***Regulatory Oversight Podcast*: 12 Days of Regulatory Insights: Day 3 - State AG Oversight in the Health Care Industry**
Speakers: Barry Boise and Chris Carlson
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Chris Carlson:

Hello, and welcome back to our special holiday edition of the *Regulatory Oversight* podcast, "The 12 Days of Regulatory Insights." In these 12 episodes, we will highlight key trends and developments from the past year across various areas, keeping informed and engaged during this festive season. I'm Chris Carlson, a member of our Regulatory Investigation, Strategy and Enforcement Practice, and nationally recognized state attorneys general team.

Before we get started today, I want to remind all our listeners to visit and subscribe to our blog and RegulatoryOversight.com to stay up-to-date on developments and changes in the regulatory landscape. Today, I'm joined by my colleague Barry Boise to discuss the increasing state attorneys general scrutiny of the healthcare industry in 2024 while also looking ahead to 2025.

Barry's a partner in the firm's health sciences litigation practice group. And he has decades of experience helping health sciences clients navigate complex issues. Barry joins us today because of his extensive experience defending the healthcare industry for state AG investigations and litigation.

Barry, thank you for being here today.

Barry Boise:

Thank you, Chris. It's great to be here.

Chris Carlson:

Before we jump into the state AG actions that happened this year and what we can expect in 2025 and beyond, Barry, can you give us a quick summary of the state AGs authority and how this authority has been historically used to scrutinize the industry?

Barry Boise:

Sure. In this case, past is certainly prologue. The historical grounding is really important to think about what has occurred in 2024 and think about the future. As you alluded to, state attorney generals have broad statutory authority under the Unfair and Deceptive Trade Practices Acts, along with state equivalents to False Claims Act statutes. The False Claims Act statutes largely mirror their federal counterpart. However, the UPA, the Unfair Practices Act statutes, allow broad authority to enjoin, penalize, and seek restitution among the remedies for conduct that is defined as either capable of being deceptive, doesn't have to be deceptive in itself, or even deemed unfair, unconscionable, or violative of some broad public policies.

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Historically, states have applied the UPA statute in otherwise heavily regulated industries such as the healthcare space. This could mean, for example, even with an FDA-approved label, that product label could nonetheless be found false, or misleading, or deceptive in the context of an Unfair Practices Act state. And in the context of healthcare, states have often used collective law enforcement called multi-state actions, which form in order to investigate the healthcare industry.

There are triggers for these historically. Historically, a high-profile criminal prosecution of pharmaceutical companies around issues of, say, off-label promotion, a congressional investigation, a mass tort, all of those things have triggered state attorney general multi-state investigations.

Chris Carlson:

Barry, that's very helpful just to understand the statutory authority of a state attorney general. And you mentioned triggering events. So often, historically, state AGs were really driven as almost a follow-on to federal action or some other high-profile event. Did you see that historically in the healthcare industry in terms of enforcement actions?

Barry Boise:

Absolutely. And really post 1998, and that is a benchmark timeline and date, and that's the date in which there's a master settlement agreement with big tobacco and the tobacco litigation. And in that litigation, private counsel was intimately involved in pursuing those claims. And what has occurred post that time period with respect to the healthcare industry is some of those same network of private counsel started working on contingency fee arrangements on behalf of state attorney generals after a triggering event.

There might be an investigation of one pharmaceutical company for allegations of off-label promotion in that early 2000s timeframe. Next thing you know, you had state attorney generals represented by private counsel not only pursuing that particular manufacturer, but also each of that manufacturer's competitors. We saw actions brought against makers of any psychotic medications. First against one manufacturer, then against an entire class of manufacturers in that space.

We saw that repeated in other neuroscience medications. We saw that in medical devices. We saw that for diabetes medications as well. These private counsel relationships in that early 2000 time period were often challenged in court. They were challenged in the court of public opinion. And while there's ways to attack that model, it is largely held and one that continues obviously through today.

Chris Carlson:

Barry, that's very helpful, and I love your saying about past is prologue. As we move into the actions by state AGs and 2024, we want to start with just the opioid crisis. And what we expect is the most amount of time and energy state AGs have spent scrutinizing the healthcare industry. What are some lasting takeaways that you expect to have arisen based on the opioid crisis?

