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July 7, 2017

Dr. Scott Gottlieb  
Commissioner  
U.S. Food and Drug Administration  
10903 New Hampshire Avenue  
Silver Spring, MD 20857

Dear Dr. Gottlieb:

We are aware that FDA is facing pressure from various sources to weaken the Deeming Rule promulgated in May 2016, in which the agency asserted jurisdiction over e-cigarettes and other tobacco products,<sup>1</sup> including multiple lawsuits by cigar and e-cigarette interests continuing their long history of seeking to escape all meaningful regulation. You also were sent a letter dated June 14, 2017 (“June 14 letter”) from a number of individuals who have asked you to ignore the voluminous record developed by FDA during the multi-year comment period. They ask that while FDA “reconsiders” the Deeming Rule, the agency should set aside, for four years, any obligation for the manufacturers of non-combustible products, primarily e-cigarettes and their progeny, to file an application for authorization to continue to market these products under Sections 905 or 910 of the Food, Drug and Cosmetic Act, as amended by the Family Smoking Prevention and Tobacco Control Act (“Tobacco Control Act” or “TCA”).

As we and fifty other national organizations, representing virtually every major public health organization directly involved in tobacco control matters in the U.S., noted in a letter sent to U.S. Department of Health and Human Services Secretary Price on May 17, 2017, the Deeming Rule was the product of a multi-year rulemaking, supported by detailed findings by FDA after considering all the comments submitted and the full scientific and factual record available to FDA, multiple policy options and all of the issues now being raised by the opponents of the Rule. The scientific evidence in support of the Deeming Rule was overwhelming, as FDA itself noted and summarized in the brief it filed in defense of the Rule in *Nicopure Labs LLC v. FDA* during the summer of 2016. The importance of the Rule was reinforced by the Report of the Surgeon General, “E-Cigarette Use Among Youth and Young Adults” issued in January 2017.

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<sup>1</sup> See 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, 81 Fed. Reg. at 28973 (May 10, 2016) (the “Deeming Rule”).



Despite the dissent from the cigar and e-cigarette industry, who have sought to evade meaningful regulation time and again, and the disagreement with the findings and conclusions by FDA by those who signed the June 14, 2017 letter, the public health justification and support for the regulation promulgated by FDA remains as strong today as when FDA issued the Rule.

While much of the focus is often on the need for regulation to prevent the marketing of products and marketing strategies that appeal to youth, inadequate regulation has also had a negative effect on the introduction of products that will be effective in helping cigarette smokers quit or switch. Rather than facilitating the role of e-cigarettes in promoting smoking cessation, adoption of the proposal to delay for four years any obligation for manufacturers of e-cigarettes to apply for authorization to market individual products would retard the development of the science needed to understand which such products, if any, actually do promote cessation and how they can be marketed without exposing young people to unnecessary risks.

Indeed, full implementation of the Deeming Rule is essential to protect the public, including both young people and smokers trying to determine which products will be most effective at helping them to quit, from the adverse effects of the unregulated market for e-cigarettes. At the same time, the Deeming Rule—which faithfully implements the requirements and standards established by Congress in the Tobacco Control Act—gives FDA the necessary tools to arrive at science-based judgments about the public health impact of particular e-cigarette products.

***Requests to Weaken the Deeming Rule Are Inconsistent with FDA’s Findings about the Adverse Health Risks Posed by Unregulated E-Cigarettes.***

Although FDA itself recognized, in issuing the Deeming Rule, that smokers of conventional cigarettes may reduce their risk of tobacco-related disease by completely switching to e-cigarettes,<sup>2</sup> FDA properly recognized that the current unregulated market for e-cigarettes poses substantial risks to public health that opponents of the Rule ignore or downplay.

For example, as FDA found, e-cigarettes typically contain nicotine, described by FDA as “one of the most addictive substances used by humans.”<sup>3</sup> Indeed, e-cigarettes can deliver as much nicotine as conventional cigarettes – sometimes more.<sup>4</sup> According to the Surgeon General, nicotine exposure during adolescence “may have lasting adverse consequences for brain development.”<sup>5</sup> Nicotine exposure during pregnancy also “contribut[es] to multiple adverse outcomes, such as pre-term delivery and stillbirth,” and “has lasting adverse consequences for [fetal] brain development.”<sup>6</sup> Nicotine is a powerful neurotoxin and ingesting or directly touching e-liquids can cause nicotine poisoning, which can be fatal.<sup>7</sup>

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<sup>2</sup> 81 Fed. Reg. at 29,037.

