



January 17, 2017

The Honorable Mitch McConnell  
Senate Majority Leader  
S-230, The Capitol  
Washington, DC 20510

The Honorable Paul Ryan  
Speaker of the House  
H-232, The Capitol  
Washington, DC 20515

We, the undersigned organizations dedicated to free markets and innovation, urge you to amend the Food and Drug Administration’s Deeming Rule, which heavily restricts the development and availability of e-cigarettes and vapor products that have proven to be less harmful alternatives to combustible cigarettes. The FDA’s regulations threaten to kill an industry that has created tens of thousands of jobs by producing safer products that help many Americans quit smoking.<sup>1</sup>

The FDA’s Deeming Rule, which took effect August 16, 2016, requires e-vapor product manufacturers to endure a lengthy and expensive pre-market tobacco application process for all products not brought to market before the predicate date of February 15, 2007.<sup>2</sup> Unless a product is “substantially equivalent” to decade-old products, the FDA estimates that a single application will take 5,000 hours and cost \$330,000.<sup>3</sup> The FDA estimates that companies will need to file 20 applications for each product within the first two years of regulation, setting the cost around \$6 million per product. Even that would be enough to exclude all but the largest companies, but the National Center for Public Policy Research estimates the real cost will be closer to \$1 million per application.<sup>4</sup> The industry has seen massive growth and innovation in the last decade.<sup>5</sup> By setting the predicate date well before the introduction of most modern vapor products, the FDA has ensured that most manufacturers will be forced to shut down, as 99% of products will not go through the required process.<sup>6</sup>

Small businesses, which make up much of the vaping industry, will be hit hardest by the regulations.<sup>7</sup> The Smoke-Free Alternatives Trade Association estimates that there are as many as 15,000 vape shops, in addition to about 1,200 manufacturers of e-liquid and 22 manufacturers of

hardware.<sup>8</sup> Together, these companies have created approximately 70,000 jobs, most of which are in danger thanks to the FDA's onerous application processes.<sup>9</sup> Businesses must make irreversible decisions often based on 5-10 year investment and innovation cycles — not on the pendulum swing of elections.

The world has made enormous progress in reducing smoking. Decades of improvements in education, research, and cessation methods have helped reduce the percentage of smokers in the US from 42.4% in 1965<sup>10</sup> to 15.1% today.<sup>11</sup> Despite those efforts, nearly 40 million Americans and a billion people worldwide still smoke — most in low and middle-income countries that are hit harder by tobacco-related illness.<sup>12</sup> How the FDA regulates new, life-saving technology will influence regulators and policymakers throughout the world.

The FDA's harsh approach to e-vapor ignores the facts. A study from Public Health England found that e-vapor products were 95% less harmful than combustible cigarettes.<sup>13</sup> In a joint statement, Public Health England and several other UK governmental health organizations argued that all evidence points toward vaping as a safer alternative, and that smokers should be directed toward those products.<sup>14</sup> Further, the Royal College of Physicians concluded that there is no evidence that secondhand vapor from e-cigarettes, a core focus of more recent anti-smoking campaigns, causes significant harm.<sup>15</sup>

Despite the overwhelming evidence, the FDA has reflexively applied the precautionary principle, giving more weight to theoretical concerns about problems that might arise rather than any concrete evidence of harms. In doing so, the agency is depriving smokers of a demonstrably safer alternative out of pure speculation. By failing to conduct proper scientific analysis, the FDA has clearly violated the Administrative Procedure Act.<sup>16</sup>

Further, the agency's new regulations run counter to Congressional intent in the Family Smoking Prevention and Tobacco Control Act, which was used to justify the new Deeming Rules.<sup>17</sup> By regulating e-vapor products out of existence, the FDA will push many smokers on the road to recovery back into using more harmful combustible cigarettes.

In August, TechFreedom and the National Center for Public Policy Research filed an amicus brief supporting a legal challenge to the Deeming Rules by Nicopure Labs, an e-liquid manufacturer.<sup>18</sup> The brief concluded:

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 [Family Smoking Prevention and Tobacco Control] Act.<sup>19</sup>

The FDA is mired in litigation because it has failed in its responsibility to protect consumers on this issue; Congress must correct the agency's mistake and ensure that safer tobacco alternatives remain available. The 115th Congress should pass language that would change the "grandfather date" specifically for deemed products from February 15, 2007 to the effective date of the Deeming

Regulation, which is August 16, 2016. This legislation should mirror the Cole-Bishop Amendment which was offered in the 114th Congress.

