***Regulatory Oversight* Podcast**
12 Days of Regulatory Insights: Day 7 – Tobacco and Nicotine Regulatory Roundup
Speakers: Chris Carlson, Bryan Haynes, and Agustin Rodriguez
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Chris Carlson (00:04):

Welcome back to the special holiday edition of our *Regulatory Oversight* podcast, the 12 Days of Regulatory Insights. This 12 episode series is focused on key highlights and trends from the past year in various areas and designed to keep our listeners informed and engaged during the holiday season. I'm Chris Carlson, a member of our regulatory investigation, strategy and Enforcement Team, or RISE practice, as well as our state AG practice. Before we get started today, I want to remind all our listeners to visit and subscribe to our blogs *Regulatory Oversight* and *Tobacco Law Blog* so that you can stay up to date on developments and changes in the regulatory landscape. Today I'm joined by my colleagues Bryan Haynes and Augustin Rodriguez to discuss key regulatory actions we observed at the state and federal level in the tobacco industry in 2025 and the impact of developments heading into 2026. Bryan and Augustin head up our firm's tobacco and nicotine practice, and our members of our RISE Practice Group. Our tobacco and nicotine practice advises clients up and down the supply chain on tobacco and nicotine regulatory issues across all product segments. Bryan, Augustin, thanks for joining me today.

Bryan Haynes (01:15):

Thanks for having us.

Augustin Rodriguez (01:17):

Pleasure.

Chris Carlson (01:18):

Let's start at the state level. We'll begin by discussing major state regulatory activity in the tobacco and nicotine space in 2025, and then look towards 2026. I know there's been a lot of talk about directory laws and the legal challenges associated with that. Bryan, can you just give us some background on what vapor product directories are and what effect these are in terms of the state landscape?

Bryan Haynes (01:44):

Yeah, sure, Chris. So these laws have been adopted in at least 14 states now, and they're effectively considered a gap filling measure in response to a lack of enforcement by the US Food and Drug Administration of federal pre-market authorization requirements. Just by way of background, the federal law that FDA enforces requires all new tobacco products, which

includes vapor products to receive authorization from FDA before they're sold in the United States. And although FDA has recently stepped up enforcement action, the market for illicit products remains crowded, and many of these products are manufactured offshore and illegally imported by their manufacturers. Based on this sort of flood of illegal products in the US market, many states have adopted laws to establish directories, and these are lists of vapor products that can legally be sold in the state. I'll note that in some cases, these directory laws apply not just to vapor products, but other products such as nicotine pouches, but the prevailing model is to focus on directories of vapor products that can legally be sold. And again, this is in response to a large amount of unauthorized products that are currently being sold. In any event, if a product's manufacturer doesn't submit the required certifications to be listed in the directory, the product can't be legally sold in a state that's adopted one of these laws. Importantly, most of these laws require the manufacturer to certify that their product has either been authorized by the FDA through the pre-market review process, or at least meet certain limited conditions to qualify for FDA enforcement discretion.

Chris Carlson (03:52):

And as with everything in the tobacco and nicotine space, I'd expect there's challenges. Have these laws been subject to challenge and what has been the vehicle to do so?

Bryan Haynes (04:01):

Yeah, these laws have been the subject of litigation in several states, and the issue in all of these cases is the Food Drug and Cosmetic Act, which is the law that FDA enforces, entrusts, FDA, with enforcing pre-market authorization requirements for tobacco products. And the challengers of these laws have argued that the directories are federally preempted because they are essentially state level enforcement frameworks for federal pre-market review requirements. A number of federal courts have heard this argument with airing degrees of favorability, and a number of cases remain pending. At this point, it remains to be seen whether consensus will emerge in the courts, although early indications suggests that different circuits, meaning federal courts of appeals may come to different conclusions on whether these laws are preempted or not.

Chris Carlson (05:05):

And Augustine, Brian, just picking up something that Brian said. Brian mentioned that many of the illicit vapor products are manufactured offshore and imported in the United States. I understand that two states, Alabama and Texas have enacted laws with this in mind. Augustin, can you give us some background there?

Augustin Rodriguez (05:23):

Yeah, sure. Starting with Alabama, Alabama adopted an amendment to its vapor product directory, and that amendment states that no product can be added to the directory unless the product and its components are made packaged, labeled, and manufactured in the United States or the product is FDA authorized? In other words, a product lacking FDA authorization and manufactured outside the United States could not be added to the directory. So that's Alabama in Texas, and this is outside of the directory context. Texas adopted a law that

prohibits marketing, advertising, sale, or offering for sale any e-cigarette product that's wholly or partially manufactured in or marketed as being manufactured in China or any country designated as a foreign adversary under federal law. So that's Texas.

