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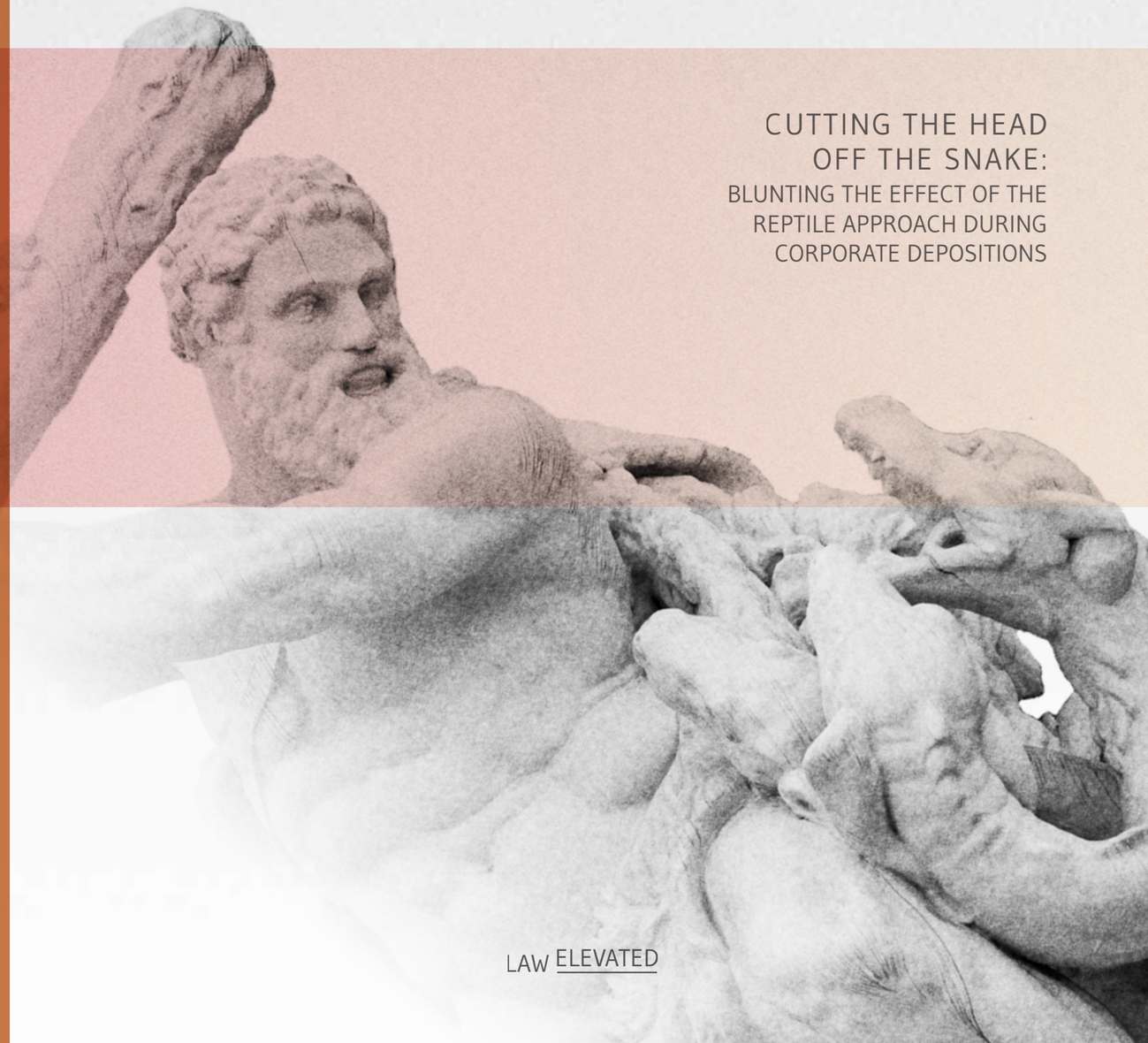

CUTTING THE HEAD OFF THE SNAKE:

BLUNTING THE EFFECT OF THE REPTILE APPROACH DURING CORPORATE DEPOSITIONS

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Admit it. You've read or watched a plaintiff's lawyer questioning one of your company's employees and thought to yourself: "That's a trick question!" We've been there. This month's article, "Cutting the Head off the Snake: Blunting the Effect of the Reptile Approach During Corporate Depositions," identifies the serpentine tactics employed by plaintiffs' counsel to appeal to a juror's primitive desire for safety and survival. The article will help you avoid these tactics altogether.

This month's issue of Pro Te Solutio also explains why effective pharmacovigilance requires regular monitoring. "Shaping Up: a Fitness Check for Pharmacovigilance Practices," provides insight to assess whether your pharmacovigilance department is in shape.

Practical tips are also given on how to prevent a business dispute from escalating into litigation. "B2B Litigation Avoidance in the Pharmaceutical & Medical Device Industry," highlights common issues that can often – regrettably and expensively – result in litigation and suggests ways to avoid those traps.

Our final article this month is a status update on the evolving federal preemption defense by brand manufacturers. In "Update: Preemption of Claims Against Brand Pharmaceutical Manufacturers After Mutual Pharmaceuticals, Co. v. Bartlett," we share cases with high (and low) points about how your company may fare in the current preemption landscape.

As always, we hope this issue of Pro Te Solutio will be both informative and useful to your pharmaceutical business. Thank you for your readership and your support.

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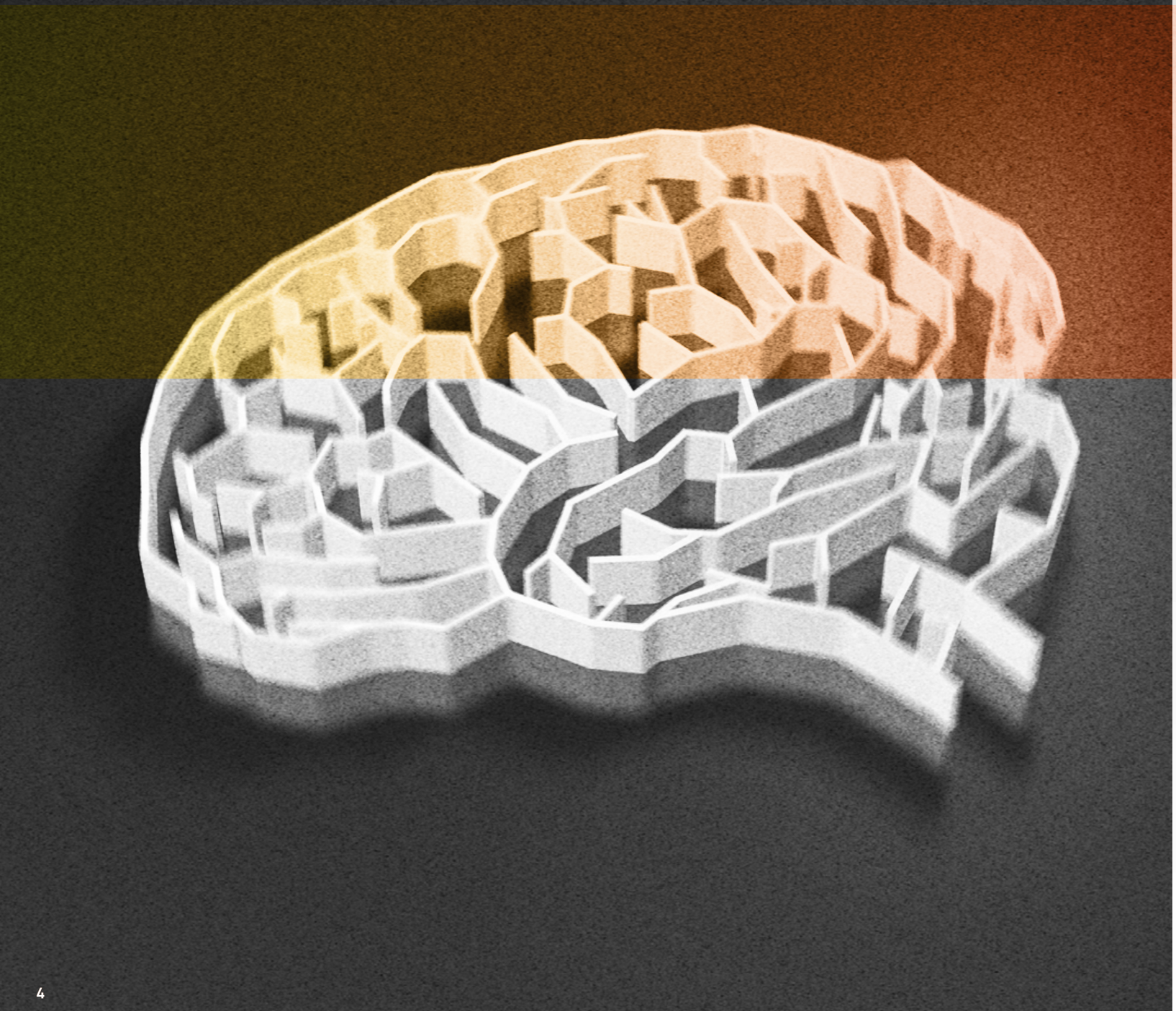


CUTTING THE HEAD OFF THE SNAKE:

BLUNTING THE EFFECT OF THE REPTILE APPROACH DURING CORPORATE DEPOSITIONS

Of all the creatures in Greek mythology, the Hydra is perhaps the most nightmarish. A nine-headed reptilian serpent-beast guarding the entrance to the underworld, the Hydra was said to be so venomous that even her breath would kill anyone who dared to come too close. It was not until Hercules, son of Zeus, set out to slay the Hydra that she finally met her match. Even then, Hercules found her to be a formidable challenge. When he cut off one head, two grew back and, of the nine original heads, only one was the immortal head that could kill off the Hydra forever – and it breathed fire. So Hercules had to get creative. He approached the reproducing heads with a one-two approach: first, he enlisted family to help him in the fight. Whenever Hercules lopped off one of the heads, his nephew immediately burned the stump, cauterizing it so a new head could not grow back. When Hercules ripped off the middle, immortal head, he buried it under a boulder.

THE HYDRA, FINALLY, WAS NO MORE.

Although the Hydra of the Mount Olympus time was destroyed, we see the modern-era serpents pop up in litigation every day, and it is most prevalent in depositions of corporate employees. Whether as a 30(b)(6) designee or fact witness, plaintiff lawyers are utilizing the corporate deposition more and more frequently as the primary platform to advance their core themes via what has been called the "Reptile approach." Identification and preparation of multiple witnesses, coupled with various degrees of expertise and experience, can turn what should

Identification and preparation of multiple witnesses coupled with various degrees of expertise and experience can turn what should be a relatively straightforward process into a multi-pronged beast involving numerous players.

be a relatively straightforward process into a multipronged beast involving numerous players. And whether the issues in your cases have reared their heads in the context of pharmacovigilance, labeling, science or FDA compliance, one thing is for certain: if not given proper deference, the Reptile approach can leave a nasty mark with after effects that can linger throughout the life of the litigation. Done right and with the proper [unprepared] witness(es), skilled plaintiff lawyers can rattle the most experienced corporate witness and create multiple jury-friendly sound bites that have the potential to reverberate far beyond the deposition and into trial.

