REGULATORY OVERSIGHT – S02 EP02, 2022 SIGNIFICANT DEVELOPMENTS IN THE TOBACCO INDUSTRY AND WHAT TO EXPECT IN 2023 (PART 1)

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Stephen Piepgrass:

Welcome to another episode of *Regulatory Oversight*, a podcast that focuses on providing expert perspective on the trends that drive regulatory enforcement activity. I'm Stephen Piepgrass, one of the hosts of the podcast and the leader of the firm's Regulatory Investigations, Strategy + Enforcement Practice Group. Our podcast also features insights from members of the practice group, including its nationally ranked State Attorneys General practice and its tobacco team, as well as guest commentary from business leaders, regulatory experts, and current and former government officials. We cover a wide range of topics affecting businesses operating in highly regulated industries.

Before we get started today, I want to remind 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 those affecting the tobacco industry. Today, I'm joined by my colleagues Bryan Haynes, Agustin Rodriguez, and Nick Ramos to look back on significant developments in the tobacco industry and related spaces from 2022 and to also discuss what we can expect in 2023. This is the first of two episodes focused on the tobacco industry. Bryan, Agustin, and Nick, thanks for joining us today and I'm very much looking forward to our discussion. Bryan, why don't we kick this off with you. Could you tell us who are the primary regulators of tobacco products in the United States?

Bryan Haynes:

Sure, Stephen, and thanks for the introduction. Just to level-set, the U.S. is somewhat unique compared to other countries in terms of the number of regulators of the tobacco industry. We have a number of regulators at both the state and federal levels. At the federal level, the principal regulators of the industry are the Alcohol and Tobacco Tax and Trade Bureau of the U.S. Treasury Department, also known as TTB, and TTB's principal responsibilities are collecting federal excise taxes and regulating the licensure and manufacture of tobacco products. Notably at this time, TTB does not regulate electronic nicotine delivery systems, or ENDS, but most other tobacco products. The other principal regulator is U.S. Food and Drug Administration, or FDA, which acquired jurisdiction over tobacco products in 2009. FDA's principal responsibilities are authorizing new tobacco products and implementing standards for the manufacture and content of tobacco products.

At the state level, you also have a number of regulators as well. Principal among them are state attorneys general. In 1998, state attorneys general undertook a significant role in the regulation of cigarettes through the Tobacco Master Settlement Agreement, and that role continues today and will continue indefinitely. State attorneys general have also taken a more recent role as it pertains to ENDS products as well as modern oral nicotine products, submitting different advocacy letters as to their view as to how those products ought to be regulated. In addition to state attorneys general, you also have state taxing authorities that are responsible for collecting state excise taxes and monitoring licensure of companies that sell tobacco products in various

states. There are also licensing authorities that are responsible, for example, for ensuring that tobacco products are only sold to adults.

Stephen Piepgrass:

During the intro, I mentioned that one of the things we would be covering were the key developments that we saw in 2022. Could you give us a sense of some of the major happenings in the world of tobacco in 2022?

Bryan Haynes:

Sure, Stephen. I'll jump off by talking about developments at the FDA. Most notable among those were two significant changes within FDA leadership. Dr. Robert Califf took the reins as the head of FDA and Dr. Brian King took the reins as the head of the FDA's Center for Tobacco Products. Both of those individuals are no strangers to tobacco, but in different ways. Dr. Califf, as some of you will know, had been the head of FDA during the Obama administration, as well as served in a high-level position with oversight over tobacco. Notable during his tenure was the issuance of the so-called Deeming Regulations in 2016 in which FDA for the first time regulated additional tobacco products including things like ENDS, cigars, and pipe tobacco. It is also notable that during Dr. Califf's tenure, he spearheaded an effort that would've effectively banned all flavored ENDS. That effort was ultimately rejected by the Obama administration, but I think perhaps foreshadowed some of FDA's future policies.

Brian King, on the other hand, is not a regulator by background, but had served for many years at the Centers for Disease Control. Dr. King's tenure there was notable for some of the commentary in 2020 regarding the supposed link between ENDS products and EVALI, which was an issue with lung injuries associated with certain vaping products. The link between nicotine vaping products in EVALI was ultimately disproved, although we haven't seen the federal government clearly walk back some of the earlier statements that were made. I'll turn next to some of FDA's actions in 2022 as it pertains to the pre-market review process, litigation around that, and enforcement of pre-market review requirements. This issue has been first and foremost in terms of public scrutiny of FDA's actions, culminating in a report in December of 2022 by the Reagan-Udall Commission, which is an organization established by Congress to provide input and oversight into FDA's operations.

