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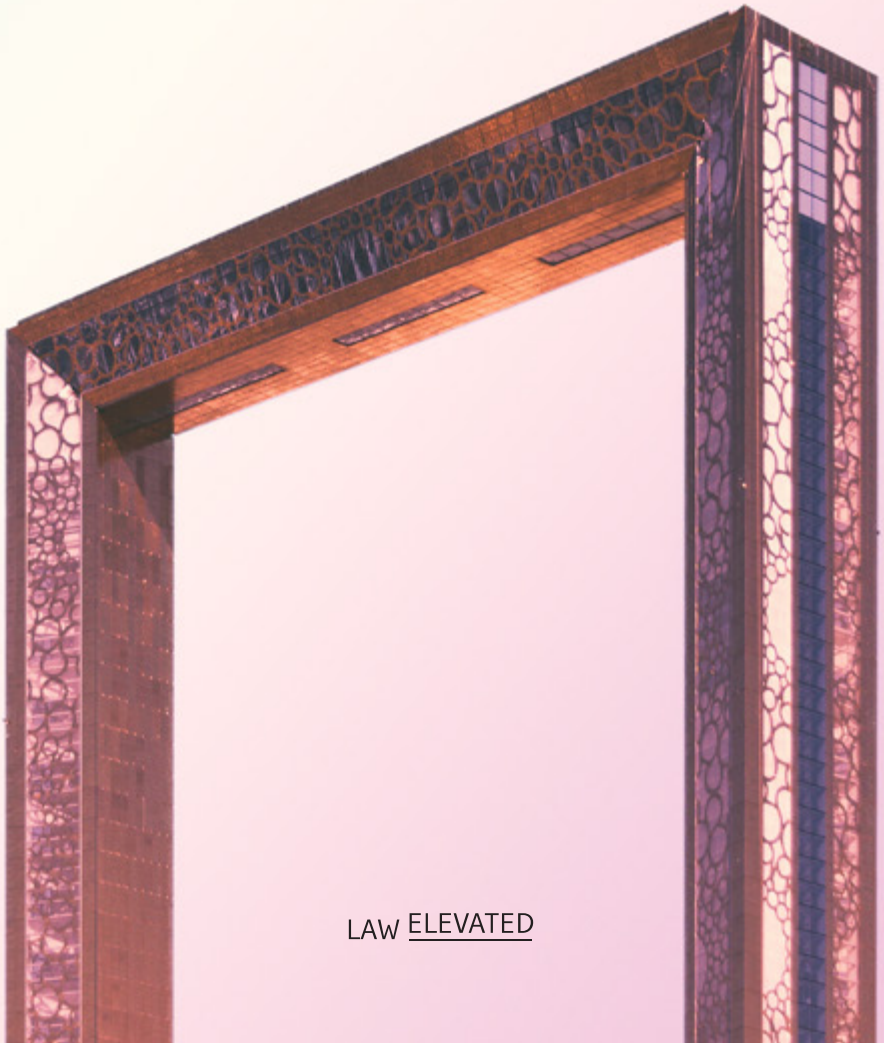


LAW ELEVATED

Dear Client,

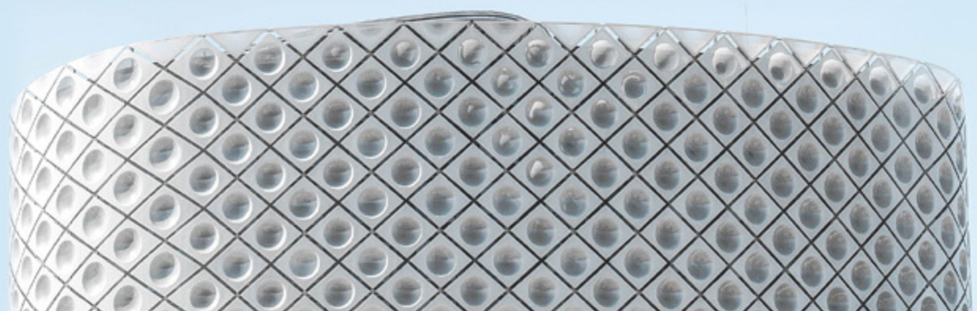
Pro Te: Solutio returns for its second edition of 2019. As the year grinds on, our attorneys at Butler Snow are taking proactive and creative steps to confront and solve the issues that affect our areas of practice.

The first article is *A New Look at The Doctor Deposition*. In this article, we address the need to change our deposition styles to conform to changes in the medical field. This article offers examples of more effective lines of questioning, and challenges practitioners to step outside of comfort zones in order to elicit better and more informative testimony.

No Way Around It addresses "special assistance and permission" preemption and its applicability beyond generic drug cases. This article includes the untapped potential of such preemption in defending against plaintiffs' claims.

Our final article, *Express Preemption of Consumer Protection Actions*, delves into express preemption in the context of state consumer protection actions. Specifically, it addresses how express preemption provisions of the FDCA provide a potent defense against state law causes of action by emphasizing against patchwork State drug and device requirements.

***Pro Te: Solutio** Editorial Board*



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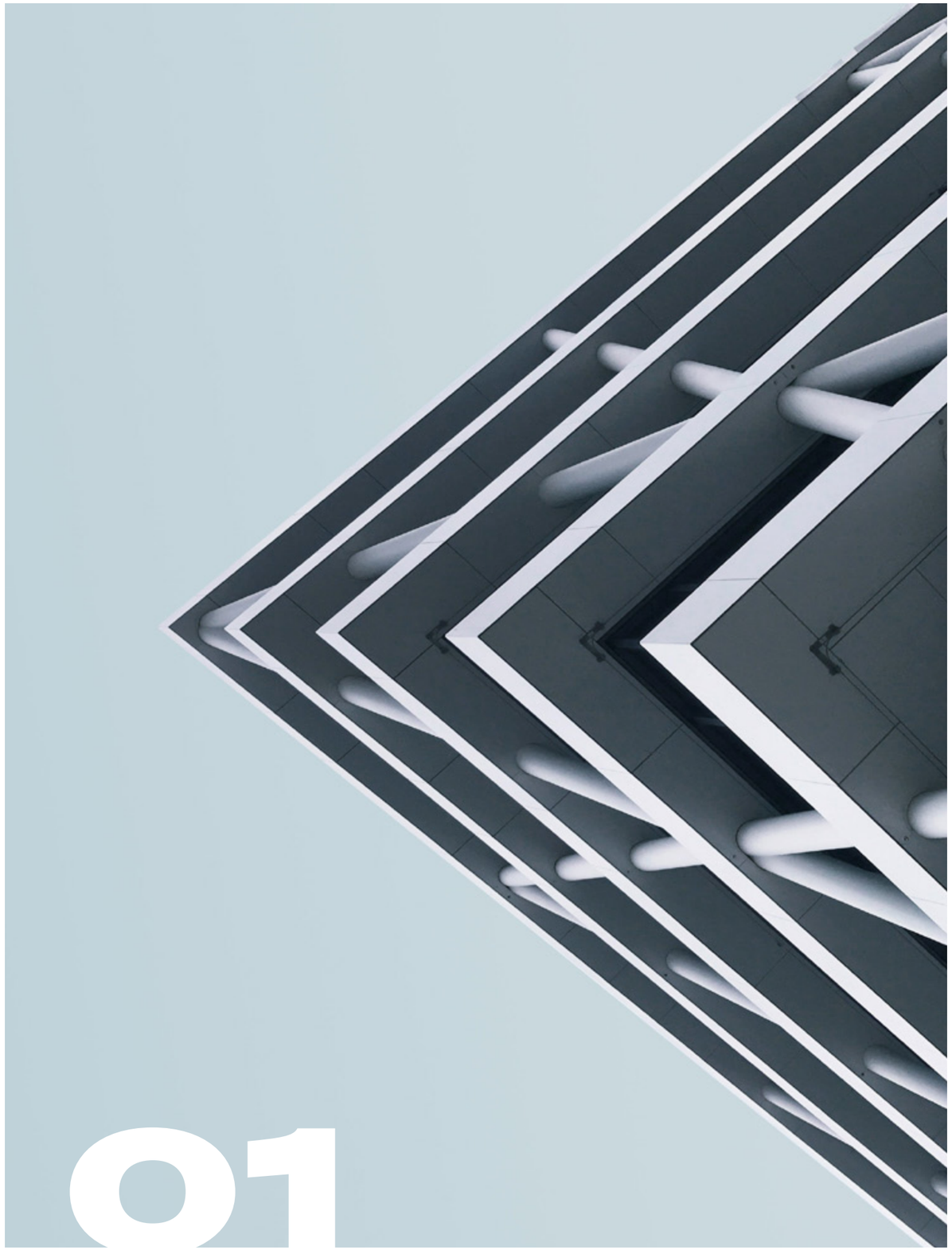


01

A Novus Vultus Ad Medicus Ante Depositionem

A New Look At The Doctor Deposition

Michael B. Hewes

In the context of the practice of medicine, we are all very familiar with the Latin phrase *primum est non nocere*. It means "first, do no harm" and is the ethical guiding principle in the medical profession. Inherent in this phrase is the understanding that physicians, as part of their work, must stay up to date with the evolving practice of medicine. Over the past 20 years, the advent of the internet and other technological innovations, coupled with novel approaches to assessing, diagnosing and treating patients, has led to a paradigm shift in the way many doctors practice medicine. In many cases, it has resulted in more efficient medicine with better outcomes for patients—ranging from curing or eliminating diseases (such as hepatitis C) to cutting inpatient hospital stays from weeks to days.

So what about us defense lawyers? Should we, as practitioners of one of the other learned professions, likewise move out of our comfort zones and embrace changing practices, thoughts or ideas? Of course we should, and while we have willingly and eagerly accepted the changes on the technology front, we have been less than zealous when it comes to adopting—or even considering—different litigation practices and techniques. This article focuses on a new, if not novel, means of approaching the heretofore routine

doctor deposition. While it certainly will not fit every situation, there are times when some of this approach can have a positive impact on the outcome of the case. We would all agree that such a result *est bonum*.

Since the publication of *Reptile: The 2009 Manual of the Plaintiff's Revolution* some 10 years ago, we have seen an evolution of tactics and styles in the way depositions of company witnesses have been taken in personal injury litigation. While these new methods may have been collectively saddled with a moniker that sounds like a title for a fifth grade science fair project, the Reptile theory is still being utilized today. Why? Because this unconventional, outside-the-box approach to corporate depositions has created a shift in the way plaintiffs' lawyers take depositions. More importantly, we are still discussing the Reptile theory today because, in many cases, it has worked.

Used effectively by plaintiff's counsel, Reptilian techniques can make a company witness squirm, flatten litigation momentum and themes, and have a tendency to lodge the stomachs of the lawyers defending those depositions squarely in their throats. Over time, however, we have adapted. Through training, targeted witness preparation, issue-focused redirect examinations and effective motion practice, we have worked to neutralize and eliminate those jury-friendly sound bites. Both sides now approach the corporate deposition with a newfound appreciation of what is at stake—and the best attorneys plan accordingly.

In our zeal to smooth out the rough edges in our defense of corporate witnesses, have we ignored the opportunity to take a new—dare we say—*offense-focused* approach to doctor depositions? Arguably, some of the most important testimony in a pharmaceutical or medical device case comes from the treater, prescriber or implanting physician. Jurors often perceive the providers as neutral players in the game, unsullied by expert fees and untethered to long histories of associating with law firms or litigation. Such doctors are seen as erudite individuals who are not out to serve as advocates for a particular person or company but rather as witnesses who, through their training, education and experience, have made objective decisions and unbiased choices in their approach to treating the named plaintiff and utilizing or prescribing the product at issue in the case.

The tired practice of following an outline loosely based on *Introduction, Credentials, Records Review, Opinion and Thank You For Your Time, Doctor* is over.

So why do we continue to take physician depositions as if we are still in the stone age? Do our court reporters come to the conference room with a pad and pencil ready to write down every word? Do the tables come outfitted with ashtrays for our smokes and carafes of stale water with cloudy ice cubes? Of course not. Likewise, the substantive material in our outlines should not elicit memories of the days of British Sterling cologne and home permanent kits.

The tired practice of following an outline loosely based on *Introduction, Credentials, Records Review, Opinion and Thank You for Your Time, Doctor* is over. Or, at least it should be. We have a duty as counsel to leave the "take the deposition now and deal with it later" attitude that seems to have become commonplace in some circles. Of course, a revolutionary, game-changing deposition may not be possible with every case. It is certainly not possible with every doctor, as some may have developed steadfast views against our product before we even serve the Notice. But it doesn't mean we shouldn't try.

Qui, Quid, Ubi, Quod, Cur, Quam?

Who, What, Where, When, Why, How?

Take Them out of *the Woodshed*

The old idiom "take them out to the woodshed" harkens back to the days when a child or individual would be taken out of the house to the proverbial woodshed for some one-on-one behavioral modification. In the context of depositions, it refers to the practice of plaintiffs' lawyers having ex parte meetings with doctors before the deposition to discuss the plaintiff's theories and to share cherry-picked, out-of-context corporate documents.

As a defense lawyer, it is important that you are aware of conversations, meetings, teleconferences, communications, etc. between counsel for the plaintiff and the doctor before the first question is asked under oath. Once the deposition starts, it is even more important to explore these meetings on the record so that the jury understands the who, what, where, when,

why and how they transpired. Those men and women in the box generally have no idea to what degree either side has discussed the case with the doctor—and most likely have no idea that contact has even been allowed. If you happen to have a judge who allows the plaintiff to have ex parte contact with healthcare providers, then you have a duty to go beyond the fact that the meeting merely occurred and let the jury know that not only did you not attend—you were never invited.

Potential lines of questioning regarding this point may include the following:

- *We met for the first time today when I introduced myself to you in advance of this deposition, correct?*
- *Have you ever been contacted by an attorney who represents the plaintiff in [current] litigation?*
  - » *By whom? When?*
  - » *What is your understanding of why the attorney contacted you?*
  - » *What was the nature of the conversation?*
- *Did you meet with any lawyers prior to the deposition?*
  - » *If so, with whom did you meet?*
  - » *Were they lawyers retained by the plaintiff in this litigation?*
  - » *When? Where? For how long?*

If the doctor met with plaintiff's counsel, ask the following questions:

- *Plaintiff's counsel is not representing you at this deposition, correct?*
- *What did you discuss with plaintiff's counsel?*
- *Did plaintiff's counsel compensate you for your time?*
- *Have you had any discussions with plaintiff's counsel about being compensated for your time meeting with them or reviewing documents?*
- *Did they show you any documents?*
- *Did they show you any internal company documents?*
- *Did they show you any scientific literature?*
- *Did they discuss with you any internal company documents?*
- *Did they discuss with you any scientific literature?*
- *Did they discuss with you any studies that have been conducted on [product]?*
- *Did they ask you to appear at a future trial of this case?*
- *Was I present?*
- *Was anyone representing [product or client] present?*
- *Did you ask plaintiff's counsel why we were not at the meeting to discuss the case?*
- *Did plaintiff's counsel say or suggest we were invited but did not show up?*
- *In fact, plaintiff's counsel had this meeting with you and showed you documents and discussed the case, yet they made no effort to include us—the lawyers representing [product or client]—in that meeting or discussion?*

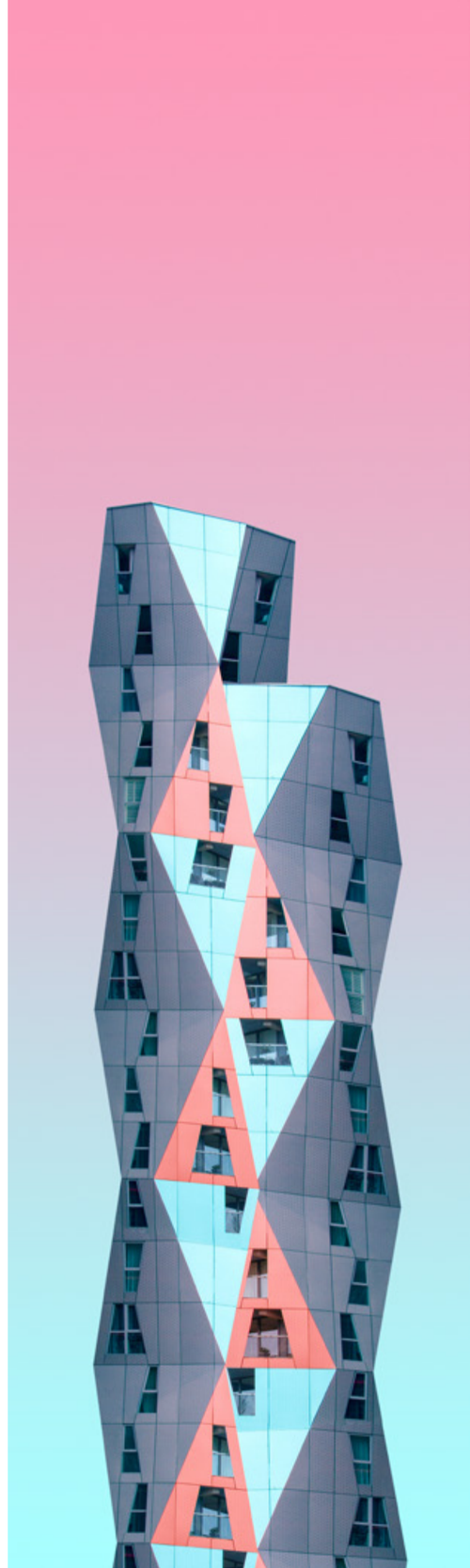
Timendi Causa Est Nescire

The Cause of Fear Is Ignorance

Put Corporate Documents in Context

It is no secret that in most personal injury cases involving pharmaceuticals or medical devices, counsel for the plaintiff would prefer to spend 90% of their case trying the company and 10% (or less) trying the particular facts related to the allegedly injured party at hand. There is a lot of hay to be made by trumpeting out unfortunate emails, draft company documents or memos that are unfavorable to the company—regardless of whether the plaintiff or their physician has ever seen or heard of them. That is precisely why, in pre-deposition prep sessions, plaintiffs' lawyers may spend hours with a doctor walking through document after company document to set the table for the "wouldn't you have liked to have known" questioning. It does not matter that the doctor has not seen the documents, that the documents have little or nothing to do with the science of medicine surrounding the product, or that the documents are in no way temporally related to the care and treatment of the patient. What matters is that effective use of corporate documents can poison the well as to the physician's impression of the company and its behavior—and make them less reluctant to make concessions that may play against the patient.

If you learn during the early questions that a doctor has reviewed certain documents, you must assume they have seen the worst of the worst. You must also assume that in their meeting with the doctor, counsel



for plaintiff did little or nothing to provide a balanced assessment of the documents or to put those documents in context. They certainly did not show them the documents or timeline surrounding whatever issues were discussed or referenced therein. Likewise, they did not show the doctor any of the corporate testimony involving drafters of the documents, emails or memos that may have shed some light on what was said, when it was said and why it was sa*Id.* It is up to you to remind the jury—early on—that once again, plaintiff's counsel did their best to stack the deck before the process started.

It is up to you to remind the jury—early on—that once again, plaintiff's counsel did their best to stack the deck before the process started.

The purpose of going through this exercise is twofold. First, it shows that the documents were shown in a vacuum, without regard to context or content. Second, it provides you, the questioner, an opportunity to bring the line of questioning back to the documents that doctors are most familiar with—medical records—and show, by analogy, that a single document, standing alone, does little to educate the physician on the issue at hand.

Potential lines of questioning regarding placing documents in context may include the following:

- *Did plaintiff's counsel show you several documents prior to this deposition?*
- *As you understand it, those documents are corporate documents that the plaintiff's lawyer told you were from [company]?*
- *I want to bring the facts of this case back to the jury. But before I do, just so there is no confusion:*
  - » *You do not work for [company]?*
  - » *You have never worked for [company]?*
  - » *Before your deposition in this case, you never even saw any of those documents?*
  - » *The first time you saw the documents were **before** today where you are being recorded and have been sworn in under oath?*
  - » *Since the deposition, you have not seen any company documents?*
  - » *You did not ask for the documents that you were shown?*
  - » *You did not even know the plaintiff's lawyer was going to show you [company documents]?*
  - » *Do you know how many millions of documents [company] has produced in this case?*
  - » *Yet the plaintiff's lawyer only showed you a few of them?*
  - » *Do you agree it is important when you look at a document to put it into context?*
    - *Like a medical record?*
      - *When you see a patient for the first time, you want to know the history?*
      - *You want to put what they are telling you in terms of their presentation into context?*
      - *In fact, is it important for you to have a history of the patient's prior injuries, treatment and health conditions for you to make an educated assessment about the condition?*
      - *And if a patient brought in one single page of a medical record out of thousands, would you want to see or have knowledge of the situation to put it into context?*
      - *Otherwise, you may misinterpret it?*
      - *Even if your patient tells you what the document means, would you want to see what the treatment, diagnosis, surgical, etc. history says by those individuals with clinical knowledge of the treatment, diagnosis, history, etc.?*
  - » *When the plaintiff's lawyer showed you those documents:*
    - *They did not put it into context?*
    - *They did not invite me to attend?*
    - *They did not invite any of the authors of the documents to attend?*
    - *They did not invite any of the recipients of the documents to attend?*
    - *They did not provide any of the background data, underlying documents or emails leading up to that document?*
  - » *That being the case, for you to fully understand that document and be educated on it—like a medical record—would you need a proper and thorough history of that document?*
  - » *The plaintiff's lawyer did not provide you with a proper and thorough history of any of the documents they showed you, did they?*
  - » *But what you do have here is your history in the care and treatment of the plaintiff, correct?*
    - *You took those histories?*
    - *You had the benefit of the plaintiff's medical record and past illnesses, ailments and comorbidities?*
    - *Unlike the company records, you have an educated background as to the medical records and documents for [plaintiff]?*
  - » *For the jury, I want to shift gears and let's finally talk about what you know and what you were asked to come here to talk about—your records and your care and treatment of [plaintiff].*

Veritas Odit Moras

Truth Hates Delay

Put the Plaintiff's Medical History Front and Center

At this point, you should have the attention of both the doctor and jury. By now, before any substantive shots have been fired, you will have established that the corporate documents were not only shown out of context but also that they have nothing to do with the plaintiff—which is why the doctor is here. Now you have a logical segue to the medical records. If the facts warrant, you should use this moment to detail the plaintiff's relevant preexisting clinical conditions—and put them front and center before the jury and the doctor.

It is not uncommon for a treating physician giving a deposition to have little or no independent recollection of the plaintiff or of their treatment of the plaintiff. If this is the case and if the plaintiff experienced substantive or significant comorbidities leading up to the implant, prescription or ingestion, then take the time to walk

through those comorbidities in a linear fashion. If they are numerous, authenticate and mark each individual medical record that identifies a history of infarctions, diabetes, smoking, noncompliance, etc. as an individual exhibit. It makes it easier if the records ultimately go back to the deliberation room to be broken down and separated—much easier than an unwieldy stack of hundreds of pages of records.

Moreover, if you feel that a list of significant comorbidities would serve as an impressive demonstrative, then itemize the comorbidities on a piece of paper as the doctor identifies each item as clinically significant. When you are done, have the doctor clearly confirm what the list represents. Ask the doctor to sign it before you mark it as a separate exhibit. It is one more way to indirectly and tangibly bring the doctor back into the courtroom months down the road.

Use Informed Consent, Warnings and Expectations to Your Advantage

Having now laid the foundation for the plaintiff's health condition and having taken a trip through time leading up to the allegations at issue, you must then make the call to determine how deep you want to go regarding substantive opinions about the product, outcomes, diagnosis and prognosis. This line of questioning would generally fall into those reserved traditional outlines. However, you now have the added benefit of having refreshed the physician's recollection while educating the jury on the relevant health issues and history saddling the plaintiff—before the product was ever used and before the alleged injury occurred.

Now you must decide if any of the allegations in the complaint can be taken down or neutralized by the consent process; the warnings from the Instructions For Use (IFU), product label or package insert; or common knowledge in the medical field. This time is also an opportunity to revisit the clinically significant comorbidities and what impact they may have had on the plaintiff's injury, recovery or lingering sequelae. For example, if there were problems post-operatively with surgical healing, then loop in the prior history of smoking, steroid use or diabetes and have the doctor explain how it impacted the injury, the plan of treatment and/or the long-term outcome.

Establish Absence of Injury in Medical Records

By this point, you have established the importance of medical records as a critical part of a true and accurate history. You should also incorporate questioning to elicit testimony that physicians rely on prior histories for a number of reasons—not the least of which is to make good, solid, history-based medical decisions going forward. If a physician thinks a certain medication caused an adverse outcome for a patient, then they would certainly chart it so that future treaters would have the benefit of that knowledge and steer the patient away from such therapies in the future. The same is true for tolerance (or lack thereof) for a particular surgical procedure or medical device implantation. If yours is a case where the healthcare providers did not cite or blame your product on the outcome, then establish the absence of any causal link between the product and the outcome. Also establish the absence of any addendum, correction or revision to the record since the filing of the lawsuit and since the deponent has discussed the case with the plaintiff's counsel. Many physicians will admit they are trained—for charting purposes—that if it's not in the medical record, it didn't happen. If the records do not reflect a causal link, then the physician's opinion as to your product or device should be consistent.

Pro Re Nata

As Needed; As the Occasion Arises

Qualify the Physician—Maybe

Back in the day, one of the first topics covered at the deposition was the physician's credentials. After the Notice of Deposition is marked and covered, per tradition, the next exhibit would have been the physician's curriculum vitae, which would have been covered from A to Z. Medical school, internship, residency, fellowship? Check. Board certified? Check. Privileges in hospitals in the area? Check. Published on the topic? Check. And the list goes on, with most of us quietly congratulating ourselves after the fact on our ability to read a CV into the record.

But you have to ask yourself this question: Why qualify early? Other than having the doctor introduce themselves as a physician who participated in the care and treatment of the plaintiff, why would you go any deeper at the beginning of the deposition? A better, more reasoned approach would be to make the call

regarding qualification at the end of the deposition. If the doctor flips on you, is difficult or provides testimony that you hope to never see or hear again, then you certainly would not take steps as your questioning winds down to walk through their training, education and experience, would you? After you have been beaten up and down, would you pump the brakes and show the jury what an educated, upstanding, well-published and well-credentialed healthcare provider this individual is? No. So why do it at the beginning—before you know what they are going to say?

Vicis, Vices

Change, Changes

As noted above, these practice points may not be applicable for every case, in whole or in part, nor should they be interpreted as suggesting change for the sake of change. What they should do is challenge us to take the reins and step outside our comfort zones. Plaintiffs' lawyers and seasoned doctors are expecting the same old, same old when it comes to questioning. Use the few hours you have to educate the doctor and the jury in a manner that allows you to frame client-friendly lines of questions. After all, innovation in your questioning could very well be the *sine qua non* of your success.

Finis

NO WAY AROUND IT:

THE NEED FOR FEDERAL "PERMISSION AND ASSISTANCE" CAN PREEMPT A STATE TORT DUTY

Luther T. Munford and Erin P. Lane

Note: Butler Snow represents companies that have been parties to cases referenced in this article. The information in this article derives solely from an analysis of the publicly reported decisions.

In the simplest case for federal preemption, federal law prohibits conduct that a state tort duty would require, such as a change in the design of an approved medical device to cure an alleged defect. Because federal law is supreme, it preempts that duty.[1]

In 2011, the U.S. Supreme Court extended this principle and held that, even absent a federal prohibition, federal law would preempt a state tort duty if federal "permission or assistance" were required before the defendant could comply with the state duty. In *PLIVA, Inc. v. Mensing,*[2] the plaintiff challenged the accuracy of the label on a generic drug. Under federal law, the manufacturer could not change the label without the permission of the Food and Drug Administration (FDA). In an opinion by Justice Clarence Thomas, the Court not only found preemption but also rejected a claim that the manufacturer had a duty to ask for the change.

The test, the Court said, was whether the defendant could "independently do under federal law what state law requires of it,"[3] and:

> [W]hen a party cannot satisfy its state duties without the federal government's special permission and assistance, which is dependent on the exercise of judgment by a federal agency, the party cannot independently satisfy those state duties for preemption purposes.[4]

The Court dismissed contentions about what the FDA might do if a change had been requested as mere "conjectures."[5]

Since *Mensing,* parties have debated the reach of this doctrine. While the answers have not been uniform, in general they have been as follows:

- *Is it limited to generic drug cases? No.*
- *Is it limited to FDA cases? No.*
- *Can it be avoided by arguing that the defendant should have simply stopped selling the drug or device? No.*
- *Can it be avoided by arguing the defendant had a duty to act differently when the defendant first sought permission to market the drug or device? No.*

Here are some of the leading decisions on both sides:

"Special assistance and permission" preemption is not limited to generic drug cases.

As would be expected, defendants have successfully invoked "special assistance and permission" preemption in cases (like *Mensing*) that challenge the composition or labeling of a generic drug.

Defendants have successfully invoked "special assistance and permission" preemption in cases, like *Mensing*, that challenge the composition or labeling of a generic drug.

In *Metz v. Wyeth LLC*,[6] the United States District Court for the Middle District of Florida held that any claim that a generic drug manufacturer "should have redesigned metoclopramide to alleviate the risks associated with its long-term use" as well as any claim that it "should have pulled the generic version … from the market," were preempted.[7]

In *Strayhorn v. Wyeth Pharms., Inc.*,[8] the United States District Court for the Western District of Tennessee decisively stated, "*Mensing* means what it says: all failure-to-warn claims against generic drug manufacturers are preempted if generic manufacturers cannot independently alter their warning labels."[9]

But the courts have not stopped there. They have also applied the doctrine to brand-name drugs in rejecting design defect claims, i.e. claims that the manufacturer should have changed the formulation or dosage of the drug or made some other "major change" to the drug's design.[10] Such a change requires FDA permission, even though it is not necessarily required to change brand-name labeling.

For example, in *Yates v. Ortho-McNeil Pharm., Inc.*,[11] the Sixth Circuit determined that a plaintiff's design defect claim was preempted when the plaintiff's state law claim would have required the defendant (a brand-name manufacturer) to change the product's design.[12] The Sixth Circuit held that the plaintiff's claim was "clearly preempted" because "[q]uite simply, federal law prohibited defendants from decreasing the dosage of estrogen post-approval." In other words, any such design change would require the FDA's permission.[13]

In *Barcal v. EMD Serono, Inc.*,[14] the United States District Court for the Northern District of Alabama found that the plaintiff's design defect claims were preempted because once the FDA approved the formulation of the prescription fertility drug at issue, the manufacturer could not change the drug's composition without the FDA's prior approval (i.e., the FDA's special permission and assistance).[15]

In *Robinson on Behalf of T.R. v. Eli Lilly & Co.*,[16] the plaintiff's design defect claim was that "the chemical makeup of Prozac … created the risk suffered by T.R." In other words, the plaintiff claimed the formula of Prozac itself was defective.[17] The United States District Court for the Eastern District of Kentucky found that the plaintiff's design defect claims were preempted because "Eli Lilly could not have independently made such fundamental changes to Prozac's formula."[18]

At issue in *Gustavsen v. Alcon Laboratories, Inc.*[19] was whether the defendants could be required by state law to design the dropper tips of the containers dispensing their respective prescription eye drops in such a way as to dispense smaller drops (i.e., to dispense less solution).[20] The United States District Court for the District of Massachusetts determined that because changes to the size or shape of the dropper tip would be "major changes" under the applicable FDA regulations,[21] such changes would require preapproval by the FDA. In other words, once the original container or container closure system was approved by the FDA, additional changes to the container closure system could not be made without the FDA's special permission and assistance.[22] *See also Mutual Pharmaceutical Co., Inc. v. Bartlett:* ("[o]nce 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'").[23]

"Special permission and assistance" preemption is not limited to FDA cases.

Courts have applied this conflict preemption principle in cases that have nothing to do with the FDA or with drugs or devices, which reinforces the view that it is not confined to generic drug cases.

In *Horsemen's Benevolent & Protective Ass'n-Ohio Div. Inc. v. DeWine*,[24] the Sixth Circuit Court of Appeals examined whether an Ohio statute allowing racetracks to "secure authorization to simulcast races [for purposes of off-track wagering] even if they have not obtained consent from the horsemen's group" was preempted by a federal statute requiring written consent of the horsemen's group to off-track wagering.[25] Applying *Mensing,* the Sixth Circuit found that the state and federal laws "directly conflict[ed]" and, as a result, the Ohio statute was preempted.[26]

In *Sikkelee v. Precision Airmotive Corp.*,[27] the Third Circuit Court of Appeals vacated a summary judgment ruling based on "field preemption" but remanded the case so that the district court could consider the application of "traditional conflict preemption principles."[28] Field preemption applies when "federal law leaves no room for state regulation" and when Congress has expressed "a clear and manifest intent to supersede state law" in a certain field.[29] With respect to conflict preemption, the Third Circuit drew an analogy between the issuance of "type certificates" by the Federal Aviation Administration (FAA) under the Civil Aeronautics Act and Federal Aviation Act[30] and the FDA's preapproval process for pharmaceutical labeling, as well as the preapproval process for certain medical devices under the Federal Food, Drug and Cosmetic Act.[31]

The court noted that the FAA issues a type certificate when it has determined that a product is "properly designed and manufactured, performs properly, and meets the regulations and minimum standards prescribed under [49 U.S.C. §] 44701(a)."[32]

Further, with respect to medical devices, the court noted that "just as aircraft manufacturers may not make major changes to or deviate from their type certificates without the FAA's sign-off," medical device manufacturers are required to obtain approval from the FDA before deviating from an FDA-approved design.[33] The court recognized that under these "analogous preapproval scheme[s] … where manufacturers are unable to simultaneously comply with both federal and state requirements, state law design defect claims are conflict preempted …"[34]

Finally, the court confirmed that, "[u]ltimately, where a party cannot 'independently do under federal law what state law requires of it,' the state law is conflict preempted."[35] On remand, the United States District Court for the Middle District of Pennsylvania granted the manufacturer's motion for reconsideration and entered summary judgment in the manufacturer's favor.[36]

On a further appeal, however, the Third Circuit reversed the portion of the district court's summary judgment opinion finding Sikkelee's claims to be conflict-preempted.[37] The Third Circuit found that the manufacturer could have and in fact did change the design set forth in the type certificate. Thus, it was not like the generic manufacturers in *Mensing* and *Bartlett* "who were unable to deviate from the brand-name manufacturers' labels."[38]

In *BP America Inc. v. Chustz*,[39] the United States District Court for the Middle District of Louisiana applied "impossibility preemption" to a Louisiana state law cease and desist order requiring removal of orphaned anchors, finding it was impossible for BP to comply with both Louisiana law and a federal on-scene coordinator's prohibition.[40] In doing so, the court noted that "[t]he question for 'impossibility' is whether the private party could independently do under federal law what state law requires of it."[41]

In *Backus v. General Mills Inc.*,[42] the United States District Court for the Northern District of California found that the plaintiff's claims regarding "the use of trans fats in the form of partially hydrogenated oil (PHO) in their baking mix products" were preempted where such claims "deal[t] with regulation of exactly the same products under both state and federal law and [sought] to render PHOs illegal before the compliance date despite the FDA's intentional setting of the compliance date in June 2018."[43]

Preemption cannot be avoided by arguing that the defendant should have stopped selling the drug or device.

In *Bartlett, supra,* the Court held that a state law failure-to-warn claim was preempted by federal law that prohibited generic manufacturers from making any unilateral changes to a drug's label. It rejected a claim that the defendant could comply with state law and not violate federal law if it stopped the sale of the drug altogether:

> We reject this "stop-selling" rationale as incompatible with our preemption jurisprudence. Our preemption cases presume that an actor seeking to satisfy both his federal and state obligations is not required to cease acting altogether in order to avoid liability.[44]

Preemption cannot be avoided by arguing that the defendant had a duty to act differently before the FDA granted permission to market the drug or device.

The Sixth Circuit in Yates followed *Mensing* and rejected the plaintiff's argument that no federal law would have prohibited defendants from designing a different drug *before* FDA approval:

> To imagine such a preapproval duty exists, we would have to speculate that had defendants designed [the drug] differently, the FDA would have approved the alternate design. Next, we would have to assume that [plaintiff] would have selected this method of birth control. Further yet, we would have to suppose that this alternate design would not have caused [plaintiff] to suffer a stroke. This is several steps too far … [T]he ultimate availability to [plaintiff] is contingent upon whether the FDA would approve that alternate design in the first place … Defendants could not have complied with whatever preapproval duty might exist without ultimately seeking the FDA's approval prior to marketing [the drug], and certainly prior to [plaintiff's] use of the drug.[45]

This was not enough, however, to convince the court in *Guidry v. Janseen Pharms., Inc.*[46] There, the United States District Court for the Eastern District of Louisiana expressed a concern that adhering to Yates's rejection of the "preapproval" design defect theory would effectively foreclose Louisiana plaintiffs from ever bringing a defective design claim against drug manufacturers.[47] The court went on to embrace the "preapproval" theory, holding that pursuant to the Louisiana Products Liability Act:

> Louisiana law imposes a duty on all manufacturers to consider feasible, alternative designs and

> reasonably weigh the risks and utility of the final product before it leaves the manufacturer's control. Federal law does not prevent a drug manufacturer from complying with this state-imposed duty before seeking FDA approval. Far from impossible, the two are complimentary, preferable and perhaps necessary to protect the public health and assure the safety, effectiveness and reliability of drugs.[48]

On this basis, the court found that "in the narrow, pre-FDA approval context, the plaintiff's defective design claim is not preempted by federal drug law."[49]

The United States District Court for the Southern District of Indiana also declined to follow *Yates.* In *Warren v. Boehringer Ingleheim Pharmaceuticals, Inc.*, [50] the court expressed its belief that the Sixth Circuit's impossibility preemption analysis was too "simple" and failed to interpret *Mensing* correctly. The court concluded:

> [B]ecause the manufacturers have neither identified the specific state and federal duties at stake in this case, nor shown clear evidence that, if FDA approval of the state-mandated change is required, such approval would be withheld, the manufacturers are not now entitled to dismissal based on impossibility preemption.[51]

On the other hand, in *Gustavsen v. Alcon Labs., Inc.*,[52] discussed *supra,* the United States District Court for the District of Massachusetts, examining *Yates* and *Guidry,* found "the Sixth Circuit's conclusion in Yates more consistent with [*Mensing*] and *Bartlett.*" Following *Yates,* the court found:

> As in *Bartlett,* defendants here could not have marketed droppers that complied with state consumer protection and unjust enrichment laws in the manner plaintiffs advocate without the FDA's prior approval. It is irrelevant that the defendants could have designed an entirely different product before they sought approval, which may never have been granted. … Therefore the court concludes that plaintiff's claims are preempted.[53]

"Special assistance and permission" preemption is not limited to generic drug cases—or FDA cases for that matter.

In short, "special assistance and permission" preemption is not limited to generic drug cases—or FDA cases for that matter. Nor can this preemption be avoided by arguing that the defendant should have stopped selling the drug or device, or that the defendant should have acted differently before the federal agency in question gave permission for the defendant to act. From a defendant's perspective, there is great potential to use this somewhat narrow area of the law strategically.

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[1] *Riegel v. Medtronic,* 552 U.S. 312 (2008).
[2] *PLIVA, Inc. v. Mensing,* 564 U.S. 604 (2011).
[3] *Id.* at 620.
[4] *Id.* at 623-24.
[5] *Id.* at 621.
[6] 872 F. Supp. 2d 1335 (M.D. Fla. 2012).
[7] *Id.* at 1341.
[8] 887 F. Supp. 2d 799 (W.D. Tenn. 2012).
[9] *Id.* at 813.
[10] In the context of FDA-approved Class III devices, manufacturers—like generic drug manufacturers—cannot change the design of a device without the "special permission and assistance" of the FDA. However, in *Fronczak v. Depuy Orthopaedics, Inc.,* 2014 WL 5175857, at *1 (M.D. Fla. Oct. 14, 2014), the United States District Court for the Middle District of Florida was persuaded by the plaintiff's argument that "uncertainties exist as to the applicability of *Mensing's* preemption with regard to the distributors of medical devices"—a category including the non-diverse defendant in the case. The device at issue was the Class III ASRTM XL artificial hip prosthesis. *See* 21 CFR 888.330 (Hip joint metal/metal semi constrained, with an uncemented acetabular component, prosthesis). The court noted that in resolving "uncertainties about the applicable law in favor of the plaintiff[,] … The plaintiff need not have a winning case; rather, the plaintiff need have only a possibility of stating a valid cause of action in order for the joinder to be legitimate." *Id.* at *2. Ultimately, the court concluded that

> The question of a generic drug manufacturer's ability to simultaneously comply with both state law and specific federal regulations governing pharmaceuticals is not analogous to the question of a distributor of a brand name medical device's ability to comply with both Florida law and federal regulations governing medical devices … [Indeed,] "[t]here is a marked difference between a duty requiring a drug manufacturer to physically change its federally approved label and a duty requiring a distributor to warn a third party of what the federally approved label or warning on file with the FDA says."

Id. at 3 (quoting *Zaremba v. Orthopedics, Inc.,* 2014 WL 3057400, at *4 n.2 (M.D. Fla. July 7, 2014)). As a result, the court "appl[ied] a presumption against the exercise of federal jurisdiction" and remanded the case.
Id. This reasoning seems directly contrary to *Mensing's* refusal to engage in "conjecture" as to what the FDA might or might not do.
[11] 808 F.3d 281 (6th Cir. 2015).
[12] *Id.* at 298.
[13] *Id.* at 298-99.
[14] 2016 WL 1086028, at *4 (N.D. Ala. Mar. 21, 2016).
[15] *Id.* at *4. *See Chambers v. Boehringer Ingelheim Pharms., Inc.,* 2018 WL 849081, at *4-5 (M.D. Ga. Jan. 2, 2018), *rev'd in part on other grounds,* 2018 WL 847246 (M.D. Ga. Feb. 13, 2018) (finding plaintiff's failure-to-warn claims that that would have required a 110-mg dose of Pradaxa in certain circumstances—a dose that has not been approved by the FDA—were preempted because any such dosage changes would have required the FDA's approval).
[16] 2018 WL 4039701 (E.D. Ky. Aug. 23, 2018).
[17] *Id.* at *6.
[18] *Id. See* generally *Barcal v. EMD Serono, Inc.,* 2016 WL 1086028, at *4 (N.D. Ala. Mar. 21, 2016) (finding plaintiff's design defect claims to be preempted because, once the FDA approved the formulation of the prescription fertility drug at issue, the manufacturer could not change the drug's composition without the FDA's prior permission).
[19] 272 F. Supp. 3d 241 (D. Mass. 2017).
[20] *Id.* at 249-50.
[21] *See Id.* at 250-51 (discussing "'reporting categories' for changes to previously approved drug products: major, moderate and minor"). *See also* 21 C.F.R. § 314.70(b)(2)(iii) (major changes requiring preapproval by the FDA include "[c]hanges that may affect drug substance or drug product sterility assurance, such as changes in the drug substance, drug product or component sterilization method(s) or an addition, deletion or substitution of steps in an aseptic processing operation"); Supplements and Other Changes to an Approved Application, 69 Fed. Reg. 18728, 18745 (April 8, 2004) (explaining that "[c]hanges in the container closure system, even if minimal, may affect the sterility assurance of the drug product and are a major change.").
[22] *See also Thompson v. Allergan USA, Inc.,* 993 F. Supp. 2d 1007, 1013-14 (E.D. Mo. 2014) (concluding "that reducing the amount of medicine in each [prescription eye drop] vial is a major change requiring prior FDA approval" and, accordingly, plaintiff's claims were preempted).
[23] 570 U.S. 472 (2013).
[24] 666 F.3d 997 (6th Cir. 2012).
[25] *Id.* at 999-1000 (citing Ohio Rev. Code § 3769.089(G) and 15 U.S.C. § 3004(a)).
[26] *Id.* at 1000-01.
[27] 822 F.3d 680, 703-04 (3d Cir. 2016).
[28] *Id.* at 708.
[29] *Id.* at 687-88.
[30] *Id.* at 683-84.
[31] *Id.* at 702-04.
[32] *Id.* at 684 (quoting 49 U.S.C. § 44704(a)(1)).
[33] *Id.* at 704.
[34] *Id.* at 702-03 (citing *Bartlett,* 570 U.S. at 480; *Mensing,* 564 U.S. at 618).
[35] *Id.* at 703 (quoting *Mensing,* 564 U.S. at 620).
[36] *See* 268 F. Supp. 3d 660 (M.D. Pa. 2017).
[37] 907 F.3d 701, 714 (3d Cir. 2018).
[38] *Id.*
[39] 33 F. Supp. 3d 676 (M.D. La. 2014).
[40] *Id.* at 694, 699-700.
[41] *Id.* at 684 (quoting *Mensing,* 564 U.S. at 620) (citing *Levine,* 555 U.S. at 573).
[42] 2018 WL 6460441 (N.D. Cal. Dec. 10, 2018).
[43] *Id.* at *1, *5.
[44] *Id.* at 487.
[45] Yates, 808 F.3d at 299-300.
[46] 206 F. Supp. 3d 1187 (E.D. La. 2016). *See also Mullins v. Ethicon, Inc.,* 147 F. Supp. 3d 478 (S.D.W. Va. 2015) (refusing to find preemption in medical device case on ground that FDA clearance is "unrelated" to a state safety requirement).
[47] *Id.*
[48] *Id.* at 1209.
[49] *Id.*
[50] 2017 WL 3970666 (S.D. Ind. Sept. 8, 2017).
[51] *Id.* at 15.
[52] 272 F. Supp. 3d 241 (D. Mass. 2017).
[53] *Id.* at 255 (internal citation omitted).

EXPRESS PREEMPTION OF CONSUMER PROTECTION ACTIONS:

PREVENTING A PATCHWORK OF STATE DRUG AND DEVICE REGULATIONS

Charles A. Byrd

The Supremacy Clause of the United States Constitution declares federal law to be the "supreme Law of the Land."[1] Thus, when federal law and state law conflict, the state law is preempted, or rendered without effect.[2] Under the Supremacy Clause, Congress has the authority to expressly preempt state law by including preemptive language in federal statutes. The Federal Food, Drug and Cosmetic Act (FDCA) contains several express preemption provisions that prohibit states from imposing certain regulatory requirements on food, non-prescription drugs, medical devices and cosmetics that do not mirror the requirements imposed by federal law.[3] These provisions apply not only to state statutes and regulations but also to legal claims brought by plaintiffs under state law.

The purpose of this article is to explore express preemption in the context of consumer protection actions, which are becoming more prevalent for drug and device manufacturers. State consumer protection acts (CPAs) historically have been viewed as a way for states to exercise their police powers over consumer health and safety by providing a private right of action for violations of the FDCA.[4] More recently, though, plaintiffs have begun to rely on CPAs to go beyond the FDCA and impose requirements on manufacturers that do not exist under federal law. Additionally, many CPAs empower state attorneys general and, in some cases, private plaintiffs to seek injunctive relief preventing manufacturers from marketing, labeling or selling their products in a manner that would violate the CPA, even if the manufacturer's conduct is in compliance with the FDCA. Thus, while a judgment in a typical product liability action may *induce* a manufacturer to alter its conduct, a consumer protection action presumably *requires* a change in conduct, and thus could require a manufacturer to violate federal law. This is the type of inconsistency that the FDCA's express preemption provisions were designed to prevent. Thefore, it is critical that manufacturers are able to identify the competing federal and state requirements implicated by a consumer protection action when evaluating the viability of an express preemption defense.

1. The First Step to Preemption: Identifying Applicable Federal Requirements

"The purpose of Congress is the ultimate touchstone in any preemption case."[5] Courts typically presume that Congress did not intend to preempt state law, especially on matters related to the states' historic police powers.[6] However, no such presumption exists where Congress has enacted an express preemption statute.[7] The existence of such a statute is clear evidence of Congress's preemptive intent with respect to a certain subject matter. "[W]hen Congress has made its intent known through explicit statutory language, the courts' task is an easy one."[8]

The FDCA contains express preemption provisions covering food,[9] medical devices,[10] non-prescription drugs[11] and cosmetics.[12] One court has explained that "[t]he whole point of [the FDCA's preemption provisions] is that it is not up to private litigants—or judges—to decide what is 'false or misleading.' It is up to the FDA."[13] These statutes all share a common thread of prohibiting any "state or political subdivision of a state" from "establish[ing] or continu[ing] in effect any requirement" that is "different from or in addition to, or that is otherwise not identical with, a requirement" under the FDCA or other applicable law.[14] The first step in the preemption analysis, then, is to identify any federal statutes or regulations that impose requirements that would be impacted by the plaintiff's lawsuit.

In *Riegel v. