***Regulatory Oversight Podcast*: 12 Days of Regulatory Insights - Day 9: Trends in the Tobacco Industry**
Speakers: Bryan Haynes, Agustin Rodriguez, Michael Jordan
Date Aired: December 17, 2024

Michael Jordan:

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 this past year in various areas and designed to keep our listeners informed and engaged during the holiday season. I am Michael Jordan, a member of our Regulatory Investigation, Strategy, Enforcement or RISE Practices, as well as our Tobacco and Nicotine practice.

Before we get started today, I wanted to remind all of our listeners to visit and subscribe to our blogs at RegulatoryOversight.com, and TobaccoLawBlog.com, so you can stay up-to-date on developments and changes in the regulatory landscape. Today, I'm joined by my colleague, Bryan Haynes and Agustin Rodriguez to discuss the regulatory actions we observed at the state level in the tobacco industry in 2024, as well as what we anticipate from state attorneys general and the FDA in 2025.

Bryan is the head of the firm's Tobacco and Nicotine practice, as well as a member of our RISE Practice Group. He focuses on representing tobacco manufacturers, distributors, retailers, and suppliers in all aspects of their business. Agustin is also a member of our Tobacco and Nicotine, and RISE Practices. He advises clients on regulatory issues, including the Tobacco Master Settlement Agreement, enforcement investigations, licensing and excise tax, compliant programs, and advertising and marketing practices. Bryan and Agustin, thank you for joining me today.

To get started, I'd like to discuss what we saw in the tobacco space this past year at the state level. Agustin, looking back on 2024, what issues did state AGs focus on for tobacco products?

Agustin Rodriguez:

Well, thanks, Michael. I think, this year, we clearly saw at least some state attorneys general enter the fray in an effort to combat so-called enlisted-flavored disposable electronic nicotine delivery systems or ENDS. These products are perceived by many as having flooded the market in clear disregard of the Food and Drug Administration's pre-market authorization process. Their popularity has soared to levels that are quite threatening to the established tobacco companies in their combustible cigarette segments. FDA seems unable to get any hold on this from an unfortunate perspective.

Michael Jordan:

Thanks. Touching on that, the FDA inaction, how have states reacted to FDA's real failure to get these products off of shelves?

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Agustin Rodriguez:

Yes. Well, for example, in September, we saw the Minnesota State Attorney General Keith Ellison issue a letter and a press release to 5,000 Minnesota retailers, informing them that the only products that could lawfully be sold were those products that had actual marketing-granted order or MGO from FDA. Other state AGs have also sent out several letters. You've seen Ohio, Vermont, and Arizona, for example. We even saw some local health departments up in Massachusetts take on a similar threatening posture vis-a-vis retailer.

Another example is that a number of states have passed statutes, establishing registries or directories. Whereby, if you're a manufacturer who wants to have their product available in the state, to be sold in the state lawfully, the manufacturer has to convince a state agency, usually, in the AG's office, to list its brands on that directory. So, you have to file an application, and you have to demonstrate to the AG satisfaction that you are permitted to remain on the market, and that's typically going to be by showing marketing credit order, or that you have a timely file PMTA that's awaiting FDA's determination.

Michael Jordan:

Agustin, in your view, do you think these efforts have worked, the registries, the letters to retailers?

Agustin Rodriguez:

Not to sound too much like a lawyer, but the jury is still out. I've not seen any data showing that these efforts have reduced the overall consumption of these types of products. Most of the directories I just spoke of, they're not yet in effect. We'll start to see them come online early next year, still in minority states. The letters in particular seem to me to have been slightly misguided. Those products that have timely filed PMTAs and should be enjoying FDA's enforcement discretion, they've seen to thrown those in with the products that have no PMTA at all or are not entitled to the agency's enforcement discretion. That's just disruptive, and inefficient, and it works to hurt lawful players.

Having said that, it's not entirely the fault of these state and local folks. FDA just hasn't been clear with the public about what products it views as having the right to be on the market and what products do not. The public has to wait for the agency to issue a warning letter or put out and sure of import alert on a product in order to find out whether a product is lawfully on the market. FDA's public pronouncements on its enforcement discretion policy also have been riddled with inconsistencies and have left everybody confused, especially state agencies wondering if FDA is seriously enforcing its own statute.

