a variety of products, or drive them out of business altogether. The enormous expenses required to comply with the Deeming Rule will very likely render economically unfeasible the e-cigarette industry's ability to continue providing competitive pricing against traditional tobacco products. This, in turn, will eradicate a major incentive for traditional tobacco product users ("smokers") to cease using those products in favor of more affordable e-cigarettes, price e-cigarette users ("vapers") out of the e-cigarette market, and force them to return to using more dangerous traditional smoking products.[1]

Smoking-related illness in the United States costs more than $300 billion each year, including nearly $170 billion for direct medical care, and more than $156 billion in lost productivity, which in turn includes $5.6 billion due to secondhand smoke exposure.[2] According

[1] Counsel states that this brief was not written either in whole or in part by counsel for any party and that no person or entity has provided monetary contribution to the preparation of this brief. Amici have authority to file this brief due to the Court's August 2, 2016 Order.

[2] Centers for Disease Control and Prevention, *Economic Facts about U.S. Tobacco Production and Use*, http://www.cdc.gov/tobacco/data_statistics/fact_sheets/economics/econ_facts/Pechacek TF. *Annual Healthcare Spending Attributable to Cigarette Smoking: An Update*, American Journal of Preventive Medicine 2014;48(3):326–33.

to the CDC, "443,000 Americans die of smoking or exposure to secondhand smoke each year."[3] In contrast, the United Kingdom's Royal College of Physicians found that "although it is not possible to quantify the long-term health risks associated with e-cigarettes precisely, 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." Report at 84. Indeed, the Report states, "Large-scale substitution of e-cigarettes … for tobacco smoking has the potential to prevent almost all the harm from smoking in society." *Id*. at 189.

The Deeming Rule was promulgated by the FDA under the authority of the Family Smoking Prevention and Tobacco Control Act (the "Act"), which was passed by Congress in order to combat the public health crisis spawned by traditional tobacco products—*i.e.*, smoking. Indeed, the second paragraph of the Act notes: "A consensus exists within the scientific and medical communities that tobacco products are inherently dangerous and cause cancer, heart disease, and other serious adverse health effects." Pub. L. No. 111-31, 123 Stat. 1776, 1777, § 2(2) (2009). The Deeming Rule will prompt consumers to revert back to traditional tobacco products—precisely the opposite of the what Congress intended: curbing traditional tobacco use to reduce the harmful effects of smoking.

Yet instead of weighing this evidence, the FDA has chosen to disregard it, reverting to the precautionary principle. Perversely, attempting to avoid any possible harm to consumers (from vaping), no matter how small compared to the harms of smoking, means a great many consumers will continue to suffer the very real, proven harms from smoking. Amici submit that the FDA failed in its "breakeven analysis" to consider the negative impact the Deeming Rule will have on consumers and the public generally, and moreover is acting in direct conflict against

[3]Centers for Disease Control and Prevention, *Adult Smoking in the US*, http://www.cdc.gov/VitalSigns/AdultSmoking/index.html

the intent of Congress in passing the Act. Thus, this court should invalidate the Deeming Rule for being arbitrary, capricious, an abuse of discretion, and otherwise not in accordance with law.

## STATEMENT OF INTEREST

The National Center for Public Policy Research ("NCPPR"), founded in 1982, is a communications and research foundation dedicated to providing free market solutions to today's public policy problems. The NCPPR believes that the principles of a free market, individual liberty, and personal responsibility provide the greatest efficacy for meeting the challenges facing America in the 21st century.

The director of NCPPR Risk Analysis Division, Jeff Stier, has long been a leading advocate for market-based solutions to public health challenges. As such, Mr. Stier has worked to educate legislators, administration officials, regulators, and the public on the potential to dramatically reduce smoking-related disease and death by encouraging smokers to switch to lower-risk products. Mr. Stier successfully advised legislators considering the Act to allow for the marketing of lower risk nicotine products, and to require that products be regulated based on scientific evidence.

Founded in 2011, TechFreedom is a non-profit, non-partisan think tank dedicated to educating policymakers, the media and the public about technology policy. TechFreedom advocates for policies that promote dynamism, entrepreneurship, and permissionless innovation. TechFreedom has argued against overly prescriptive regulations from the Food and Drug Administration that stifled innovative start-ups, such as home-genetic-testing service 23andMe. TechFreedom has a similar interest in this case, arguing against overly prescriptive regulations

that unduly stifle innovation and entrepreneurship in the market for e-cigarettes and other tobacco-replacement products.