<sup>3</sup> 81 Fed. Reg. at 29,988.

<sup>4</sup> *Id.* at 29,031.

<sup>5</sup> U.S. Department of Health and Human Services, *The Health Consequences of Smoking: 50 Years of Progress: A Report of the Surgeon General* (2014), at 126.

<sup>6</sup> *Id.* at 126.

<sup>7</sup> 81 Fed. Reg. at 29,032.



As FDA also found, other ingredients in e-liquids pose further public health concerns. E-liquids come in a dizzying array of thousands of different flavors, many of which present health risks when inhaled. FDA reported a study of 159 e-liquids with sweet flavors finding that “almost three quarters of the samples (74 percent) contained diacetyl or acetyl propionyl, both of which pose known inhalation risks.”<sup>8</sup> A second study, of 30 e-liquids, “found that many flavors, including cotton candy and bubble gum, contain aldehydes, a class of chemicals that can cause respiratory irritation [and] airway constriction,” and noted that “two flavors, a dark chocolate and a wild cherry, would expose e-cigarette users to more than twice the recommended workplace safety limit for the aldehydes vanillin and benzaldehyde.”<sup>9</sup> Yet another study found that several cinnamon-flavored e-liquids contained yet another aldehyde, “cinnamaldehyde, which [is] highly toxic to human cells in laboratory tests.”<sup>10</sup> The evidence supports the conclusion that the unregulated addition of flavors increases the risk that users will be exposed to hazardous substances.

Moreover, as FDA observed in its brief defending the Deeming Rule against legal attack from the e-cigarette industry in the *Nicopure Labs* case, consumers currently have no way of knowing what they are inhaling with e-cigarette products, and the wide variability in the design and performance of these products affects the amount of chemicals that are actually inhaled.<sup>11</sup> Thus, for example, the solvents used in e-liquids, when vaporized at certain voltages, can produce some of the same harmful byproducts, including formaldehyde (a known carcinogen) as conventional cigarettes, sometimes at higher levels.<sup>12</sup> Finally, the batteries and other components used in e-cigarettes pose health and safety risks, as serious injuries have been reported from exploding e-cigarette batteries.<sup>13</sup> Moreover, many manufacturers of e-cigarette products – particularly vape shops that mix their own e-liquids – lack the ability to manufacture products to specification and one batch of what is supposed to be the same product may differ substantially from the next.

As FDA observed, many of the thousands of available e-cigarette products are fruit- and candy-flavored, making them especially appealing to youth and young adults. DOJ cited evidence that 73 percent of e-cigarette brands offer fruit flavors and 71 percent offer candy flavors; indeed, the three top-selling flavors at e-liquids.com, a large online retailer, are “Unicorn Milk” (strawberries and cream), “TNT” (strawberry, apple and peach) and “I Love Donuts” (blueberries and pastry).<sup>14</sup> According to FDA’s Population Assessment of Tobacco and Health (PATH) study, 85.3 percent of current e-cigarette users aged 12-17 had used a flavored e-cigarette in the past month and 81.5 percent of current youth e-cigarette users said they used e-cigarettes “because they come in flavors I like.”<sup>15</sup> The TCA prohibited characterizing flavors in cigarettes (except menthol), but the unregulated market in e-cigarettes has allowed kid-friendly flavors to proliferate.<sup>16</sup> Thus, the flavoring

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<sup>8</sup> *Id.* at 29,029.

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

<sup>10</sup> *Id.*

<sup>11</sup> See Memorandum in Opposition to Plaintiffs’ Motions for Summary Judgment and in Support of Defendants’ Cross-Motion for Summary Judgment, *Nicopure Labs, LLC v. FDA and Right to be Smoke-Free Coalition v. FDA* (consolidated), CA Nos. 16-878, CA No. 16-1210 (D.D.C. filed August 16, 2016) (“FDA Brief”), at 11, 12-13.

<sup>12</sup> *Id.* at 13.

<sup>13</sup> *Id.* at 14.

<sup>14</sup> FDA Brief at 10.

<sup>15</sup> Ambrose, BK, et al., “Flavored Tobacco Product Use Among US Youth Aged 12-17 Years, 2013-2014,” *Journal of the American Medical Association*, published online October 26, 2015. Study cited at 81 Fed. Reg. at 29014.

<sup>16</sup> See generally, *The Flavor Trap: How Tobacco Companies Are Luring Kids with Candy-Flavored E-Cigarettes and Cigars*, Campaign for Tobacco-Free Kids, et al. (March 15, 2017).



chemicals used in e-cigarette products not only pose health risks to individual users, they also increase the number of people exposed to these chemicals by making e-cigarettes especially appealing to young people.

AS FDA noted, the appeal of these flavored products to young people has been magnified by e-cigarette marketing. The FDA *Nicopure Labs* brief cites abundant evidence that “e-cigarette advertising specifically targets youth, mimicking the strategies previously used by ‘Big Tobacco’ – to devastating effect – and thus banned for conventional cigarettes.”<sup>17</sup> FDA cites several examples, including advertising during events and programming with high levels of youth viewership, advertising using celebrity endorsements to depict e-cigarette use as “glamorous, rebellious, sexy, and masculine,” and the distribution of free samples at events geared toward youth, including concerts, music festivals, parties and sporting events.<sup>18</sup>

Given the proliferation of flavored products and the industry’s youth-targeted marketing strategies, it is hardly surprising that youth use of e-cigarettes has soared in the unregulated marketplace. Current (past 30-day) use of e-cigarettes by high school students increased dramatically from 1.5 percent in 2011 to 16 percent in 2015, before declining to 11.3 percent in 2016, a rate that exceeds use of conventional cigarettes.<sup>19</sup> The significant use of e-cigarettes by young people is not only troubling because of the addictiveness of nicotine and its impact on the developing adolescent brain, as noted above, but also because WAVE 2 of FDA’s PATH study found that of youth who used e-cigarettes exclusively in PATH 1, 24 percent were smoking cigarettes in PATH 2.<sup>20</sup> At the very least these results warrant caution and vigilance about the potential impact of e-cigarette use among youth.<sup>21</sup> We cannot yet be certain about the long-term impact of e-cigarette use among youth, but as FDA found, there is evidence to suggest that “youth may initiate tobacco use with [e-cigarettes], become addicted [to nicotine], and then dual use or move on to traditional tobacco products.”<sup>22</sup> In a one-year study of initially nonsmoking youth and young adults, 68.8 percent of e-cigarette users progressed toward smoking (i.e., either tried conventional cigarettes or indicated that they might), compared to just 18.9 percent of nonusers.<sup>23</sup> A more recent meta-analysis of nine longitudinal studies found that e-cigarette use is associated with an increased risk of future cigarette smoking initiation and current cigarette smoking, even after adjusting for potentially confounding risk factors.<sup>24</sup> These studies cannot be ignored, but one impact of the recommendations contained in the June 14 letter would be to weaken, if not gut, FDA’s authority to remove from the market the e-cigarette products most attractive to kids and to ignore, for years, the potential interconnection between the use of e-cigarettes and traditional cigarettes among young people. The effect of such a policy would be to leave young people totally unprotected from even the most irresponsibly manufactured and marketed products.

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<sup>17</sup> FDA Brief at 15.

<sup>18</sup> *Id.* at 15-16.

<sup>19</sup> U.S. Centers for Disease Control and Prevention (CDC), “Tobacco Use Among Middle and High School Students – United States, 2011-2015,” *Morbidity and Mortality Weekly Report (MMWR)* 65(14):361-367, April 14, 2016.

<sup>20</sup> Hyland, A. et al., “Tobacco Use Transitions Among Youth and Adults: Descriptive Longitudinal Data From Waves 1 and 2 of the PATH Study, 2017 SRNT Symposium (March 2017).

<sup>21</sup> See FDA Brief, at 17.

<sup>22</sup> 81 Fed. Reg. at 29,040.

<sup>23</sup> *Id.* at 29,040-41.

