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The Deeming Regulation: Why the Future of the E-Cigarette Industry Hangs in the Balance

By Caitlin Bradley

Recently, the U.S. Food and Drug Administration (“FDA”) finalized its widely anticipated “Deeming Regulation” subjecting electronic nicotine delivery systems (“ENDS”), including e-cigarettes, to FDA regulation under the Food, Drug and Cosmetic Act (“FDCA”). The Deeming Regulation has sent shockwaves throughout the e-cigarette industry as many are struggling to understand the impact it will have on the industry, with many forecasting doom. Although many questions remain unanswered, it is clear that the Deeming Regulation will have an enormous impact on the e-cigarette industry and will likely force many players out of the industry. By 2019, the e-cigarette industry is likely to look very different than the current one.

In order to understand the impact of the Deeming Regulation and the cause for concern among industry members, it is vital to first understand the development of the e-cigarette industry as well as the history of the Tobacco Control Act and its impact on the traditional cigarette industry. This article is not an exhaustive discussion of the regulatory issues at play; however, it is a primer of the major concerns facing the industry. Part I of this article will discuss the rise of the e-cigarette industry and the unique issues facing it. Then Part II of this article explores the impact of the Tobacco Control Act on the traditional cigarette industry as the same impact is expected for e-cigarettes. Finally, in Part III, the key components of the Deeming Regulation and the legal challenges being mounted against it are discussed.

I. The Rise of E-Cigarettes

The e-cigarette and vaping industry is a relatively new industry seeing a dramatic rise in the last decade. Although the first e-cigarette was patented in 1963 by Herbert A. Gilbert, it was never manufactured. E-cigarettes were largely ignored until the early 2000s when Chinese pharmacist Hon Lik invented the modern e-cigarette. Lik, whose father died of lung cancer and who was a smoker himself with several failed cessation attempts, filed the first patent for an e-cigarette in China in 2003. The device was intended to be a cessation aid and manufacturing began within a year. The popularity of e-cigarettes spread quickly throughout China and Europe, and by 2014, the World Health Organization (“WHO”) estimated that there were 466 brands and US$ 3 billion spent on ENDS globally.

From its onset, this young industry has been controversial within the scientific community as cessation experts have grappled to understand the risks and benefits of these new products. While some tobacco control experts believe that ENDS, and e-cigarettes in particular, present an alternative to cigarettes for current smokers hoping to quit smoking, others are wary of the potential they present for people who have never tried tobacco (or “never-smokers”). Among never-smokers, use among youth is the greatest concern. On the one hand, experts and industry members argue that e-cigarettes have been the only effective means for cessation for many smokers. On the other hand, this new technology may present one additional tempting gateway to smoking for youth. Additionally, although many claim that e-cigarettes are safer than traditional cigarettes, studies are still developing to determine the veracity of this claim.
Underlying this debate is a pervasive fear of the unknown. The e-cigarette industry is new and rapidly developing, therefore, longitudinal data related to use patterns and safety is unavailable. In the absence of robust data, researchers are struggling to understand the long-term effects and trends of e-cigarette use by extrapolating the limited data available. One of the most difficult aspects of studying the e-cigarette industry is the extreme stratification within the industry. In the absence of regulation, the market has become flooded with players of all sizes. E-cigarettes and e-liquids are manufactured locally by mom-and-pop-style vape shops and by Big Tobacco giants alike. Because manufacturing standards are not uniform, quality of e-cigarettes, including components of e-cigarettes, such as batteries, vary widely. Experts warn that this variance can affect the safety of the product. For instance, improperly manufactured e-cigarettes have led to several reports of “exploding batteries” causing injuries to consumers.4 The variance in quality, and thus the safety, of these products, is one of the major issues that needs to be addressed in order to better understand this category of products and its effects on public health.

Regulators have been quick to take notice of this dramatic trend and the issues facing consumers. In the U.S., the FDA held extensive public meetings in preparation for the regulation of these products under the Tobacco Control Act wherein these issues were debated and studied extensively. To understand the current issues affecting the regulation of e-cigarettes, it is important to first understand the larger context of tobacco regulation.

