# A Regulatory Lawyer Predicts the 2015 US Regulatory Landscape

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The vapor industry has been characterized, perhaps aptly, as the regulatory "wild west." There are currently very few regulations governing the manufacture and sale of vapor products. Although many manufacturers have voluntarily implemented product quality standards, no government – state or federal – imposes any quality control requirements on the products' ingredients or how they are manufactured, leading some to question whether certain vapor products are safe and effective.

The regulatory landscape for vapor products will soon change. Between the FDA's proposal to regulate vapor products as "tobacco products" under the Tobacco Control Act and various state and federal proposals to tax vapor products, businesses in the vapor industry should expect the coming year to bring more legal requirements for conducting business. Although many hail some regulation as potentially bringing more order and credibility to this industry, it remains to be seen whether regulators will seek to treat vapor products in a "one size fits all" manner akin to traditional tobacco products, or whether regulators will treat vapor products consistent with their fundamental differences from traditional tobacco products.

With this background in mind, I will try to forecast how the regulatory environment is likely to change in the next twelve months.

The FDA has issued proposed regulations governing the vapor industry. Those regulations would subject vapor products to the Tobacco Control Act's basic requirements currently governing cigarettes and other tobacco products. The proposed regulations were published in April 2014, and the public comment period ended in August. Many in the public health community have called for the FDA to finalize its proposal by the end of 2014, while others believe it will be years before the FDA issues final regulations, particularly considering the threat of legal challenges.

**Prediction #1: In 2015 the FDA WILL Finalize Its Proposal to Regulate Vaping Products**

Some might argue that it would be appropriate for the FDA to take more time to consider the voluminous comments on the proposed regulations, particularly in light of the emerging research supporting the products' likely benefits. I agree. Under this scenario, the FDA could consider the various industry comments, rework its proposal into a more concrete form specific to the industry, and issue a new set of proposed regulations for another round of public comment. This approach is not unprecedented. Indeed, when the FDA first attempted to regulate the tobacco industry in the mid-1990s, it reopened the public comment period, thereby extending the timetable.

I believe that political and public pressure will probably cause the FDA to finalize the regulations sooner than they should be finalized. As for those pesky little details of how to fit the "square peg" of vapor products into the "round hole" of regulations governing tobacco products? Unfortunately, I do not believe that the FDA will fully sort out those details in the final regulations, and instead will address the more specific nuances of the regulations through informal "guidance" issued shortly before the effective date of the various requirements.

**Prediction #2 The Final FDA Regulations WILL Essentially Match the Current Proposed Regulations.**

As for the content of the final regulations, I believe they will be very similar to the content of the proposed regulations. However, changes in regulations in response to public comments are common, and indeed an expected part of the notice and comment

period. This is likely to be particularly true where, as here, the FDA admittedly has more questions than answers about the regulatory science of vapor products.

**Prediction #3 In 2015 the FDA WILL NOT enact regulations regarding "The Flavor Issue".**

In 2014, the FDA came under fire from some for not taking action to ban or otherwise regulate so-called "characterizing flavors." I was not surprised. Although the FDA has taken a keen interest in flavored tobacco products and their potential impact on youth consumption, the Tobacco Control Act lays out a specific set of criteria in order for the FDA to regulate flavors. This criteria is akin to the process that the FDA must undertake in regulating menthol cigarettes, and we all know how long that process has taken.

**Prediction #4 In 2015 the FDA WILL NOT enact Rgulations Regarding Internet Sales of Vapor Products**

In 2014, he FDA did not take action to ban or otherwise regulate remote sales of e-Cigarettes. Again, I was not surprised. The FDA regards the deeming regulations as a so-called "foundational document," meaning that the FDA must first subject e-cigarettes to the law's generally-applicable provisions, and then later decide whether other measures are appropriate. Internet regulations are not one of the Tobacco Control Act's generally-applicable provisions, meaning that the FDA must first finalize this proposal, and then later consider specific regulations. This process likely will take several years.

**Prediction #5 In 2015 the FDA WILL NOT enact regulations regarding the Manufacturing Standards for e-Liquids**

The FDA's proposal does not address basic standards for quality in ingredients or the manufacturing process. And although the lack of any mandated standards has been the subject of some concern, I do not believe that the FDA's final regulations will include any requirements for the manufacturing process or for ingredient quality. At this juncture, the FDA knows too little about the products or their manufacturing process to implement a credible proposal.

**Prediction #6 In 2015 the FDA WILL AMEND the "Premarket Review" of New Vapor Products**

This is perhaps the most controversial element of the FDA's proposal. This process would require the FDA to approve any products that are newly-introduced or changed since 2007, although there would be a two-year window for companies to submit applications. Given the emerging nature of this industry, it appears that all products would be subject to the time-consuming and expensive premarket review process. I do believe, however, that the process – at least as applied to vapor products – will be changed in certain key respects. Although I believe that new vapor products will be subject to some form of premarket review, I believe (and hope) that the FDA will amend the requirements to change the so-called "grandfather" date for products that are exempt from review.

**Prediction #7 In 2015 the North Carolina Tax Model WILL Prevail**

In 2015, I expect that the vast majority of state legislatures will consider some form of vapor product taxes, with new measures being implemented in many states. The question then arises – how will these products be taxed? There are two principal models. In the Minnesota model, vapor products are taxed as a percentage of the wholesale price, which is consistent with the way that states generally tax so-called "other tobacco products." In the North Carolina Model, vapor products are included in an entirely different category and NC taxes the products at five cents per milliliter of e-Liquid.

The principal difference between the two models is that the Minnesota model also taxes the product's electronics, generally leading to higher excise taxes for e-Cigarettes than other products that have demonstrably higher health risks.

I believe the North Carolina model will prevail. It makes little sense to tax the inactive components of a vapor product – namely the battery and other hardware – particularly when those components are often used to consume non-nicotine products. The North Carolina model also better recognizes the fundamental differences between vapor products and other tobacco products, and provides less of a disincentive for consumers to switch.

SUMMARY: In summary, like it or not, the "wild west" era of vapor products will soon be over. Is your business ready? Forward-thinking and proactive businesses are already planning for compliance with the proposed regulations. Are you?