

Litigators of the Week: A Complete Defense Win for Distributors in a Federal Opioid Bellwether Trial in West Virginia

Following a three-month bench trial last summer, a federal judge in West Virginia last week handed a major victor to defense teams for the three largest wholesale distributors of prescription painkillers led by Paul Schmidt of Covington & Burling, Enu Mainigi of Williams & Connolly and Robert Nicholas of Reed Smith.

By Ross Todd
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After a three-month, 70-witness bench trial in West Virginia last summer, lawyers for the nation's three largest wholesale distributors of pain drugs spent the better part of a year waiting for a ruling in the bellwether case targeting their clients with claims stemming from the opioid crisis.

On Independence Day, Senior U.S. District Judge David Faber finally dropped a 184-page opinion that handed the companies, McKesson, Cardinal Health and AmerisourceBergen, a complete defense victory. Faber found the plaintiffs' central liability theory inconsistent with "historical and traditional" legal notions of nuisance. "To apply the law of public nuisance to the sale, marketing and distribution of products would invite litigation against any product with a known risk of harm, regardless of the benefits conferred on the public from proper use of the product," Faber wrote.

The win has landed Litigator of the Week honors for the companies' lead counsel — **Paul Schmidt of Covington & Burling**, **Enu Mainigi of Williams & Connolly**, and **Robert Nicholas of Reed Smith** respectively.

Lit Daily: Who were your clients and what was at stake?

Robert Nicholas, Reed Smith: Our three firms represent the three largest wholesale distributors of prescription medications and other healthcare products



Courtesy photos

L-R: Robert Nicholas of Reed Smith, Paul Schmidt of Covington & Burling and Enu Mainigi of Williams & Connolly.

in the United States. Reed Smith represents AmerisourceBergen; Williams & Connolly represents Cardinal; and Covington represents McKesson. These companies play an incredibly important role in the delivery of healthcare. Most of the prescriptions you fill or items you buy at a Walgreens or a CVS or any other large or small pharmacy were distributed by one of these three companies.

There were thousands of cases filed in the opioid litigation against manufacturers, distributors and pharmacies, accusing these companies of causing the opioid

crisis. Most of the cases were consolidated in an MDL in the Northern District of Ohio before Judge Polster. This West Virginia case was selected by Judge Polster to be the bellwether trial for the distributors, and it was in fact the first case in the country to be tried against the distributors. It was very closely followed in the legal and business communities, because it was well understood that the outcome here would influence current and future litigation. So there was a lot at stake.

Who all was on your teams and how did you divide the work?

Nicholas: We all had great teams. For Reed Smith, I shared stand-up trial responsibilities with my partners **Shannon McClure** and **Joe Mahady**. Our local counsel, **Gretchen Callas** of **Jackson Kelly**, also examined witnesses at trial. **Kim Watterson** from Reed Smith covered the legal landscape for our team. In addition, we had an incredibly dedicated and smart group of lawyers working on-site, and off-site, to support this 4-month effort, including **Anne Rollins**, **Lou Shack**, **Jeff Melton**, **Abby Pierce**, **Kristen Ashe**, **Alyssa Conn** and **Cliff Breese**. Also, AmerisourceBergen's in-house lawyers and nonlawyers alike played a major role in the defense of the case, which I thought was exceptionally valuable and important. In terms of the division of labor, these three law firms, on behalf of our respective clients, have been working together on this nationwide litigation for several years now. We have each developed areas of expertise, on legal issues and factual issues, and we are very collaborative. Honestly, the level of coordination and cooperation among these three major law firms was revelatory, at least for me.

Paul Schmidt, Covington & Burling: I co-tried the case for McKesson with outstanding trial lawyers **Tim Hester**, **Laura Flahive Wu** and **Andrew Stanner**. **Chris Eppich**, **Maureen Brown** and **Amber Charles** played key senior leadership roles, including with witnesses, and **Chris Pistilli** spearheaded our legal thinking. We had a remarkable group of trial associates, including **Greg Halperin**, **Steve Petkis**, **Meghan Monaghan**, **Nicole Antoine**, **Clayton Bailey**, **Marc Capuano** and **Kevin Kelly**, every one of whom made critical contributions to case strategy and execution. Our West Virginia colleague **Jeff Wakefield** provided crucial case guidance. And our McKesson in-house

colleagues played a key role in shaping our strategy and its implementation throughout the trial.

Enu Mainigi, Williams & Connolly: I led the team for Cardinal along with my Williams & Connolly partners **Jen Wicht**, **Lane Heard** and **Ashley Hardin**. I did the opening and closing arguments and examined some of the key plaintiff and defense witnesses, Jen cross-examined key experts, and Ashley handled thorny legal issues and also examined witnesses. Lane was our legal guru and delivered a superb argument for a directed verdict. We had excellent West Virginia counsel in **Steve Ruby**, who was with us in the courtroom every day and examined some of the local witnesses. And we were supported throughout the trial by a fantastic team of Williams & Connolly associates and paralegals—including associates **Suzanne Salgado** and **Isia Jasiewicz**, who each examined witnesses and **Joseph Bushur** who was critical to us on all things experts. Our entire team met daily to discuss strategy and coordinate our efforts, and the input received from each member was invaluable. It was a true team effort.

At trial the former West Virginia Bureau of Public Health Commissioner described West Virginia as “ground zero” for the opioid crisis. Were there specific concerns for the defense team tied to how hard the state where the trial was taking place has been hit by opioid abuse even though the case was tried to the bench?

Schmidt: Our case never depended on challenging the seriousness of the opioid crisis, particularly in Huntington. We each made a point of recognizing that fact in our opening statements and throughout the trial.

We also made a point of not blaming the crisis on other participants in the healthcare system. We instead based our case on the fact that opioid prescribing increased because doctors legitimately attempted to address pain, which in turn explained why our clients increased their distribution of prescription opioids.

We were successful in telling this story through every one of the plaintiffs' expert witnesses and through several of their fact witnesses, so that it was an uncontested and central truth of the case before we presented even a single witness. Judge Faber let both sides try their cases in a remarkably fair and even-handed manner, and we were grateful for that opportunity, which we tried to use from the time of the plaintiffs' first witness.

Nicholas: Just about the first thing we did in this trial was to acknowledge the opioid crisis and say that we would not seek to minimize or downplay it. And we did not. We tried this case on its facts and on the law – our essential point being that it was misguided, contrived, and legally unsupportable to place blame for the opioid crisis with the distributors whose role in the supply chain is to deliver medication that has been prescribed by licensed physicians to be dispensed by licensed pharmacies and hospitals. Judge Faber's reputation as a smart, conscientious, hardworking, and fair-minded judge had preceded him of course. We believed that he would hear the evidence and apply the law fairly and impartially, and he did.

What were your key trial themes and how did you try to hammer them home with the judge?

Mainigi: A critical theme for us has always been the changing standard of care. What I mean by that is the volume of opioid medications was driven by legitimate prescribing consistent with the evolving standard of care. Plaintiffs pointed to large volumes of pills and asked, "How could this have happened?" Well, what happened was the federal government, state government, and medical associations all told doctors that pain had been undertreated, opioid medications were safe and effective, and doctors should prescribe opioid medications to treat pain. Doctors acting in good faith prescribed opioid medications consistent with that guidance, and our clients shipped pills to pharmacies that filled those good-faith prescriptions. We built this theme throughout the plaintiffs' case through cross-examination of their experts and fact witnesses—all of whom supported our points—and it was solidly established before the plaintiffs rested. Then, in our case, we were able to bring all of the evidence together through the testimony of our standard-of-care experts.

Another key theme for us was DEA's endorsement of distributors' systems over time. Like the standard of care, the DEA's regulatory guidance—and our systems—evolved over time. We were able to show that DEA had approved distributor systems, communicated that approval to the industry, and that our clients designed their systems to meet DEA's expectations. We made this point through our company witnesses and also through DEA witnesses.

How much coordination was there between the defendants?

Mainigi: We've been working together on these cases for years, so we had a solid base of cooperation to start with and worked well together throughout the case. That being said, we each represent our own clients and bring a different perspective to the case which was a strength for all of us. It meant that a stone rarely failed to get turned over.

We would, for example, designate a lead for cross-examination of plaintiffs' witnesses and work to have that person cover much of the questioning on behalf of defendants as a whole. But, oftentimes, other defendants would ask additional questions that they believed were necessary.

Nicholas: As I said above, the degree of cooperation and teamwork among the three law firms was a revelation – really a wonderful experience.

How closely did you monitor proceedings in prior and concurrent opioid trials? What did you pick up from the experiences of prior teams in those cases?

Nicholas: Although this was the first distributor case to be tried, there were things to learn from the trials and proceedings against the manufacturers and pharmacies, and of course we tracked them. We monitored some trials more closely than others. It is always interesting to see how other cases play out, especially given that there are both jury and bench trials in this litigation. And there are terrific lawyers on both sides of the aisle here, so there is always something to learn. The issues in any given trial can vary, especially depending on where in the supply chain the defendants fit. But even in trials that have only involved just manufacturers or pharmacy chains, there can be interesting legal developments, familiar expert witnesses, and so on. We of course have to pay the most attention to our own cases, but we do like to know what's happening elsewhere.

Schmidt: We monitored what happened in other opioid trials, but because ours was the first trial against distributors, it was unique, with us presenting our core themes and key witnesses for the first time. We've since been able to use that experience across two other distributor trials.

Judge Faber's decision echoed some of the findings of the Oklahoma Supreme Court and Judge Wilson

in the Orange County case, but he also introduced a lot of his own findings specific to this case, including about your clients' programs for monitoring suspicious prescription orders. How do you see this decision impacting other opioid cases?

Mainigi: Judge Faber's decision shows that there is no merit to these claims against our clients—both as a matter of law and as a matter of fact. Judge Faber's opinion provides other courts with a persuasive rationale for holding that nuisance law does not embrace claims against distributors of lawful medications and that huge sums of money derived from lawsuits that have no basis in law or fact to address broad societal problems are not proper "abatement." The opinion also demonstrates that plaintiffs' theory of liability is unsupported on every dimension: it is inconsistent with distributors' obligations under the relevant regulations; it is contrary to DEA guidance; and it ignores the reality of the changing standard of care and the roles of doctors and pharmacists in providing medications to patients. The opinion also exhaustively details the suspicious order monitoring programs that our clients implemented over time, conclusively demonstrating that they were compliant with legal requirements at every point.

What's next for all of you and your firms in the opioid litigation?

Schmidt: The verdict in this case marks the end of most of the cases brought by states and localities against McKesson, which is a terrific outcome for them. Other non-governmental plaintiffs are still pursuing opioid lawsuits that we are working with McKesson to defend.

We also see plaintiffs trying to use some of the novel legal theories from opioid lawsuits in other settings, and we are working with firm clients to defend such claims.

Mainigi: We have reached resolution (or are on the path toward resolution) of most of the cases brought by states, counties, and cities. We are working on behalf of Cardinal Health to defeat claims brought by other classes of plaintiffs, including hospitals and individuals.

Nicholas: As Paul and Enu both said, this is unfortunately not the end of the road for the opioid litigation, although we believe that Judge Faber's thoroughly reasoned decision will have a major positive impact for the distributors. We at Reed Smith have worked with AmerisourceBergen in defending this litigation

for several years now. We have tremendous respect for AmerisourceBergen's people and for the company as a whole. We want the company to be able to put the litigation behind it and our efforts will be singularly focused on that goal. The resounding outcome of this bellwether trial will help.

What will you remember most about this matter?

Schmidt: Our goal was to make our key points every day of the trial, when every trial day felt incredibly high-stakes because we were addressing the claims of a remarkably hard-hit city and county, when this was the first bellwether trial against distributors, and when it involved a multi-billion-dollar claim. Even with the even-handedness and civility that Judge Faber and his staff ensured, that made the trial remarkably challenging. What made it memorable in the best way for me was the McKesson/Covington team.

I benefited from incredible thinking and dedication from colleagues that drove my opening statement and the examinations I undertook, including examinations of key witnesses like the plaintiffs' star DEA witness, their conduct witness, and the opening defense witness. At the same time, I enjoyed my partners' outstanding witness examinations, and Tim Hester's case-sealing closing argument. Every member of the Covington team showed remarkable creativity and dedication at every step of the case. Having an in-house team at McKesson who had the conviction to see the case through to verdict, while fundamentally shaping the substance of our presentation throughout, was a career-defining experience.

Mainigi: I will remember most that both sides got a fair shake. Judge Faber has got to be one of the most patient jurists around. He let both sides put on the case we wanted and listened carefully to all of it.

Nicholas: I think what will stay with me longest is the way Judge Faber and his staff ran their courtroom and presided over the case. As intense as the whole experience was, they exuded calm and thoughtfulness and professionalism, and I believe everyone in the courtroom knew that this was going to be a fair proceeding.

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