Regulatory Oversight Podcast — S02 Ep03, 2022 Significant Developments in the Tobacco Industry and What to Expect in 2023 (Part 2)
Host: Stephen Piepgrass
Guests: Bryan Haynes, Agustin Rodriguez, and Nick Ramos

Stephen Piepgrass:

Welcome to another episode of *Regulatory Oversight*, a podcast that focuses on providing expert perspective on trends that drive regulatory enforcement activity. I'm Stephen Piepgrass, one of the hosts of this podcast, and the leader of the firm's Regulatory Investigations Strategy and Enforcement Practice Group. This podcast features insights from members of our practice group, including its nationally ranked state attorney's general practice, as well as guest commentary from business leaders, regulatory experts, and current and former government officials on a range of topics affecting businesses operating in highly regulated areas.

Before we get started today, I want 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 and in the tobacco industry. Today in our second episode focused on the tobacco industry, I'm again joined by my colleagues Bryan Haynes, Agustin Rodriguez and Nick Ramos. We will continue our conversation on significant developments in the tobacco industry during 2022 and discuss what we can expect in 2023. Bryan, Agustin, and Nick, thank you for joining us today. I'm very much looking forward to continuing our discussion. Since we spent a good amount of time during the last episode talking about developments at the federal level, let's start by talking about developments at the state level. Agustin, would you like to kick us off?

Agustin Rodriguez:

Absolutely and thank you for the introduction, Stephen. The big cigarette companies have seen a busy year in matters pertaining to the 1998 Tobacco Master Settlement Agreement. This is that landmark agreement that the major cigarette companies signed with 46 states and six territories to settle healthcare cost recovery claims brought by the Attorney's General of those states and territories. In July of this past year, Iowa's Attorney's General office filed suit against Philip Morris USA, R.J. Reynolds, and 16 other tobacco companies accusing them of defrauding Iowa of over $133 million by allegedly engaging in bad faith disputes over amounts due under the MSA. This dispute has to do with a feature in the MSA that's known as the NPM adjustment.

Bear with me here guys. This gets a little technical, but the tobacco companies that signed the MSA are also known as participating manufacturers or PMs. They have to pay to settling states their respective portions of $9 billion on an annual basis, and this $9 billion payment is subject to a handful of upward and downward adjustments, one of which is known as the Non-participating Manufacturer Adjustment or the NPM adjustment. The NPM adjustment has the potential to reduce the amount of money a state is due from the PMs in a given year if the state did not enact and diligently enforce an escrow statute, and that's a defined term, the escrow statute, requiring non-participating manufacturers place money into an escrow account in proportion to their sales made into that state.

The rationale for this NPM adjustment is that as a result of complying with the MSA, these participating manufacturers may suffer a loss in market share due to the financial advantages gained by NPMs who aren't signatories to the MSA and don't bear the marketing restriction and payment obligations of the MSA. So as part of the MSA bargain to level the playing field, each settling state had the option to pass and diligently enforce an agreed model statute that obligated NPMs to make escrow payments on their units sold into that state. If the state fails to pass that statute or fail to diligently enforce it, it would risk having the NPM adjustment applied to it.

Now, it would be capped by the PM's full annual payment owed to the state, but in other words, a non-diligent state could suffer a complete loss of its annual MSA payment, which would create a potentially significant budgetary hit because, let's face it, many of these states have come to depend on MSA payments to balance their annual budgets. So, when a PM believes an NPM adjustment should apply to a particular state, it can put money into a what's called a disputed payments account under the MSA, or it can just withhold it all together, not pay it at all until the appropriate NPM adjustment is determined.

So, what's happened is that companies have done that. They've put money away into a disputed payments account or they've just withheld it. And this has been going on since 2004, 2005, 2006. What's happened in this case with Iowa has now brought in its state court. Okay, mind you, the NPM adjustment for most states, all the states except for Montana are required to arbitrate the NPM adjustment and the NPM adjustment arbitrations can take a very long time. Iowa says that since 2006 and then every year thereafter, the defendants have disputed the NPM adjustment in bad faith, at least as to Iowa, without evidence that Iowa has failed to diligently enforce its escrow statute, and as part of the scheme to generally withhold MSA payments, Iowa's claiming that defendants have tied up the money owed to it for the last 15 years, resulting in a lower annual payment than it might've otherwise received. There's also the time value of money.

Then in addition to just contractual claims under the MSA, Iowa is asking the court to enforce the State False Claims Act and it's asking for treble damages, punitive damages, maximum statutory damages that could be brought under the Iowa False Claims Act in addition to further declaratory and injunctive relief. In my view, with all due respect to Iowa, this should be a long shot. It's unclear whether the court has jurisdiction over this dispute, given that the MSA has a mandatory arbitration clause that applies to disputes arising out of or relating to calculations performed by, or any determinations in fact made by the independent auditor that's tasked with determining amounts owed to each state. And the courts of 47 states and territories, including Iowa, have ruled that state's claims related to diligent enforcement and application of any adjustments are subject to this binding arbitration provision.