The Commission was fairly critical of FDA's approach to the pre-market review process, critiquing the lack of transparency in terms of standards for adjudication and the lack of enforcement with respect to companies that have not adhered to pre-market review requirements. FDA throughout 2022 came under a fair amount of scrutiny for the lack of enforcement for companies that utterly failed to comply with PMTA requirements. Toward the end of 2022, FDA picked up enforcement a bit, seeking injunctions against certain companies that had failed to seek or obtain marketing authorization, but there's still much work to be done in that area. In 2022, FDA also continued to make decisions on pre-market tobacco applications for ENDS products.

By and large FDA's actions have been limited to authorizing a few tobacco variants with FDA really denying all other products, with a focus on FDA's specific policies requiring a higher evidentiary showing for flavored products. Those policies have been challenged in litigation, which continues to this day. Some cases have been decided and many cases remain pending. And the courts have been fallen on both sides of this issue with some courts giving relief to the

industry, finding that FDA did not fully consider all of the relevant evidence, with other courts upholding FDA's determination. And it will be interesting to see as we look to 2023 how all that unfolds. I'm going to stop there and pass the baton to Agustin, because I know Agustin, you wanted to talk about FDA's actions with respect to non-tobacco nicotine products.

Agustin Rodriguez:

Yeah, thanks Bryan. This has to do with a change that Congress made last year in the scope of FDA's authorization to regulate nicotine products. Until last year, FDA's jurisdiction over nicotine products was limited to products that contain tobacco derived nicotine, and, as FDA regulations developed and intensified in some instances, a number of companies began to introduce products that were purely based on synthetic nicotine – that is nicotine that was not derived from tobacco. The most common formats for these products have been electronic nicotine delivery systems and modern oral nicotine pouch products. And so as part of the federal funding bill last year, language giving the FDA authority over synthetic nicotine and any other nicotine that's not derived from tobacco was passed by Congress back in March and signed by the president to law.

This law gave manufacturers of the so-called NTN, or non-tobacco nicotine products, 30 days after the effective day of the law to file a pre-market tobacco application, PMTA, with FDA. And the law states that if FDA has not authorized the product within 90 days after the effective day, the product must be removed from the market. FDA, not surprisingly, has not authorized any such PMTAs, notwithstanding that a number of companies filed PMTAs within the 90-day period. And what's also interesting is that originally this legislation was seen by many as tantamount to an effective ban on synthetic nicotine products, but FDA really has not acted in any significant way to remove these products from the market, contrary to a statutory mandate.

It's worth noting that the state AGs have weighed in and have taken note. And on June 10th, a bipartisan coalition of 31 state attorneys general led by Idaho, Illinois, Nebraska, and Pennsylvania sent a letter to FDA Commissioner Califf asking the agency to reject the PMTAs for all synthetic nicotine products. The letter expressed concerns that some manufacturers of ENDS have been marketing NTN products with minimal oversight, risking the addiction of new youth to such products, and urging FDA to deny marketing authorization for at a minimum the flavored NTN products. The agency, to my knowledge, has not issued any mandate removing these products, possibly worried that it'll be sued if it does so, and we will have to wait and see when the agency gets around to this. Speaking of litigation, another interesting 2022 topic is the litigation the cigar industry pursued last year. Bryan, do you want to talk about that?

Bryan Haynes:

Yeah, happy to, Agustin. As some of our listeners will know, since the deeming regulations were issued in 2016, the premium cigar industry has been active in litigation, challenging various aspects of those regulations, and has found some success. First starting with the premium cigar industry's challenge to FDA's warning label requirement, which was enjoined by a federal court later in 2020. A federal court based on the premium cigar industry's challenge enjoined pre-market review requirements with respect to premium cigars and then, most notably in 2022, that same federal court found that FDA's regulation of the premium cigar category as a whole was arbitrary and capricious. Effectively, what the court said is that the FDA did not adequately consider comments that were made by the industry during the regulatory process to the effect

that premium cigars have very different usage patterns, have a very different risk profile, and therefore all of that needed to be taken into account in regulating the category.

The federal court found that FDA's failure to adequately consider these comments was arbitrary and capricious, with the only outstanding issue to be determined being the appropriate remedy. The court has two choices: it can vacate the rule altogether, which would mean that FDA cannot regulate premium cigars at all under the Tobacco Control Act unless and until it issues a new rule, or it can keep premium cigar regulation intact while FDA is required to reconsider the comments that were made by the industry. And into 2023, we'll look forward to the federal court's decision on that issue. I know another issue that came up last year was the industry's challenge to FDA's cigarette graphic warning rule. Nick, I think you wanted to talk about that.

