

Pro Te: SOLUTIONTM

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Dear Client,

Summer is winding down, and Fall texted to say she is on her way. This means that *Pro Te: Solutio* is returning for its third edition of 2019. As always, our authors have taken the time to research and address current issues facing attorneys and their clients in today's legal climate.

The first article is entitled *The Mongoose Strikes Back: How to Thwart a Reptilian Attack*. This article discusses the now well-known "Reptile strategy" and how to counteract and neutralize reptilian questions with mongoose-style preparation and questioning.

The second article, *Walking the Line Between Marketing and Malfeasance*, addresses some of the origins of the current opioid litigation. Reviewing the history of Insys and its resulting legal troubles, we look into the fallout, current AG and DOJ positions, and the foreseeable trends that may emerge.

The third article in this issue is *Expert Disclosures: Navigating the Distinction Between Retained and Non-Retained Experts*. Here, we look into the murky distinction that courts have developed between retained and non-retained experts for the purposes of the Federal Rules of Civil Procedure.

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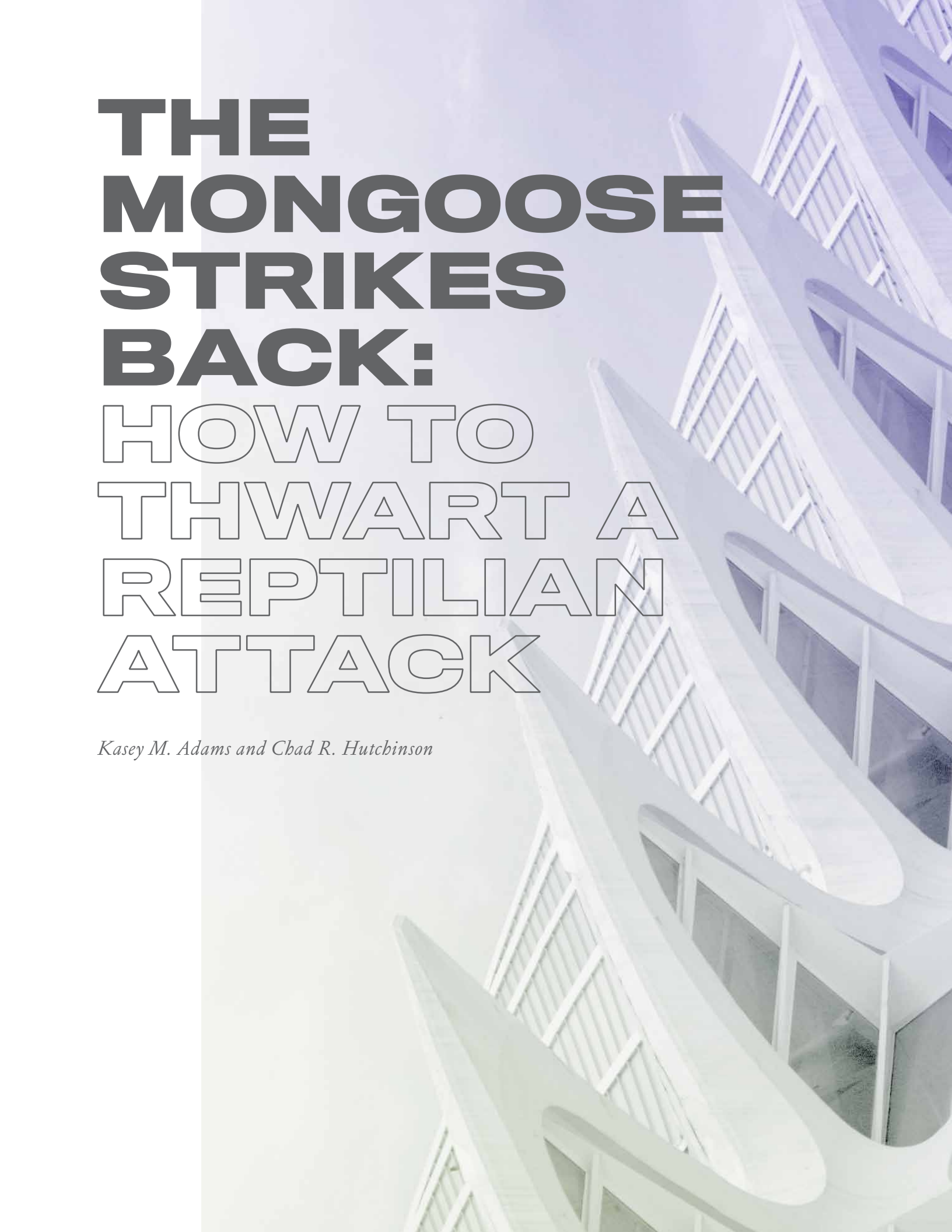
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THE MONGOOSE STRIKES BACK: HOW TO THWART A REPTILIAN ATTACK

Kasey M. Adams and Chad R. Hutchinson

If you have ever read *The Jungle Book*, a collection of stories by Rudyard Kipling, Rikki-Tikki-Tavi should sound familiar. Rikki-Tikki-Tavi follows the adventures of a brave young mongoose who, despite his size and position, valiantly conquers a venomous snake to protect his human family. Kipling's tale is based in fact: Real-life mongooses are immune to snake venom and are known for their ability to attack snakes.

The Reptile Attacks

Even if you are not familiar with Rikki-Tikki-Tavi, as a litigator, you are certainly familiar with the infamous “Reptile theory.” The series of questions we refer to as Reptilian are now commonplace for plaintiff lawyers everywhere after becoming a nationwide phenomenon in 2009 when David Ball and Don Keenan published *Reptile: The 2009 Manual of the Plaintiff's Revolution*. Following the theory, Reptile questioners start a deposition innocently enough, asking the company witness to acknowledge basic propositions of safety with which most everyone would agree. For example, plaintiff's counsel will ask a general question about the importance of safety to consumers or ask the witness to agree that the company they work for should make safety a top priority.

The real Reptile is in the details—these questions are repeated in slightly different forms with slightly different language, all with the ultimate goal of equating the company's ruler to the company's legal duty. These sound bites are often used easily and effectively at trial by showing the company witness video depositions to the jury. The goal is a subtle, psychological pressure on jurors to find fault in the company's conduct based on these alleged admissions on video, without regard to the evidence presented at trial.

How It Works

On a subliminal level, the Reptile's purpose is to make jurors feel as though the company's conduct has put not only the plaintiff in danger but also the jurors themselves. Reptile questions are formulated carefully to appeal to the part of a juror's brain that is inherently programmed to evaluate safety and respond in a defensive way: If anything threatens that sense of safety, the Reptile responds to keep itself safe. In trial, the Reptile is the juror, and the goal is to have the juror keep himself safe by “sending a message.” Jurors send a message by reaching a verdict that deters the defendant from behavior that not only threatened the plaintiff but also threatens the juror's safety and

well-being. When the Reptile theory is employed successfully, one little sound bite in a video deposition can do just that.

To avoid this viper pit, company witnesses are taught trigger words to look for and given tips to sidestep the reptiles. But that is not enough. There must be a strategy for company counsel and witnesses to use offensively: a mongoose. Seemingly harmless questions about safety should be rejoined with similar questions—like asking the witness if a patient should make safety and health their number one priority.