To complicate matters further for the cigarette companies, the state of New Mexico filed a similar lawsuit in November with similar allegations. We'll see if any other states are still arbitrating the NPM adjustment want to follow a suit. Nick, speaking of states, tell us what you're seeing at the state level on excise taxes.

Nick Ramos:

Yes, the wonderful world of excise taxes. As you might suspect, we saw a pretty significant dip in tax assessments during the pandemic, but as the world opened back up and state agencies went back to work, we started to see an uptick in Departments of Revenue issuing assessments for taxes owed, taxes miscalculated, et cetera. 2022 was no exception. In fact, I think our team in 2022 assisted clients in successfully disputing more than $45 million in tobacco taxes. That was a great thing for our clients in 2022, and obviously the amount is an important indicator of how your compliant systems can really start to rack up potential amounts due, owed, disputed, et cetera, especially when some of these systems get put on autopilot.

You put a system in place based on one set of facts or assumptions, and you get a letter in the mail one day for an investigation and you maybe learn that something in your system wasn't quite accurate or was and the department's wrong. So, these systems are really important and there are a number of things that you can do to prepare for any type of assessment, avoid or certainly contest them. I think that's all I have on the excise tax topic, but we'd probably be remiss if we closed out the state development discussion without talking about flavor bans, and I think Agustin might add a couple things to say about those.

Agustin Rodriguez:

While there weren't a lot of new state flavor bans passed in 2022, Nick, we did see some developments related to challenges of flavor bans. Folks might recall at the state level in 2020, California Governor Gavin Newsom signed a law to ban products including menthol cigarettes and flavored vaping products. This ban's implementation was delayed after a coalition representing the tobacco industry. Both manufacturers and retailers gathered enough signatures to put to voters a ballot measure that would halt California from becoming the largest state to date to bar flavored tobacco product sales. This past year, nearly two-thirds of California voters casting ballots on the measure nevertheless approved the sales ban. So, R.J. Reynolds, along with a group of tobacco retailers, then sued to block California officials from allowing the ban to take effect as planned on December 21st. The lawsuit was fast tracked by all the parties. The plaintiffs lost both at the U.S. District Court and the Ninth Federal Circuit. And then earlier last month, the request for an appeal before the U.S. Supreme Court was denied, thereby ending this almost two-year battle.

Thus far, the tobacco industry's been unable to stop any state law flavor ban, notwithstanding preemption provisions in the Tobacco Control Act that, in my view, should stop states from imposing product standards on tobacco products. It says so pretty clearly in the Tobacco Control Act, maybe we'll see the industry try again, particularly if FDA issues and successfully promulgates what the agency itself calls product standards, banning flavored cigarettes and cigars. You have the menthol ban and the ban on flavored cigars that have been issued. Maybe we'll see courts face up to the fact that the flavor ban is a tobacco product standard or maybe not. On an interesting note, 2022 also saw some local bans overturned, but these really didn't happen on federal preemption grounds. Really what happened is localities in Pennsylvania and Oregon both saw their local bans overturned on state preemption grounds. So that's a different world. So, I guess what this kind of leaves us is what type of significant developments could we expect in 2023? So, Nick, why don't you talk a little bit about FDA's regulation of nicotine levels?

Nick Ramos:

Yeah, sure, Agustin. This is an interesting topic that's seen some movement over the last few years, and that is essentially there's been this trend of FDA favoring lower nicotine levels in cigarettes and other tobacco products. For example, in late 2021, FDA issued what's called a Modified Risk Tobacco Product Authorization to a company seeking to sell low nicotine cigarettes, and this was a first in the industry in late 2021, and pretty soon after that, in 2022, FDA issued a notice that it plans to issue a proposed rule. Last time I looked at it, it was planned for May of 2023, and this proposal would essentially seek to set a maximum nicotine level in cigarettes and other "combusted" products, whatever that means. It wasn't defined in the notice to be determined, right? The FDA would rely on authority to promulgate this type of rule under the Tobacco Control Act, under its ability to set tobacco product standards to protect public health.

You know, without seeing details, folks listening to the podcast might already be thinking, "Well, I can already see a world where FDA attempts to do this." Some of the counter-arguments would be, "Aren't there numerous low and zero nicotine alternatives already on the market? Why would FDA seek to lower nicotine levels in cigarettes, for example, when there are a plethora of other types of products out there with zero or low nicotine?" That would be one potential pushback on FDA's proposal, and there are likely others. There's always the illicit trade argument, right? Couldn't this result in the substantial increase in illicit trade products? If in the US, there's a max ceiling on nicotine products, but nowhere else in the world or in few other places in the world, there's obviously a market there for what I'd call at that point regular nicotine cigarettes or higher nicotine cigarettes, however you wanted to frame it. So, there's the illicit trade argument that could be made when FDA proposes this type of rule.

