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Litigators of the Week: An Early Knockout Win in the Decongestant MDL

By Ross Todd
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After an FDA advisory committee found last year that scientific data did not support the use of phenylephrine as a decongestant, makers of over-the-counter cough and cold medicines were hit with more than 100 class actions.

Our Litigators of the Week are **Andrew Soukup** of **Covington & Burling** and **Jay Lefkowitz** of **Kirkland & Ellis,** who scored a key, early victory for the defendants in those cases. With Soukup and Lefkowitz arguing for all defendants, U.S. District Judge Brian Cogan in Brooklyn, who is overseeing the decongestant multidistrict litigation, granted their motion to dismiss a «skinny» complaint focusing on claims brought under New York state law claims and the U.S. Racketeer Influenced and Corrupt Organizations Act. Cogan found the state law claims concerning the effectiveness of the decongestants were preempted by federal law, an issue that Soukup focused on during oral argument. Cogan further found the plaintiffs were indirect purchasers who lacked standing to pursue RICO claims, an issue that Lefkowitz had argued.

Courtesy photos

Andrew Soukup of Covington & Burling, left, and Jay Lefkowitz of Kirkland & Ellis, right.

Litigation Daily: How would you describe what was at stake for your clients?

Andrew Soukup: We are proud to represent The Procter & Gamble Co., which sells DayQuil and NyQuil cough and cold medicine. One of the active ingredients in this medicine is phenylephrine, which for decades has been approved by the FDA as an over-the-counter treatment for nasal decongestion. In September 2023, an FDA advisory committee voted that oral phenylephrine is ineffective—a vote that is not binding on the FDA,

and on which the FDA has not acted—and that vote touched off a flood of nearly 100 class-action lawsuits seeking economic damages against the entire industry.

This case is not just about whether a particular medicine works or not. Rather, it is about whether plaintiffs can use class-action litigation to challenge a federal agency's long-standing judgment about when medicine is effective and what information must be provided to consumers about that medicine. If manufacturers could not rely on the FDA's judgments on these issues, the uniform federal regulatory regime governing over-the-counter drugs created by Congress would be thrown into disarray. Congress passed a law giving the FDA the exclusive authority to make these determinations, and we are grateful that the Court enforced that provision here.

Jay Lefkowitz: Phenylephrine (or PE) is an ingredient that has been safely used in cold and cough medications for decades, and this litigation challenged the marketing and sale of PE-containing products that our client, Haleon, had been selling with FDA's blessing for many years. The stakes were high for Haleon and all of the defendants in this MDL, as they faced dozens of class action complaints trying to litigate the labeling and efficacy of these products and insisting on getting all the money that they paid for these products back. Of course, the court recognized that the FDA is the ultimate arbiter of which over-the-counter drug products can be sold and how they must be labeled and there is no basis under the FDA regulations for those judgments to be challenged by the plaintiffs.

Who was part of the broader defense team and how have the defendants been coordinating the efforts?

Soukup: In large, industry-wide MDLs like this one, defendants often closely collaborate on areas that are of joint interest to them, and this case was no exception. This case benefited from the tremendous thinking and teamwork of many excellent defense counsel, including Jay and **Robyn Bladow** and the rest of the Kirkland team, **Hannah Chanoine** and **Amy Laurendeau** (**O'Melveny & Myers**, who represented Johnson & Johnson Consumer Inc.), **Lauren Colton** and **James Bernard** (**Hogan Lovells**, who represented RB Health), **Chris Campbell**, **Christopher Young** and **Cara Edwards** (**DLA Piper**, who represented Bayer HealthCare), and **Sara Thompson**, **Mark Lesko** and **Nilda Isidro** (**Greenberg Traurig**, who represented CVS, Target, Walgreens and Walmart). This was among the most collegial and collaborative joint defense groups that I have had the privilege of being a part of.