<sup>24</sup> Soneji, S. et al., “Association Between Initial Use of e-Cigarettes and Subsequent Cigarette Smoking Among Adolescents and Young Adults: A Systematic Review and Meta-analysis, *JAMA Pediatrics*, published online June 26, 2017.



In short, even as we learn more about the long term impact of e-cigarette use among youth, as FDA stated in its *Nicopure Labs* brief, the “explosion in virtually unregulated products raises significant public health concerns.”<sup>25</sup>

***Premarket Review of Individual Products and Product Standards Are Both Necessary and Complementary Parts of An Effective Regulatory Regime.***

Suspending the exercise of FDA’s premarket review authority for an additional four years deprives the agency of a critical tool Congress established to ensure that tobacco products entering the market do not imperil the public health.

Under the Deeming Rule, e-cigarettes marketed after February 15, 2007 (“new tobacco products” as defined by the TCA) must undergo premarket review by FDA to determine if they are “appropriate for the protection of the public health,” unless they are shown to be “substantially equivalent” to a grandfathered product already on the market as of that date. For products already on the market as of the Rule’s effective date of August 8, 2016, the Deeming Rule allows manufacturers to keep their products on the market for a two-year period during which they can file Premarket Tobacco Product Applications (PMTAs) seeking marketing authorization, and for up to a third year, or until August 2019, while FDA reviews those applications. If enforcement were suspended *for at least an additional four years*, it would allow the most egregious products to stay on the market without any review until August 2023, *seven years* after the effective date of the Deeming Rule. During those years, FDA would be deprived of its power to protect the public from e-cigarette products that are of the lowest quality, generate the highest levels of toxins, have highly variable nicotine levels and are marketed to young people, with flavors like cotton candy and bubblegum.

The proposal of a four-year suspension of premarket review compliance to “allow time to introduce a new standards-based regime,” fails to recognize that, under the TCA, premarket review of new products and the issuance of product standards are not alternatives; indeed, premarket review can and should be a key mechanism to inform the standard-setting process.

The authority to set product standards, under Section 907 of the TCA, is one of the most consequential powers granted to FDA by the statute. Indeed, the lifesaving potential of product standards is demonstrated by the agency’s first proposed product standard for a tobacco product: the proposed rule to establish a limit on a known carcinogen in smokeless tobacco products.<sup>26</sup> There is no reason, however, to suspend premarket review of new e-cigarette products, beyond that already provided in the Deeming Rule. Premarket review requires e-cigarette manufacturers to submit to FDA their best available data and other information on the individual and population-wide effects of their products. Indeed, much of that information may not be available to FDA absent

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<sup>25</sup> *Id.* at 10.

<sup>26</sup> U.S. Food and Drug Administration, Tobacco Product Standard for N-Nitrosornicotine Level in Finished Smokeless Tobacco Products, 82 Fed. Reg. 8004 (January 23, 2017). The June 14 letter, despite its advocacy of a “standards-based regime” for e-cigarettes, incorporates by reference a document that calls on FDA to “formally withdraw the proposed NNN rule for smokeless tobacco.” See C. Bates, “Rethinking nicotine: implications for U.S. federal tobacco policy: A discussion paper, Version 1.1” at 10 (June 2017). The document offers unsupported speculation that the proposed smokeless standard is “unachievable” for at least 95% of the smokeless tobacco market and would increase uptake of smoking.



the premarket review process. The information provided by manufacturers during premarket review in turn may be critical to the agency's development of industry-wide standards.

The wide range of e-cigarette products on the market further underscores the need to allow the premarket review process to go forward. The FDA *Nicopure Labs* brief cites estimates of 640 to 800 different e-cigarette devices (or 800 to 1,000 unique packaging configurations) and 4,000 to 8,000 different varieties of e-liquids (or 5,000 to 10,000 unique packaging configurations) now sold in the United States.<sup>27</sup> Given the substantial differences in design between "cig-alikes," "closed systems" and "open systems," there is likely to be significant variability among products in the way they function and the way they are used by consumers, causing great variations in both individual health risks and population-wide effects. The premarket review process affords FDA the flexibility to make individualized determinations that recognize this likely variability and then to set viable product standards that govern the marketplace.