In any event, we expect in 2023, unless things change in the regulatory calendars, that FDA will seek to propose this type of rule. We'll keep an eye on it and it could certainly assist with any type of comments on that process. Speaking of the nicotine levels in cigarettes, I know that there are some other developments that we're anticipating in 2023, and maybe Bryan could tell us a little bit about menthol cigarettes and flavored cigars.

Bryan Haynes:

Sure, Nick. Continuing in the same vein of FDA rulemakings, we think it's pretty likely in 2023 that FDA is going to issue two rules. One that would ban menthol as a characterizing flavor in cigarettes, and another rule that would ban all characterizing flavors in cigars. By way of background under the Tobacco Control Act, characterizing flavors other than menthol are already banned in cigarettes, but not in cigars. But FDA does have some authority under section 907 of the Tobacco Control Act to implement other product standards, and FDA has not made it a secret that for a long time that it has been looking at extending the characterizing flavor ban to menthol and cigarettes and all characterizing flavors in cigars. It issued a proposed rule to that effect in 2022, and that proposed rule was accompanied by significant stakeholder engagement on all sides.

But it's our observation that FDA does seem committed to issuing the rule and issuing it soon. It is said in its regulatory agenda that it plans to finalize this rule by August of 2023, which by the way would be lightning quick for a rule of this magnitude. Normally, rules of this magnitude you could expect to take at least a couple of years after the proposed rule is issued. This time FDA's talking about a little over a year. Importantly, I think it's reasonable to assume that any final rule will be closely followed by litigation challenging it. In addition, FDA has indicated that assuming the rule is issued, it would not be expected to take effect for at least a year after it's finalized. So, industry is expected to have some time to challenge the rule and ultimately address next steps.

Continuing in the same vein of FDA actions, we expect continued activity in FDA determinations on requests from marketing authorization. FDA has stated publicly that it intends to complete its review of all pre-market tobacco applications filed by the major ENDS companies by the summer of this year. It has quite a lot of work to do between now and then to complete that process. Looming in the background are FDA's determinations on PMTAs for modern oral nicotine products, which continues to be the fastest growing segment in the tobacco industry. But with that said, FDA has not acted on a request for marketing authorization for any of these products, and all of them require it because they're all new products. So, it'll be very interesting to see how FDA evaluates these products, particularly the flavored products, whether it employs a similar methodology for the applications for ENDS products, and again, likely litigation to follow.

I know another interesting thing that we saw toward the end of 2022 and coming into 2023, Agustin, was the enforcement of the PACT Act, and I think it'd be great if you could talk about what we're seeing there.

Agustin Rodriguez:

Yeah. Just for context, back in late 2020 as part of the 2021 Consolidated Appropriations Act, those budget bills that passed in the middle of the night as Congress was trying to get home for the holidays. Congress passed an amendment to the Federal Jenkins Act or PACT Act that subjected Electronic Nicotine Delivery Systems or ENDS to the Jenkins Act. This made anyone selling these products subject to stringent registration and reporting requirements, state tax and online retail compliance requirements, and also made Electronic Nicotine Delivery Systems generally non-mailable. While no one can say for sure, I wouldn't be surprised if in 2023 the ENDS industry and particularly the online ENDS retail industry might see an uptick in ATF enforcement for ENDS.

This isn't going to just affect nicotine vapor products. It can potentially affect anyone selling any vapor product online, including CBD or marijuana vaping product suppliers. The ENDS definition is so broad under this amended statute that it covers "any electronic device that through an aerosolized solution, delivers nicotine flavor or any other substance to the user inhaling from the device." It's so broad, it can cover aromatherapy steamers, and it's been almost two years since the measure passed, and so I won't be surprised if more law enforcement activities occur in connection with it. We've seen a little bit of it so far, but I think just given that two years have passed, it seems like we might be seeing some new things come down the pike in 2023. Bryan, what are your thoughts on the general prospects for other legislation we might see in 2023?

Bryan Haynes:

Yeah, sure, Agustin. Let me close this out by talking about that. I may be being overly optimistic here, but I'm consciously optimistic in 2023 that we won't see significant activity as it pertains to tobacco tax increases. Of course, as states face budget pinches, which is inevitable from time to time, tobacco tax increases can always be on the menu. So far, we're not seeing significant momentum toward that, nor did we last year. Of course, in Congress, there was a significant effort to increase tobacco taxes and impose an unprecedented federal excise tax on ENDS products, but that was ultimately rejected, and given the change in control of the U.S. House of Representatives, it seems unlikely that anything like that would happen in Congress.

Those are my two cents. I hope I'm right about that.

Stephen Piepgrass:

Well, Bryan, Agustin, and Nick, thank you very much for joining us today. I really appreciated the overview of regulatory action in the tobacco space and in related spaces in 2022 and having you look into the crystal ball about the future for 2023. I know our audience enjoyed that too and thank you to the audience for joining in today. As always, we appreciate you listening and don't hesitate to reach out to our tobacco team if we can help. Please make sure to subscribe to the podcast through Apple Podcast, Google Play, Stitcher, or whatever platform you use, and we look forward to having you join us next time.