Lefkowitz: I am proud to have been part of a tremendous team effort by a very strong joint defense group in this MDL, where every firm attended regular meetings and offered critical input on our defense every step of the way. We were all focused on presenting the strongest defense possible, and we worked collaboratively to achieve that goal. There were no egos and little to no disagreement on strategy. Robyn Bladow and I led our Kirkland team, working closely with Andrew Soukup and the Covington team, as well as the entire joint defense group, including all the folks Andrew mentioned, each of whom contributed to this outcome. This truly was a team effort.

Here you were taking aim at what the court called "the skinny complaint." For lawyers who might not be conversant in the MDL process, can you give a quick summary of what that means?

Lefkowitz: The MDL consolidated almost 100 lawsuits, and the complaints in those lawsuits asserted various claims under different states' laws. Once we were in the MDL court before Judge Cogan, the joint defense previewed that we would be raising preemption as a threshold basis to dispose of every complaint in the MDL. To proceed efficiently, the parties agreed that the plaintiffs could file a "skinny" (or streamlined) complaint on behalf of a limited set of plaintiffs asserting certain state law claims, and that the defendants could move to dismiss that streamlined complaint on preemption grounds, reserving all other defenses in the event the complaint survived the preemption challenge. Plaintiffs then added a RICO claim to their streamlined complaint, and defendants raised threshold standing and preclusion arguments supporting dismissal of the RICO claim as well. The parties agreed that the court's decision on those threshold preemption and RICO arguments directed at the streamlined complaint would then apply to all actions in the MDL. In other words, if defendants were to win the motion, the MDL in its entirety would be dismissed.

How did the team divide the work on briefing the motion to dismiss?

Soukup: Our Covington team—which included **Laura Flahive Wu**, **Cort Lannin**, **Dillon Grimm**, **Amy Health**, **Jeff Huberman** and **Ethan Treacy**—and the Kirkland team—which included, in addition to Jay, Robyn Bladow, **Jacob Rae**, **Cole Carter** and **Joey Resnick**—worked together on the initial drafts. We also benefited from the excellent input and suggestions from the entire joint defense group, including very sophisticated in-house counsel.

Lefkowitz: While Kirkland and Covington took the lead on the motion to dismiss briefing, every joint defense firm added great value to the arguments and was directly involved in the editing process. It was really a tremendous group effort that resulted in great work product and a great outcome for our clients.

In a large multi-defendant case such as this one, how do you decide who is going to handle oral arguments? And how did you prepare for them?

Soukup: Ultimately, our clients determine who they think will be the right fit to handle a particular hearing. This group featured an all-star assortment of lawyers, all of whom would have done an excellent job, and Jay and I were honored that we were tapped to represent all the defendants at the hearing.

To prepare for this argument, I followed my typical approach: I spent a lot of time reading the briefs and authorities cited by the parties, and then brainstorming issues that might come up or questions that the court might ask. From there, I worked with the Covington team to come up with short and effective responses to the trickiest issues that could have come up. We then tested and discussed those themes with the broader joint defense group, which had additional good and helpful suggestions. The final product was a true team effort.

Lefkowitz: Several members of the joint defense group handled various hearings in this litigation, and Kirkland and Covington took the lead on this one primarily because we had taken

the lead on the briefing. As for who argued which issues, although I am usually the preemption guy, here the argument before Judge Cogan came on the heels of Andrew's recent preemption argument in C.D. Cal. in another case he and I are both involved in and just a few weeks after Cole Carter and I won a Sixth Circuit case on the same RICO standing issue in this case. So that offered a natural split of responsibility here. In terms of argument preparation, it was a full-court joint defense group effort. We worked closely on strategy, shared ideas and participated in moot courts as we prepared for oral argument.

The plaintiffs brought their lawsuits after an FDA advisory committee found last year that the decongestants weren't effective at treating congestion, but the FDA hasn't changed its official position. Was this key to your defense?

Soukup: No. Our clients have remained consistent: they sell FDA-approved medicine, for an FDA-approved purpose, with FDA-regulated labeling, as permitted by FDA regulations. Even if the FDA changes its position in the future, that change would only apply on a go-forward basis. Any future change would not alter the fact that federal law deemed our medicine effective at the time it was sold.