As experience has demonstrated, even though *exclusive* use of e-cigarettes presents lower individual risks than smoking, and, according to FDA, there is "some indication that such products may have the potential to help some individual users to quit using combusted tobacco products or to reduce their use of such products," "other evidence is to the contrary," and "some systematic reviews of available evidence indicate that there is currently insufficient data to draw a conclusion about the efficacy of e-cigarettes as a cessation device."<sup>28</sup> Indeed, as FDA's *Nicopure Labs* brief indicates, there is some evidence that e-cigarettes may actually inhibit quitting conventional cigarettes, as "adult smokers who begin to use e-cigarettes seldom completely quit combustible products . . . ."<sup>29</sup> The U.S. Preventive Services Task Force has concluded that "available data on the use of [e-cigarettes] for smoking cessation are quite limited and suggest no benefit among smokers intending to quit."<sup>30</sup>

It is likely that certain e-cigarette products are more effective than others in enabling smokers to quit. However, in the absence of the type of regulatory requirements contained in the Deeming Rule, there has been no incentive to conduct well-conceived, independently reviewed studies using e-cigarettes, under conditions of actual use, that enable cigarette smokers in the US to identify the products most effective as helping them to stop using cigarettes. In the absence of regulation that rewards the marketing of products that are effective at helping cigarette smokers quit, and the research to validate their effectiveness, manufacturers have been more focused on marketing products that appeal to the widest possible consumer base without any incentive to conduct the research that would inform consumers or FDA. Premarket review gives responsible companies an incentive to perform the research to demonstrate the value of their products for quitting, and to present that science to FDA. A company that can show that its products help smokers quit, minimize the delivery of toxins, consistently deliver nicotine levels in accord with their labeling and do not appeal to kids should meet the public health standard for new products and may well point the way toward industry product standards. However, without premarket review, smokers have no way of distinguishing between products that can help them quit and those that may only sustain their smoking addiction.

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<sup>27</sup> FDA Brief at 9-10.

<sup>28</sup> 81 Fed. Reg. at 29,037. See FDA Brief at 16.

<sup>29</sup> FDA Brief at 16 [citations omitted].

<sup>30</sup> *Id.*



In your confirmation hearing before the Senate Health, Education, Labor and Pension Committee, you repeatedly made the insightful observation that the net public health impact of particular e-cigarette products is an issue of facts and data and should be resolved as such:

These are ultimately empiric questions that can be adjudicated by FDA in a proper regulatory context. An e-cigarette for example or a vaping product might be a good smoking cessation tool and an e-cigarette flavored like chocolate chip cookie dough may not be. So I think that in a proper regulatory context we have the tools, thanks to Congress, to adjudicate these questions . . .

These are empiric questions in my view . . . about when a reduced harm product can be a useful tool for transitioning people off of combustible cigarettes and onto a reduced harm product or when they might be a gateway toward adolescent smoking . . . And I think in a properly constructed and properly overseen regulatory context and regulatory process we should have the capacity under the authority Congress gave us to make these determinations . . . .

The current Deeming Rule provides the greatest opportunity to resolve precisely those kinds of factual, data-driven issues as to individual products.

Finally, it would be contrary to FDA's policies regarding all other products under its authority that are addictive, potentially harmful and/or marketed to address a serious health problem (cigarette smoking in this case) to exempt manufacturers from being required to seek authorization for marketing e-cigarette products in order to protect public health. Because, under Section 907 of the TCA, the burden is on the agency to demonstrate that its proposed standard is "appropriate for the protection of the public health," it may take many years for FDA to issue its first product standards on a class of products as new to the market as e-cigarettes and e-liquids, particularly in the absence of the premarket review process, which requires the manufacturers to supply critical data to FDA about their newly-emergent products. The agency's first proposed product standard (limiting n-nitrosornicotine, or NNN, in smokeless tobacco) was not published until over seven years after enactment of the TCA. Moreover, despite the claim that "useful" standards already have been developed for e-cigarettes, those standards, largely developed by the e-cigarette industry itself, are entirely inadequate. For example, the industry has yet to develop a single standard limiting the production of flavored products that appeal to kids. Its standards also do not include any criteria to identify which products are effective at helping cigarette smokers quit. It has little incentive to develop adequate standards voluntarily.

***The Deeming Rule Carefully Evaluated its Impact on the E-Cigarette Market and on Constructive Innovation.***

The industry and others have claimed the Deeming Rule puts such undue cost burdens on manufacturers of e-cigarettes and e-liquids that it may eliminate almost all of the vapor products on the market, while more hazardous products like cigarettes have been "grandfathered" and therefore are not subject to a similar premarket review. This argument for weakening regulation of e-cigarettes suffers from logical and factual flaws.



First, the Tobacco Control Act's grandfathering of all tobacco products on the market as of February 15, 2007, including cigarettes, does not justify reducing FDA's authority to make science-based judgments about the public health impact of tobacco products introduced to the market after that date, including e-cigarettes. This is particularly unwise given what has happened in the absence of regulation. There has been no control over quality, clear evidence that many of the products have been designed in ways that appeal to youth, legitimate questions raised about whether e-cigarettes may in some cases function as a starter tobacco product for young people and continued uncertainty about whether some of these products may lead to an increased likelihood of smoking. FDA has broad authority under the TCA to address the hazards of cigarettes, including grandfathered products, through product standards, graphic health warnings, marketing restrictions, disclosure requirements, etc., and it should use that authority. At the same time, the agency should use all powers at its disposal to assess the potential product and public health hazards of individual new tobacco products, including e-cigarettes.

Second, the industry has created a misleading picture of the cost to manufacturers of compliance, including pursuing a PMTA. Although the industry and others refer to FDA's estimates of the range of application costs for e-cigarette PMTAs (running as high as \$2.6 million for electronic nicotine delivery devices and \$2.0 million for e-liquids), they fail to mention that FDA also determined that a relatively low percentage of manufacturers would actually face costs at the highest levels and that the weighted average cost is estimated at \$466,563 per e-cigarette device and \$131,643 per e-liquid.<sup>31</sup> FDA also predicted that, over time, these costs would decline, due to added efficiencies, more research, and the bundling of applications by manufacturers, as well as bridging data from one product to another.<sup>32</sup> As FDA's Regulatory Impact Analysis (RIA) points out, the research burdens of PMTAs are quite different from premarket applications for new drugs, as PMTAs are not expected to include randomized clinical trials like those conducted to support drug approvals.<sup>33</sup> Instead, many applications will be able to rely on existing research on the toxicological properties of the ingredients in their products, from the manufacturers' own data as well as public sources, existing scholarly research on usage patterns or characteristics of similar products, the availability of public dockets to allow access to already available data and studies, FDA's own research studies of various products and the use of tobacco product master files, which will allow manufacturers to rely on confidential information from suppliers.<sup>34</sup>

Third, the industry and others have inaccurately claimed that such costs will destroy the market for these products. These claims ignore the careful consideration FDA gave to this issue during the rulemaking process. FDA concluded that the Deeming Rule likely will accelerate consolidation in the e-cigarette industry, both because manufacturers of poor-selling products will forego premarket authorization and because vape shops that currently mix their own e-liquids (and therefore are considered "manufacturers" under the TCA) would likely convert to a pure retail model. Overall, FDA projects that makers of 360 to 450 e-cigarette devices, and 1,250 to 2,500 e-liquids, will submit premarket applications.<sup>35</sup> FDA further estimates that 266 to 322 e-cigarette devices and 900-1,800 e-liquids would remain available after the first round of premarket review.<sup>36</sup> Thus, there is no basis for the assertion that the costs associated with the premarket process will itself deprive

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<sup>31</sup> Department of Health and Human Services, Food and Drug Administration, Deeming Tobacco Products to be Subject to the Food, Drug and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act, Docket No. FDA-2014-N-0189, Final Regulatory Impact Analysis (May 2016) (RIA), at 87-92. *See also* FDA Brief, at 20, n.6.

<sup>32</sup> *Id.*

<sup>33</sup> RIA at 86.

<sup>34</sup> *Id.* at 85.

<sup>35</sup> *Id.* at 84.

