



Free markets. Real solutions.

R STREET SHORTS NO. 17
February 2016

H.R. 2058 AND THE REGULATION OF E-CIGARETTES

Dr. Joel Nitzkin

INTRODUCTION

H.R. 2058, recently introduced in May 2015 by U.S. Rep. Tom Cole, R-Okla., draws the attention of policymakers to the structure of the Food and Drug Administration's regulatory regime for tobacco products. One must ask if the process truly is designed to protect public health or if it is instead designed to protect the sales and profits of the major "Big Tobacco" cigarette companies.

Tobacco use kills an estimated 480,000 Americans each year, a death toll that has been remarkably stable for quite some time.¹ However, a closer look shows that all of the frequently referenced data on illness, addiction and other harms attributed to tobacco are, in fact, due to just a single product: the tobacco cigarette. Deaths and other harms from all other tobacco-related products on the U.S. market are so few in number and so hard to separate from background noise that they are not tracked by any federal agency.

Back in the 1900s, then-Food and Drug Administration Commissioner David Kessler, with the assistance of staff member Mitch Zeller, investigated and documented the risks posed by cigarettes and the steps taken by Big Tobacco both to hide this information from the public and to manipulate the manufacture and marketing of cigarettes to attract and addict teen smokers.² At the time, Kessler and Zeller's response was to try to assert FDA control over tobacco products to reduce the toll of addiction, illness and death due to cigarettes and what they perceived to be the socially irresponsible behavior of the major cigarette companies.

The groundwork for what would become the FDA Tobacco Law was laid by Kessler and Zeller's work, and by the U.S. Supreme Court, which in March 2000 handed down a 5-4 decision authored by Justice Sandra Day O'Connor in the case of *FDA v. Brown & Williamson, et al.* The ruling prohibited the FDA from regulating tobacco products without express congressional authorization to do so.²

Initial attempts to secure congressional support went nowhere, due in large part to strong opposition from the cigarette lobby. In 2004, Rep. Henry Waxman, D-Calif., initiated closed-door negotiations to craft the Family Smoking Prevention and Tobacco Control Act, with significant input from the Campaign for Tobacco Free Kids (TFK) and Philip Morris (now Altria).³ Those secret talks were the genesis of a wrong-headed shift in public-health policy whose effects still can be felt. Waxman's bill shifted the regulatory burden from cigarettes to lower-risk tobacco-related products.

In those talks, TFK represented a common, though by no means universal, belief within the public-health community that the only reason any non-pharmaceutical tobacco-related company might offer a lower-risk product would be to addict more teens to nicotine. Reflected in the final bill was the presumption that public health would best be served by preventing the entry of any new products into the marketplace. For its part, Philip Morris was pleased with this approach, as it protected their cigarette sales from competition from alternative products.

Lung, heart and cancer associations, along with others in the public-health and tobacco-control communities, recruited others to endorse the newly proposed FDA tobacco law. They circulated a summary that alluded to major public-health benefits the law could not possibly deliver. Ultimately, nearly all major health and social-service organizations endorsed the bill, seemingly unaware of the provisions protecting Philip Morris. Attempts to amend the bill and strengthen it from a public-health perspective were brushed aside by Waxman's office as poison-pill amendments that would risk losing Philip Morris' support.

Since its passage in 2009, the law's effects have been the opposite of Kessler's original intent. Rather than creating legal and regulatory processes that secure public-health benefits by substantially reducing consumption of cigarettes and reducing teen recruitment to nicotine addiction, the current process protects cigarettes from competition from lower-risk and less addictive products. In essence, the law solidifies cigarettes as the default means to deliver nicotine to Americans. In the almost seven years since the law's adoption, the FDA has done nothing to regulate the quality of manufacture of any tobacco product. Marketing regulations have been limited to enforcing provisions of the 1998 Tobacco Master Settlement Agreement, which were established a decade before the law's enactment.⁴

DEEMING, THE 'GRANDFATHER DATE' AND THE PMTA PROCESS

The FDA Tobacco Law does not currently cover e-cigarettes or selected other tobacco-related products. However, the law provides a "deeming" procedure through which the FDA could bring other tobacco-related products under its jurisdiction. As part of this procedure, new products must submit a "Premarket Review of New Tobacco Products Application" (PMTA), a process that is estimated to cost \$2 to \$10 million per product. Those new products that do not submit an application or whose applications are rejected face removal from the market.⁵

The law provides that products that were on the market prior to February 2007 – two years prior to the bill's enactment – are "grandfathered" from the PMTA process. Thus, no such application, threat or cost would be imposed on any major brand cigarette product.