Barry Boise:

Well, first, unlike that historical model with this triggering event where attorney generals followed on other activity by federal regulators, or by mass tort lawyers, or by congressional activity, here it was both state attorney generals and municipalities, such as the city of Chicago being an early example, bringing litigation under Unfair Trade Practices Act, that broad statutory authority, in a setting in which they believe the federal government was leaving a gap. Where whether it was DEA or Congress not doing in their mind jobs in combating the opioid crisis.

This is a situation where state attorney generals and municipalities stepped in in order to fill what they'd perceived to be a failing at the federal level. That's one difference and one I believe will be a lasting difference. Second, the states broadened some of the tools that they used. These broad statutory authority under False Claims Act, State Equivalence, or Unfair Practices Act so were used. But for reasons we can discuss a little bit more, they also utilized other enforcement tools they found in the common law or other statutes.

For example, early cases in opioids were brought under RICO theories. And more recently, for the cases that went to trial, were brought under public nuisance theories. Borrowing from actions they may have brought for someone who's claiming to pollute the environment, they would have used those same tools in order to go after an FDA-regulated lawful distribution of a product.

Chris Carlson:

Barry, you remarked earlier that there was typically a triggering event for state AG enforcement actions. Would you say that under the opioids concept that the triggering event was the perceived lack of activity by the federal government?

Barry Boise:

I would. There was certainly a perception that enough was not being done to combat the opioid crisis, and there was an opportunity seen by private counsel to obtain large contingent fees in pursuing that perceived lack of enforcement utilizing state remedies which would allow for the payment of outside counsel which are not present with our federal government.

Chris Carlson:

While you have a different strategy, you still have the same players. You referenced outside counsel, similar to their role in traditional scrutiny of the healthcare industry. Has the opioids crisis and the related litigation been any different because political subdivisions have had a seat at the table?

Barry Boise:

Absolutely. Those relationships with state attorney generals have only deepened, become more concrete. With municipalities, both large cities like City of Philadelphia, City of Chicago that brought large cases on behalf of their municipalities, small towns all across the country brought opioid cases as well. It might be a county, it might be a small town, it may be a large city all

represented by outside counsel. Those outside counsel relationships have not only deepened, but they broadened across other government players that number now in the thousands.

Chris Carlson:

And one area of differentiation that fascinates me about the opioids context is that the scrutiny span the entire industry supply chain. Where, typically and traditionally, state AGs really have honed in on what they have deemed to be one target and sending a message through a settlement with that target. But here, the entire supply chain has been under scrutiny. Why do you think it's been different?

Barry Boise:

I think it's been a situation of that model evolving. The main target in opioids was initially Purdue and OxyContin. Then it became a situation where all the manufacturers were brought in, branded manufacturers were brought in, in those initial early opioid cases. But then it wasn't just the branded manufacturers. As you mentioned, it was the entire supply chain. It was distributors. It was pharmacies. It was pharmacy benefit managers. We saw consultants to manufacturers as well being brought in. We saw big box stores that had distribution networks, as well as pharmacies associated with them.

Once attorney generals and/or their counsel starts to understand a product and now understand an industry, the entire supply chain became under attack. And I mentioned earlier that state attorney general started using broader and different tools. The Unfair Practices Act Statue really is not a fit for this broadened effort to go after a supply chain that does not promote product.

Unfair Practices is usually focused on advertising and promotion, not done by the supply chain to consumers. It was less about consumer protection and more about trying to broaden the concept of public nuisance. And I would be remiss without saying these broadened theories are not fully tested. And where they have been tested, they have so far failed.

For example, the first verdict by a state attorney general using private counsel was in Oklahoma, dig verdict against a manufacturer only to be reversed by the Oklahoma Supreme Court on appeal, finding that public nuisance law under state common law in Oklahoma was a misfit for the opioid litigation attacking a manufacturer. And others in the supply chain have other appeals in Ohio and West Virginia where their highest courts will rule on whether public nuisance is even a viable theory in those jurisdictions in the coming months.

Chris Carlson:

Understanding that there are going to be so many implications following the opioids litigation, I want to focus on another area that state AGs and the nation as a whole is focusing on, which is drug pricing. What activities have you seen state AGs do in this space?

Barry Boise:

Certainly, we've heard a lot in the recent campaign about claims of price gouging, and inflation, and costs, and trying to fight drug costs. And attorney generals certainly take note of that interest by the public and look for a place at the table in order to engage in the debate over the

price of medications. There's a couple of ways in which attorney generals have started to intervene in this space. One is to use more traditional antitrust tools, partnering with the FTC, for example, and the Martin Shkreli, the so-called "Pharma Bro" situation was a case in which antitrust claims were brought both by state attorney generals and the FTC over thoughts and claims, allegations of price gouging.