II. The Tobacco Control Act

As e-cigarettes were finding their way into the U.S. markets, President Obama signed into law the Family Smoking Prevention and Tobacco Control Act (“TCA”) as an effort to curb traditional cigarette use. The TCA was passed in 2009 as an amendment to the Food, Drug and Cosmetic Act (“FDCA”). The TCA granted FDA authority to regulate all “Tobacco Products” defined as “cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco and to any other tobacco products that [FDA] by regulation deems to be subject to [the Tobacco Control Act].”5 Note that this deeming authority, granted by the TCA, is the basis for the Deeming Regulation, discussed below, where FDA deems ENDS, including e-cigarettes, to be “Tobacco Products” subject to FDA regulation. The TCA also established the Center for Tobacco Products (“CTP”) as a center of the FDA responsible for overseeing the implementation of the TCA and the regulation of the manufacturing, distribution, and marketing of tobacco products.6

Under the TCA, manufacturers of Tobacco Products must seek premarket review of each Tobacco Product before any such product can be marketed or manufactured. This is similar to the premarket review FDA conducts over drugs, devices and biologics to determine their safety and efficacy before such products can legally be marketed. The TCA outlines the various options for premarket review, or regulatory “pathways to market” for all tobacco products. One option is the “Grandfather Option.” Products that were commercially marketed in the U.S. as of February 15, 2007 (the “Grandfather Date”) are considered grandfathered products and are exempt from premarket review requirements. New tobacco products on the other hand, or tobacco products that were commercially marketed after the grandfather date, must submit a Premarket Tobacco Product Application (“PMTA”) for review by the CTP. PMTAs must include, at a minimum:

(i) full reports of all information, published or known to, or which should reasonably be known to, the applicant, concerning investigations which have been made to show the health risks of such tobacco product and whether such tobacco product presents less risk than other tobacco products;

(ii) a full statement of the components, ingredients, additives, and properties, and of the principle or principles of operation, of such tobacco product;

(iii) a full description of the methods used in, and the facilities and controls used for, the


6 Id.
manufacture, processing, and, when relevant, packing and installation of, such tobacco product;

(iv) an identifying reference to any tobacco product standard under [21 U.S.C.S § 387g] which would be applicable to any aspect of such tobacco product, and either adequate information to show that such aspect of such tobacco product fully meets such tobacco product standard or adequate information to justify any deviation from such standard;

(v) such samples of such tobacco product and of components thereof as FDA may reasonably require;

(vi) specimens of the labeling proposed to be used for such tobacco product; and

(vii) such other information relevant to the subject matter of the application as FDA may require.7

Although FDA estimates that a PMTA will cost an average applicant 5,000 staff hours and $333,554 to submit, industry analysts estimate the cost coming closer to $2 to $10 million, with the bulk of the costs going toward the required clinical studies.8 The “full reports and investigations of health risks” required by the TCA include extensive clinical and nonclinical data related to each component of the product. For instance, each constituent or additive of the product must be supported by extensive toxicology data.9 Proposed labelling and packaging must also be supported by consumer perception study data.10 Trials of this nature are typically very expensive, at least in part due to extensive regulatory requirements for clinical studies involving human subjects (such as requirements for Institutional Review Boards, or IRBs). Although these kinds of studies are regularly commissioned by large pharmaceutical and medical device companies, many of which are publicly traded companies funded by investors, very few tobacco companies have the resources to fund the kinds of studies required. As a result, in the 7 years following the TCA, only a handful of PMTAs have ever been filed by manufacturers.

Furthermore, FDA is only authorized to grant PMTAs when the applicant makes a showing that such tobacco product to be marketed would be “appropriate for the protection of the public health.”11 To date, FDA has only issued 8 PMTA orders, all for Swedish Match North America Inc.’s snus smokeless tobacco products due to the unique safety profile of Swedish Snus.12 No PMTAs have ever been granted for traditional cigarettes.

As an alternative to the PMTA route, products that were commercially marketed after the grandfather date, but are “substantially equivalent” to a predicate tobacco product commercially marketed as of the grandfather date or otherwise exempt from the TCA may submit what is known as a Substantial Equivalence Report (“SE Report”) to FDA. In a Substantial Equivalence Report, applicants must show that the proposed tobacco product has the same characteristics as the predicate product, or has different characteristics but does not “raise different questions of public health” than the predicate product.13 This became the preferred route for many manufacturers who would otherwise face the daunting task of submitting a PMTA.