Nicholas Ramos:

Yeah, thanks Bryan. Certainly there was some significant developments on this rule in 2022, but it's been more of what I would describe as a rulemaking saga that began way back in March of 2020 as the pandemic was kicking off. When FDA initially promulgated this final rule, which as many of you may have seen, would've imposed some pretty graphic photorealistic images be displayed on essentially the top half of cigarette package labels and also on cigarette advertisements, in color, very graphic images, almost immediately after the rule was promulgated in March of 2020, a number of tobacco manufacturers challenged it in federal courts. Those challenges came in April and May of 2020, and the thrust of those arguments were essentially that FDA's rule violated their First Amendment rights. As is somewhat common in this type of litigation, while the tobacco manufacturers were challenging the rule in federal court, they simultaneously asked the courts to delay the effective date of the rule pending the court's resolution of the litigation on its merits.

So while the litigation proceeded, the effective date for that rule was postponed, and I don't have a total count here, but it was at least eight times. So I feel like we've been providing periodic updates on this rulemaking over the last few years, particularly every time a court decided to delay it again. However, the saga came to an almost close back in December of 2022 when Judge Barker in the Eastern District of Texas ruled in favor of the manufacturers and vacated the rule. Essentially, Judge Barker ruled against the FDA. FDA argued that a more lenient test should have been applied to determine whether there was this First Amendment violation because the warnings were not "purely factual or uncontroversial," and Judge Barker wasn't convinced by FDA's arguments on those points. So as many of you know, especially when it comes to constitutional arguments, a lot of the outcome can depend on the specific test that the judge applies to the facts based on case law.

And in this case, Judge Barker thought it was best to apply a more stringent test, and he found that essentially while there's a government interest in reducing smoking, FDA would have to come up with a less burdensome requirement to meet its goal without violating the First Amendment. So Judge Barker ruled against FDA in this case back in December. FDA is going to appeal Judge Barker's order. That's the saga of the cigarette warning statements.

Agustin Rodriguez:

Thanks, Nick. I mean, speaking of sagas, I think I've got you beat on this one. Early last month, that is December of 2022, the U.S. Department of Justice, together with the Department of Health and Human Services, announced the entry of a court order that resolved the

government's long-running civil racketeering lawsuit against the largest U.S. cigarette companies. And these are companies like Altria, Philip Morris USA, R.J. Reynolds, and ITG Brands. Now, this lawsuit was filed in 1999 in the U.S. District Court for the District of Columbia, and it was brought under a variety of federal statutes, and it sought to recover billions of dollars in healthcare costs for tobacco related illnesses. And this is all separate from the state lawsuits brought by state AGs for healthcare costs, and the government also sought disgorgement of company profits and an injunction prohibiting certain actions going forward by these defendants.

And the court eventually dismissed all of the government's claims but one and rejected the monetary penalties that the government sought. But in 2006, after years of discovery, pretrial litigation and a nine-month bench trial, Judge Gladys Kessler issued an opinion concluding that the defendants had maintained an illegal racketeering enterprise in violation of the RICO statute, and she issued an injunction as her sole remedy ordering that the companies issue so-called corrective statements. Since that year, 2006, the parties have been variously litigating various aspects of the injunction, including the content of these corrective statements, and what this order now does is require the defending tobacco companies to display signs in retail stores featuring corrective statements about the health effects and addictiveness of smoking.

And these statements include things like, "Smoking cigarettes causes numerous diseases" and "Nicotine in cigarettes is highly addictive." A lot of these are pretty much just the warnings on the cigarettes today in slightly different phraseology, all of which has been court approved and agreed to by the defendants. The order will go into effect July 1, 2023, and defendants are going to have three months to post these corrective statements. Retailers are going to display the signs for 21 months thereafter. The corrective statements will be in both English and Spanish. The mechanics for retailers are somewhat complicated and are going to be tied to the retailers' merchandising agreements with these defendant manufacturers. So if anyone has any questions about those, they should feel free to reach out to us, but in any event, this litigation is over. The order imposes the last of these corrective remedies ordered by the court 24 years after the case began.

Stephen Piepgrass:

Bryan, Agustin, and Nick, I want to thank you again for joining us today. I know our listeners very much enjoyed your valuable insights and I want to thank our audience for tuning in today, too. I hope you will join us for the second tobacco podcast episode where we continue our conversation on significant developments in the tobacco industry from 2022 and discuss more of what we expect in 2023. Please make sure to subscribe to this podcast via Apple Podcast, Google Play, Stitcher, or whatever platform you use, and we look forward to having you join us next time.