## ARGUMENT

### I. THE DEEMING RULE FAILS TO PROPERLY ANALYZE THE COSTS TO CONSUMERS THAT THE FDA ALLEGES IT IS PROTECTING AGAINST, AND CONFLICTS WITH CONGRESSIONAL INTENT OF THE ACT.

While vaping technologies are in their relative infancy, many smokers have already switched to them (becoming vapers) because of their dramatically reduced risk of a range of smoking-related diseases, including cancer and heart disease. The FDA's goal under the Act is to aid cessation of smoking traditional tobacco products in order to prevent cancer and other diseases such products cause. Pub. L. No. 111-31, 123 Stat. 1777, §§ 2(2), (13–14), (16), (23–25), (31–32), (34), (38–39), (45), (47–48) (2009). As outlined in the Plaintiff's memo, the Deeming Rule's heavy-handed regulation of the e-cigarette industry will not only dissuade smokers from transitioning to e-cigarettes, but may also induce vapers to use traditional tobacco products instead, in spite of the fact that research indicates that e-cigarettes pose only a small fraction of the health risks as traditional cigarettes.

#### A. The Deeming Rule Harms Smokers by Disincentivizing Use of an Emerging and Effective Alternative to Smoking Tobacco.

In April 2016, the Royal College of Physicians released a comprehensive report on e-cigarettes and the state of smoking in the United Kingdom, noting that "e-cigarettes have the potential to help smokers quit smoking, and the evidence indicates they carry a fraction of the risk of smoking cigarettes but are not risk free." Tobacco Advisory Group of the Royal College of Physicians, *Nicotine Without Smoke: Tobacco Harm Reduction,* 4 (Apr. 2016), www.rcplondon.ac.uk/file/3563 ("The Report"). The Report analyzed and summarized the

results of numerous tests, and is the most comprehensive scientific material on vaping to date. The FDA took note of the Report in the Deeming Rule, despite apparently failing to consider the same in its breakeven analysis, stating:

> [A] recent evaluation of the relative health risks of ENDS [electronic nicotine delivery systems] products conducted by Public Health England has drawn attention to scientific reviews concluding that ENDS are "likely to be much less, if at all, harmful to users or bystanders" and a prior paper that reported the findings from an international expert panel of academics. Employing an analysis model that quantifies the relative health harms of 12 tobacco products using a series of 14 harm criteria, the expert panel determined that while cigarettes scored 100 percent in their assessment of maximum relative harm, ENDS products were rated to have only 4 percent maximum relative harm, which contributed to Public Health England's assessment that ENDS are around 95 percent safer than smoking combusted cigarettes.

AR023, 960 (internal citations omitted).

The appeal of e-cigarettes to consumers, and their virtue as an effective smoking-cessation tool, is that they provide an alternative that is similar to smoking in both speed and manner of delivery (as opposed to nicotine patches or gum). Report at 84. Despite this similarity, studies show vapers are less dependent on nicotine than smokers. *Id.* Even those who use both traditional and e-cigarettes simultaneously were found to have significantly lower amounts of smoke and related toxins in their lungs, despite maintaining their nicotine levels. Report at 85.

In July 2016, Public Health England and other United Kingdom governmental health organizations solidified their position that e-cigarettes are a public health benefit by releasing a joint statement noting a "developing public health consensus," and calling a "public health *opportunity* in helping smokers quit." Public Health England, *E-cigarettes: A Developing Public Health Consensus* (July 2016), https://goo.gl/YvXBbm (emphasis added). "We all agree that e-cigarettes are significantly less harmful than smoking. *All* the evidence suggests that the health risks posed by e-cigarettes are relatively small by comparison but we must continue to study the long-term effects." *Id.* (emphasis added). The joint statement goes on further to say "[W]e may

encourage smokers to try vaping." *Id.* In fact, Public Health England is concerned that "[M]illions of smokers have the [wrong] impression that e-cigarettes are at least as harmful as tobacco." *Id.* The ringing endorsement provided by this study clearly shows the availability and affordability of e-cigarettes are vital to the fight against cancer and the diseases caused by smoking.

In short, this is what a non-arbitrary and non-capricious analysis of the issue by an expert agency would look like. By contrast, the Deeming Rule dramatically restricts the choices available to smokers and harms vapers by taking away this powerful tool to stop smoking.