The Amendment would change only the predicate date, not the FDA's rules themselves. This would have no effect on the FDA's ability to protect consumers and regulate vapor products, including safety standards, marketing, sale to minors, and batteries. Manufacturers would still be regulated under the Deeming Rule and would have to abide by FDA standards for their products to remain on the market. In requiring the FDA to consider the vapor market through a modern lens, the Amendment simply makes the approval process more fair, realistic, and affordable.

Congress has a bipartisan opportunity to save the e-vapor industry and the lives of many who rely on safer alternatives to smoking. Lawmakers should proceed with dispatch, and give American businesses the certainty they need in order to thrive and innovate.

Sincerely,

TechFreedom  
Campaign for Liberty  
Competitive Enterprise Institute  
Council for Citizens Against Government Waste  
FreedomWorks  
Heartland Institute  
High Tech Forum  
Log Cabin Republicans  
National Center for Public Policy Research  
National Taxpayers Union  
R Street Institute  
Taxpayers Protection Alliance

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<sup>1</sup> See Dep't. of Health & Human Servs., Fed. Drug Admin., *Deeming Tobacco Products to be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Restrictions on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products*, Final Rule, Docket No. FDA-2014-N-0189, 81 Fed. Reg. 28974, 29036–39 (May 10, 2016), available at <https://goo.gl/En0oRo>.

<sup>2</sup> *Id.*

<sup>3</sup> Dep't. of Health & Human Servs., Fed. Drug Admin., *Deeming Tobacco Products to be Subject to the Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Regulations Restricting the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Product Packages and Advertisements*, Docket No. FDA-2014-N-0189, at 35–39 (Apr. 2014), available at <https://goo.gl/KOHqiG>; Thomas A. Briant, *FDA Deeming Regulations: What's Next*, CSP (May 12, 2016), available at <https://goo.gl/oMbY1Y>.

<sup>4</sup> Smoke-Free Alts. Trade Assoc., *FDA Deeming Regulations Analysis*, at 3 (May 2016), available at <https://goo.gl/0nQYcG>.

<sup>5</sup> See, e.g., BIS Research, *Electronic Cigarette and E Vapor (Vaporizer) Market Research Reports* (2016), available at <https://goo.gl/MxF845> (“The demand for e-cigarettes escalated since 2012 and is anticipated to grow over \$50 billion by 2025 at an estimated CAGR of 22.36% from 2015 to 2025 as per our latest market research report on global e cigarette industry.”).

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<sup>6</sup> Guy Bentley, *FDA Announces Rule to Ban 99 Percent of E-Cigarettes*, The Daily Caller (May 5, 2016), available at <https://goo.gl/wiS1CU>.

<sup>7</sup> See, e.g., Smoke-Free Alts. Trade Assoc., *About SAFTA* (last visited Dec. 5, 2016), available at <https://goo.gl/r3VAGn>.

<sup>8</sup> *Id.*

<sup>9</sup> *Id.*

<sup>10</sup> Ctrs. for Disease Control. & Prevention, *Trends in Current Cigarette Smoking Among High School Students and Adults, United States, 1965–2014* (last updated Mar. 30, 2016), available at <https://goo.gl/B7bsPz>.

<sup>11</sup> Ctrs. for Disease Control. & Prevention,

<sup>12</sup> *Id.*; World Health Org., *Fact Sheet: Tobacco* (last updated June 2016), available at <https://goo.gl/Njc4Tk>.

<sup>13</sup> Pub. Health England, *Press Release: E-Cigarettes Around 95% Less Harmful Than Tobacco Estimates Landmark Review* (Aug. 19, 2015), available at <https://goo.gl/udRFeh>.

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

<sup>15</sup> Royal Coll. of Physicians, *Nicotine Without Smoke: Tobacco Harm Reduction*, at 30 (Apr. 2016), available at <https://goo.gl/OF8aTQ>.

<sup>16</sup> See 5 U.S.C. § 706 (empowering courts to set aside and declare unlawful any agency actions found to be, *inter alia*, “arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law;”).

<sup>17</sup> See Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111-31, § 3(9), 123 Stat. 1782 (2009) (“The purposes of this [Act] are— . . . to promote cessation to reduce disease risk and the social costs associated with tobacco-related diseases[.]”).

<sup>18</sup> Brief for the National Center for Public Policy Research and TechFreedom as Amici Curiae in Support of Plaintiff, *Nicopure Labs v. Fed. Drug Admin.* (D.D.C. Aug. 4, 2016) (No. 1:16-cv-0878-ABJ), available at <https://goo.gl/3udgSc>.

<sup>19</sup> *Id.* at 9.