By contrast, all of the e-cig and related vapor products now on the market are substantially different from the relatively primitive first-generation e-cig products that were on the market in early 2007. Thus, without a change in the grandfather date, each and every e-cig product – categorized separately by brand, flavor and strength of nicotine – will be required to incur substantial costs to avoid removal from the market.

Given these costs, compliance with the PMTA process and deeming process envisioned by the current law would eliminate the entire "vape shop" component of the e-cigarette industry and all of the customizable products they produce.⁶ Laying a destructive and undue cost burden on less harmful and less addictive products that could draw consumers away from cigarettes does not protect public health.

SAFETY OF E-CIGS AND RELATED VAPOR PRODUCTS

It's been almost a decade since e-cigarettes first were introduced in the United States. In that time, despite millions of users and hundreds of products, there are no confirmed reports of harm coming to any user or bystander from a commercially available vapor product that was used in accordance with manufacturer recommendations.

There have been a fairly large number of inadvertent exposures to e-cigarette liquid, though the only actual poisonings reported to-date have been to individuals exposed to concentrated nicotine liquids that were intended for use in manufacturing the e-cigs. In an October 2014 Federal Emergency Management Agency summary of all known e-cigarette fires and explosions,⁷ FEMA could only find 25 such reports. Of these 25 reports, 20 were due to use of the wrong charger. Of the nine reported injuries, only two were serious and both were related to user-modified products. There were no fatalities. The report recognized that, at that time, about 2.5 million Americans used e-cigarettes.

Perhaps the most onerous and costly aspect of the PMTA process, other than the grandfather date, is its requirement to produce studies demonstrating that each proposed product would not harm nonusers by recruiting significant numbers of them to nicotine use. In fact, when it comes to e-cigs and related vapor devices, there already is substantial evidence on this point provided by major surveys in both the United States⁸⁻¹⁰ and the United Kingdom.¹¹ As a class of product, experience to date from these surveys clearly demonstrates the vast majority of those attracted to e-cig products are current smokers. Use by nonsmokers is almost entirely limited to one-time or occasional experimentation or social use, often with zero-nicotine e-cig products. It is exceedingly rare to find progression to consistent use of e-cigarettes by those who were not previously smokers and progression to consistent cigarette smoking has not, to date, been demonstrated at all.

The FDA's insistence that each individual e-cig or other nicotine vapor product separately demonstrate that it would not recruit non-nicotine users is an onerous and totally unnecessary regulatory requirement.

POPULARITY OF E-CIGS AND RELATED VAPOR PRODUCTS

The last six years have seen skyrocketing sales of e-cigarettes and related vapor products, concurrent with record annual reductions of both teen and adult smoking.⁸⁻¹¹ The data available from these governmental sources strongly suggests the increasing popularity of vapor devices may be part of the cause of these decreases in smoking prevalence.

In a December 2015 report, analyst Bonnie Herzog of Wells Fargo Securities estimated the total anticipated U.S. vapor market to be about \$3.5 billion.¹² Of this, “cig-a-like” product sales were estimated at \$1.5 billion. Sales of more customized products – given the category heading of “VTM” (Vapors/Tanks/Mods & Personal Vaporizer) – were estimated at \$2.0 billion. On a per-cigarette-equivalent basis, the VTM products are far less expensive than the cig-a-like products, due to the extremely low cost of the refill fluids and the durability of the devices. Thus, it’s fair to say the VTM products now dominate this market in terms of dollars, cigarette-equivalents and, more likely than not, number of users.