Chris Carlson (06:18):

And have there been any unique challenges to these Alabama and Texas directory laws?

Augustin Rodriguez (06:23):

Yes, as you can imagine, both of these laws are currently subject to pending litigation, one in state court in Alabama and in Texas and federal court At a high level, the plaintiffs in both cases are arguing that states are prohibited from enacting these sorts of restrictions under the US Constitution's dormant commerce clause. The dormant commerce clause generally prohibit state laws that facially discriminate against foreign commerce, although certain exceptions and nuances apply. We're going to be following this litigation into 2026 to see how each of these tribunals resolves these challenges

Chris Carlson (07:02):

And understanding the goal of vapor directories really are trying to get to the point of mitigating these illicit products coming to the country. Bryan, beyond the directory laws, state AGs have also relied on their own state laws to target these illicit vapor products. How are states attempting to carry out such actions?

Bryan Haynes (07:25):

Yeah, it's been interesting. Some state AGs, as opposed to enacting new laws, have engaged in a somewhat novel use of state consumer protection laws that are already on the books to target vapor products that lack FDA authorization. This year we saw significant developments in one case involving the Ohio AG’s consumer protection action against a vapor products retailer. In that case, the AG alleged that the retailer sold vapor products that lacked FDA authorization and thereby violated the state's Consumer Sales practices Act by failing to inform consumers about the lack of authorization. But in October, just last month, the Ohio Court of Appeals upheld the dismissal of the Attorney General's Enforcement action. As we alluded to earlier, the court found that the FDCA preempted the AGs action because the state law consumer protection claim would not exist, but for the F DCAS pre-market authorization requirement,

Chris Carlson (08:41):

And to round out our discussion on regulation at the state level, there's been a ton of discussion from California and its unflavored tobacco list. Augustin, can you give us some background on what the unflavored tobacco list is and what have been the major developments in this area this year?

Augustin Rodriguez (09:00):

Yeah, so the statute for the unflavored tobacco list or UTL was passed in California back in 2024, became effective this year on January 1st, 2025. And to understand the UTL, it's worth talking briefly about the interplay with the state's general flavor ban. California has had a flavor ban in place for a number of years. By statute, it prohibits the sale of flavored tobacco products, and the UTL essentially is going to work in conjunction with the flavor ban by establishing a list of unflavored tobacco products that may be lawfully sold in California. So if a product is not listed on the UTL once it's published, it will be considered a flavored tobacco product under the flavor ban and therefore can't be lawfully sold in the state. So as directed by the UTL statute, the California Department of Justice has developed regulations or proposed regulations requiring manufacturers to submit applications by October 9th to be included on the initial publication of the list, which will occur on or before December 31st of this year.

Chris Carlson (10:07):

Thanks, Augustine. And now talking at the federal level, let's talk a little bit about the graphic warning label final rule that the FDA did publish. Can you give us the status of that, Bryan?

Bryan Haynes (10:19):

Yeah, absolutely. The Tobacco Control Act requires FDA to establish rules for graphic warning labels for cigarettes, which would differ notably from the current textual labels that are required right now, really since the inception of the FDA regulation of tobacco products in 2009, this has been the subject of litigation, but there have been notable developments in the last year. At one point a US district court in Texas invalidated the most recent iteration of the graphic warning label rule on First Amendment grounds, but the US Court of Appeals for the Fifth Circuit ultimately reversed, but then on remand, the same US district court found that FDA's warning statements were likely unlawful this time because FDA increased the number of warning statements that Congress selected from nine to 11, and also changed the wording of some of the health warnings. Then in August, a different district court in Georgia and validated the rule on separate grounds. Appeals are pending in both cases, but for now we're left with the existing textual health warning framework that Surgeon General implemented a long time ago.

Chris Carlson (11:45):

And Bryan, you referenced the FDA last year when we were thinking through the implications of the Trump administration, how FDA's role would potentially be shifting, we anticipated more decisive action and potentially a fast tracking in the fda, a review process. Has that come to pass Augustin? And can you just talk through some of the key takeaways from FDA's review of pre-market tobacco product applications in 2025?

Augustin Rodriguez (12:15):

Yeah, there's been a lot going on with FDA this year under the new administration, particularly more recently, I guess three developments come to mind. First, in January, FDA issued the first marketing grant orders for nicotine pouch products, and this was for Zinn nicotine pouch

products. This was the first time that the agency authorized nicotine pouches. The agency authorized the product in a variety of flavors. Notably and unlike FDA's approach with e-cigarettes, the agency did not require a demonstration of comparative efficacy between tobacco flavors versus other zen flavors. This was due to the relatively low youth use of nicotine pouches. Second, in July, FDA issued marketing granite orders to JUUL labs for its tobacco and menthol e-cigarettes after previously denying juul's application in 2022 and then withdrawing denials in 2024. And this lengthy process is a good example of how difficult FDA has made the pre-market review process for even sophisticated companies with well supported applications.

And the third development I would note is that in September, FDA announced that it is undertaking a nicotine pouch pilot program. And the goal of the program is to streamline PMTA review for nicotine pouches, which generally pose lower health risks compared to other tobacco products. And they plan to do this by focusing reportedly on the most critical elements of the PMTA and by engaging in real time quicker communication with applicants to request additional information and clarification. Now, Brian and I were recently at the Food and Drug Law Institute Tobacco and Nicotine Conference, and at this conference, representatives from FDA shared that they hope to take learnings from this program to extend to other nicotine pouch products and even other product categories. And this program appears to signal that the agency may finally be looking for ways to help increase the pace of authorizations for less harmful alternatives.

Chris Carlson (14:28):

Touching on the pace of the FDA's review, I understand that in August, Enjo sued the FDA over the agency's failure to issue a timely decision on the company's flavored products. Bryan, what motivated that lawsuit?

Bryan Haynes (14:43):

Yeah, so FDA's pre-market review process, the fundamental problem is that FDA's pre-market review has been extremely slow. The underlying law requires FDA to adjudicate PTAs within 180 days, but that's never happened. Typically, the agency takes many years to review these applications, some of which have been pending for more than five years. Now, InJoy case, the company had submitted PTAs for its flavored products back in March, 2020, and after FDA denied those applications, njo filed a request for supervisory review in November of 2022. Supervisory review is a different way of appealing an FDA decision on A-P-M-T-A as opposed to going to court, but that request for supervisory review has now been pending at this point for three years. N Joy's lawsuit essentially argues that the company is entitled to have an agency review its supervisory appeal within a reasonable time. I'll note it's not clear whether that case will be successful. Courts often give agencies allotted deference in managing resources when faced with a backlog of applications, but in this case, the longer those delays continue, the greater the chance that a court might be willing to intervene.

Chris Carlson (16:19):

Let's transition to talk about premium cigars quickly. I recall that in 2023, a district court found that the FDA did not properly extend its authority to cover premium cigars. Bryan and Augustin, what's the status of that litigation?

Bryan Haynes (16:33):

Yeah, so FDA appealed that decision, but it lost in January of this year before the DC Circuit Court of Appeals. The court agreed with the industry plaintiffs that they had provide evidence that premium cigars were used less frequently and posed lower health risks and other types of products. And the final rule, however, FDA incorrectly stated that such evidence had not been provided and did not exist because FDA's rationale was simply not correct. The DC circuit concluded that FDA acted arbitrarily and capriciously by not examining the relevant data and therefore upheld the district court's decision. However, there are going proceedings with respect to the remedy. The DC circuit remanded the case to the district court to invite briefings from the parties on the appropriate definition of a premium cigar. The parties have now fully briefed the issue, and the district court now has to determine the scope of premium cigars that are not subject to FDA regulation.

Chris Carlson (17:43):

Bryan Augustin, this has all been really helpful as a debrief to 2025, and so many of these issues clearly are going to continue to be relevant in 2026. Looking into your crystal ball into 2026, what do you expect to be key issues for companies in this space really to be mindful of and what are key takeaways for what to expect next year?

Bryan Haynes (18:06):

Yeah, Chris, I'll kick it off with FDA pre-market authorization, based on what we're seeing so far from new FDA leadership, they seem much more favorably inclined to tobacco harm reduction than their predecessors under the prior administration. And what we're hoping and expecting is that the pace of FDA authorizations for novel and less risky products will improve. We'll see a greater diversity of products that have been authorized and ultimately clearer standards for FDA review of those products.

Augustin Rodriguez (18:47):

Yeah, yeah, I totally agree with that. And I would also just indicate to folks that I think enforcement is going to continue to be a trend in 2026. I think we'll continue to see the federal government looking to make splashes in the enforcement landscape along with the states. I think we'll see states continuing to look for ways to address the concerns around illicit vaping products. And so I think we're going to continue to see multi-state coordination around those efforts as well as continued legislation in that area.

Chris Carlson (19:24):

That's extremely helpful. Bryan, Augustin, thank you again for joining me today and sharing your valuable insights with our listeners. I want to thank our audience for tuning into this special holiday series. Tune in next time as we continue our 12 Days of Regulatory Insights series. Please make sure to subscribe to this podcast via Apple Podcast, Google Play, Stitcher, or whatever platform you use, and we look forward to next time.

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