Tobacco products originally regulated under the TCA were given a provisional period during which to submit initial applications and reports. SE Reports submitted before March 22, 2011 were granted provisional status and such products were permitted to remain on the market pending FDA’s review of the report. During the provisional period, approximately 3,517 provisional SE Reports were submitted to FDA.14 Following the provisional period, an additional

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10 Id.
1,926 regular (or non-provisional) SE Reports were filed,15 for a total of 5,443 SE Reports. To date, FDA has reviewed approximately 731 of the 5,443 backlogged SE Reports, with approximately 176 resulting in Not Substantially Equivalent Orders (“NSE Orders”).16 Note, however, that almost 79% of these reviews were not completed until 2015, leaving the vast majority of pending reports untouched for several years after submission.

This massive backlog of SE Reports has generally resulted in the freezing of the tobacco market as manufacturers are unable to introduce “new” tobacco products onto the market without FDA approval. Modifications to an existing tobacco product grandfathered or subject to a provisional SE Report may render the tobacco product a “new” tobacco product requiring the submission of a PMTA. Under the TCA, “new tobacco products” include products that have any modification since the grandfather date, “including a change in design, any component, any part, or any constituent, including a smoke constituent, or in the content, delivery or form of nicotine, or any other additive or ingredient.”17 FDA’s current guidance regarding Substantial Equivalence reveals that any change that renders the product distinct from the predicate will be considered a change that deems a product a “new tobacco product” subject to premarket review.18 Because FDA regulates all “components” of a tobacco product, any change to any part of the product, including its labelling and packaging, are under the purview of FDA. For instance, brand name and labelling changes may render a product a “new” tobacco product even if the product itself remains physically identical to a predicate product. By way of example, FDA states that changing background color of a label from green to red or changing the object depicted in the logo (e.g., star to lion) may render a product distinct from its predicate, therefore rendering it a “new” product requiring premarket review.19 Given FDA’s broad interpretation of “modification,” any change or modification, no matter how slight, carries the risk that a product will be required to submit a lengthy and expensive PMTA, or be required to submit a new SE Report to wait at the back of a massive queue of SE Reports awaiting review.

As a result of the high cost of filing a PMTA and the seemingly endless backlog of SE Reports, tobacco manufacturers have been hesitant to make any change, no matter how slight, to tobacco products on the market. This includes changes that manufacturers perceive to be beneficial to the public health (such as lowering levels of harmful constituents) as any change will likely render the product a “new” tobacco product requiring premarket review under FDA’s current interpretation of “modification.” As the provisional period is over, any “new” tobacco product will need to be taken off the market pending FDA review. Faced with this reality, the tobacco market has frozen in time to avoid the possibility products of being taken off the market (perhaps indefinitely).

III. The Deeming Regulation

Amidst the ongoing controversy surrounding currently regulated tobacco products, FDA finalized its regulation deeming additional products as “Tobacco Products” subject to regulation under the TCA. After an extensive notice and comment period, the regulation, known as the “Deeming Regulation” was finalized on May 10, 2016. As expected, newly deemed tobacco products include dissolvables not already regulated by FDA, gels, waterpipes tobacco, ENDS (including e-cigarettes, ehookah, e-cigars, vape pens, advanced refillable personal vaporizers, and electronic pipes), cigars, and pipe tobacco.20 FDA also claims jurisdiction to regulate all “components” and “parts” of newly deemed tobacco products, including e-liquids, atomizers, batteries (with or without variable voltage), cartomizers (atomizer plus replaceable fluid-filled cartridge), digital display/lights

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16 U.S. Food and Drug Administration, Tobacco Product Marketing Orders, available at http://www.fda.gov/tobaccoproducts/labeling/marketingandadvertising/ucm339928.htm#2. (Note that an NSE Order requires a product to be removed from the market while the manufacturer pursues the PMTA pathway).
19 Id.
to adjust settings, clearomisers, tank systems, flavors, vials that contain eliquids, and programmable software. Manufacturers of Newly Deemed Tobacco Products and their Components are now required, under the Deeming Rule, to seek premarket approval before marketing any such product.

This expansive rule is designed to encompass the e-cigarette industry entirely, including small vape shops that may be unfamiliar with complex federal regulatory schemes. Mitch Zeller, the Director of the CTP, recently commented that FDA estimates that there are somewhere between 5,000 and 10,000 vape shops that will be affected by this rule, most of which operate as both “manufacturers” as well as “retailers” under the rule due to the common practice of mixing e-liquids on site. Manufacturers of these newly deemed products will be subject to the same extensive regulatory requirements as manufacturers or traditional cigarettes, including registration and product listing requirements and the need to submit appropriate applications for each product. As discussed above, the cost of compliance may be too great to bear, particularly for many small businesses. The failure to abide by FDA regulations can result in seizure of unapproved products, civil monetary fines, and, in some cases, criminal sanctions under the FDCA.

The two aspects of the Deeming Regulation that have caused the greatest shockwaves through the industry have been FDA’s refusal to change the grandfather date for newly deemed products and FDA’s deadline for compliance. Each regulatory pathway for tobacco products is available for manufacturers of newly deemed products, however, for purposes of SE Reports, the grandfather date for predicate products is still the original grandfather date in the TCA—February 15, 2007. This is hugely problematic for e-cigarette manufacturers because e-cigarettes were only beginning to enter U.S. markets in 2007 and very few e-cigarette products currently marketed are substantially equivalent to any products marketed in the U.S. prior to February of 2007. These products have evolved rapidly over time, and any modification, including improvements to products, will likely render these products distinct from any predicate e-cigarette, and therefore a “new” tobacco product requiring a PMTA. Given the cost of filing a PMTA, very few e-cigarette manufacturers will be able to afford the cost of filing.

Additionally, even if manufacturers of newly deemed products are able to identify appropriate predicate products, they are unlikely to be permitted to stay on the market while their applications are being reviewed. Unlike the original TCA granting an indefinite “provisional” period for manufacturers submitting SE Reports during the provisional period, the Deeming Regulation includes a sunset date for all applications and reports. Under the Deeming Regulation, each regulatory pathway is subject to a staggered deadline. Manufacturers submitting PMTAs for newly deemed products are given 24 months to submit applications, while manufacturers have only 18 months to submit SE Reports. After this initial deadline, manufacturers are granted an additional 12 month “continued compliance period” wherein FDA has stated that it does not intend to initiate enforcement against products on the market for failure to have premarket authorization. At the end of this continued compliance period, however, newly deemed products on the market without premarket authorization will be subject to FDA enforcement if their applications have not been processed. Given the existing backlog of SE Reports and the wave of new SE Reports sure to come during the 18 months following the Deeming Regulation, it is very unlikely that FDA will be able to review the thousands of SE Reports already awaiting review, much less the new reports to come before the end of the continued compliance period. In theory, many products are likely to be forced off the market before FDA has had a chance to review its submitted SE Report. This has led to widespread uncertainty throughout the vaping industry as manufacturers and retailers grapple with the looming realities under the Deeming Regulation.

Adding to the increasing uncertainty surrounding the Deeming Regulation, it is unclear how courts will interpret various provisions of the rule and how legislators will react. For instance, legal claims are being mounted against FDA challenging various provisions

21 Id. at 28975.


23 Id. at 29011.

24 Id. at 29011.

25 Id.
of the Deeming Regulation. One lawsuit filed by Nicopure Labs, LLC claims that the Deeming Regulation creates a “de facto moratorium” on e-liquids and will cause irreparable harm on its business—namely, that Nicopure will be required to submit hundreds of PMTAs for each of its products. The company claims that FDA’s “one-size-fits all approach” to tobacco regulation is problematic because it prevents smokers from accessing potentially safer products. These concerns are shared by many industry members and other lawsuits are expected, particularly if and when FDA pursues enforcement actions against e-cigarette and e-liquid manufacturers. It is also possible that legislators will act quickly to suspend portions of the Deeming Regulation. At this point, it is unclear how the chips will fall related to the enforcement of the Deeming Regulation.

V. Conclusion

For many smokers, e-cigarettes and other ENDS have been the only successful path away from traditional cigarette use. The Deeming Regulation presents a major challenge to the current vaping industry and may result in driving out many smaller entities who find themselves unable to comply with the regulations. It is unclear how this will shape the vaping industry, but many suspect that the market will become dominated by the few large tobacco manufacturers already familiar with complex regulatory requirements.

As manufacturers of e-cigarettes and other ENDS products evaluate the path forward, it will be essential to consult with legal counsel early in the process to determine feasibility of compliance with the Deeming Regulation and TCA requirements. In particular, manufacturers should identify which products will be subject to unique applications or SE Reports. Each product should be analyzed to determine whether modifications are likely to be the kind FDA will consider significant enough to render products distinct from potential predicate products. Additionally, industry members and legal counsel should closely monitor the developments in this area as FDA continues to publish applicable guidance and courts begin to weigh these issues.