The best way for defendants to blunt the attack is to follow Hercules' lead by getting creative in our approach to witness preparation and defense – and by fighting back. We must effectively and aggressively counterattack these approaches by plaintiffs' counsel before they get any traction. It may require extra preparation time and it will not be easy, but if we come prepared to the deposition, neither chicanery nor misdirection will rear their cunning heads, and plaintiff attorneys will be forced to do what many would rather not: try the actual facts of the case without the use of smoke and mirrors (or flutes and baskets).

THE REPTILE APPROACH

"*Snakes. Why'd it have to be snakes?*"
-Indiana Jones, "Raiders of the Lost Ark"

In 2009, jury consultant David Ball and trial attorney Don Keenan published a book on trial strategy entitled *Reptile: The 2009 Manual of the Plaintiff's Revolution*. The book's Dedication page reads as follows:

> The first edition of *Reptile* is dedicated to the pioneers: the national array of trial attorneys who, instead of caving to mean times, have allied themselves with the Reptile by successfully field-testing her in negotiations and in trial after trial.

So what is the "Reptile?" According to Ball & Keenan, Yale neuroscientist Paul D. McLean's research identified what he called the three-part "triune" brain. Dr. McLean identified one of these parts as the "Reptilian brain," also known as the "R-Complex." It is the oldest part of the brain and over time, the R-Complex ultimately gave rise to those parts of the brain that think and feel. The Reptilian brain houses basic life functions such as breathing, balance, hunger, sex drive and, most importantly in the context of litigation, *survival*.

Why is survival so important? According to Ball and Keenan, the most powerful decision-making occurs when the reptile brain senses danger and survival are at stake; accordingly, *in trial the goal is to get the juror's brain into survival mode by framing the case in terms of Reptilian survival*. This approach is done by equating "justice" with "safety" by convincing the jury that community safety is enhanced by means of justice. Thus, the "major axiom" throughout the Reptile theory is "when the Reptile sees a survival danger,

In sum, plaintiff's lawyers use the Reptile approach to sell danger – make the jurors believe that the dangers identified in the lawsuit go well beyond the courtroom and into their cities, neighborhoods and homes.

she protects her genes by impelling the juror to protect himself and the community." In sum, plaintiff lawyers use the Reptile approach to sell danger – make the jurors believe that the dangers identified in the lawsuit go well beyond the courtroom and into their cities, neighborhoods and homes.

TACTIC 1: ESTABLISH IMMEDIATE DANGER

One of the primary goals of employing the "reptile" theory is to show the immediate danger of the kind of thing the defendant did and how fair compensation can diminish that danger in the community. In other words, demonstrate a *danger* to the community. In the context of drug and device litigation, for example, plaintiff lawyers may try to establish this tactic by giving the jurors the impression that the label is dangerous. Is it transparent? Does it contain all of the risks associated with the medication? Does it reference reported adverse events? Does it contain all the risks identified during clinical trials? Does it reflect all patient experiences? Would mothers buying this drug for their children want to know that the medication has a risk of [injury/adverse event at issue]? This type of focus extends the juror's thought beyond that of the immediate plaintiff to his or her own household and community. If effective, the juror will believe a verdict against the defendant will not only compensate the plaintiff, but will give the juror the power to enhance the safety of his or her community by encouraging (if not forcing) the company to change its label to make it safer – thus satisfying the survival instinct, sometimes at the expense of logic or emotion.

TACTIC 2: ESTABLISH VIOLATION OF A SAFETY RULE

In addition to establishing an immediate, community danger, attorneys using the reptile theory must likewise establish the defendant's violation of an existing "safety rule." When someone breaks a safety rule that protects others, the jurors are not very motivated to act. If, however, someone breaks a safety rule that affects the juror or the juror's family, the "Reptile" takes over and compels the juror to act. For purposes of Reptilian behavior, a safety rule has six characteristics:

1. It must prevent danger;
2. It must protect people in a wide variety of situations, not just someone who was in your client's position;
3. It must be clear with no legalese or technical jargon;
4. It must expressly state what a person can or cannot do;
5. It must be practical and easy to follow; and
6. It must be one a defendant has to agree with (or looks foolish or dishonest disagreeing with).

The plaintiff's ultimate objective when utilizing the safety rule is to show that "every wrongful defendant act derives from a choice to violate a safety rule." Once a safety rule has been established *and the defendant has agreed to the existence of a safety rule*, a plaintiff lawyer can then show how violations of the rule endanger everyone, not just the plaintiff. At the outset, plaintiff lawyers utilizing the Reptile theory are encouraged to always have an "umbrella" rule. An umbrella rule is the widest rule the defendant violated – wide enough to encompass every juror's Reptile. For drug and medical devices, the umbrella rule is as follows:

A drug/device company is not allowed to needlessly endanger the public.

Once the umbrella rule has been established, plaintiff lawyers are then instructed to develop and establish case-specific rules. The case-specific rules are subsets of the umbrella rule that "protects us all" that further assist in "spreading the tentacles of danger." That is, like the umbrella rule, the case-specific rules are designed to apply to not only the plaintiff, but the community (including the jurors) as a whole. In the context of drugs and medical devices, case-specific safety rules may include the following:

- Company must ensure its products are safe
- Company must ensure its products are labeled properly
- Company must ensure the general public is adequately apprised of the risks associated with its product
- Company must do adequate research and testing of its product before it reaches the market
- Company marketing materials must be accurate, transparent and thorough
- Company must monitor its product post-marketing
- Company must continue to investigate warning signs/adverse events associated with its product
- Company must not improperly influence healthcare professionals and thought leaders

The ultimate goal after identifying the rule is to have the defendants, via their company witnesses, agree with the rules by essentially admitting that these rules exist. Once the umbrella and case-specific rules are established, the effective plaintiff lawyer will use the reptile approach to show:

1. how the defendant violated these established safety rules relating to its product;
2. how the defendant's violation endangered the public (and thus endangered the jurors/jurors' families);
3. how the violation ultimately led to the injuries alleged in the lawsuit; and
4. how the jury has the power to improve *everyone's* safety by rendering a verdict that will correct or eliminate the danger posed by the defendants.

THE REPTILE APPROACH – ANTICIPATED QUESTIONS AT DEPOSITION

"Round and round they went with their snakes, snakily..."
-Aldous Huxley, *Brave New World*

Not surprisingly, plaintiff lawyers utilizing the Reptile strategy do not wait until trial to put the gears in motion. In fact, the book encourages attorneys to start utilizing the Reptile strategy early by seeking admissions from defendants "in paper and oral discovery." Because these lawyers will see the deposition as an opportunity to have the company agree to the safety rules at play in the litigation – and thus set the table for plaintiff's trial and settlement strategy – it is imperative that corporate witnesses have some familiarity with these Reptilian themes as they come up during deposition. Below is a sampling of the types of Reptile questions often seen in products cases involving pharmaceuticals and medical devices:

GENERAL MANUFACTURER DUTY QUESTIONS

- Do you agree that a manufacturer assumes the responsibility for the safety of consumers using its products?
- Do you agree that part of that responsibility includes providing products that are as safe as they can be for the reasonable use of those products by the consumers that use them?
- Do you agree that a manufacturer should adequately warn public of known dangers associated with its product?
- Do you agree that it is the duty of a manufacturer to design, formulate and manufacture a safe product for customers?
- Do you agree that after a product hits market, certain adverse effects become known?
- Do you agree that it's the duty of the manufacturer to adequately warn of adverse effects?
- Do you agree that, once a manufacturer becomes aware of adverse events related to its product, a company should proactively try to reduce these adverse events from occurring?
- Do you agree that a manufacturer has a duty to continue to seek ways to improve the efficacy and safety of products?
- Do you agree that, if a manufacturer makes a product that is defective and someone is injured because of that defect, then the manufacturer is responsible for the injuries/losses caused?
- Do you agree that a manufacturer should communicate what it knows to the public about the devices and pharmaceuticals they place into the market?
- Do you agree that a manufacturer should never expose a consumer to unnecessary danger?

REGULATORY-RELATED QUESTIONS

- Do you agree that a manufacturer can take its own measures to protect the safety of patients taking a drug without approval of the FDA if it wants to?
- Do you agree that [your company] can ask the FDA at any time to revise the label to make it stronger?
- Is a manufacturer allowed to needlessly endanger the public?
- Even if the manufacturer has met all the Federal regulations?
- Is a manufacturer allowed to hide a danger?
- Even if the manufacturer has met all the Federal regulations?
- Is a manufacturer allowed to ignore a known danger in its products?
- Even if the manufacturer has met all the Federal regulations?

COMPANY-SPECIFIC SAFETY QUESTIONS

- Is [your company] an ethical company?
- Does [your company] believe in safety?

- Do you agree that, if [your company] violates any public-safety rules, it is responsible for any harm caused by that violation?
- Should [your company] have to make safety more important than profit?
- Do you agree that, if [your company] can make the product that it is selling to consumers safer, it should?
- Is it ever proper for a company to refrain from making labeling/warning changes because it is concerned that a change would have a negative impact on sales?

PERSONAL OPINION QUESTIONS

- Do you not have an opinion, as a mother/father/provider [not corporate representative], as to whether customers have a right to know about the risks and adverse events associated with a medical product?
- As a mother/father/provider, wouldn't you want to know the scope of what [your company] knew in terms of life-threating complications associated with the medication/product?
- If a medication/product had the potential to cause life-threatening side effects or illnesses, wouldn't you like to know before giving or recommending it to your child/spouse/family member?
- As a parent, wouldn't you want to know everything you can about a product before giving it to your children?
- As a parent, do you rely on pharmaceutical/medical device manufacturers to provide all safety information relating to a product so you can make an informed decision?
- Would you as a user of the product not expect the manufacturer to hold back or not disclose any safety information relating to a product?
- Would you as a user of the product be surprised if you were taking/using a product that had a risk of death or severe injury if that risk wasn't disclosed in the labeling/medication guide/PPI, etc.?
- Do you believe everyone in [your company] is responsible for safety?
- Do you, as [insert job title], hold yourself accountable for the safety of users of [your company's] products?

The first rule in all depositions is that the witness should tell the truth, regardless of the form or substance of the question.

PREPARING CORPORATE WITNESSES FOR THE REPTILE APPROACH

"*If you see a snake, kill it.*" -H. Ross Perot

The first rule in all depositions is that the witness should tell the truth, regardless of the form or substance of the question. If a witness understands and gets comfortable with this principle, the witness should be able to effectively address any Reptilian questions thrown his or her way, because almost every Reptile question lacks one key element: *specificity*. Lacking this element leaves the door open for truth telling because it provides a witness with a foothold to bring clarity to the question and focus the response in a manner that eliminates the sound bite the plaintiff lawyers seek.

Consider the below scenario, which is based on an actual exchange a colleague of mine had while preparing a senior, seasoned corporate witness for deposition. Although this witness had testified before, the witness had never been cross-examined by a plaintiff lawyer using the Reptile theory. The opening line of the mock went something like this:

"Do you believe [your company] is a good company?"
"Yes."