We've also seen cases brought against PBMs and manufacturers over the price of insulin, again trying to use some of the tools that I mentioned in efforts to claim that insulin prices as a result of some either unfair competition or other consumer protection violation. A lot of these theories remain untested. Finally, we've seen state legislators provide attorney generals additional tools in transparency laws that would require manufacturers and others in a supply chain to alert the state when there is an increase in a certain pricing of product. Those pricing increases can be either investigated or addressed in the court of public opinion or perhaps addressed with some sort of enforcement action.

Chris Carlson:

And now, Barry, looking ahead to 2025, what do you see in your crystal ball as areas that the state AGs will be focusing on understanding that drug pricing and the opioid crisis aren't going to be done today?

Barry Boise:

I think a couple of things. I think any entity that is working with new and disruptive technology, AI is an example, can expect attorney generals to also be curious, especially in a space that lacks regulation or perhaps will lack federal enforcement. I would expect attorney generals to step into that place and rely on meat and potatoes, consumer protection, enforcement action.

For example, we've seen some activity in the AI space where there are allegations that certain providers are overstating or overhyping what their AI products can and cannot do and the capabilities And those types of advertising, promotion claims, irrespective of technology, can fit within the confines of broad consumer protection statutes.

Chris Carlson:

I think you make a great point there. I was in a meeting with the Massachusetts attorney general's office and they were talking about AI. And they said, "We don't need a new statute to enforce AI. We look to our UDAP statute. And we look to whether you're making truthful and accurate statements." And so, I completely agree that you're going to see state agencies using our meat and potatoes consumer protection enforcement as it relates to AI.

Barry Boise:

Yeah. And you see in the health care space an increase in private equity ownership of healthcare systems and providers. Attorney generals are interested there. Going back to the 1990s, attorney generals have looked at nursing homes, for example, and whether claims about the quality of care that's being provided are actually being lived up to. There's at least a suspicion by attorney generals that for-profit healthcare institutions may be more prone to corner-cutting. And that will be, I think, an area that will continue to see targeting.

Chris Carlson:

And finally, unless you've been living under a rock, you know we're about to have a new president, our country. Any potential takeaways based on the first Trump administration that you can see state AGs really focus on enforcement activity?

Barry Boise:

Yeah. And Chris, I would broaden that question and really look at the last eight years. Whether it's Trump 45 or the Biden administration, we've seen really a profound role played by attorney generals where they see themselves as the loyal opposition. It's agnostic as to whether it's a Republican or Democrat holding the office of presidency, where there is a view by attorney generals that there is administrative, executive power, overreach, there has been efforts to litigate those issues against the sitting president.

We certainly saw that in the first Trump administration with a very active Democratic attorney general leadership going after all types of executive orders. That only, I think, continued and increased during the Biden administration where Republican attorney generals saw executive power overreach and used the same playbook as the Democratic attorney generals. And, in fact, probably expanded that playbook to include things like the major questions doctrine or also using the demise of the Chevron doctrine to really go after executive power and the administrative state. Now, with a new Trump presidency coming in 2025, I think we can expect the Democrats to use some of those tools as well.

Chris Carlson:

Acknowledging you just discussed some political issues and the role of executive power, as it relates to consumer protection issues in the healthcare space, do you expect any changes there?

Barry Boise:

I don't see consumer protection as really a Democrat or a Republican issue. It's a popular issue on both sides of the aisle if the view is there has been some consumer protection issue at play. Certainly, in the last 20 or so years in which I have litigated against attorney generals, I have not noted in that time period recently or in the distant past a significant difference as to Republican attorney generals or Democratic attorney generals pursuing consumer claims or hiring outside counsel for that matter.

Chris Carlson:

I completely agree, Barry. We always say that whether you're a Republican or a Democrat, you have to check the box of consumer protection. And I don't see that being true and differently in the healthcare space.

Barry, I want to thank you again for joining me. I know our listeners enjoyed your very valuable insights. I want to thank our audience for tuning into this special holiday series. Tune in tomorrow as we continue our “12 Days of Regulatory Insights.” Please make sure to subscribe

to our podcast via Apple Podcast, Google Play, Stitcher, or wherever else you may view your podcast. We look forward to seeing you next time.