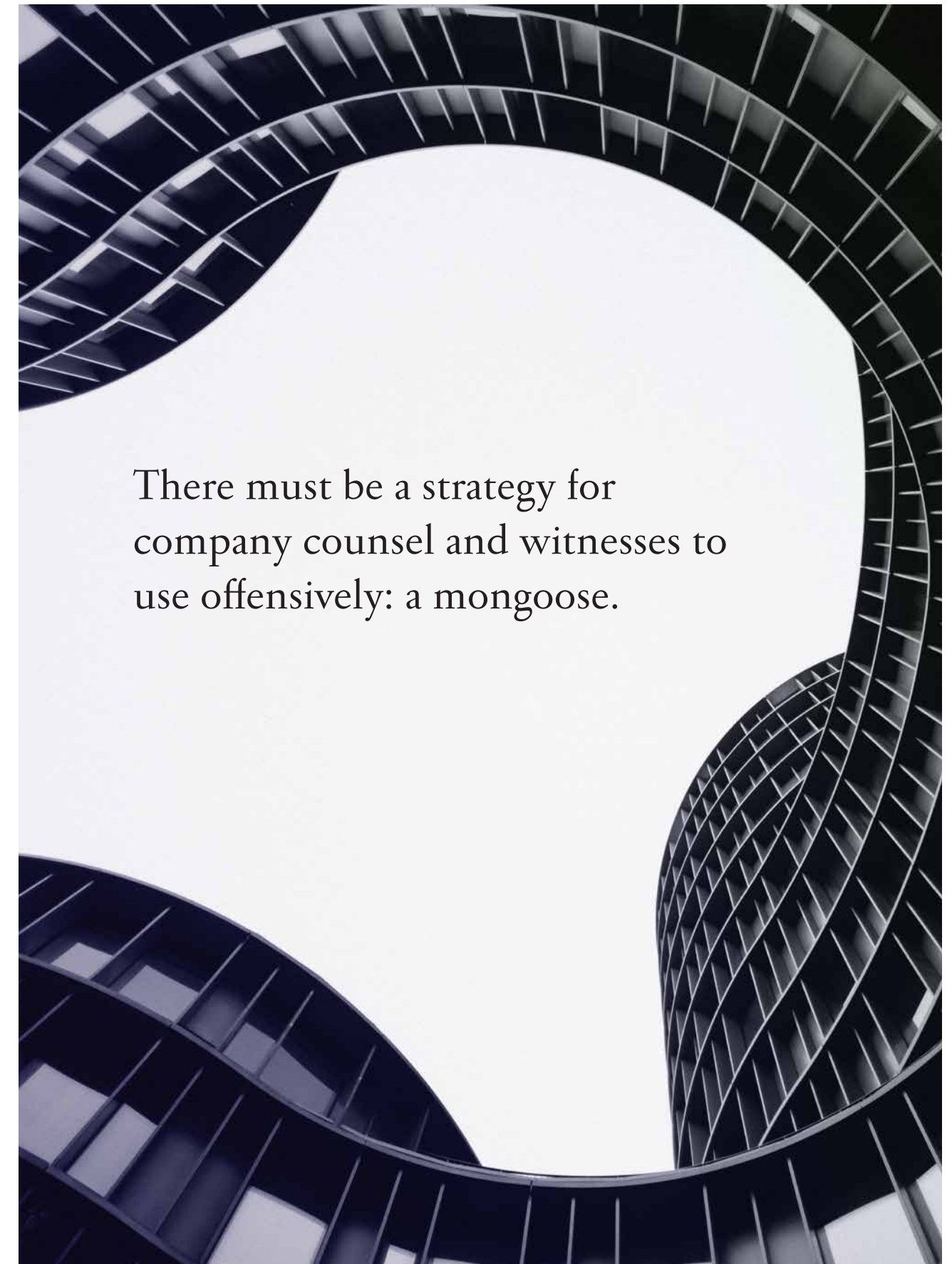
Why Unleash the Mongoose?

Or perhaps a better question: Why not? In a broad sense, a mongoose question is any question asked at a deposition that develops using evidence of the corporate defendant's genuine concern for the safety and well-being of anyone using its product. The successful Mongoose question and answer make plaintiff's counsel cringe when the video deposition is played at trial. Though unleashing the Mongoose may not be appropriate in every context, if the plaintiff engages in Reptilian conduct, asking countervailing Mongoose questions could prove quite effective. As trials become increasingly more dependent on presentation of key evidence by video deposition and as plaintiff lawyers embrace the Reptile theory, defense lawyers must understand the impact that this subtle, psychological approach can produce. Preparations must be made to counter that prejudice forcefully and effectively.

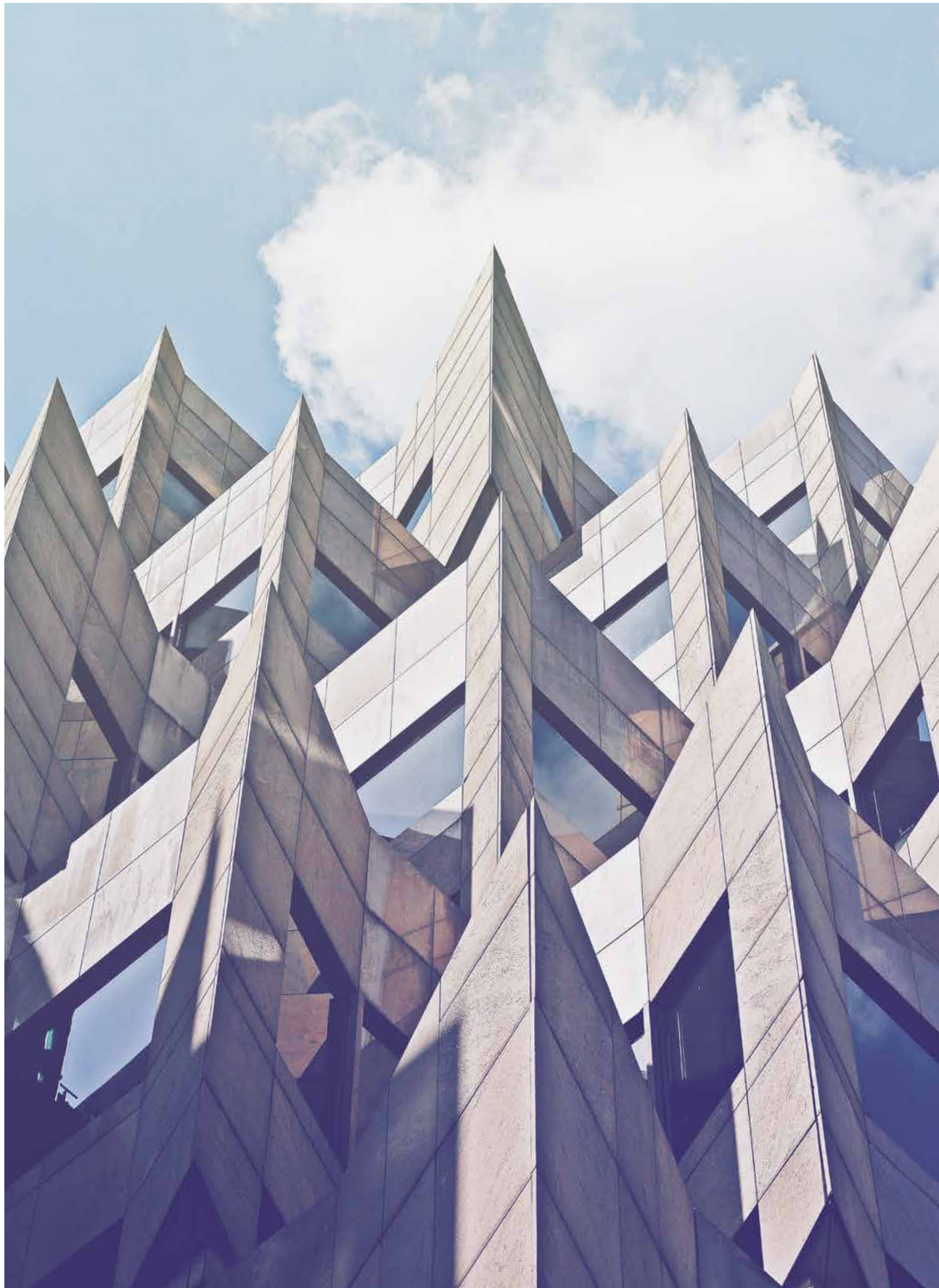
How to Be a Mongoose

To unleash the Mongoose, you must prepare your witness for redirect questions that will be responsive to some of the more common Reptilian questions. This is more than just an aggressive redirect exam. This is a pointed, specific focus on key points, designed to dispute and neutralize Reptilian questions from plaintiff's counsel. Just as the plaintiff starts out with soft, seemingly innocent Reptile questions, we can start out with soft, non-controversial Mongoose questions, too.

For example, the plaintiff's attorney will often ask the witness to agree that the company has a duty to make a safe product. When questions like this are raised, we should be prepared to counter it. Here is an example: "You were asked if a product is unsafe if it causes injury. Can you tell the jury which medical devices are 100% risk-free?"



There must be a strategy for
company counsel and witnesses to
use offensively: a mongoose.



Some other examples:

- When your witness is asked about an alternative design that the company is working on, you might ask some of the following:
 - » *Does innovation help or hurt patients?*
 - » *Which departments are involved in product development?*
 - » *Do each of these departments have different perspectives?*
 - » *When a company develops a new product, how many different perspectives do you want?*
 - » *Do different people have different ideas?*
 - » *How does that help with innovation?*
- When your witness is asked if the company should have warned of all risks, you can ask some of the following:
 - » *Is it reasonable and feasible to warn doctors about each and every reported adverse event?*
 - » *Is it possible to predict every potential risk for every person?*
 - » *Can there be too many warnings on a label?*
 - » *Could an overly strong warning cause a patient not to use a drug or device that could help them?*

As a practice pointer, be prepared at the *beginning* of your redirect examination (so the jury will be sure to remember it) to relate back to the questions the witness was asked about a company's duty to make a safe product. Then start with other Mongoose questions, depending on the nature of your case, such as:

- *Doctor _____, what is your number one priority when you come to work every day? (Safety)*
- *What have you seen personally in the last 25 years about whether [insert company] values safety?*
- *How do you know this?*

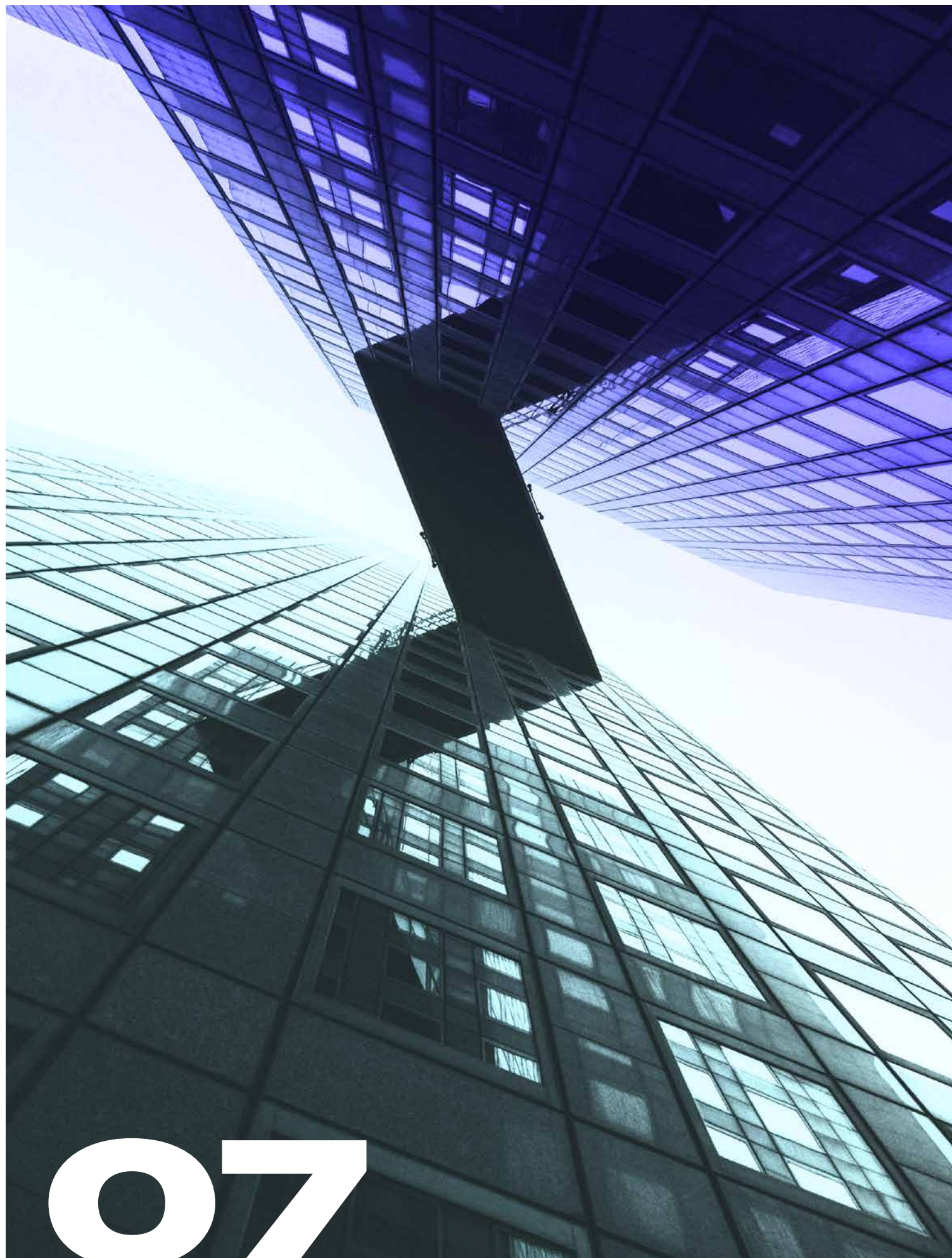
At first blush, one might think these types of questions will draw objections from plaintiff's counsel. But if the trial judge rules that plaintiff's Reptile questions are proper, then so too are the defendant's Mongoose questions.

Taking the Mongoose a step farther, defense counsel may also find value in asking questions about the plaintiff's own responsibilities, although questions like these carry risks. One benefit, though, of plaintiff-directed questions is that they may convince a plaintiff's lawyer to abandon the Reptile theory. Too harsh a treatment of the plaintiff may be off-putting for jurors, but striking an effective balance in tone and approach is worth consideration. Examples of duty-oriented questions for the plaintiff include:

- *Should a plaintiff never accept any potential risk, regardless of the potential for benefit?*
- *Does the plaintiff have a duty to take good care of himself/herself?*
 - » *Exercise? Eat healthy? Not smoke?*
- *Does a plaintiff have a duty to minimize risks?*
- *Does a plaintiff have a duty to heed warnings and safety information?*

The purpose of unleashing the Mongoose is to counter the questions our company witnesses face nearly every time they are deposed, questions designed to create a perceived danger that is very personal to them. When a Reptile is lurking, prepare your defense but also consider going on the offense. After all, as Kipling concluded, "It is the hardest thing in the world to frighten a mongoose."

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WALKING THE LINE BETWEEN
MARKETING
— & —
MALFEASANCE

Taylor B. Mayes & Katelyn E. Marshall

Opioid manufacturers, distributors, pharmacies and prescribers are facing a deluge of lawsuits that involve criminal and civil claims in both federal and state courts. On May 2, 2019, a federal jury in Boston, Massachusetts, found John Kapoor, the self-made billionaire and founder of Insys Pharmaceuticals, along with four other executives, guilty of RICO conspiracy for their roles in Insys' scheme to bribe medical practitioners and defraud Medicare and private insurance carriers.¹ The verdict followed a 10-week trial during which jurors heard testimony concerning the plan Insys employed to market Subsys, a highly powerful fentanyl spray.² Kapoor and his former colleagues are scheduled to be sentenced in September.³ Each defendant faces up to 20 years in prison for their crimes.⁴

The fallout for Insys did not end with these convictions. On June 5, 2019, Insys agreed to pay \$225 million dollars, plead guilty to five counts of mail fraud and admit violations of the False Claims Act to settle civil and criminal federal investigations into

the Subsys scheme.⁵ The Department of Justice (DOJ) celebrated the settlement as a major victory.⁶ However, the celebration was short-lived: The government will likely recover only a fraction of the settlement amount.⁷ On June 10, 2019, Insys filed for Chapter 11 bankruptcy protection in which the company declared assets worth \$175 million and debts of \$262 million.⁸ This marks the first time a pharmaceutical company has filed bankruptcy because of opioid-related litigation costs.⁹

The pharmaceutical industry, private attorneys and prosecutors are closely watching the opioid litigation playing out in forums across the country. Plaintiffs' lawyers are fond of drawing comparisons between the opioid litigation and the tobacco litigation in the 1990s in which tobacco companies were spurred to accept the largest civil litigation settlement in history, in the very early stages of the proceedings.¹⁰ Yet, there is a major problem in comparing opioids with tobacco: Few doctors would dispute that opioids are "essential medication, the most effective drugs for the relief of pain and suffering."¹¹

The necessity of these drugs and the flood of recent litigation over their abuse have raised many legal questions concerning the roles of industry members and the judicial system. Where is the line between marketing and racketeering? Between physician education and bribery? Are the recent headlines signs of a future uptick in criminal and civil prosecutions against corporations? What about against individual executives? This article explores the criminal and civil liability involved in the Insys scandal and the implications for the pharmaceutical industry in an age where prescription opioids are not going anywhere.

Insys Therapeutics and Subsys

John Kapoor, now 74, founded Insys in 2002.¹² Kapoor was already extremely wealthy, and he personally bankrolled Insys for years before Subsys was approved by the FDA in early 2012.¹³ Subsys belongs to a class of fentanyl products known as TIRF drugs, which have been approved by the FDA exclusively for use by adult cancer patients who are already receiving around-the-clock opioid therapy and are experiencing “breakthrough” pain.¹⁴ TIRF drugs are incredibly valuable and necessary to those patients with extreme pain. They also happen to be lucrative—a single patient taking Subsys could produce up to \$19,000 in revenue per month.¹⁵

When Subsys launched in 2012, the Insys board, led by Kapoor, selected Michael Babich, a thirty-six-year-old with negligible industry experience, to serve as CEO.¹⁶ Kapoor was disappointed reportedly with the sales of Subsys during its first months on the market, and there was high turnover of sales personnel, who were also almost all young and inexperienced.¹⁷ To resolve these problems, Babich brought in Alec Burlakoff.¹⁸ Burlakoff had experience in the industry, but his previous sales tactics had led him into

trouble.¹⁹ In 2002, the Florida Attorney General’s Office investigated him for mailing unsolicited pills to potential consumers.²⁰ He was thereafter fired by his employer, Eli Lilly, whom Burlakoff then sued, claiming the plan was orchestrated by management.²¹

With Burlakoff at the wheel, Insys quickly ramped up its sales efforts, including its now-infamous “speaker program.”²² Only high-volume opioid prescribers, referred to by Insys sales representatives as “whales,” were recruited to participate in the speaker program.²³ Top prescribers of Subsys were paid four figures to speak over fancy dinners to audiences of their friends and family, none of whom were qualified to become prescribers themselves.²⁴ At least one whale even received a lap dance from an Insys sales representative in an attempt to secure him as a speaker.²⁵ Insys quadrupled the budget for the speaker program to more than \$10 million by 2014.²⁶ Prosecutors would later present evidence that the Insys executives had even calculated the potential return on investment for each of the speakers.²⁷ Burlakoff also encouraged sales representatives to push doctors into prescribing higher doses of Subsys than the recommended, on-label dose of 100 mcg.²⁸ Sales representatives were threatened through emails with “immediate negative consequences” if they failed to comply with his orders.²⁹ Fortunately for prosecutors, top executives, including Kapoor, were copied on these emails.³⁰

Burlakoff and Babich eventually struck deals to testify against Kapoor and their former colleagues, which resulted in some of the most powerful testimony for prosecutors.³¹ According to Burlakoff, Insys was “up front” with doctors about the bribery scheme, and Kapoor would regularly ask interviewees whether they preferred “loyalty” or “integrity” to determine whether they would be willing to “go along with our scheme to bribe doctors to prescribe Subsys.”³²



Subsys sales skyrocketed from \$8.6 million in 2012 to \$329 million in 2015.³³ In 2013, Insys went public—resulting in the best performing IPO of the year.³⁴ However, Insys executives faced a major hurdle in their efforts to promote Subsys prescriptions for non-cancer patients: Insurance companies would not cover Subsys unless it was prescribed for on-label use. Moreover, wholesalers and pharmacies were required by the DEA to report suspicious orders.³⁵ Thus, Insys resolved to make it look like the prescriptions were being written for cancer patients and to bribe pharmacies and distributors to go along with the plan.³⁶

Insys developed a multi-pronged approach to address this problem. For the “most valuable” prescribers, Insys hired “Area Business Liaisons” to work on obtaining authorizations from within the provider’s office. Area business liaisons, who were often relatives and friends of the provider, were bankrolled by Insys to obtain final authorization for payment for Subsys prescriptions from insurance companies, Medicare and Medicaid.³⁷ Meanwhile, Insys employees in the “reimbursement center” worked to ensure prior and final authorization by contacting payors directly.³⁸ Practitioners who used the reimbursement center were required to fill out forms to opt in, and they provided information about patients that was confidential.³⁹ Callers in the reimbursement center contacted insurance companies and falsely represented that they worked in a provider’s office.⁴⁰ Then, they lied about the

medical history and diagnoses of patients so that payors would approve payment for Subsys, even though it had been prescribed for off-label use.⁴¹ When representatives from the insurance companies would inquire further about the employment status of the Insys callers, the Insys callers were instructed to hang up the phone and try to call again later—in hopes that someone less suspicious would answer.⁴²

Insys also worked with pharmacies to circumvent DEA reporting requirements for controlled substances.⁴³ One way that Insys tried to avoid triggering DEA suspicion was by constantly using new wholesalers.⁴⁴ By changing the distribution chain, they were able to access wholesalers who were unaware of previous ordering patterns and willing to distribute more Subsys than the previous wholesaler.⁴⁵ Eventually, Insys cut out the middleman entirely by shipping Subsys directly to pharmacies that were willing to bypass DEA requirements to buy Subsys at a discounted price and increase their own profits.⁴⁶ Participating pharmacies signed retail agreements with Insys that required them to make payments directly to the company rather than to a wholesaler.⁴⁷

Clearly, many of the actions of Insys executives stand out as extreme departures from legal and acceptable behavior. Their willingness to discuss their illegal actions openly in emails, texts and marketing materials also sets them apart. At trial, prosecutors played a rap video in which Burlakoff is dancing, dressed up as a Subsys bottle—with the highest possible dose.⁴⁸ As discussed in greater detail below, the copious evidence against the defendants allowed prosecutors to bury them at trial.

The Insys Trial

It doesn't take a law degree to know that the actions of the Insys executives were brazenly illegal. The following section explains why their conduct made it possible for prosecutors to hold them individually, criminally accountable.

RICO, an intentionally broad statute, is designed to provide a tool against a wide array of organized crime. To prove RICO conspiracy, the government must prove the defendant: (1) through the commission of two or more acts; (2) engaged in a "racketeering activity" (i.e., violated a qualifying federal or state law);⁴⁹ (3) by directly or indirectly investing in, maintaining an interest in or participating in an enterprise (e.g., a



business); (4) the activities of which affected interstate or foreign commerce.⁵⁰ Conspiracy is sometimes referred to as an inchoate, or incomplete crime, because a defendant *may not* be found guilty of the *completed* offense but *may still* be found guilty of conspiracy—so long as there is proof of their intentional involvement in a plan to commit the crime.⁵¹ The Anti-Kickback Statute punishes individuals in the healthcare industry who offer bribes to healthcare providers to arrange for medical services that will be paid for by a federal healthcare program, including Medicare and Medicaid.⁵² The Insys defendants were also charged under the mail and wire fraud statutes, which prohibit schemes developed to obtain money or property by means of "false or fraudulent pretenses, representations or promises" over the mail system or wires.⁵³

Prosecutors were able to establish RICO conspiracy based upon several underlying crimes or "racketeering activities,"⁵⁴ including drug distribution,⁵⁵ mail and wire fraud,⁵⁶ breach of the duty of honest services⁵⁷ and bribery.⁵⁸ They were also able to establish violations of the Anti-Kickback Statute. As discussed above, Insys offered a creative array of bribes to its "speakers" for writing Subsys prescriptions, including compensation, lap dances, area business liaisons and fancy dinners.⁵⁹ These bribes violated, *inter alia*, the Controlled Substance Act and state fraud statutes, which can both support a RICO claim. Insys executives regularly conducted their illegal activities using emails and texts, thus implicating the wire fraud statute. These communications, which clearly crossed the desk of Kapoor and other top executives, made it possible for prosecutors to prove

they participated in the conspiracy. Insys executives also committed wire fraud by setting up the "reimbursement center" to contact insurance companies directly and to say whatever was necessary to gain authorization for payment. They committed mail fraud by bypassing distributors and sending Subsys directly to pharmacies.

The well-documented, egregious conduct of the Insys executives sets their case apart from previous cases involving executive misconduct in the pharmaceutical industry. Prosecutors have celebrated their case against the executives as a great success and have vowed to continue to hold executives individually liable for wrongful conduct.^{60, 61} However, events since the trial may compel prosecutors to pause before throwing the book at executives in the future.

Settlement and Bankruptcy

On June 5, 2019, the U.S. Attorney's Office released news that a settlement had been reached with the operating subsidiary of Insys, including payment of a \$2 million fine, a \$28 million forfeiture, and payment of \$195 million to settle False Claims Act allegations.⁶²

Just five days after agreeing to the settlement, Insys filed for Chapter 11 bankruptcy protection.⁶³ In addition to this settlement, Insys still faced over 1,000 lawsuits, including 10 filed by state attorneys general.⁶⁴ It remains unclear how much of this settlement the government will ever see.

Insys offered a creative array of bribes to its "speakers" for writing Subsys prescriptions, including compensation, lap dances, area business liaisons and fancy dinners.

Public Nuisance Litigation

William Prosser, the leading authority of his generation on tort law, famously blasted nuisance law as a “legal garbage can,” opining, “there is perhaps no more impenetrable jungle in the entire law than that which surrounds the word ‘nuisance.’ It has meant all things to all people, and has been applied indiscriminately to everything from an alarming advertisement to a cockroach in a baked pie.”⁶⁵

Some prosecutors and plaintiff attorneys use the age-old legal garbage can in pursuit of recovery. Public nuisance theory has been criticized widely because of its vagueness, unpredictability and tendency to compel a judge to step into the shoes of a legislator.⁶⁶ Despite this criticism from the bench and the bar, attempts have been made to expand this theory into opioid litigation. This is by no means the first time plaintiffs have attempted to expand public nuisance law, which has historically been used to address harms such as toxic fumes, water pollution and bright lights from stadiums. Plaintiff lawyers who are active in the opioid litigation have drawn comparisons to the successful strategy employed to compel enormous settlements from the tobacco companies in the 1990s based on such theories.⁶⁷ The settlements were obtained even though no tobacco case was ever brought to trial on a public nuisance theory.⁶⁸

The Eighth Circuit rejected a public nuisance claim when plaintiffs attempted to apply it to a manufacturer of cold medicine containing ephedrine, based upon the manufacturer’s alleged failure to prevent criminals from using the medication to make methamphetamine.⁶⁹ The court reasoned that the independent criminal actions of the methamphetamine cooks caused the injury and stated that it was “reluctant to open Pandora’s Box to the avalanche of actions that would follow if we found this case to state a cause of action.”⁷⁰

Department of Justice Policy Shifts

A brief review of shifting DOJ policy helps elucidate the course of the DOJ’s role in the opioid litigation thus far and may assist those in the industry in making predictions concerning the likelihood of civil and criminal actions against pharmaceutical manufacturers, distributors, pharmacies and individual doctors.⁷¹ On September 5, 2015, Sally Yates, the deputy attorney general, issued a policy announcement now known as the Yates Memorandum on the subject of civil and criminal “Individual Accountability for Corporate Wrongdoing.”⁷² The memorandum announced a shifting emphasis from corporate to individual prosecution, stating: “One of the most effective ways to combat corporate misconduct is by seeking accountability from the individuals who perpetrated the wrongdoing.”⁷³ With respect to both criminal and civil suits, the policy imposed a “condition of cooperation,” which mandated that a company identify “all individuals involved in or responsible for the misconduct at issue, regardless of their position, status or seniority, and provide to the Department all facts relating to the misconduct,” or its cooperation would not be considered a mitigating factor for sentencing or settlement amounts.⁷⁴ The policy also announced that considerable deference has been removed from civil attorneys at DOJ: “Absent extraordinary circumstances,” department lawyers are no longer permitted to agree to corporate resolutions that provide immunity to individual officers or employees.⁷⁵ Moreover, attorneys are not permitted to consider an individual officer’s ability to pay when determining whether to pursue action against him or her.⁷⁶

However, the Yates Memorandum did not have the intended effect and has since been largely walked back. On November 29, 2018, Deputy Attorney General Rod Rosenstein highlighted the failures of the Yates

Memorandum policies. Rosenstein announced that the DOJ would shift away from duplicative prosecutions, stating: “It is important to punish wrongdoers. But we should discourage the sort of disproportionate and inefficient enforcement that can result if multiple authorities repeatedly pursue the same violator for the same misconduct.” He also highlighted the unfair effects that prosecutions can have on employees and shareholders.⁷⁷

Moreover, Rosenstein indicated that the focus of investigations would be on top officials going forward, and a company must only identify the individuals who were “substantially involved,” in order to qualify for cooperation credit.⁷⁸ He also restored discretion to the civil DOJ attorneys to close a case without investigating every employee, to negotiate civil releases for individuals who will not be prosecuted criminally and to consider an individual’s ability to pay in deciding whether to pursue a civil judgment.⁷⁹ Rosenstein stated, “We generally do not want attorneys to spend time pursuing civil litigation that is unlikely to yield any benefit; not while other worthy cases are competing for our attention.”⁸⁰

Possible Trends Q&A

Will there be additional criminal prosecutions of pharmaceutical executives?

There may be some, but it is unlikely we will see widespread criminal prosecutions against individuals. The DOJ has indicated it plans to focus its limited resources on catching the biggest fish. Per Rosenstein: “We want to focus on the individuals who play significant roles in setting a company on a course of criminal conduct. We want to know who authorized the misconduct, and what they knew about it.” However, he also admitted: “Our policies need to work in the real world of limited investigative resources.”

The Insys trial lasted 10 weeks, and the jury deliberated for 15 days. The government spent considerable resources pursuing the criminal case against those individuals. The DOJ recognizes that it is important to hold individuals accountable, but it is also important to recover resources to put toward solutions. Only one of these goals was achieved with Insys because the criminal prosecution destroyed the company.

Does AG litigation pose an existential threat to pharmaceutical companies?

It depends on the company. Obviously, the conduct of the company is the most important factor. Size also matters because the more dispersed the company structure, the harder it will be to establish claims such as those based upon RICO. Insys was unusual, in part, because top executives were copied on multiple highly incriminating emails and could not plead ignorance to the actions of their subordinates.

Moreover, the DOJ has evidenced a policy shift that supports a more moderate approach to enforcement efforts to mitigate the unfair effects on innocent shareholders and employees.

Should we expect to see an uptick in civil litigation, criminal suits or both?

Unfortunately, the kind of misconduct featured in the Insys case can negatively color public perception of the industry as a whole—and capture the attention of prosecutors. But that misconduct was an outlier, not the norm. Illegal conduct warrants prosecution, but

the Insys result should not be read as a red flag for good corporate citizens in this sector. On the civil side, plaintiffs' lawyers typically file suits where there is a reasonable chance of recovery. To that end, companies facing bankruptcy amid government prosecution provide long odds for pragmatic plaintiffs. So, it's difficult to see these types of actions paired together going forward to any increased degree of frequency.

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¹See *Founder and Four Executives of Insys Therapeutics Convicted of Racketeering Conspiracy*, U.S. DEPT OF JUSTICE (May 2, 2019), <https://www.justice.gov/usao-ma/pr/founder-and-four-executives-insys-therapeutics-convicted-racketeering-conspiracy>; Taylor Telford, *Insys becomes first drugmaker to file for bankruptcy to cover opioid penalties*, WASHINGTON POST (June 10, 2019), <https://www.washingtonpost.com/business/2019/06/10/insys-becomes-first-drugmaker-file-bankruptcy-cover-opioid-penalties/>.

²See Telford, *supra* note 1.

³*United States v. Michael Babich, Alec Burlakoff, Richard Simon, Sunrise Lee, Joseph Rowan, and Michael Gurry, John Kapoor, Docket 16-cr-10343-ADB*, <https://www.justice.gov/usao-ma/victim-and-witness-assistance-program/united-states-v-michael-babich-alec-burlakoff-richard-simon-sunrise-lee-joseph-rowan-and>.

⁴*Id.*

⁵See *Opioid Manufacturer Insys Therapeutics Agrees to Enter \$225 Million Global Resolution of Criminal and Civil Investigations*, U.S. DEPT OF JUSTICE (June 5, 2019), <https://www.justice.gov/opa/pr/opioid-manufacturer-insys-therapeutics-agrees-enter-225-million-global-resolution-criminal>.

⁶*Id.*

⁷See Robert Field & Vincent Buccola, *Opioid Settlements: Why Insys Is the Tip of the Iceberg*, KNOWLEDGE@WHARTON (June 18, 2019), <https://knowledge.wharton.upenn.edu/article/opioid-settlements-is-insys-the-tip-of-the-iceberg/>.

⁸*Id.*

⁹*Id.*

¹⁰James K. Holder, *Opening the Door Wider? Opioid Litigation and the Scope of Public Nuisance Law*, 13 No. 2, IN-HOUSE DEF. Q. 33 (2018).

¹¹Andrew Rosenblum, et al., *Opioids and the Treatment of Chronic Pain: Controversies, Current Status, and Future Directions*, J. EXPERIMENTAL & CLINICAL PSYCHOPHARMACOLOGY (2008).

¹²See Matthew Herper, *An Opioid Spray Showered Billionaire John Kapoor In Riches. Now He's Feeling The Pain*, FORBES (October 25, 2016), <https://www.forbes.com/sites/matthewherper/2016/10/04/death-kickbacks-and-a-billionaire-the-story-of-a-dangerous-opioid/>.

¹³See Evan Hughes, *The Pain Hustlers*, NEW YORK TIMES (May 2, 2019), <https://www.nytimes.com/interactive/2018/05/02/magazine/money-issue-insys-opioids-kickbacks.html>.

¹⁴See *Opioid Manufacturer Insys Therapeutics Agrees to Enter \$225 Million Global Resolution of Criminal and Civil Investigations*, *supra* note 4.

¹⁵Chris Villani, *Ex-Insys Execs Found Guilty in RICO Opioid Bribe Scheme*, LAW360 (May 2, 2019, 2:42 PM EDT), <https://www.law360.com/articles/1148719/ex-insys-exec-s-found-guilty-in-rico-opioid-bribe-scheme>.

¹⁶See Herper, *supra* note 12.

¹⁷*Id.*

¹⁸*Id.*

¹⁹See Hughes, *supra* note 13.

²⁰*Id.*

²¹*Id.*

²²*Id.*

²³*Id.*

²⁴*Id.*

²⁵Alexandria Hein, *Former stripper-turned-drug exec gave doctor lap dance while pitching painkiller, witness testifies*, FOX NEWS (January 30, 2019), <https://www.foxnews.com/us/former-stripper-turned-drug-exec-gave-doctor-lap-dance-while-pitching-painkiller-witness-testifies>.

²⁶Indictment, ¶ 64.

²⁷See Hughes, *supra* note 13.

²⁸Indictment, ¶ 81.

²⁹*Id.* at ¶ 85.

³⁰*Id.*

³¹See Villani, *supra* note 15.

³²*Id.*

³³See Telford, *supra* note 1.

³⁴*Id.*

³⁵Indictment, ¶ 92.

³⁶See Telford, *supra* note 1.

³⁷Indictment, ¶¶ 71-73, 155.

³⁸Indictment, ¶ 97.

³⁹Indictment, ¶ 98.

⁴⁰Indictment, ¶ 105.

⁴¹Indictment, ¶ 102.

⁴²Indictment, ¶ 105.

⁴³Indictment, ¶ 92.

⁴⁴*Id.*

⁴⁵*Id.*

⁴⁶*Id.*

⁴⁷*Id.*

⁴⁸See *Insys executives used rap video to push sales of potentially lethal opioid*, CBS NEWS (Feb. 14, 2019), <https://www.cbsnews.com/news/insys-executives-used-rap-video-to-push-sales-of-highly-addictive-opioid/>.

⁴⁹See Jake DuCharme, et al., *Racketeer Influenced and Corrupt Organizations*, 56 AM. CRIM. L. REV. 1323, 1326 (2019) (listing the crimes that qualify as a racketeering activity).

⁵⁰*Id.* Although the RICO statute does not contain an explicit statute of limitations, the Supreme Court has ruled that there is a five-year limitations period for criminal RICO prosecutions "because Congress explicitly provided a five-year term as the default statute of limitations for criminal actions." *Id.* (citing *Agency Holding Corp. v. Malley-Duff & Assoc., Inc.*, 483 U.S. 143 (1987)). There is a four-year statute of limitations for civil RICO actions. *Id.*

⁵¹See *Id.*

⁵²See 42 U.S.C.A. § 1320(a)-7b(b)(2).

⁵³Indictment, ¶ 97.

⁵⁴See Peter Henning, *RICO Offers a Powerful Tool to Punish Executives for the Opioid Crisis*, NEW YORK TIMES (May 23, 2019), <https://www.nytimes.com/2019/05/23/business/dealbook/rico-insys-opioid-executives.html>.

⁵⁵See 21 U.S.C. § 841.

⁵⁶See 18 U.S.C. §§ 1341, 1343, 1346; Indictment ¶ 246.

⁵⁷*Id.*

⁵⁸*Id.*

⁵⁹Indictment, ¶ 71-73.

⁶⁰See *Opioid Manufacturer Insys Therapeutics Agrees to Enter \$225 Million Global Resolution of Criminal and Civil Investigations*, *supra* note 5.

⁶¹Indeed, by mid-summer 2019, the DOJ had also charged executives with Rochester Drug Co-Operative (RDC) and Miami-Luken with illegal distribution of opioids. The RDC executives were potentially spared since the company paid a penalty and agreed to make changes to its operations. But Miami-Luken was no longer in business when the charges were filed against its ex-president, compliance officer and two pharmacists. <https://www.fiercepharma.com/manufacturing/drug-distributor-and-two-its-executives-hammered-felony-criminal-charges-for-opioid>; <https://www.fiercepharma.com/pharma/doj-indicts-second-opioid-distributor-for-role-illegally-pushing-pills-despite-warning-signs>.

⁶²*Id.*

⁶³*Id.*

⁶⁴See Field & Buccola, *supra* note 7.

⁶⁵Ryan Boysen, *Insys Hit With Nationwide Opioid Class Claim In Ch. 11*, LAW360 (June 17, 2019, 6:01 PM EDT), <https://www.law360.com/articles/1169821/insys-hit-with-nationwide-opioid-class-claim-in-ch-11>.

⁶⁶See Holder, *supra* note 10.

⁶⁷*Id.*

⁶⁸*Id.*

⁶⁹Yet the general public nuisance theory has not borne fruit against gun manufacturers, who have aggressively and successfully defended similar lawsuits. Public nuisance claims against gun manufacturers have been dismissed based upon several theories, including the following: "(1) the lawful sale of guns did not meet the requirement of a nuisance that interfered with a right common to the general public, (2) the gun manufacturers did not have control over the use of guns once they had been shipped to licensed distributors and dealers and thus the manufacturers [could] not have caused the nuisance; and (3) proximate causation was missing between the criminal misuse of handguns and the mere manufacture of the guns themselves, which were a lawful and legitimate product when used appropriately." See Holder, *supra*, note 10.

⁷⁰See *Asbley Cty. v. Pfizer*, 532 F.3d 659 (8th Cir. 2009).

⁷¹*Id.* at 671.

⁷²Sally Quillian Yates, *Memorandum for the Assistant Attorney General: Individual Accountability for Corporate Wrongdoing*, U.S. DEPT OF JUSTICE (Sept. 9, 2015).

⁷³*Id.*

⁷⁴*Id.*

⁷⁵*Id.*

⁷⁶*Id.*

⁷⁷*Id.*

⁷⁸*Id.*

⁷⁹*Id.*

⁸⁰*Id.*



EXPERT DISCLOSURES: NAVIGATING THE DISTINCTION BETWEEN RETAINED AND NON-RETAINED EXPERTS

David L. Johnson



In 2010, Fed. R. Civ. P. 26 was amended to require full expert reports and other disclosures for retained expert witnesses, but only summaries of anticipated opinion testimony of non-retained experts. During the ensuing nine years, courts have weighed in on the distinctions between retained experts and non-retained experts. Even still, the distinctions are murky.

Under Fed. R. Civ. P. 26(a)(2)(B), a full expert report is required “if the witness is one retained or specially employed to provide expert testimony in the case.” If the expert witness is non-retained then, under Rule 26(a)(2)(C), the party must disclose only “a summary of the facts and opinions to which the witness is expected to testify.” According to the Advisory Committee, “[f]requent examples [of non-retained expert witnesses] include physicians or other health care professionals and employees of a party who do not regularly provide expert testimony.”

Indeed, treating physicians are perhaps the most common non-retained experts. Many courts have found that a treating physician is not considered a retained expert witness if the physician testifies about their medical treatment and other observations based on personal knowledge. However, when the “treating physician’s testimony is based on a hypothesis, not the experience of treating the patient, it crosses the line from lay to expert testimony.”

Other examples of non-retained experts are scientists or engineers involved in the development of a drug or medical device. The key to determining whether a witness should be considered a retained expert is whether their opinions were developed based on the witness’s personal involvement in the facts giving rise to the lawsuit or whether the witness developed their opinions for purposes of the lawsuit.

Differing Court Standards

A leading case on this issue is the United States Court of Appeals for the First Circuit’s decision in *Downey v. Bob’s Discount Furniture Holdings, Inc.*³ There, the plaintiffs alleged damages from a bedbug infestation, and the court considered whether the plaintiffs were required to produce an expert report for an exterminator, Edward Gordinier, who had inspected their home. The court found that Gordinier was not “retained or specially employed” by the plaintiffs because he did not “h[o]ld himself out for hire as a purveyor of expert testimony” and was not “charging a fee for his testimony.”⁴ The court further stated:

In order to give the phrase “retained or specially employed” any real meaning, a court must acknowledge the difference between a percipient witness who happens to be an expert and an expert who without prior knowledge of the facts giving rise to litigation is recruited to provide expert opinion testimony. It is this difference, we think, that best informs the language of the rule.

Gordinier was “an actor with regard to the occurrences from which the tapestry of the lawsuit was woven.” Put another way, his opinion testimony arises not from his enlistment as an expert but, rather, from his ground-level involvement in the events giving rise to the litigation. Thus, he falls outside the compass of Rule 26(a)(2)(B).

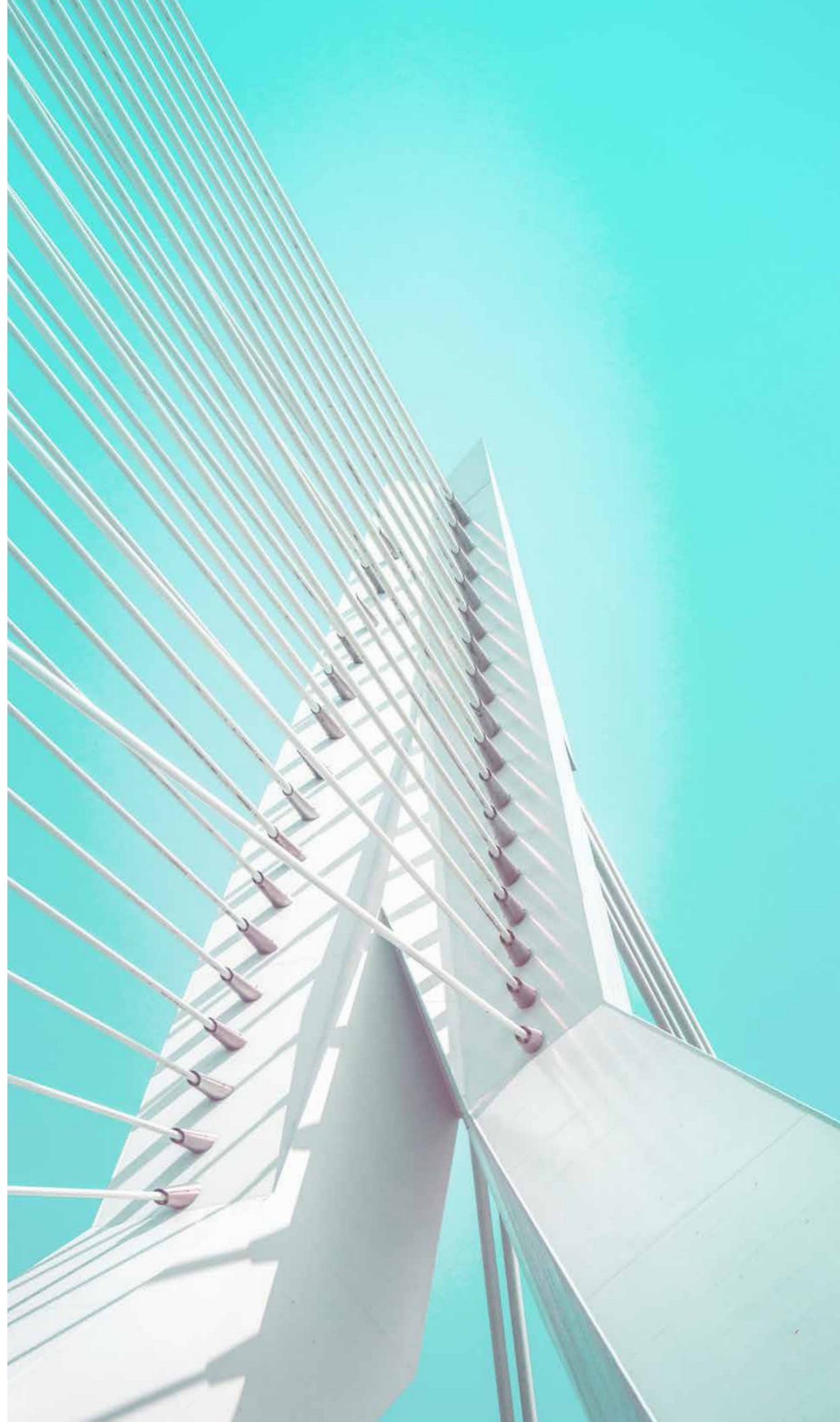
In an effort to blunt the force of this reasoning, the defendant contends that Gordinier should be considered “retained” because his inspection reports do not indicate that he deduced the cause of the infestation in the process of inspecting and treating the plaintiffs’ premises. This contention misperceives both the law and the facts.

Interpreting the words “retained or specially employed” in a common-sense manner, consistent with their plain meaning, we conclude that as long as an expert was not retained or specially employed in connection with the litigation, and his opinion about causation is premised on personal knowledge and observations made in the course of treatment, no report is required under the terms of Rule 26(a)(2)(B).

If, however, the expert comes to the case as a stranger and draws the opinion from facts supplied by others, in preparation for trial, he reasonably can be viewed as retained or specially employed for that purpose, within the purview of Rule 26(a)(2)(B).⁵

“Several district courts have followed the lead of *Downey* and held that the distinction between a Rule 26(a)(2)(B) expert and a 26(a)(2)(C) expert is that 26(a)(2)(C) experts’ conclusions and opinions arise from firsthand knowledge of activities they were personally involved in before the commencement of the lawsuit, and not conclusions they formed because they were recruited to testify as an expert after-the-fact.”⁶

Compensation of the witness may have only marginal relevance. For instance, in *Caruso v. Bon Secours Charity Health Sys., Inc.*,⁷ the Second Circuit found that “[t]he reporting requirement in Rule 26(a)(2)(B) does not turn solely on an expert’s compensation or lack thereof. Rather, the more relevant distinction is between an expert who happened to have personal involvement with the events giving rise to litigation and an expert whose only involvement consists of aiding the already-initiated litigation.” And in *Spears v. U.S.*,⁸ a federal district court found that “[it] is irrelevant for purposes of Rule 26 whether an expert has been compensated for his or her testimony or simply volunteers that testimony.”⁹



In *Tolan v. Cotton*,¹⁰ a Texas federal district court discussed at length what is meant by “retained or specially employed.” According to the court:

The term “specially employed” is a non-specific, catch-all phrase that encompasses experts whose relationship to the party employing them defies ordinary classifications or more specific labels. Thus the Court holds that a witness is “retained” if she is to provide expert opinion and testimony in exchange for a fee; a witness is “specially employed” if she has no personal involvement in the facts giving rise to a case and is instead engaged specifically by a party to provide opinions and testimony bearing on the particulars of a case, without monetary payment for those services.¹¹

The court concluded there are “three categories of witnesses who are required to produce written reports during discovery: ‘retained’ witnesses, ‘specially employed’ witnesses, and party employees whose duties ‘regularly involve giving expert testimony.’”¹² A retained expert was defined as one who is hired by payment of a retainer. By contrast, a specially employed witness does not require monetary payment.

In *Aynet, Inc. v. Motio, Inc.*,¹³ the defendant disclosed that its CEO, Lynn Moore, intended to provide expert opinions about patent issues, and the plaintiff moved to exclude his testimony because he did not provide an expert report. The Illinois federal district court described multiple approaches that courts have taken in considering this issue. Some courts have followed *Downey* in distinguishing percipient witnesses from experts who become knowledgeable after being enlisted as an expert.¹⁴ Other courts “have addressed this topic slightly differently by examining the expert’s relationship with the litigation” such that the key factor is whether the expert’s relationship to the issues in the lawsuit “developed prior to the commencement of

[In *Tolan v. Cotton*], the court concluded there are “three categories of witnesses who are required to produce written reports during discovery: ‘retained’ witnesses, ‘specially employed’ witnesses, and party employees whose duties ‘regularly involve giving expert testimony.’”¹²

the lawsuit.”¹⁵ Finally, other courts, such as *Tolan*, have focused on the meaning of the terms “retained” and “specially employed.”¹⁶

Appearing to follow the *Tolan* approach, the *Avnet* court concluded that Moore was required to provide a report for most of his opinions.¹⁷ The court stated that the defendant intended to elicit numerous expert opinions from the CEO “without offering any meaningful explanation to show that these are matters Mr. Moore would know about as a result of his normal role as CEO.”¹⁸ Further, the defendant “offered nothing to indicate that Mr. Moore derived his opinions for any purpose other than this lawsuit.”¹⁹ Finally, the court stated:

We also reject Defendant’s argument that Mr. Moore was not “specially employed” to offer expert testimony. We do not read this phrase to mean “hired,” in the sense of a retained expert who has no ongoing relationship with a party but is paid for his or her services in a particular case. Such an interpretation would render the phrase “specially

employed” superfluous to the immediately preceding word “retained,” and we will not interpret statutory language in a way that renders it superfluous. Instead, we agree with the *Tolan* court that a more natural reading of “specially employed” is that of a person who is not a percipient witness but who is being specially “used” to offer expert testimony.²⁰

Former Employees

Case law suggests that the analysis does not change merely because a percipient witness is a former employee who is being compensated for their time assisting in the litigation. In *Guarantee Trust Life Ins. Co. v. Am. Med. & Life Ins. Co.*,²¹ the defendant retained its former CFO, Scott McGregor, as a consultant (who presumably was compensated) and then disclosed him as a non-retained expert. The court found that “a former employee may be a non-retained expert for the purposes of Rule 26(a)(2) if he is a percipient witness and is testifying based upon his personal knowledge of the facts or data at issue in the litigation.”²² Because McGregor intended to provide

opinions based on the scope of his employment and “not for the purpose of reviewing new materials expressly for litigation,” the defendant appropriately disclosed him as a non-retained expert.²³

In the Cook IVC Filters MDL, a plaintiff took issue with the defendants’ disclosure of a former engineer as a non-retained expert to render opinions about design, development and testing of the devices at issue.²⁴ Relying on *Guarantee Trust*, the district court found that the engineer’s testimony must be limited to the scope of his personal knowledge and experience while employed and stated as follows:

“[A] former employee may be a non-retained expert for the purposes of Rule 26(a)(2) if he is a percipient witness and is testifying based upon his personal knowledge of the facts or data at issue in the litigation.” If he testifies beyond the scope of his observation, however, he is treated as a retained expert and must provide a written report pursuant to Rule 26(a)(2)(B).²⁵

In that same MDL the following year, the defendants took issue with a plaintiff’s designation of another former Cook engineer as a non-retained expert. The district court found that “[o]ver Cook’s objection, the court finds Dr. Carlson was not required to submit an expert report because his testimony is based on his observations and opinions he formed during his metallurgical evaluations of Celect filter fractures.”²⁶

Bear in mind that many witnesses are “hybrid” witnesses such that the witness “may be subject to Rule 26(a)(2)(C) as to portions of his or her testimony and may be deemed a retained or specially employed expert who is subject to Rule 26(a)(2)(B) as to other portions.”²⁷ Courts have held that the party providing the summary disclosure bears the burden of showing that an expert report was not required.²⁸

Bear in mind that many witnesses are “hybrid” witnesses such that the witness “may be subject to Rule 26(a)(2)(C) as to portions of his or her testimony and may be deemed a retained or specially employed expert who is subject to Rule 26(a)(2)(B) as to other portions.”²⁷

Effect of Improper Failure to Provide Report

All is not necessarily lost if a party neglects to provide a full report for a witness who is deemed a retained expert. Under Fed. R. Civ. P. 37(c)(1), “[i]f a party fails to provide information or identify a witness as required by Rule 26(a) or (e), the party is not allowed to use that information or witness to supply evidence on a motion, at a hearing or at a trial, unless the failure was substantially justified or is harmless.”

Many courts employ a multi-factor test in making this determination. For instance, the Fourth Circuit has identified the following factors as pertinent: “(1) the surprise to the [other] party ... ; (2) the ability of the party to cure that surprise; (3) the extent to which allowing the testimony would disrupt the trial; (4) the explanation for the party’s failure to” properly disclose the information; and “(5) the importance of the testimony.”²⁹

Litigants should not assume that expert reports are not required for certain individuals who have personal knowledge of the events giving rise to the litigation and who intend to provide expert opinions. Litigants should, instead, carefully analyze Rule 26(a)(2) and thoughtfully consider whether the witness will be providing opinions for which an expert report is required.

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²⁷Fed. R. Civ. P. 26, Committee Notes (2010).

²⁸*Williams v. Mast Biosurgery USA, Inc.*, 644 F.3d 1312, 1317–18 (11th Cir. 2011).

²⁹633 F.3d 1 (1st Cir. 2011).

³⁰*Id.* at 6.

³¹*Id.* at 6–7 (citations and footnotes omitted).

³²*Beane v. Utility Trailer Manuf. Co.*, 2013 WL 1344763, at *3 (W.D. La. Feb. 25, 2013) (citations omitted); see also *Indianapolis Airport Auth. v. Travelers Prop. Cas. Co. of Am.*, 849 F.3d 355, 371 (7th Cir. 2017) (quoting Downey); *Goodman v. Staples The Office Superstore, LLC*, 644 F.3d 817, 826 (9th Cir. 2011) (discussing how a non-retained expert may morph into a Rule 26(a)(2)(B) expert); *United States v. Sierra Pac. Indus.*, 2011 WL 2119078, at *4 (E.D. Cal. May 26, 2011) (“The distinguishing characteristics between expert opinions that require a report and those that do not is whether the opinion is based on information the expert witness acquired through percipient observations or whether, as in the case of retained experts, the opinion is based on information provided by others or in a manner other than by being a percipient witness to the events in issue”).

³³703 F. App’x 31, 33 (2d Cir. 2017).

³⁴2014 WL 258766, at *8 (W.D. Tex. Jan. 23, 2014).

³⁵See also *Ulbrick v. UPR Prod., Inc.*, 2011 WL 500034, at *4 (E.D. Mich. Feb. 8, 2011) (“If a witness falls within this requirement is determined primarily by the scope, substance, and source of the intended testimony—not on whether the witness is being compensated”) (citing *Fielden v. CSX Transp., Inc.*, 482 F.3d 866, 871 (6th Cir. 2007)).

³⁶2015 WL 5332171 (S.D. Tex. Sept. 14, 2015).

³⁷*Id.* at *7.

³⁸*Id.* at *6 (quoting *Huffman v. City of Conroe*, No. H–07–1964, at *6–7 (S.D. Tex. July 31, 2008); footnote and citations omitted); see also *KW Plastics v. U.S. Can Co.*, 199 F.R.D. 687, 690 (M.D. Ala. 2000) (citing dictionary and finding that a person is “employed” when she is “put to use or service” and that “[t]he adverb ‘specially’ is ‘used with reference to a particular purpose’ that is ‘surpassing what is common or usual.’”).

³⁹2016 WL 927194 (N.D. Ill. Mar. 4, 2016).

⁴⁰*Id.* at *2.

⁴¹*Id.* (quoting *Brainstorm Interactive, Inc. v. School Specialty, Inc.*, 2014 WL 5817327, at *3 (W.D. Wis. Nov. 10, 2014)).

⁴²*Id.* at *3.

⁴³*Id.* at *4–5.

⁴⁴*Id.* at *4.

⁴⁵*Id.* at *5.

⁴⁶*Id.* (citation omitted).

⁴⁷291 F.R.D. 234, 236 (N.D. Ill. 2013).

⁴⁸*Id.* at 237.

⁴⁹*Id.*; see also *Speare Tools, Inc. v. Klein Tools, Inc.*, 2014 WL 3533235, at *1 (E.D. Wis. July 15, 2014) (finding that retired employee who no longer received a salary but continued to perform accounting services (presumably for pay) was a non-retained expert whose opinions arose from her “ground-level involvement in the events giving rise to the litigation”); *Addison Express, LLC v. Medway Air Ambulance, Inc.*, 2005 WL 2738309, at *2 (N.D. Tex. Oct. 24, 2005) (employees and former employee deemed non-retained experts).

⁵⁰See *In re: Cook Med., Inc., IVC Filters Mktg., Sales Prac. & Prod. Liab. Litig.*, 2017 WL 9251216 (S.D. Ind. Oct. 19, 2017).

⁵¹*In re: Cook*, 2017 WL 9251216, at *1 (citations omitted).

⁵²*In re: Cook Med., Inc., IVC Filters Mktg., Sales Prac. & Prod. Liab. Litig.*, 2018 WL 5885539, at *2 (S.D. Ind. Nov. 9, 2018).

⁵³*Kondragunta v. Ace Doran Hauling & Rigging Co.*, 2013 WL 1189493, at *10 (N.D. Ga. Mar. 21, 2013) (quoting *In re: Denture Cream Prods. Liab. Litig.*, 2012 WL 5199597, at *4 (S.D. Fla. Oct. 22, 2012)).

⁵⁴*Avnet, Inc. v. Motio, Inc.*, 2016 WL 927194, at *4 (N.D. Ill. Mar. 4, 2016); see also citations therein.

⁵⁵*Hoyle v. Freightliner, LLC*, 650 F.3d 321, 329 (4th Cir. 2011).

Author Bios

KASEY M. ADAMS

Kasey Adams focuses her practice on all types of pharmaceutical, medical device and healthcare litigation, including drug and device litigation and product liability litigation.

Kasey holds a B.S. degree in business administration from the University of Southern Mississippi and obtained her J.D. from Mississippi College. Kasey is admitted to the Mississippi State Bar, both districts of the U.S. District Court of Mississippi and the Fifth Circuit of the U.S. Court of Appeals.



CHAD R. HUTCHINSON

Chad Hutchinson is experienced in a variety of litigation matters, including drug and device, product liability, professional liability, premises liability and insurance defense. He has spent the majority of his career defending clients in the pharmaceutical and medical device industry.

Chad obtained his J.D. from Mississippi College and his M.A. in taxation from the University of Mississippi. He is admitted to the Mississippi State Bar, the U.S. District Courts for the Northern and Southern Districts of Mississippi, the U.S. Court of Appeals for the Fifth Circuit and pro hac vice in seven states.



KATELYN E. MARSHALL

Katie Marshall is a member of Butler Snow's litigation department and practices within the firm's Pharmaceutical, Medical Device and Healthcare Litigation Group.

Katie completed her undergraduate education at the University of North Carolina and earned her J.D. from Vanderbilt University Law School. She is admitted to the Tennessee State Bar.



TAYLOR B. MAYES

Taylor Mayes is an experienced litigator who focuses his practice on healthcare law, professional liability defense, product liability defense and commercial litigation. He has tried, or assisted in trying, over 30 jury trials to verdict and has extensive experience in all forms of alternative dispute resolution.

Taylor received his B.A. from Vanderbilt University and obtained his J.D. from the University of Tennessee. He is admitted to the Tennessee State Bar and the U.S. District Courts for the Eastern, Middle and Western Districts of Tennessee.



DAVID L. JOHNSON

David Johnson is a member of the firm's Labor and Employment Group as well as the Appellate and Written Advocacy Group. He works from the firm's Nashville office and focuses his practice on business litigation, employment litigation, non-compete and trade secret matters and appellate issues.

David received his B.A. at Wake Forest University and obtained his J.D. from Vanderbilt University. He is admitted to the Tennessee State Bar; the U.S. District Courts for all districts of Tennessee; the U.S. Courts of Appeals for the Sixth, Eighth and Federal Circuits; and the U.S. Supreme Court.



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