Michael Jordan:

What I'm hearing you say, Agustin is, really this last year, state attorneys general have principally been focused in addressing FDA's inaction on illicit e-cigarettes for which companies haven't played by FDA's own rules, and FDA hasn't stepped up and enforced. So, the states are

taking action in their own hands, but not always doing it in the most thought-out way. Is that more or less?

Agustin Rodriguez:

I think that's exactly right. I think that you're seeing an interesting alignment between state enforcement and tobacco with some established companies on this front, where everybody really wants to have a lawful and functioning marketplace of authorized products. But really, FDA has caused this problem. The states are trying to step in and fix it. It's unclear whether they have the tools to be able to do so.

Michael Jordan:

Bryan, I want to get you in on this. I'm wondering, as we look forward to 2025, do you see the state AG's emphasis on e-cigarettes and FDA inaction as a continuing sort of point of emphasis for state attorneys general in the new year?

Bryan Haynes:

Well, Michael, I expect state enforcement efforts to continue into 2025, although it may not be as pressing of an issue next year as it was this year. As Agustin pointed out, notwithstanding some of the state efforts that have occurred thus far, illicit e-cigarette products continue to be an issue. However, with the upcoming change of administration, with the incoming Trump administration, we expect that some of the FDA processes will improve.

There's been two FDA-related factors that have prompted the proliferation of illicit e-cigarettes. The first being, a relative lack of enforcement from the Food and Drug Administration. And the second, being the simple lack of authorized products from the FDA. There are just a few handfuls of products that the FDA has authorized. It's really no surprise when FDA delays authorizing products that have proven that they're appropriate for the protection of public health, that illicit markets will proliferate. It's an act that under the Trump administration, FDA's efficiency and predictability will improve, which will in turn facilitate a lawful marketplace.

Likewise, as I mentioned earlier, the relative lax enforcement from the FDA has prompted state action. It is our expectation that under the next administration, enforcement will improve, particularly given President elect Trump's position relative to certain imported products. It would be relatively low-hanging fruit for this administration to focus on prohibiting the entry of imports of products that have no legal justification for their sale in the United States.

Michael Jordan:

Agustin, do you see the issues presented with the e-cigarette market in the industry, do you see in the burgeoning new modern oral nicotine pouch space? How do you view this issue with nicotine pouches in the new year?

Agustin Rodriguez:

It's a little unclear. We are seeing new nicotine pouch products entering the US market. It's unclear how those products are entitled to FDA's enforcement discretion. We have a couple of different FDA authorization processes that are out there, one for tobacco-derived nicotine products, one for all other nicotine products. It's sort of unclear which of these new products are coming under those two separate processes. So, I would say, it's still early to tell.

Michael Jordan:

Just to follow up on that. Do you think that nicotine pouches are going to be treated differently because they have a lower risk profile?

Agustin Rodriguez:

Well, from the perspective of FDA's pre-market review process, I would hope that the agency does not treat these products with the same rigid opposition to the flavors. The risk profile is exceedingly lower than almost any other nicotine product. They're really no different than nicotine replacement therapies, and there simply isn't the data to show that there is significant youth uptake. We've seen that in the recent HTUS data that's come out. So, I do hope that these types of prongs will be treated differently by FDA, because it does appear that they do have a lower risk profile, both from a consumption standpoint and from a youth attraction standpoint.

Michael Jordan:

Shifting gears a little bit, I just want to hear a little bit from you all regarding sort of the combustible category. I'm thinking about cigarettes in particular. Bryan, in 2025, can you help explain the MPM escrow refunds? What are those and why is that an issue in 2025?

Bryan Haynes:

Absolutely, Michael. So, as part of the 1998 Tobacco Master Settlement Agreement, the major tobacco companies settled state claims, asserting that the larger manufacturers were obligated to compensate the states for the health care costs caused by cigarettes. As part of the Master Settlement Agreement, there was a group of smaller manufacturers, generally, non-signatories that are not party to that agreement. In order to "level the playing field," the master settlement agreement settling states passed laws obligating these non -settling companies, known as non -participating manufacturers, to place a comparable amount into an escrow account.

The concept being that the escrow account would serve as a judgment call in the event that these non-settling companies were proven to have acted culpably. Importantly, those escrow funds are to be released back to the non-participating manufacturers 25 years after the initial deposit provided there are no successful state judgments or claims.

The first escrow deposits were made in the year 2000 and April of 2000, and therefore, the first escrow deposits would become eligible for release in April of 2025. We expect there will be

activity on that front, which will come in the form of either releases of the escrows to the non-participating manufacturers in the event of no state judgments or claims, or perhaps, certain states will assert claims against the non-participating manufacturers. Similar to the claims that prompted the Master Settlement Agreement, namely for reported health care costs caused by these non-settling companies.

Michael Jordan:

What you're saying is, litigation is inevitable?

Bryan Haynes:

I think we should assume there will be some litigation in this area in 2025. Yes, sir.

Michael Jordan:

Understood. Turning back to new and novel products. Agustin, what types of new products do you see coming to market in 2025? And what types of challenges might they present for regulators?

Agustin Rodriguez:

Well, this is an industry that is motivated by innovation, especially in non-combustible nicotine products. I think FDA's authority over nicotine products is now quite clear. There's going to be less and less clarity over the extent to which these products are taxed or neatly fallen to existing state definitions. We've seen that vapes and nicotine pouches bear no federal excise tax and are not yet taxed in many states. We've also seen announcements by some of the tobacco giants regarding products that clearly are designed to not be a cigarette for state purposes. Thereby, avoiding intentionally or not coverage by state excise taxes and the Cigarettes Master Settlement Agreement that Bryan was just talking about. Finally, we're aware of people talking about metanine [phonetic 0:14:02], and other nicotine [analogues? inaudible 0:14:02]. These are chemicals that function similarly to nicotine, but do not themselves comprise the nicotine molecule. That space is, it's really FDA's ability to regulate that. It seems quite clear, does not exist, and would require an act of Congress to address. So, I think that's an area where we could see some innovation in the space.

Michael Jordan:

Bryan, one last issue that I wanted to touch on concerns restrictions on flavors and tobacco products. Do you think that FDA is going to finalize the menthol cigarette ban and characterizing flavor ban for cigars in 2025?

Bryan Haynes:

Well, Michael, FDA currently has proposed rules that would ban menthol as a characterizing flavor in cigarettes, and that would ban any characterizing flavor other than tobacco and cigars. It's quite clear that FDA would like to finalize those rules. It is very publicly communicated that

intent, and the Biden administration signaled that it was supportive of that initiative. It temporarily paused that initiative pending the election, and it was my expectation that if Vice President Harris were elected, the initiative would move forward.

However, with President-elect Trump, it is not clear to me that that initiative will move forward. I'm not aware of any public statements to that effect, but it's no secret that those rules would be devastating to many industry stakeholders as well as tobacco distributors and retailers. And so, it's my expectation that the incoming administration will take a very hard look at those proposals and possibly not let them go forward.

Michael Jordan:

How might that be relevant for potential state actions regulating the products? Obviously, we don't know exactly what the next administration will do, but if you see the administration abandon, for example, this proposed rule, how might that influence states and state legislatures?

Bryan Haynes:

Well, Michael, this is consistent with the theme that we discussed at the outset, when there's a perception that the federal government is not acting in ways that state politicians or law enforcement wish sometimes states seek to fill the void. As we sit here now, certain states and localities have already implemented their own flavor bands, and it's quite possible that other states have delayed action in anticipation of possible federal action. If the FDA does not act in this space, it would be reasonable to assume that other states and localities will look at banning flavors at the state and local levels.

Michael Jordan:

Well, that's all the time we have for today. Bryan and Agustin, I want to thank you again for joining me today. I know our listeners enjoyed your valuable insights, and 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 Podcasts, Google Play, Stitcher, or whatever platform you use. We look forward to next time.