### B. E-cigarettes Do Not Pose Significant Dangers of Secondhand Smoke as Do Traditional Tobacco Products.

Anti-smoking efforts in the U.S. have increasingly shifted to combatting secondhand smoke. The CDC attributes 2.5 million deaths since 1964 to secondhand smoke, and also cites smoking (rather than nicotine) as a cause of many health problems including asthma attacks, respiratory infections, ear infections, sudden infant death syndrome in children, and coronary heart disease, strokes, or lung cancer in adults.[4] To combat the effects of secondhand smoke, many States have enacted laws prohibiting smoking in enclosed public places. *See, e.g.*, D.C. Code §§ 20-2100 *et seq.* (2007).

The Report states that, unlike traditional tobacco products, "[t]here is, so far, no direct evidence that such passive exposure [to e-cigarette vapor] is likely to cause significant harm . . . ." Report at 84. Indeed, the Royal College of Physicians does not consider it necessary to regulate vaping in public: "Given the lack of evidence on the harmfulness of e-cigarette vapour

[4]Centers for Disease Control and Prevention, *Health Effects of Second Hand Smoke*, https://www.cdc.gov/tobacco/data_statistics/fact_sheets/secondhand_smoke/health_effects/index.htm

to others … it would be inappropriate for national legislation to prohibit their use in public places and workplaces." Report at 153. The Deeming Rule therefore affects not merely vapers but also the public-at-large who may be susceptible to greater exposure to secondhand smoke from traditional tobacco products than they would otherwise had the Rule not gone into effect.

### C. The FDA is Applying a Precautionary Principle in the Deeming Rule that Will Harm Consumers Despite Significant Evidence Being Available that E-cigarettes Are Extraordinarily Less Harmful than Traditional Tobacco Products.

Although the FDA considers the possibility that consumers will revert to traditional tobacco products if vaping technologies are made less available, it fails to consider this consequence in its breakeven analysis. Plaintiff's Memorandum at 31. The FDA's analysis does not point to a single substantial concern about vaping, but rather states that there *may* be an issue *in the future* that these regulations *could possibly* prevent. The FDA has not taken a scientific approach here and is implicitly rejecting available evidence indicating that e-cigarettes do not require the same kind of regulation intended to curtail the health risks posed by traditional tobacco products.

Ignoring the evidence provided by the tests referenced in the Report, the FDA claims multiple times throughout the rule that it does not have "sufficient data … to determine what effects e-cigarettes have on public health." 81 Fed. Reg. at 29, 984; *see also* AR023, 930, 970. While the FDA insists it does not know the effect of e-cigarettes on public health (despite the evidence available), and thus cannot properly account for them, it fails to properly account for the risks of the alternative, traditional tobacco products, which are well known and researched. Rather, the Deeming Rule attempts simply to prevent some indeterminate, undefined harm in the future.

This analysis supporting the Deeming Rule is arbitrary, capricious, an abuse of discretion, and otherwise not in accordance with law, and should therefore be deemed unlawful. 5 U.S.C. § 706. By discounting two reduced threats to public health resulting from the shift from smoking to far, far safer vaping technologies — (i) the reduced harm to smokers themselves, and (ii) the reduced harm to the public, given the complete absence of any evidence of a health threat posed by secondhand vapor — the FDA "entirely failed to consider an important aspect of the problem," *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Automobile Ins. Co.*, 463 U.S. 29, 43 (1983), rendering the rationale for the Deeming Rule arbitrary and capricious. Moreover, the Deeming Rule runs contrary to Congress's intent in the Act to reduce tobacco smoking and aid cessation thereof, so it is also an abuse of discretion by the FDA and otherwise not in accordance with law. Act § 3(9).

## II. CONCLUSION

The FDA's Deeming Rule fails to consider the scientific evidence readily available to the agency regarding the safety and the public health benefits of e-cigarettes. The Deeming Rule is improper under the APA not merely because it fails any manner of scientific analysis, and is therefore arbitrary and capricious, but also because it is in direct conflict with Congress's intent to prevent smoking and aid cessation through the Act. Act § 3(9).

Amici urge this court to set aside the Deeming Rule's regulation specific to vaping devices and e-liquids.

DATED: August 4, 2016

Respectfully submitted,


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**CERTIFICATE OF SERVICE**

Pursuant to Local Civil Rule 5.4, I hereby certify that on August 4, 2016, I electronically filed the foregoing document with the Court using the CM/ECF system. All parties to the case have been served through the CM/ECF system.

/s/ *Jonathan W. Emord*
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