"Do you believe products manufactured by [your company] should be safe?"
"Yes."

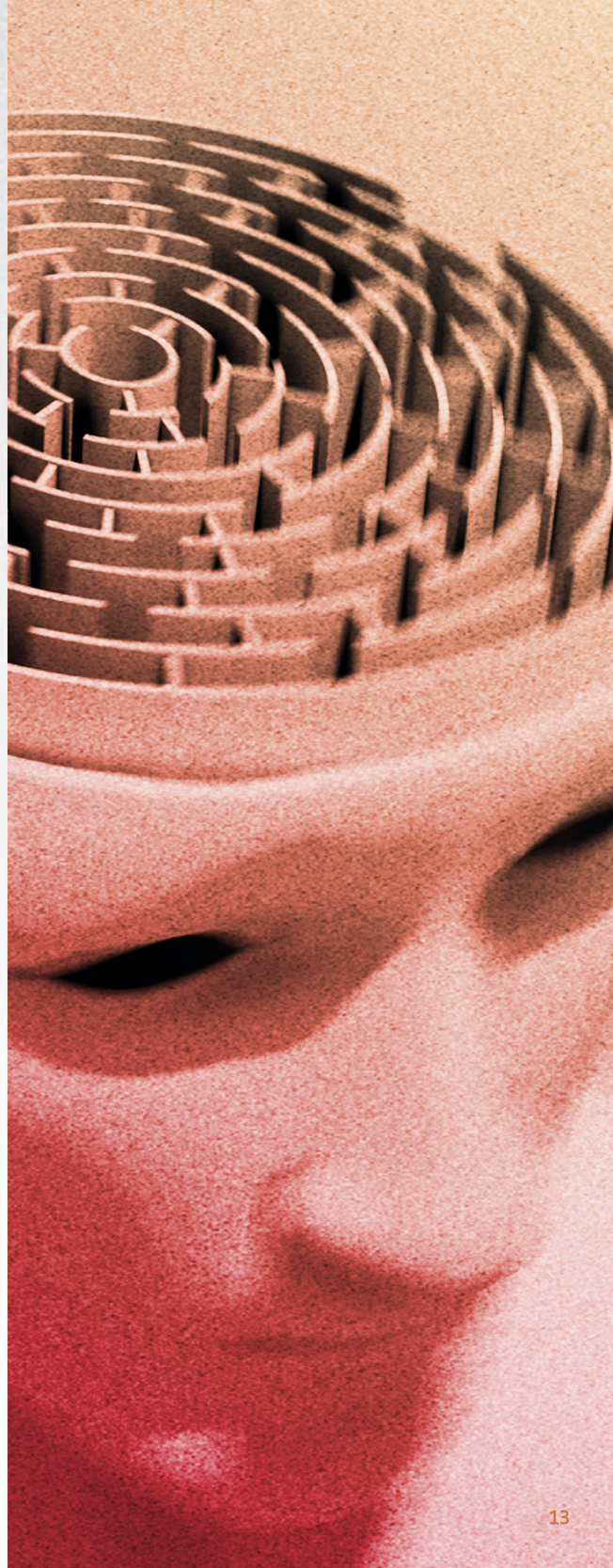
"Do you believe products manufactured by [your company] are safe?"
"Yes."

"But a product is not safe if it causes [known adverse event] is it?"
[Pause] *"Let's take a break from this exercise and talk about these questions some more."*

Needless to say, when the witness found himself in a corner two questions in to the mock cross, the witness realized there was more work to be done. A better and more accurate response to these questions would have been as follows:

"Do you believe [your company] is a good company?"
"Yes."

"Do you believe products manufactured by [your company] should be safe?"
"It depends on what you mean by safe. All products have risks and benefits, and those risks and benefits have to be weighed for each individual using the product. What works for one individual may not be proper for another."



"Do you believe products manufactured by [your company] are safe?"

"I would defer to my prior answer. All products have risks and benefits which must be weighed before using the product. Moreover, when you ask if our products are 'safe,' are we assuming that the individuals using the products are doing so in accordance with the labeling? If so, the product has been approved by the FDA as safe and effective when used according to the labeling, recognizing that the FDA approved the product with the knowledge that certain adverse events have been associated with the product."

"But a product is not safe if it causes [known adverse event] is it?"

"Again, I defer to my two prior answers."

When preparing a corporate witness for a deposition, a substantial amount of time will be spent covering substantive issues: case history, case facts, timelines, relevant documents, etc. Prior to getting into those issues, however, the persons responsible for preparing the witness should consider addressing the Reptile questions first. Using a Reptilian exercise at the outset serves two purposes. One, it snaps the witness to attention. These questions seem simple and straightforward on their face, but as noted in the above example, they are laced with pitfalls and let the witness know that they are serious and dangerous. Second, these types of questions provide the witness with a good mental workout up front, allowing the witness to flex his or her mental muscles and thus providing the proper context for discussing the substantive deposition materials.

While there may be more than one way to skin a cat, the best way to maneuver through a pit of vipers is by 1) being prepared for strikes from all directions; and 2) having an end game in mind before taking the first step. This strategy is accomplished in the Reptile deposition by: 1) identifying and addressing Reptile questions head on; 2) having a working knowledge of the defense themes; and 3) using the themes as go-tos when responding to Reptilian inquiries.

IDENTIFYING REPTILE QUESTIONS

Section II, *supra*, lists a series of representative Reptile-type questions. While it is not intended to be an exhaustive list, it provides a foundation that can be tailored to the facts of your individual case. Because the plaintiffs design the questions to be as general as possible, they potentially apply across the board, regardless of the corporate designee. Each and every question can be asked of each and every individual – from a line worker to the CEO – keeping in mind that and the scope and quality of the answers or your corporate witness will resonate with jurors – regardless of the status of the witness within the company. That being the case, depending on time considerations, the preparation session should cover as many Reptile questions and answers as time permits. The more questions are covered, the better equipped the witness will be to not only answer Reptile-type inquiries, but to recognize Reptile questions when they are shuffled into the case-specific substantive areas of inquiry.

DEVELOP AND COVER THEMES

By the time the corporate depositions begin, you should have a decent understanding of the general themes of the case. Where are your weak points and strong points? What do you want to tell the jury? What themes do you anticipate being covered with this particular witness? These themes should be addressed during prep, and the witness should understand how to use these themes to advance the truth during a Reptile deposition. Some key themes to cover with your witnesses regardless of the specific facts of your case follow:

STAY IN YOUR LANES

During the weapons-training phase of United States Army Basic Training, one of the first things privates are

taught is to "stay in your lane." "Staying in your lane" on the battlefield means that you must observe your left and right limits of fire when discharging your weapon. This approach ensures that your designated lane will be covered, thus preventing the enemy's advance. At the same time, it ensures you don't venture into lanes assigned to others (which keeps you from getting shot). The same principle applies at these depositions.

Your witness likely has expertise in one, maybe two areas within the company. He or she should understand his or her testimony should *not* go beyond his or her qualifications. Stated simply: it is perfectly fine for your witness, in response to a Reptile question, to respond by saying: "I don't know," "That's not my area of expertise," "I don't have familiarity with that topic," or "You'll have to ask someone in another department about that" – so long as the witness is speaking the truth. For example, if the witness works in pharmacovigilance and is asked "shouldn't a company include all of the risks of its product on the label?," the witness should recognize the question is out of her lane, and respond by saying as much.

Witnesses should be encouraged to keep the "stay in your lane" mantra in mind throughout the deposition. Many witnesses will, in fact, embrace the opportunity to push back on a question that they are not qualified to answer in order to keep them out of the weeds. Conversely, they should feel comfortable testifying about the topics within the zone of their expertise. This box, however, should be drawn around those individualized topics of expertise with a bright line, and the witness must stay in the box to stay out of trouble.

KEEP IN MIND THAT ALL DRUGS/DEVICES HAVE RISKS

The underlying goal of the plaintiff lawyer during a Reptile deposition is to show that your company has needlessly placed an unsafe product on the market. These attorneys would prefer that the suit be tried in absolutes: a product should be absolutely safe for absolutely everyone. That is simply not the case. The FDA recognizes that all products/drugs have risks and the risks must be weighed against the benefits. The witness should keep this theme in mind when questions of product safety and risk come into play.

HAVE A GOOD KNOWLEDGE OF THE REGULATORY HISTORY

Where relevant, the corporate witness should have a general appreciation of the regulatory history of the product at issue. He or she should also understand that the FDA's involvement with the product extends far beyond the approval process, but may also extend into advertising, labeling, package inserts, patient medication guides, warnings, postmarketing surveillance, adverse-event reporting and safety. Where applicable, when questions pertaining to these issues come up, the witness should only offer testimony on these topics and, as noted above, "stay within the lanes."

A confident, educated witness, armed with the truth, having knowledge of the salient themes, with the ability to anticipate and understand the types of questions being asked forces the plaintiff's lawyers to engage on an equitable playing field – trying the case on its merits.

TAKE ADVANTAGE OF THE OPPORTUNITY TO CONDUCT A THOROUGH REDIRECT

The corporate witness should be reminded that when the plaintiff's counsel completes his questioning, the deposition is not over. In today's drug and device litigation, plaintiff lawyers are trending toward marathon depositions, trying every possible angle and tactic to exhaust the witness and in so doing, get the sound bites and admissions they seek for purposes of settlement or jury consideration. There is rarely a situation in the current environment where defense counsel should forego the opportunity to conduct a thorough redirect. A redirect serves a number of purposes: 1) it can rehabilitate any questionable or unclear testimony from the corporate witness; 2) it provides an opportunity to place the themes developed by the plaintiff lawyer into context and to show the jury the flip side of the proverbial coin; 3) it gives the witness a venue to discuss those topics where he or she has expertise and by so doing provides an opportunity to build the witnesses' credibility with the jury. Finally, and perhaps most importantly, if the testimony of the witness is played via video at trial, it creates a bookend to counter the points made by plaintiffs and doesn't leave unfinished or unrealized issues dangling in front of the jury during the critical days or weeks before plaintiff rests and you are able to put on your case.

CONCLUSION

"...the serpent you will trample down."
-Psalms 91:13

The Reptile method of examination can be a dangerous tool for the skilled examiner. When used effectively, it can shape the outcome of the litigation – for both the settlement and trial. When a corporate witness is properly prepared for the Reptile, however, the approach has little impact. A confident, educated witness, armed with the truth, having knowledge of the salient themes, with the ability to anticipate and understand the types of questions being asked, forces the plaintiff lawyers to engage on an equitable playing field – trying the case on its merits and essentially leaving the serpent lifeless, defanged and defeated. ■

By Michael Hewes

SHAPING UP:

A FITNESS CHECK FOR PHARMACOVIGILANCE PRACTICES

THE IMPORTANCE OF FITNESS

The beginning of a new year is normally the time when people (author included) make resolutions and decide to work out and get in shape. Some people set measurable goals and work to achieve them. Others (author included) eventually find themselves back in the same ole rut with little improvement. No judgment here. Finding a level of comfort with one's body is a personal journey, and only you can determine which fitness practices work best for you. Evaluating the fitness of a pharmaceutical company, however, is a different story and a judge or jury may decide whether certain exercises and practices are rigorous enough. This article provides information to permit a self-check on how well your company's Pharmacovigilance department is functioning. Read further to brush up on requirements and case law to make sure that your company's Pharmacovigilance department is in shape.

PHARMACOVIGILANCE IN THE REGULATIONS

The World Health Organization defines Pharmacovigilance ("PV") as the science and activities related to the detection, assessment, understanding and prevention of adverse effects or other drug-related problems. Regardless of the

moniker, most – if not all – pharmaceutical companies have a PV or Drug Safety department. And, most pharmaceutical companies are all too familiar with the regulations that govern PV practices. Here are some examples:

21 CFR § 314.80 governs postmarketing reporting of adverse drug experiences and, in part, provides:

> New Drug Applicant ("NDA") Holders shall promptly review all adverse drug experience information obtained or otherwise received by the applicant from any source, foreign or domestic, including information derived from commercial marketing experience, postmarketing clinical investigations, postmarketing epidemiological/surveillance studies, reports in the scientific literature and unpublished scientific papers.... Applicants shall also develop written procedures for the surveillance, receipt, evaluation and reporting of postmarketing adverse drug experiences to FDA.

21 CFR § 314.98 requires Abbreviated New Drug Applicant ("ANDA") Holders to comply with 21 CFR § 314.80. And, 21 CFR § 600.80 requires biologics license holders to report adverse experiences as well.

21 CFR § 310.305 governs records and reports concerning adverse drug experiences on marketed prescription drugs and, in part, provides:

> FDA is requiring manufacturers, packers and distributors of marketed prescription drug products that are not the subject of an approved new drug or abbreviated new drug application to establish and maintain records and make reports to FDA of all serious, unexpected adverse drug experiences associated with the use of their drug products and they shall also develop written procedures for the surveillance, receipt, evaluation and reporting of postmarketing adverse drug experiences to FDA.

21 CFR § 201.80(e) governs the warnings on prescription product labels and, in part, provides:

> The labeling shall describe serious adverse reactions and potential safety hazards, limitations in use imposed by them, and steps that should be taken if they occur. The labeling shall be revised to include a warning as soon as there is reasonable evidence of an association of a serious hazard with a drug; a causal relationship need not have been proved.

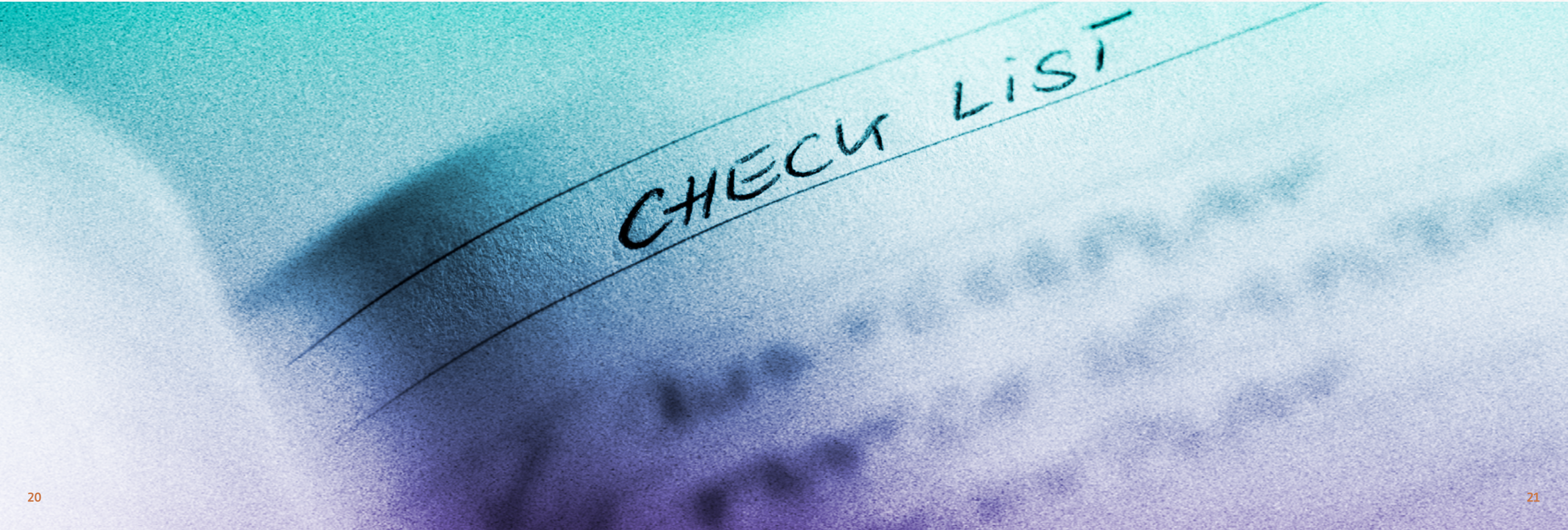
PHARMACOVIGILANCE IN CASE LAW

A review of case law reveals the importance of PV and its role in pharmaceutical litigation.

MANUFACTURERS ARE RESPONSIBLE FOR PV ACTIVITIES

Although the regulations require pharmaceutical companies to report PV information to the FDA, "Congress did not intend FDA oversight to be the *exclusive* means of ensuring drug safety and effectiveness." The Supreme Court, in *Wyeth v. Levine*, clarified that pharmaceutical companies are responsible for monitoring their drugs:

It has remained a central premise of federal drug regulation that the manufacturer bears responsibility for the content of its label at all times. It is charged both with crafting an adequate label and with ensuring that its warnings remain adequate as long as the drug is on the market.



THE USE OF PV INFORMATION TO SHOW NOTICE

In *Decker v. GE Healthcare, Inc.* (*In re Gadolinium-Based Contrast Agents Products Liability Litigation*), the plaintiff filed suit against the manufacturer of an injectable dye used to enhance the quality of magnetic-resonance-imaging. Plaintiff alleged that the defendant's injectable dye caused him to develop a debilitating disease, Nephrogenic Systemic Fibrosis ("NSF"), and the defendant failed to warn that its product could cause such injuries to renal-impaired persons. To support the failure-to-warn claim, plaintiff presented evidence that defendant was aware of four (4) related adverse-event reports ("AERs") prior to plaintiff's use of the injectable dye. Plaintiff also presented scientific evidence to include chemistry, toxicology and human studies to show the defendant was aware that its product was toxic to renal-impaired patients. After 12 days of testimony, the jury determined that defendant knew or should have known about the risks of its product in renal-impaired patients and failed to warn about them. The jury returned a verdict for plaintiff and awarded $4.5 million in compensatory damages, $1 million for economic loss, $3.5 million for noneconomic loss and $500,000 to plaintiff's spouse for loss of consortium.

The defendant filed a motion for a new trial or remittitur on several grounds, two of which had a basis in PV. As to PV, the defendant first argued that the court should have given a limiting instruction on the use of AERs. While an AER tells the company that a patient experienced a harmful event after using its product, the defendant argued that AERs are not proof of causation. The court disagreed, however, and noted that "courts have held that AERs may be used to prove causation." Further, the court noted that plaintiff did not present the AERs as evidence of causation; instead, plaintiff presented the AERs to show notice. The court held "it is entirely proper to use AERs to show that a drug manufacturer had notice of adverse events of the type suffered by plaintiffs in failure-to-warn claims."

As to the second PV-related argument for a new trial, the defendant argued unfair prejudice based on the admission of a foreign AER. Plaintiff presented evidence that the defendant's PV department received letters from a governmental agency in Denmark, and those letters concluded the product at issue caused NSF in a patient in 2003 (two years prior to plaintiff's use of the product). The defendant acknowledged that the foreign AER was admissible to prove notice; however, the defendant argued it was unfairly prejudiced because plaintiff used the foreign AER to show causation. The court disagreed and found that plaintiff presented the foreign AER only to show notice. The court ultimately denied the defendant's motion for a new trial.

THE RED FLAGS IN PV INFORMATION

In *Fraser v. Wyeth, Inc.*, the plaintiff filed suit against the manufacturer of a hormone therapy medication and alleged failure to warn, failure to test and a host of other claims. Plaintiff alleged the defendant's product caused her breast cancer, and plaintiff presented evidence that the defendant's label failed to warn about the serious risks of breast cancer. Plaintiff presented testimony from her expert

as to the industry standard for PV and how the defendant violated the standard by failing to include the severity of the risk of breast cancer and death on the product label. Specifically, plaintiff presented evidence that the defendant failed to study/test whether its product caused breast cancer in the face of mounting evidence (or "red flags") that suggested it did. Such evidence included: internal documents that expressed concern as to whether defendant's product caused an increase in the incidence of breast cancer, minutes from a 1990 meeting with an FDA advisory committee that concluded there was insufficient data to determine if the product posed an increased risk of breast cancer, testimony that the defendant failed to perform the necessary studies to answer the question in twenty-five (25) years, testimony that the defendant "*ignored multiple red flags*" about the risks of breast cancer from its product, and testimony that the defendant actively failed to perform studies and tests that would have required stronger warnings on its product.

Following three-and-a-half weeks of trial, the jury returned a verdict for plaintiff and awarded $3.75 million in compensatory damages, $250,000 to plaintiff's spouse for loss of consortium and $1.7 million in punitive damages. The defendant filed a motion for a new trial and remittitur on several grounds, but the court denied the motion.

PHARMACOVIGILANCE IN PRACTICE

The purpose of PV is to ensure that all drugs are "used as safely as possible and that, where necessary, steps [are] taken to improve [their] safety and ensure that users are informed promptly." The goal is straightforward, but much is required for the practice. To help provide a roadmap for "good PV practices," the FDA issued a Guidance for Industry: Good Pharmacovigilance Practices and Pharmacoepidemiologic Assessment. While certainly not intended to substitute a much-needed, careful review of the FDA's PV Guidance for Industry, the pointers below permit an initial self-check of your company's PV practices.

