Proposal 2: Cancel the FDA deeming rule before it destroys the U.S. vaping market

Recommendation 2. An *emergency response* is required to prevent the near complete and needless destruction of the US vapor industry by crudely designed and wholly inappropriate regulation. The following approaches are an urgent response:

a. Put the implementation process on hold and quickly pass legislation that changes the Tobacco Control Act predicate date to 8 August 2016 for nicotine products that do not contain tobacco.
b. Replace the costly, opaque and politicized product-by-product authorization regime with a standards-based regime where it is clear what is required of manufacturers (recommendation 3).
c. Add a range of interim safeguards concerning common ground issues such as battery and fluid safety if a standards regime will take time to agree. These should be applied by Congress in the instrument it uses to affect the changes above.

In May 2016, the Food and Drug Administration published a 134-page regulation[1] deeming e-cigarettes and some tobacco products to fall under the Family Smoking Prevention and Tobacco Control Act. In doing so, the FDA has applied extremely burdensome regulatory burdens and an opaque authorization regime, the Pre-Market Tobacco Application (PMTA)[2] to many thousands of products made by thousands of businesses, the vast majority being small-scale American enterprises. The arguments against this rule are summarized in legal arguments in proceedings brought against the FDA by an American medium-scale advanced technology business[3], and in a supportive *amici curiae* brief by public health experts[4]. The case against these regulations is broadly as follows:

- There is no problem to which the proposed rule provides a solution. In fact, the picture is one of public health success, with adult[5] and youth smoking[6] falling to record lows and at rapid rates.
- Despite alarmist claims about youth vaping, most teenage vaping does not involve nicotine[7], is occasional or experimental[8] and frequent use is concentrated in young people who are already smokers[9]
- The claimed benefits of these regulations[10] are, in fact, nugatory or negative when examined[11].
- The costs and burdens of the regulations are so large that they will destroy almost all the vaping market while leaving the cigarette market intact. All vaping products currently on the market and serving more than 8 million Americans[12] will be taken off the market by default and be required to regain access to the market via the PMTA authorization process, at a cost of at least $182k-$2.01m per application for liquids and $286k-$2.62m per application for devices[13]. (And some experts believe these costs are understated.)
- FDA will need to create a vast bureaucracy of scientists and evaluators to process the 6-7,000 PMTA applications it anticipates receiving. Yet even this volume assumes most of the industry is not a burden because it 'exits' the market. By 'exit' FDA means 'put out of business', not because there is anything wrong with their products, but because they cannot afford the costs and uncertainty of FDA's PMTA process and do not have the compliance experience that will be necessary.

- Vaping and use of other alternatives to cigarettes creates new pathways out of smoking for people who do not wish to quit or find it difficult[14]. The FDA has failed to assess the likely impact of its own highly burdensome intervention on the resulting patterns of vaping and smoking. There are many scenarios in which its rules could *increase* smoking and cause harm by reducing the appeal of vaping products compared to cigarettes. FDA's regulation is reckless and amounts to an unjustified and harmful protection of the cigarette trade.
- FDA's intervention is certain to stimulate cross-border internet shopping as users try to source the products they currently use and take advantage of new innovations that FDA will obstruct from the US market. In doing so, it will be piling costs onto American businesses while subjecting them to cut-throat price competition from foreign internet vendors.
- Though regulation is supposed to be proportionate to risk, the most toxic products (cigarettes) were given a broad exemption to the authorization regime. The regulation of vaping products is not just disproportionate, but it is 'anti-proportionate', perverse and unfair compared to cigarettes.

Safeguards can be introduced rapidly pending the development of a full standards based regime, for example like those added to the Cole-Bishop amendment to the Agricultural Appropriations Bill[15].

References

1 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, 81 FR 28973, 10 May 2016 [link]

2 Pre-market Tobacco Application. FDA information [link]. FDA, Premarket Tobacco Product Applications for Electronic Nicotine Delivery Systems: Guidance for Industry. May 2016 [link]

3 Nicopure Labs et al vs Food and Drug Administration et al, Motion for Summary Judgement, 8 July 2016 [link]

4 Brief of *amici curiae* of Clive Bates and other in support of plaintiffs' motion for summary judgement, 5 August 2016 [link]

5 National Center for Health Statistics, National Health Interview Survey, 1997–2015, Sample Adult Core component. Figure 8.1. Prevalence of current cigarette smoking among adults aged 18 and over: United States, 1997–2015. [link]

6 Singh T, Arrazola RA, Corey CG, et al. Tobacco Use Among Middle and High School Students — United States, 2011–2015. *MMWR Morb Mortal Wkly* Rep 2016;65:361–367. [link]

7 Miech R, Patrick ME, O'Malley PM, Johnston LD (2016) What are kids vaping? Results from a national survey of US adolescents. Tob Control tobaccocontrol-2016-053014. [link]

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9 Warner KE, Johnston LD, O'Malley PM, et al (2016) Frequency of E-Cigarette Use and Cigarette Smoking by American Students in 2014. Am J Prev Med 51:179–184. [link]

10 FDA, Deeming Rule Docket No. FDA-2014-N-0189: Final Regulatory Impact Analysis, 10 May 2016, *5. Willingness To Pay for Benefits of Rule*, page 67 [link]

11 Brief of *amici curiae* of Clive Bates and fifteen other in support of plaintiffs' motion for summary judgement, 5 August 2016 [link] see page 4-7 for short critique of each benefit claimed by FDA.

12 CDC, National Health Interview Survey, 2015 Data Release [link], Analysis by Rodu B. How Many Americans Vape? CDC Data Show Fewer Vapers & Smokers in 2015, Tobacco Truth 17 July 2016 [link]

13 FDA cost estimates for PMTA costs are set out in its final Regulatory Impact Analysis, May 2016 (Link – table 11 & 12 from page 85). The figures show here are for the first application.

14 Levy DT, Cummings KM, Villanti AC, Niaura R, Abrams DB, Fong GT, et al. A framework for evaluating the public health impact of e-cigarettes and other vaporized nicotine products. *Addiction*. 2016 Apr 25; [link]

15 See description at: Keller and Heckman LLP, The Cole-Bishop Amendment to the Agricultural Appropriations Bill Amending the Grandfather Date for "Deemed" Tobacco Products Passes House Committee - What Next? 29 April 2016 [link]