Your express preemption argument here targeted claims related to statements about the drug's effectiveness. Would your arguments hold up as well in a case bringing claims related to a drug's safety?

Soukup: The law at issue expressly preempts any state law "that is different from or in addition to, or that is otherwise not identical with, a requirement" under federal law. There is no dispute that Congress carved out from this express preemption provision the product liability law of any state. But none of the plaintiffs brought personal injury claims. Rather, this case involved alleged economic losses and claims seeking to recover those losses are expressly preempted.

Johnson & Johnson added a message on its website next to pictures of all its phenylephrine products stating that the advisory committee has reviewed the efficacy of PE as a decongestant and linked to the FDA's statement. But J&J, like all the defendants, continues to sell the products. Did that move create any issues for you in briefing or arguing preemption and the RICO issues?

Soukup: Although the plaintiffs at times focused on that message, it was a sideshow. The FDA's statement simply reaffirmed what our clients had been saying all along: the FDA had not changed its longstanding position that phenylephrine is an effective nasal decongestant, and if the FDA decided to change its position, it would seek public comment before making a final decision. This just reaffirms that it is up to the FDA, not private litigants, to determine when medicine is effective.

What's important in this decision for your clients and others who might face similar labeling or RICO claims?

Lefkowitz: This decision reaffirms the central and exclusive role the FDA has in determining whether or not drug products are effective to treat particular conditions or symptoms. Especially in the over-the-counter (OTC) context, neither state law nor private plaintiffs can usurp that role. This is important for our clients, the other defendants and anyone who manufactures and sells OTC drug products. The court's decision assures companies that they can continue to rely on FDA determinations of efficacy when deciding

what products to make and sell. It's also good for consumers because they can continue to buy products the FDA has determined are effective treatments for common ailments like cough and cold symptoms. The decision also rejects plaintiffs' attempt to circumvent preemption by adding a RICO claim, as the court confirmed that indirect purchasers do not have standing to bring RICO claims.

What's next for the litigation? The judge had initially ordered plaintiffs to file a master complaint following his dismissal order in this bellwether complaint, but there's not much left. What do you predict will happen?

Lefkowitz: The parties agreed and the court ordered that the decision on defendants' motion to dismiss the streamlined complaint would "apply to all cases in this multidistrict litigation." Because the defendants won dismissal of the streamlined complaint, that holding now applies to all the MDL cases and a complete dismissal order should be entered. It is certainly possible plaintiffs will appeal Judge Cogan's decision, and if they do, our joint defense team will be prepared to defend the ruling and our clients at the Second Circuit.

What will you remember most about getting this result?

Lefkowitz: We had a really amazing team here. My partner Robyn Bladow is one of Kirkland's most accomplished class action litigators and was a leader among the joint defense group in developing our defense from the beginning. Our team also included Jacob Rae, Cole Carter, Joey Resnick and **Cameron Bonk**, each an indispensable contributor to the defense's success. They all did a fantastic job developing our winning arguments and presenting them in the most compelling way possible. We also have an amazing client, Haleon, that provides consumers ready access to cough and cold remedies and other consumer products. And the in-house lawyers at Haleon, especially **Liz Balakhani** and **Sarah Jane Petersen**, were full-time partners of ours in all the key decision-making.

But the thing that stood out the most here was how collaborative the defendant group was. That was particularly true for the collaboration between the Kirkland and Covington teams on the briefing and argument of the motion to dismiss. But the work of the joint defense group here really proved that the sum really is greater than any of its constituent parts.

Soukup: Three things stand out to me. First, the trust placed in us by our longtime client P&G, which has a fantastic and sophisticated in-house legal team that is a joy to partner with, especially **Megan Frient**, **Ken Blackburn** and **Meghan Walters-Price**. Second, the hard work and late nights by the Covington team and the collaborative spirit of the entire joint defense group, both of which were essential to getting the result we achieved here. Third, the importance of the result reached by the court, which reaffirms–to use the court's words–that federal law "empowers the FDA, not drug manufacturers, to determine whether a drug is effective."