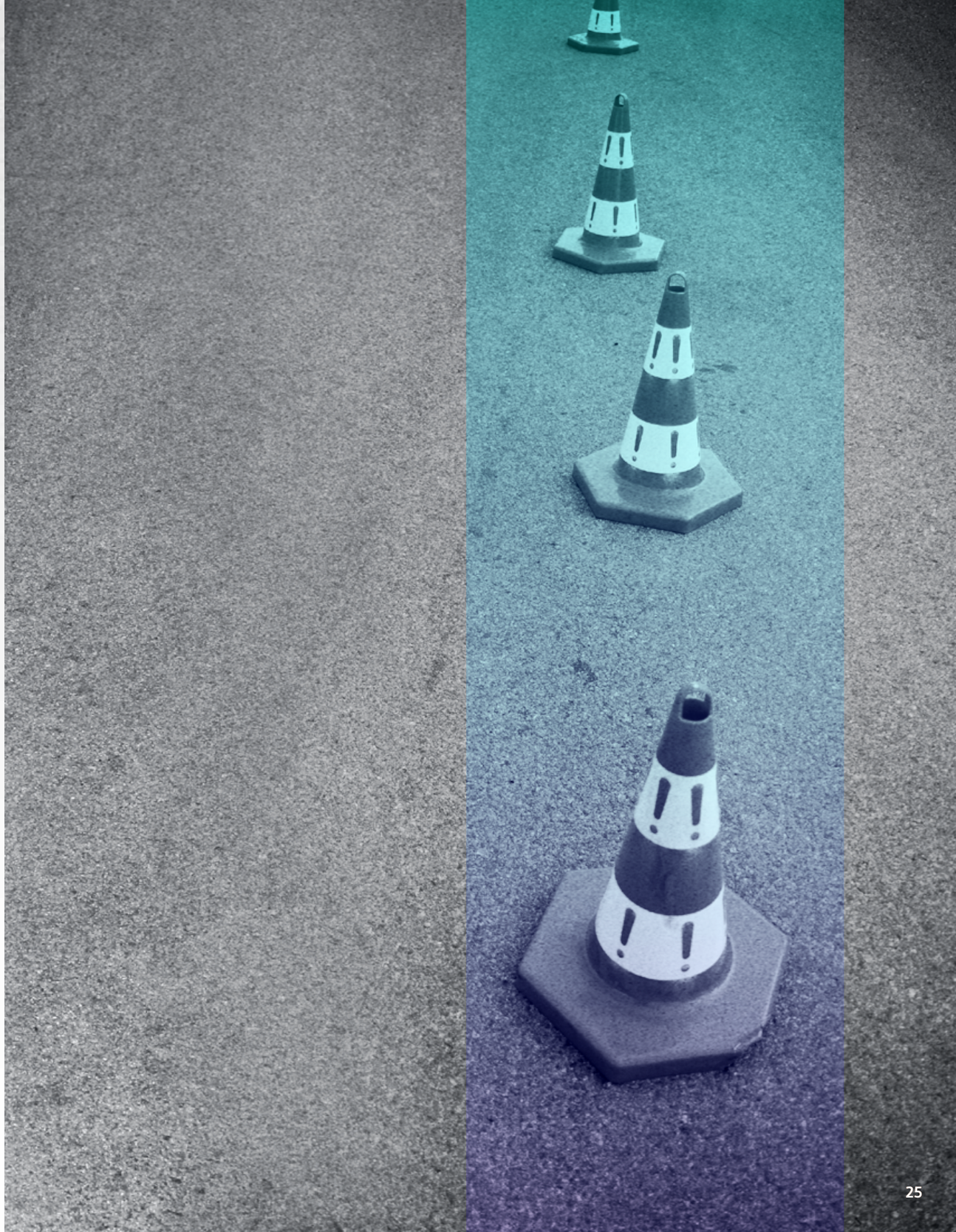
COLLECT AND REPORT ADVERSE EVENTS

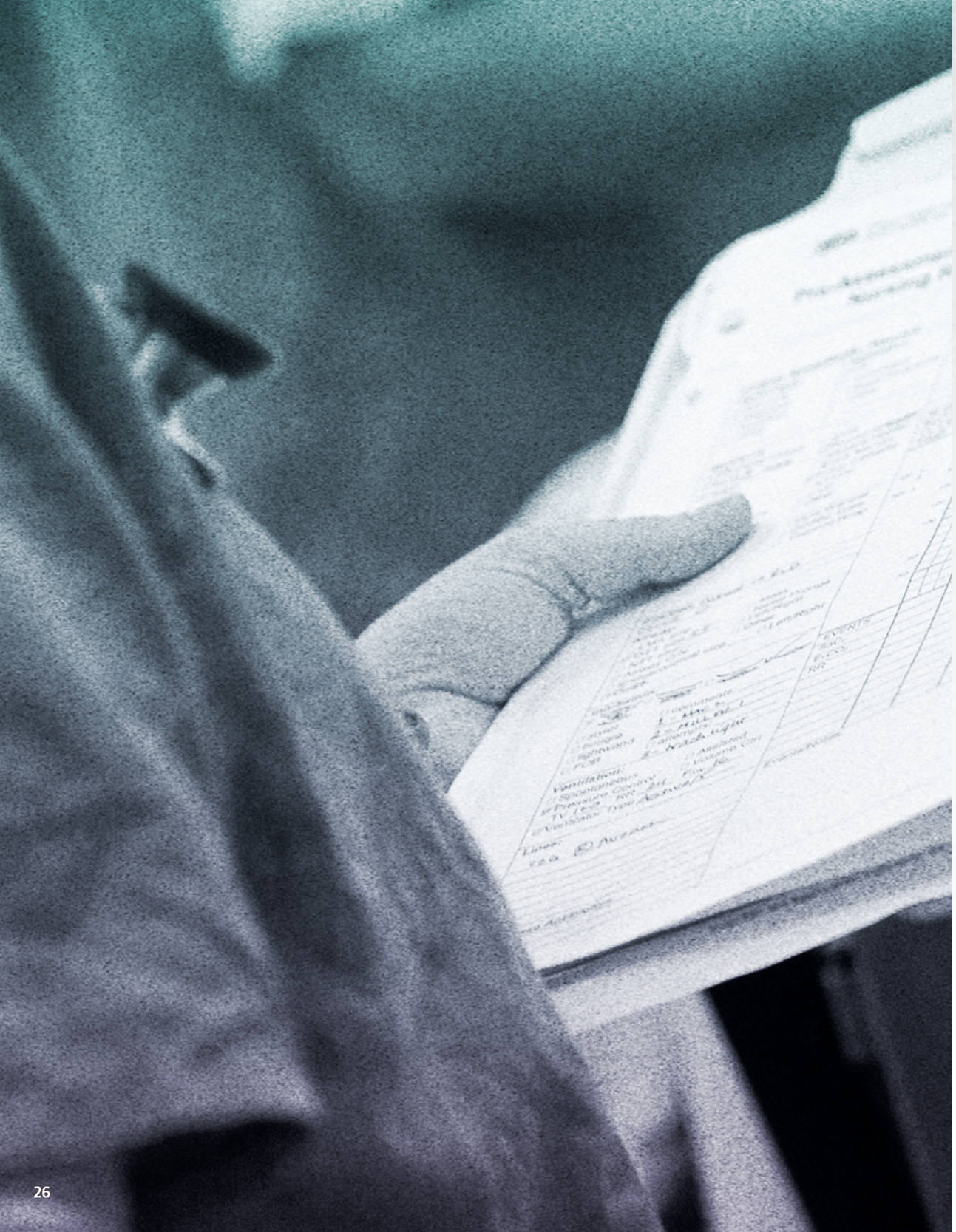
According to the FDA, "good pharmacovigilance practice is generally based on acquiring *complete data* from spontaneous adverse-event reports." Because the quality and completeness of an adverse event permits further investigation, the FDA "recommends that sponsors *make a reasonable attempt to obtain complete information for case assessment* during initial contacts and subsequent follow-up, especially for serious events." Pharmaceutical companies understand the importance of collecting and reporting adverse events. After all, the regulations clearly require the collection and reporting of AERs to the FDA; *see above*. It is the suggestion that the manufacturers collect *complete information* that likely poses the problem for most PV departments.

Adverse events are collected from multiple sources to include consumers, healthcare professionals, medical literature and clinical studies. It can be difficult to collect complete information prior to submitting timely the AER to the FDA due to cooperation (or lack thereof) from the reporter, issues with receiving medical authorizations for the collection of medical records and other factors. To assist with the endeavor of collecting complete information, PV departments should have Standard Operating Procedures ("SOPs") in place with directives regarding the information needed and the process for follow-up, documentation and storage of all information related to each adverse event. Equally important, PV departments need to ensure that staff members are actually following the SOPs. It is one thing to have an exercise plan, and another thing to activate and follow the plan. Get active.

IDENTIFY AND EVALUATE SAFETY SIGNALS

According to the FDA, the goal of PV is to understand the nature, frequency and potential risk factors of adverse events associated with a product's use to identify and evaluate safety signals. A safety signal is a concern about an excess number of adverse events compared to what a manufacturer expects to be associated with a product. Safety signals indicate the





While the FDA defines a safety signal as a concern about an excess number of adverse events, the FDA also notes that even a single case report can be viewed as a signal.

need for further investigation that may lead to the conclusion that a product causes a certain adverse event. While the FDA defines a safety signal as a concern about *an excess number of adverse events*, the FDA also notes that even a single case report can be viewed as a signal.

Identifying and evaluating safety signals require a manufacturer to go a step beyond collecting and reporting AERs to the FDA, and this additional step heavily relies on the collection of complete information. Once a PV department identifies a safety signal, the PV department should further evaluate it to determine if it presents a potential safety risk that requires additional action. An SOP regarding the identification and evaluation of safety signals may be useful to guide PV departments as to the frequency of review of collected AERs in the aggregate, the criteria to determine whether an event constitutes a safety signal, the process for potential next steps after identifying a safety signal to include determining whether the drug caused the event and requirements to document and store all related information. It bears repeating: it is one thing to have a plan, and another thing to activate and follow the plan. Get active.

INVESTIGATE SAFETY SIGNALS THROUGH STUDIES

There are multiple scenarios or occasions when a safety signal requires further investigation to include: the detection of new unlabeled adverse events, an increase in the severity of a labeled event, and the identification of a previously unrecognized at-risk population. Companies can further investigate those and other safety signals through randomized trials or nonrandomized observational studies. The FDA encourages companies "to consider all methods to evaluate a particular safety signal" and "choose the method best suited to the particular signal and research question of interest." If further evaluation suggests that a safety signal is actually a potential safety risk, a company should submit the available safety information and analysis to the FDA and, if appropriate, propose to investigate the issue further and/or propose risk minimization actions such as product label changes.

THE END RESULT

Similar to other pharmaceutical issues, there are no clear-cut answers as to how much PV is enough. Even the FDA's PV Guidance for Industry only "contains nonbinding recommendations." But keep in mind that PV practices need to be active and consistent just like an effective workout plan. (Think: reps, reps, reps.) A pharmaceutical company should not, however, permit its PV practices to become so routine to the point that it misses a signal or red flag. In other words, a PV department cannot simply just "go through the motions."

A PV department must be active. It is not easy, but getting in shape is never easy; however, the end-result is rewarding. Personally, you can wear your skinny jeans again. Professionally, you can help your company avoid becoming the "Biggest Loser" in court. ■

By Meta Cooper

B2B LITIGATION AVOIDANCE

IN THE PHARMACEUTICAL & MEDICAL DEVICE INDUSTRY

In the typical scenario, in-house counsel is notified of business disputes when a lawsuit has already been served or when negotiations have broken down and the parties are deeply entrenched in their positions. At these points, it is very difficult or impossible to avoid litigation. While we enjoy lawsuits and the courtroom, we know your business can be better served in most instances by avoiding expensive and protracted business disputes. This article provides suggestions for working with business colleagues within your company to minimize risk and proactively avoid litigation.

PREVENTION IS BETTER THAN CURE

One of the most effective ways to avoid litigation is to train your business colleagues in basic contract legal principles. It is surprising how many commercial disputes could have been avoided had the individuals negotiating the contract and monitoring performance under the contract understood basic contracting law such as offer and acceptance, breach, notice, cure and waiver. Routinely when interviewing employees who are already in the midst of a dispute, we find them truly shocked to learn that simple email exchanges between the contracting parties created a contract, amended it, or perhaps even waived a breach. They are equally befuddled to learn that email "notice" of a potential breach of contract may not be sufficient to constitute true notice, as many contracts require notice of

breach to be in writing and delivered to specified individuals. We now routinely recommend Contracts 101 training once a year for clients who engage in the contracting process on a day-to-day basis.