<sup>36</sup> RIA at 80.



consumers of access to e-cigarette products. Instead, the premarket review process will result in fewer products with defects, high levels of toxins, inconsistency in levels of nicotine and other ingredients and inaccurate labeling. The fact that some vape shops which cannot consistently produce e-liquids to specification will become retailers of products manufactured by companies with the ability to do so will not be a net detriment to public health. Just as we do not tolerate the manufacture of drugs by companies that lack the ability to produce products of consistent quality, so too we should not tolerate the manufacture of e-cigarette products by companies unable to do so.

***The Deeming Rule Preserves Incentives to Innovate.***

The Deeming Rule will promote constructive innovation by responsible manufacturers. It will discourage the kind of innovation that has led to the introduction of products like “Slurpee Very Berry” e-liquid. During the years before FDA’s Deeming Rule, the unregulated market for e-cigarette products yielded “innovation” largely in the form of more and more candy and fruit flavors that appeal to kids. A 2014 study identified 7,700 unique e-cigarette flavors available online, with an average of more than 240 new flavors being added per month.<sup>37</sup> The unregulated market incentivized manufacturers to “innovate” by marketing products that prove appealing for recreational use, not to develop products that actually help smokers quit.

The premarket review process creates a far different set of incentives. That process gives manufacturers of e-cigarettes an incentive to develop and market products that have demonstrable public health benefits, to develop the data supporting those benefits and to jettison products that create risks to consumers or are likely to attract kids. That set of incentives will ensure the marketing of the e-cigarette products most likely to enhance public health.

***The TCA Facilitates the Truthful Communication of Risk.***

Contrary to various claims, the current regulatory system does not erect high barriers to truthful communication of the relative risks of tobacco products, leaving consumers without useful information. On the contrary, Section 911 of the TCA defines the pathway for companies to make truthful, non-misleading claims of reduced risk, while protecting the public from the adverse consequences of misleading health claims. Indeed, the value and effectiveness of FDA regulation under Section 911 was demonstrated by the agency’s decision to deny the modified risk applications submitted by Swedish Match for its Swedish snus products, which would have altered the current warning labels for those products in ways that would have conveyed inadequate information to consumers about the health hazards of Swedish snus.<sup>38</sup> At the same time, however, FDA suggested that it would consider revised applications with changes in the proposed modified risk claims.<sup>39</sup> Since the Swedish Match decisions were issued, new modified risk applications have been filed for PMI’s IQOS “heat not burn” product and for snus products marketed in the U.S. by R.J. Reynolds. Nothing in FDA’s administration of Section 911 suggests that the agency has constructed excessive regulatory barriers to the communication of non-misleading information about reduced risk products.

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<sup>37</sup> Zhu, S-H, et al., “Four Hundred and Sixty Brands of E-cigarettes and Counting: Implications for Tobacco Regulation,” *Tobacco Control*, 23(Supp 3):iii3-iii9, 2014.

<sup>38</sup> See FDA Response Letter to Swedish Match North America, Inc., December 14, 2016.

<sup>39</sup> *Id.*



## ***Conclusion***

The Deeming Rule was the result of a lengthy process based upon a solid record that FDA carefully assembled after consideration of many different views and after providing every interested party an opportunity to comment and submit relevant evidence. The result may not be perfect, but it is evidence-based and flexible enough to produce sound results. As the FDA *Nicopure Labs* brief so sensibly put it, “even if e-cigarettes were ultimately proven to be a net benefit to public health, regulation of those products would *further* benefit public health, because it would improve their quality and mitigate the risks that are known now.”<sup>40</sup>

The premarket review process under the Deeming Rule provides a viable way to reach scientifically valid judgments about which products show promise in helping smokers quit and which products serve only to introduce non-smokers, particularly young people, to nicotine addiction or to enable smokers to continue to smoke. As you indicated during your confirmation hearing, this requires difficult line-drawing and “that line needs to get drawn by people who are expert in evaluating that science . . . .” We urge you to allow FDA to make full use of the premarket review mechanism for making those judgments and thereby protect the public from products that undermine the achievement of our shared public health objectives.

Respectfully submitted,



Matthew L. Myers  
President

cc: Mitch Zeller, Director, Center for Tobacco Products, FDA

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<sup>40</sup> FDA Brief at 41 (emphasis in original).