Thus, the market is no longer dominated by the standardized mass-market cig-a-like products produced and sold by the Big Tobacco cigarette companies, though these products continue to have more visible advertising.

CHANGING THE ‘GRANDFATHER DATE’

One small change in the law – shifting the “grandfather date” from Feb. 15, 2007 to the effective date of the new deeming regulations – would allow these vape-shop products to remain on the market. It would eliminate the requirement for products now on the market to submit costly PMTA applications. It also would clear the way for the FDA to begin regulating how e-cigs and related vapor products are manufactured and marketed. The costs and delays of imposing the PMTA process would be eliminated, while the FDA’s ability to regulate these products would be otherwise unimpeded.¹³

In May 2015, Rep. Cole introduced H.R. 2058,¹⁴ a bill that would do exactly that. By setting the “grandfather” date to coincide with the implementation date of the final deeming regulation, the bill would bring currently marketed e-cigarettes under FDA jurisdiction without requiring costly PMTA applications. Passage of H.R. 2058 also would enable the FDA to proceed immediately with developing and implementing regulations to assure the quality and consistency of manufacture and appropriate labeling, packaging and marketing of these newly deemed vapor products.

Conversely, failure to adopt H.R. 2058 would delay such regulation for years, as applications are prepared and reviewed. It also likely would result in costly and preventable litigation. Vapor-industry stakeholders could justifiably frame the PMTA process as a backhanded way to simply remove most, if not all, of their products from the market without regard for the public health implications of doing so. The FDA already has been beaten in court in the agency’s first attempt to summarily remove e-cigs from the U.S. market.¹⁵ Future attempts could meet similar fates.

Hundreds of thousands, if not millions, of vapers believe their lives have been saved by switching from deadly

cigarettes to far less hazardous vapor products. One would therefore expect imposition of the current PMTA process and grandfather date to generate a huge black market and the proliferation of homemade devices and e-cigarette liquids. Eliminating the current vape-shop products by FDA fiat would undoubtedly spark a backlash, and potentially a dangerous one.

Even if H.R. 2058 is adopted, additional steps will be required by the FDA and other federal agencies to support further enhancements to product development and to fully integrate a tobacco harm reduction component into current tobacco control programming. Doing so could further accelerate the remarkable recent declines in cigarette use in the United States.

In other words, adoption of H.R. 2058 would be a first step in re-orienting FDA regulation of tobacco products from a process designed to protect the sales and profits of the major cigarette makers to a process designed to reduce tobacco-related addiction, illness and death.

ENDNOTES

1. Office of the Surgeon General, USDHHS. *The health consequences of smoking - 50 years of progress*.
2. Kessler, David. 2001. *A Question of Intent: A great American battle with a deadly industry*. Public Affairs.
3. Mullins B. 2004. How Philip Morris, Tobacco Foes Tied the Knot. CTFK and PM collaborating on FDA legislation to regulate tobacco. *Roll Call* (Washington, DC), Oct. 5, 2004.
4. Wikipedia. *Tobacco Master Settlement Agreement*. Feb. 4, 2016. https://en.wikipedia.org/wiki/Tobacco_Master_Settlement_Agreement
5. American Vaping Association. Oct. 28, 2015. *Support H.R. 2058. Protects the U.S. Vapor Product Industry from the FDA Deeming Ban*. Explanation of the grandfather date of the Tobacco Control Act and how failure to change the fate will ban almost all vapor products due to cost of application.
6. Phillips, CV. May 26, 2014. *CASAA’s Comment to OMB/OIRA Regarding Paperwork Reduction Act and FDA Deeming Regulation*. <http://blog.casaa.org/2014/05/casaa-comment-to-omboira-regarding.html>
7. U.S. Fire Administration. October 2014. *Electronic Cigarette Fires and Explosions*. US Department of Homeland Security; FEMA. https://www.usfa.fema.gov/downloads/pdf/publications/electronic_cigarettes.pdf
8. National Institute on Drug Abuse. December 2015. “Monitoring the Future Survey, Overview of Findings 2015.” In *Monitoring the Future*. Dec. 24, 2015. <http://www.drugabuse.gov/related-topics/trends-statistics/monitoring-future/monitoring-future-survey-overview-findings-2015>
9. Agaku, IT, BA King, and SR Dube. 2014. Current Cigarette Smoking Among Adults - United States, 2005-2012. *Morbidity and Mortality Weekly Report* 63, no. 2, 17/Jan: 29-34.
10. Arrazola, Rene A., Tushar Singh, Catherine G. Corey, Corrinne G. Husten, Linda J. Neff, Benjamin J. Apelberg, Rebecca E. Bunnell, Conrad J. Choiniere, Brian A. King, Shanna Cox, Tim McAfee, and Ralph S. Caraballo. 2015. Tobacco Use Among Middle and High School Students - United States, 2011-2014. *Morbidity and Mortality Weekly Report* 64, no. 14, April 17, 2015: 381-85.
11. McNeill, A., L.S. Brose, R. Calder, and S.C. Hitchman. August 2015. *E-Cigarettes: An Evidence Update. A Report Commissioned by Public Health England*. An Evidence Update Plus Policy Implications. Aug. 19, 2015. <https://www.gov.uk/government/publications/e-cigarettes-an-evidence-update>

12. Herzog, Bonnie, Adam Scott, and Patty Kanada. 2015. *Nielsen: Tobacco 'All Channel' Data through 11/28*, Equity Research Department, Wells Fargo Securities. Wells Fargo Securities. 17 pages.

13. Siegel, Michael. Dec. 9, 2015. "Changing Grandfather Date Does Not Mean FDA Cannot Review E-Cigarette Products; Instead, It Will Force Agency to Regulate E-Cigarettes Properly." In *The Rest of The Story*. Feb. 4, 2016 <<http://tobaccoanalysis.blogspot.com/search?q=grandfather+date>>.

14. Buck, Ken, Rep (R-CO-4). Jan. 12, 2016. *H.R.4371 - Article I Consolidated Appropriations Amendments, 2016*. Congress.gov. <https://www.congress.gov/bill/114th-congress/house-bill/4371/text>

15. Leon, R. 14 January 2010. *Sottera, Inc, Doing Business as NJOY v. Food & Drug Administration et al*. Judge Richard Leon's ruling striking down FDA's e-cig ban as unlawful. Jan. 7, 2014 https://ecf.dcd.uscourts.gov/cgi-bin/show_public_doc?2009cv0771-54 and https://ecf.dcd.uscourts.gov/cgi-bin/show_public_doc?2009cv0771-55

ABOUT THE AUTHOR

Dr. Joel L. Nitzkin is senior fellow in tobacco policy for the R Street Institute.

Joel is a public health physician, board certified in preventive medicine as his medical specialty. He has been a local health director, a state health director and president of two national public health organizations.

Since the mid-1990s, Joel has been in the private practice of public health as a health policy consultant. In this capacity, he has taken on a number of research and teaching assignments for federal, state and local public health agencies; assisted with accreditation of a managed care organization; and done substantial expert witness work related to communicable disease control, quality of health care, and tobacco control.

In 2007, while serving as co-chair of the Tobacco Control Task Force of the American Association of Public Health Physicians, Joel played a lead role in exploring policy options for reducing tobacco-attributable illness, death and property damage in the United States. It was this effort that focused his attention on tobacco harm reduction as a potential life-saving measure and on other problematic aspects of current American tobacco control policy.

Over the next four years, Joel worked with and through the AAPHP, at his own expense, to advocate for consideration of THR within the public health community and to secure positive action on what he perceived to be related problematic issues. Finding these efforts to be extremely frustrating, Joel subsequently partnered with R Street as organizations independent of government, major pharmaceutical firms and the tobacco industry, yet interested in THR as a scientifically sound and market-oriented alternative to selected aspects of current American tobacco control policy.

In 2012, serving as a volunteer with a modicum of support to offset travel and other costs, Joel has made presentations on THR and related issues to a variety of tobacco industry, medical, public health and state legislative audiences. He has also taken action to place THR on the agenda of the House of Delegates of the American Medical Association.