Business colleagues should be provided guidance on documenting contractual activities. The tremendous speed of business activity, coupled with a pervasive concern about putting things in writing caused by discovery in product liability litigation, often leads to critical actions being undocumented. Despite concerns about discovery, there are activities in the commercial setting which should be regularly documented. Business colleagues should be trained to document concerns about another party's failure to perform under a contract, and contracts should almost never be terminated without some written memorialization to the other side. Although critical communications should involve the assistance of in-house counsel, it is not possible for legal to be involved in regular but potentially significant contract activities. The better trained the business team is to handle regular documentation, the greater the opportunity will be to avoid litigation or, if litigation occurs, prevail.

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EARLY INVOLVEMENT

Our nonlegal business colleagues are often very good at their positions, and their roles may include oversight of contractual relationships. When disputes arise over business issues, such as timing of payment, the provision or quality of services, or actual breach of contract, such roles inevitably lead to efforts on the part of the businessperson to address the situation without the involvement of in-house counsel. These efforts are often accompanied by emotion and decision-making that are not rooted in the terms of the contract or applicable law. In other words, decisions are often made after disputes arise that are not based on the parameters that will apply in the event of litigation. This may be good for outside counsel's employment, but it is a headache for you and a distraction from your company's business.

While in-house counsel are too busy to be involved in every contentious business decision, business colleagues should be advised to consult with in-house counsel whenever they believe a breach of contract has occurred and before the situation is irreparable. As part of this "reach-out to legal," business colleagues should be asked to provide the contract and all communications related to the dispute. Business relationships in the pharmaceutical and medical device industry are controlled by a wide variety of contracts, including master agreements and fine-print purchase orders, and we often see business members taking positions in a dispute without regard to the terms of the contract. This is a good training point, as it is an opportunity to remind business colleagues about the importance of contracts and a "marker" for business colleagues to use as a reminder to contact legal. Having been reminded that the terms of the contract will control in the event of a dispute, they should be instructed to contact legal anytime they find themselves reviewing a contract in an effort to address a dispute.

Even if the business colleague contacts the legal department early in the process, there will already be written communications between the parties about the dispute.

These are almost always emails, and they will inevitably be one side's exhibits in litigation. Although it seems obvious that such communications must be evaluated along with the contract terms in deciding how to address the dispute, our experience is that in-house counsel are not informed of these communications until after litigation. Reviewing these materials before becoming entrenched in a position provides a tremendous opportunity to resolve a dispute early and well before litigation or the involvement of outside counsel.

EVALUATE THE RELATIONSHIP FOR CREATIVE SOLUTIONS

No one wants business colleagues to act as lawyers, and litigators should not attempt to usurp a businessperson's industry experience and judgment. But there is an interesting role reversal that can occur as business disputes develop. Businesspersons with wonderful judgment often lose that judgment as negotiations become acrimonious and veer toward litigation. These colleagues sometimes adopt the persona of their favorite television lawyer and find they relish the opportunity to "impart some justice." Although it doesn't have to reach that point for the "role reversal" to occur, business disputes are opportunities for in-house lawyers to think like a businessperson (hopefully counteracting any television lawyering). Is there an ongoing business relationship? If so, how can the strength of that relationship or the needs of the company be factored into early dispute resolution? Can the company obtain or provide in-kind credits or offsets to resolve the dispute? Are there going-forward discounts that could be applied to resolve the situation? Ongoing business relationships provide opportunities for creative lawyering that positively impact the business. Embrace them and put on your business hat – just don't go too far in emulating your favorite television businessperson.

BE PREPARED

Choice of law and forum selection clauses can provide powerful support for early dispute resolution. Certainty about the applicable law allows you to evaluate the likely outcome in the event of litigation. If the choice of law provision applies the law of the company's home state, then in-house counsel are likely familiar with the law. This will allow informed decision making without the need for legal research at every turn and will inevitably save costs and time. Similarly, a forum selection clause lets you know what to expect in the event of litigation. Knowing the bench and typical jury can give you confidence in a position even if it leads to litigation. It can also provide confidence for providing senior management the parameters of a high-stakes dispute. If not included already, contracting templates should be modified to include choice of law and forum selection clauses.

IN SUMMARY, THE FOLLOWING ACTION ITEMS MAY BE USEFUL IN B2B LITIGATION AVOIDANCE:

1. Provide training regarding basic contract law.
2. Advise business colleagues to involve in-house legal early and proactively.
3. Identify and review the contract(s) and key correspondence about the dispute before positions are entrenched.
4. Treat ongoing business relationships as opportunities for creative solutions.
5. Review your company's contracting templates for choice of law and forum selection provisions and understand their importance to early dispute resolution. ■

By Eric Hudson

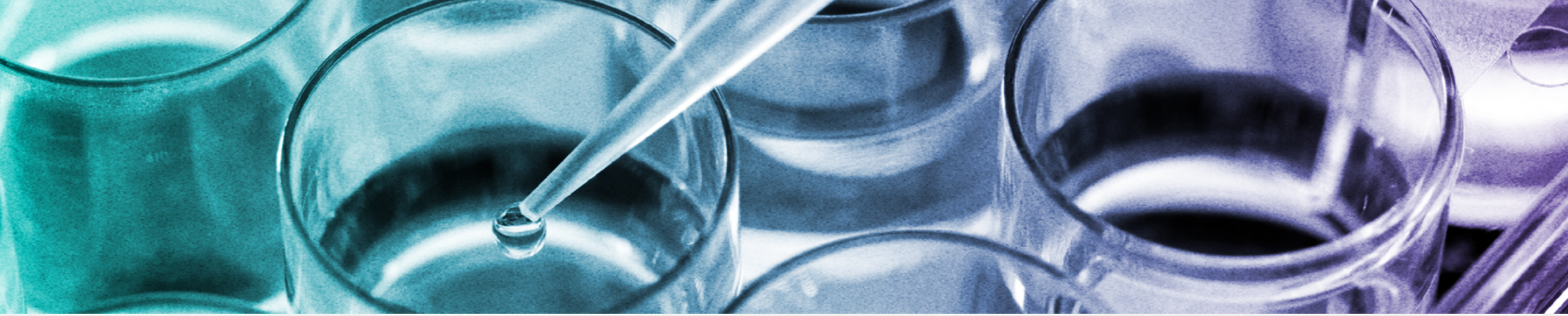
By Amy Pepke

UPDATE: PREEMPTION OF CLAIMS

AGAINST BRAND PHARMACEUTICAL MANUFACTURERS AFTER *MUTUAL PHARMACEUTICALS, CO. V. BARTLETT*

Until only recently, brand pharmaceutical manufacturers have largely been left out in the cold when arguing that plaintiffs' state-law tort claims should be impliedly preempted by federal law. Unlike their generic counterparts, absent extenuating circumstances, brand manufacturers have not been successful in arguing implied preemption of state-law claims based on either failure to warn/adequacy of warnings or design defect. In fact, just over a year ago (and some five months after the *Bartlett* decision), my colleague summed up the "scorecard" on implied preemption as follows:

- Implied conflict preemption for brand manufacturers? By and large, NO – unless the brand manufacturer can show clear evidence that the FDA considered, and rejected, proposed warnings on the same risks and injuries (*Wyeth v. Levine*[1]);
- Implied conflict preemption for generic manufacturers based on a theory of failure to warn/adequacy of warnings? Generally, YES – because generic manufacturers must ask FDA for permission (and get it) before changing a label beyond that authorized for the brand version (*PLIVA v. Mensing*[2]); and
- Implied conflict preemption for generic manufacturers based on a theory of design defect? Generally, YES – under the rationale of *Mensing*, a generic manufacturer cannot unilaterally change the design of a product that was FDA-approved, and further, the manufacturer should not be forced to make



a Hobson's choice of ceasing sales of the product altogether to avoid conflict (*Mutual Pharmaceuticals v. Bartlett*[3]).[4]

In the immediate aftermath of the Supreme Court's *Bartlett* decision, it could fairly be said that the preemption scorecard read 2-0 in favor of the generic manufacturers. However, in the roughly 18 months since Bartlett, brand prescription drug manufacturers have begun to make up some ground on the generic drug makers. While *Bartlett* did not affect a brand manufacturer's chances of success on failure-to-warn/adequacy of warnings claims, brand manufacturers have begun to gain traction on implied preemption of design defect claims.

IMPLIED PREEMPTION OF FAILURE-TO-WARN/ADEQUACY OF WARNINGS CLAIMS.

Wyeth v. Levine remains the controlling authority on whether claims sounding in failure to warn/adequacy of warnings are impliedly preempted by federal law, and the answer remains, by and large, NO. Under *Levine*, a brand manufacturer must show "clear evidence that the FDA would not have approved a change to [the drug's] label" in order to successfully argue that it was impossible for it to have complied with both federal and state law.[5] This "clear evidence" legal standard itself has remained unchanged in the years since Levine. Moreover, because the Supreme Court did not define or suggest the level of proof required to constitute "clear evidence," lower courts have been left to determine what level of proof is necessary to satisfy this standard. Given this, in the wake of *Levine*, all that is "clear" about the "clear evidence" standard is that it is a highly fact-specific and demanding defense,[6] and very few courts have found that a brand manufacturer has successfully demonstrated the requisite "clear evidence." That being said, a couple of decisions have given brand manufacturers hope that it is possible to meet the "clear evidence" standard enunciated in *Levine*.

DOBBS V. WYETH

The first court to find implied preemption of failure-to-warn claims against a brand manufacturer was the U.S. District Court for the Western District of Oklahoma in *Dobbs v. Wyeth*.[7] In *Dobbs*, the plaintiff sued brand manufacturer Wyeth for failure to warn of a risk of suicide associated with its antidepressant, Effexor, after her husband committed suicide while taking the drug.[8] Ms. Dobbs alleged that the existing suicide warning on the Effexor label was insufficient to alert patients to the suicide risk associated with the drug.[9]

The District Court initially granted summary judgment in favor of Wyeth in 2008 finding that the plaintiff's state-law failure-to-warn claims were preempted by FDA regulations.[10] That decision was vacated on appeal in light of the Supreme Court's intervening decision in Levine, and remanded for the trial court to reevaluate Wyeth's defense based on the "clear evidence" standard enunciated in *Levine*.[11] On remand, the District Court found that Wyeth met the clear evidence standard and again granted summary judgment to Wyeth.[12] Specifically, the court found that the FDA's regulatory history with regard to the class of antidepressants including Effexor showed that the agency reviewed manufacturers' reports from clinical trials and studies regarding suicidality, as well as a number of independent studies, and continually refused to enhance the suicidality warnings on these medications both before and after Mr. Dobbs' death. The FDA's decision was based on a finding that there was no scientific evidence to support a causal connection between these antidepressants and suicidality in adult patients.[13] Moreover, the court found that the FDA had approved a supplemental new drug application (sNDA) for Effexor and over a dozen new drug applications (NDAs) and sNDAs for other antidepressants with the very same suicide warnings both prior to and after Mr. Dobbs' suicide.[14] Finally, the court found it highly persuasive that the FDA had rejected a pediatric warning relating specifically to Effexor that was added by Wyeth under the CBE regulations after Mr. Dobbs' death.[15] All of these findings established "clear evidence" that the FDA would have rejected an expanded Effexor suicidality warning for patients of Mr. Dobbs' age group prior to his suicide in 2002.

While Bartlett did not affect a brand manufacturer's chances of success on failure to warn/adequacy of warnings claims, brand manufacturers have begun to gain traction on implied preemption of design defect claims.

GLYNN V. MERCK

Similarly, in June 2013, the District Court for the District of New Jersey found that Merck had demonstrated "clear evidence" that the FDA would not have approved a stronger warning about Fosamax's link to femur fractures and, therefore, held that the plaintiff's state-law failure-to-warn claims were preempted.[16] Prior to plaintiff's injury, the FDA refused to approve a change to the Precautions section of the Fosamax label relating specifically to femur fractures through a "prior approval supplement" (PAS) initiated by Merck. This refusal established clear evidence that the FDA would not have approved a CBE seeking to add the same language prior to the injuries suffered by the plaintiff.[17] Since the FDA would not have approved a CBE with the stronger warnings urged by plaintiff as the basis for failure-to-warn claims, the court held that the plaintiff's claims were impliedly preempted.

UPDATED SCORECARD – FAILURE TO WARN/ADEQUACY OF WARNINGS

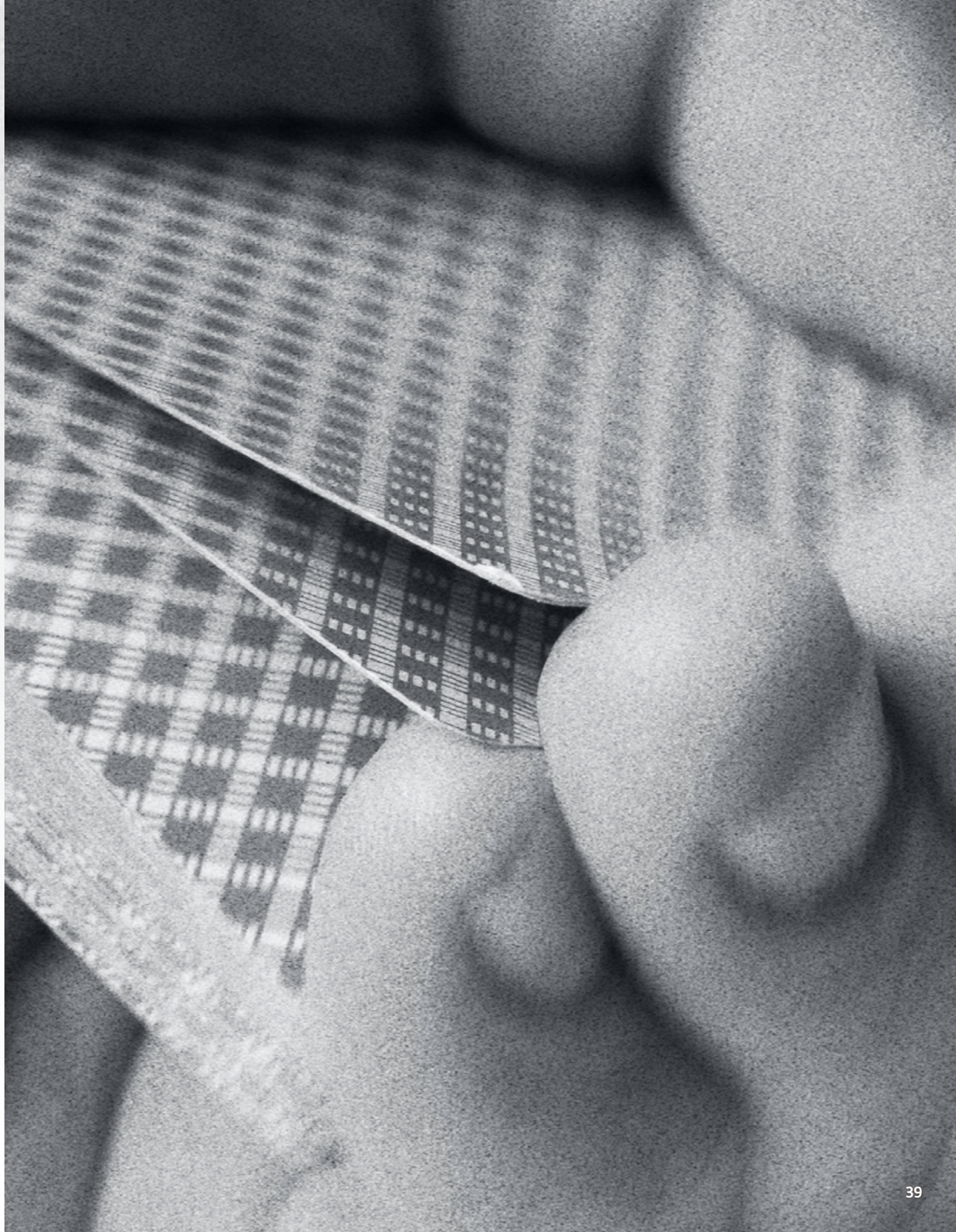
Despite favorable implied preemption decisions in *Dobbs* and *Glynn*, the deck certainly remains stacked against brand manufacturers when arguing preemption of state law failure-to-warn claims. To date, *Dobbs* and *Glynn* are the only favorable decisions for brand manufacturers on the "clear evidence" standard enunciated in *Levine*.[18] On the other hand, numerous courts across the country have found that brand manufacturers failed to meet this demanding standard for various and sundry reasons.[19] Therefore, since the score was last tallied on this topic, there has been no significant change: Implied Preemption of Failure-to- Warn/ Adequacy of Warnings Claims – Generic manufacturers – Generally, YES; Brand manufacturers – By and large, NO.

IMPLIED PREEMPTION OF DESIGN DEFECT CLAIMS

While recent Supreme Court implied preemption jurisprudence creates disparate treatment of brand and generic pharmaceutical manufacturers on state law failure-to-warn/adequacy of warnings claims, this very same jurisprudence – specifically Bartlett – creates a more equal playing field for design defect claims. Soon after the Bartlett decision, commentators argued that Bartlett should essentially apply to preempt all design defect claims asserted against FDA-regulated products – both brand and generic.

While *Bartlett* involved claims against a generic manufacturer, the Supreme Court reasoned that under FDA regulations applicable to all prescription medications – brand or generic – all changes to a drug that affect its safety or efficacy require prior FDA approval. Thus, a manufacturer could not comply with a state law duty to render a drug safer by altering its composition without prior FDA approval, and design defect claims would be impliedly preempted. The following language from *Bartlett* may have opened the door for brand manufacturers to argue implied preemption

Despite favorable implied preemption decisions in Dobbs and Glynn, the deck certainly remains stacked against brand manufacturers when arguing preemption of state law failure to warn claims.



of state law design defect claims: "Once a drug – whether generic or brand-name – is approved, the manufacturer is prohibited from making any major changes to the 'qualitative or quantitative formulation of the drug product, including active ingredients, or in the specifications provided in the approved application.'"[20] In other words, because a drug redesign requires FDA approval, claims seeking such a redesign under state law are preempted because they are in conflict with federal laws that prohibit manufacturers from unilaterally altering a drug's composition.[21]

Calls for a broad application of the *Bartlett* to both brand and generic manufacturers have been answered – though not in favor of brand manufacturers in every instance.

THOMPSON V. ALLERGAN

The favorable application of *Bartlett's* reasoning to brand manufacturers began some seven months later when the U.S. District Court for the Eastern District of Missouri held that *Bartlett* applied to the manufacturer of the brand name prescription ophthalmic medication, Restasis.[22] The plaintiffs in this putative class action alleged that the defendants overfilled Restasis dispensers so that consumers were forced to purchase more of the medication than they could use, therefore paying higher prices than necessary.[23] Upon consideration of defendant's motion to dismiss, the court agreed that the plaintiffs' claims were preempted because reducing the amount of medicine in each Restasis vial would constitute a "major change" in the specifications provided in the drug application previously approved by the FDA, thus requiring new FDA approval.[24] Based on this finding, the court dismissed the plaintiffs' state law claims as impliedly preempted.[25]

CASSEL V. ALZA CORP.

Only a little over one month later, the U.S. District Court for the Western District of Wisconsin found the exact opposite – that Bartlett is inapplicable to state law design defect claims against brand manufacturers. In Cassel, plaintiffs brought a design defect claim, among others, against the designers and manufacturers of the brand name "Duragesic Reservoir Patch" following the death of Teri Cassel by accidental overdose.[26] On summary judgment, defendants argued that plaintiffs' design defect claims were impliedly preempted.[27] The court denied defendants' motion for two reasons: (1) unlike in Bartlett, the defendants were not generic manufacturers, and thus their fentanyl patches were amenable to various designs; and (2) Bartlett was inapplicable to the facts of the case and plaintiffs' claims because plaintiffs alleged that the defendants had a duty to employ an alternative design from the beginning, i.e. before FDA approval, as opposed to engaging in a redesign of the product after initial FDA approval of the product.[28] The court noted its concern that defendants' argument would essentially foreclose all state law design defect claims against manufacturers of FDA-approved drugs, whether brand or generic, and determined that such a result was not contemplated by the Supreme Court in *Bartlett*.

AMOS V. BIOGEN IDEC INC.

In Amos, the U.S. District Court for the Western District of New York once again held that plaintiffs' state law design defect claims were impliedly preempted under the reasoning in Bartlett.[29] While the plaintiffs conceded that their state law design defect claims were preempted by federal law, the court still considered defendants' motion to dismiss the plaintiffs' design defect claims, granting it with prejudice based upon the implied preemption analysis in Bartlett.[30]

BOOKER V. JOHNSON & JOHNSON

Brand manufacturers obtained another positive implied preemption decision from the U.S. District Court for the Northern District of Ohio in Booker v. Johnson & Johnson.[31] In Booker, the plaintiff claimed that her daughter suffered pulmonary emboli and passed away due to her use of the

Ortho Evra® birth control patch.[32] After first determining that the plaintiff had sufficiently pled a claim for design defect under Georgia law, the court focused on whether such claims were nonetheless impliedly preempted under Bartlett. In short, the court determined that Bartlett governed the issue and that plaintiff's design defect claims were therefore preempted.[33] More specifically, the Court found that the essential inquiry in considering preemption of a design defect claim is whether the state law requires remedial action by the manufacturer.[34] Finding that Georgia law would indeed require the defendant to create an alternative design, thus changing the composition of the drug, the court held that the plaintiff's design defect claims were preempted.[35]

BROWN V. JOHNSON & JOHNSON

Another unfortunate decision for brand manufacturers came in December 2014 when the U.S. District Court for the Eastern District of Pennsylvania refused to dismiss the plaintiffs' state law design defect claims against the manufacturer of brand-name, over-the-counter Children's Motrin.[36] The court specifically cited to Bartlett but held that "[t]he Supreme Court has not addressed whether federal law can preempt state law design defect claims brought against manufacturers of brand-name or non-prescription drugs. I conclude that its preemption cases do not extend to the manufacturers of these products."[37] Then, apparently borrowing from the Supreme Court's reasoning from Levine, the court went on to find that the defendants failed to demonstrate that the FDA would have rejected a proposed change to Children's Motrin's chemical composition.[38]

YATES V. ORTHO-MCNEIL PHARM., INC.

Most recently, in another Ortho Evra® birth control patch case, the District Court for the Northern District of Ohio again found that a state law design defect claim was

> Nearly six years post-Levine, there remains limited case law finding implied preemption of state law failure to warn claims against brand manufacturers.

impliedly preempted.[39] Importantly, the court explicitly held, contrary to the plaintiff's assertion, that the language of Bartlett applies equally to brand and generic drugs.[40] The court cited Amos for the same proposition and specifically found that the court's holding in Cassel was incorrect and inconsistent with the Supreme Court's analysis in Bartlett.[41]

UPDATED SCORECARD – DESIGN DEFECT:

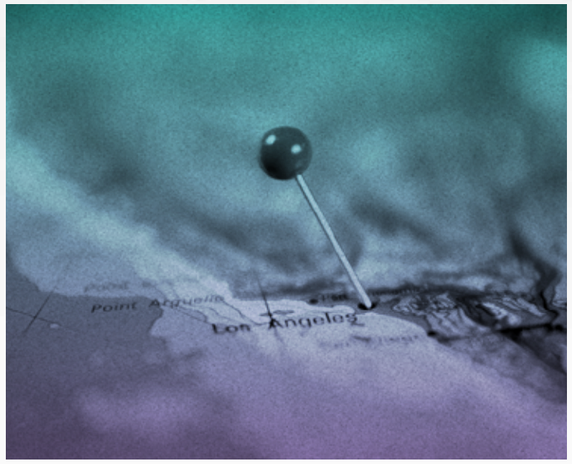
Brand manufacturers have undoubtedly made up ground on generic manufacturers when it comes to design defect claims. Aside from a few outliers in Cassel and Brown, district courts have regularly held that plaintiffs' state law design defect claims against brand manufacturers are impliedly preempted under Bartlett. The majority approach holds that Bartlett's application mandates preemption for both brand and generic drug manufacturers. While there may not be uniformity, there certainly seems to be at least a favorable trend.

WHAT DOES THE FUTURE HOLD FOR THE SCORECARD?

As it relates to preemption of failure-to-warn claims, it seems unlikely that the score will change significantly going

Conversely, the post-Bartlett trend favors preemption of design defect claims against brand and generic manufacturers alike. While Cassel and Brown held to the contrary, the majority of courts have held that Bartlett requires preemption of design defect claims.

forward. Brand manufacturers will likely continue to have difficulty satisfying the requisite "clear evidence" standard enunciated in Levine. Nearly six years post-Levine, there remains limited case law finding implied preemption of state law failure-to-warn claims against brand manufacturers. To make matters more difficult, the fact-specific nature of the findings in these cases limits their overall utility for other brand manufacturers facing similar claims.



Conversely, the post-Bartlett trend favors preemption of design defect claims against brand and generic manufacturers alike. While Cassel and Brown held to the contrary, the majority of courts have held that Bartlett requires preemption of design defect claims. There is no reason to believe, absent significant appellate authority to the contrary or legislative and/or administrative action on this subject, that this trend will not continue.

Finally, as previously discussed in this very publication, almost immediately following the Supreme Court's decision in Bartlett, the FDA announced its intention to "create parity" between brand and generic manufacturers through federal rulemaking.[42] It was initially anticipated that further information regarding this proposed rulemaking would be available in September 2013, but such was not the case. To date, there have been no further pronouncements from the FDA regarding this possible administrative action, and, at this point, it seems that the question is more "if" such rulemaking will ever occur as opposed to "when" it will occur. Therefore – despite the Supreme Court explicitly stating in Bartlett that "the Court would welcome Congress' 'explicit' resolution on the difficult preemption questions that arise in the prescription drug context" so that the Court is not "left to divine Congress' will from the duties the statute imposes"[43] – at this point it does not appear likely that courts and litigants will have the benefit of such legislative action anytime in the near future. Without this, brand manufacturers (and their counsel) can only continue their attempts to further develop post-Bartlett implied preemption jurisprudence on a case-by-case basis. ■

1. Wyeth v. Levine, 555 U.S. 555 (2009).
2. PLIVA, Inc. v. Mensing, 131 S. Ct. 2567 (U.S. 2011).
3. Mutual Pharm. Co. v. Bartlett, 133 S. Ct. 2466 (2013).
4. See Richelle Kidder, Is the Feeling Really "Mutual"?: The Supreme Court's Continued Frustration with the Prescription Drug Legal Framework, Pro Te: Solutio, November 2013, at 15 (http://www.butlersnow.com/wp-content/uploads/2014/08/Pro-Te-Solutio-Vol-6-No-4.pdf).
5. Levine, 555 U.S. at 571. Briefly, the Supreme Court's reasoning in Levine was that because a manufacturer may make certain changes to its label before receiving the FDA's approval (namely through the "changes being effected" (CBE) regulation) to "add or strengthen a contraindication, warning, precaution, or adverse reaction" or to "add or strengthen an instruction about dosage and administration that is intended to increase the safe use of the drug product," it is not impossible for a brand manufacturer to comply with both its state-law duty to warn without violating federal law unless the brand manufacturer can show "clear evidence" that such label changes would not have been approved by the FDA.
6. Id. at 573.
7. Dobbs v. Wyeth, 797 F. Supp. 2d 1264 (W.D. Okla. 2011).
8. Id. at 1266.
9. Id.
10. Id.
11. Id.
12. Id. at 1280.
13. Id. at 1276-77.
14. Id. at 1273.
15. Id. at 1276-77.
16. In re: Fosamax (Alendronate Sodium) Prods. Liab. Litig.; Glynn v. Merck Sharp & Dohme Corp., 951 F. Supp. 2d 695 (D.N.J. 2013).
17. Id. at 697-98; 703-04.
18. Robinson v. McNeil Consumer Healthcare, 615 F.3d 861 (7th Cir. 2010) could be considered an additional favorable decision. However, Robinson discussed implied preemption only briefly and on a somewhat tangential matter. This case involved an appeal of the trial court's refusal to allow the plaintiff to add a claim for breach of implied warranty on the eve of trial in a case involving claims that the plaintiff's decedent was diagnosed with toxic epidermal necrosis (TEN) after taking defendant's product Children's Motrin. On appeal, the court held that the trial court's refusal to allow the amendment was proper, in part, because such a claim would have been unlikely to succeed. The court cited Levine and held that a court cannot order a drug company to place on a label a warning if there is "clear evidence" that the FDA would not approve it. Finding that the FDA had previously refused to require a reference to SJS/TEN on the label of over-the-counter drugs containing ibuprofen, the court went on to comment that "it would be odd to think that McNeil had a legal duty to guarantee against a risk that the FDA thought not worth warning against." Id. at 873
19. See, e.g., Mason v. SmithKline Beecham Corp., 596 F.3d 387 (7th Cir. 2010); Koho v. Forest Labs., Inc., 17 F. Supp. 3d 1109 (W.D. Wash. 2014); Hunt v. McNeil Consumer Healthcare, 6 F. Supp. 3d 694 (E.D. La. 2014); Dopson-Troutt v. Novartis Pharms. Corp., 975 F. Supp. 2d 1209 (M.D. Fla. 2013); Schedin v. Ortho-McNeil-Janssen Pharms., Inc., 808 F. Supp. 2d 1125 (D. Minn. 2011); Wolfe v. McNeil--PPC, Inc., 773 F. Supp. 2d 561 (E.D. Pa. 2011); Lofton v. McNeil Consumer & Spec. Pharm., 682 F. Supp. 2d 662 (N.D. Tex. 2010); Dorsett v. Sandoz, Inc., 699 F. Supp. 2d 1142 (C.D. Cal. 2010); Forst v. SmithKline Beecham Corp., 639 F. Supp. 2d 948 (E.D. Wis. 2009); Muzichuck v. Forest Labs., Inc., 2015 U.S. Dist. LEXIS 5440 (N.D. W. Va. Jan. 16, 2015); Brown v. Johnson & Johnson, 2014 U.S. Dist. LEXIS 173800 (E.D. Pa. Dec. 9, 2014); Allen v. Takeda Pharms. N. Am., Inc., 2014 U.S. Dist. LEXIS 1749 (W.D. La. Jan. 7, 2014); Wells v. Allergan, Inc., 2013 U.S. Dist. LEXIS 13191 (W.D. Okla. Jan. 31, 2013); Newman v. McNeil Consumer Healthcare, 2012 U.S. Dist. LEXIS 2153 (N.D. Ill. Jan. 9, 2012); Baumgardner v. Wyeth Pharms., 2010 U.S. Dist. LEXIS 90263 (W.D. Pa. Aug. 31, 2010); Aaron v. Wyeth, 2010 U.S. Dist. LEXIS 14581 (W.D. Pa. Feb. 19, 2010).
20. Bartlett, 133 S. Ct. at 2471 (quoting 21 C.F.R. § 314.70(b)(2)(i)).
21. Id. at 2475, 2479.
22. Thompson v. Allergan USA, Inc., 993 F. Supp. 2d 1007 (E.D. Mo. 2014).
23. Id. at 1009.
24. Id. at 1014.
25. Id.
26. Cassel v. Alza Corp., 12 – cv-771-wmc, 2014 U.S. Dist. LEXIS 27924, at *1-*3 (W.D. Wis. Mar. 5, 2014).
27. Id. at *5.
28. Id. at *13-*14.
29. Amos v. Biogen Idec Inc., No. 13-CV-6375T, 2014 WL 2882104, at *3 (W.D.N.Y. June 25, 2014).
30. Id.
31. Booker v. Johnson & Johnson, Case No. 3:12 oe 40000, 2014 U.S. Dist. LEXIS 145442 (N.D. Ohio Oct. 10, 2014).
32. Id. at *1.
33. Id. at *11.
34. Id. at *10-*11 (citing Bartlett for the proposition that "[a]s the Supreme Court explained, when a state imposes a 'duty to ensure that one's products are not unreasonably dangerous,' it also involves a duty to make one or several changes to the composition of the drug, which conflicts with federal law prohibiting alteration of an FDA-approved design.")
35. Id. at *11.
36. Brown v. Johnson & Johnson, Civ. No. 12-4929, 2014 U.S. Dist. LEXIS 173800 (E.D. Penn. Dec. 9, 2014).
37. Id. at *5.
38. Id.
39. Yates v. Ortho-McNeil Pharm., Inc., Case No. 3:09 oe 40023, 2015 U.S. Dist. LEXIS 2838 (N.D. Ohio Jan. 5, 2015).
40. Id. at *13 (citing Bartlett, 133 S. Ct. at 2471).
41. Id. at *14.
42. Kidder, supra note 4.
43. Bartlett, 133 S. Ct. at 2480.

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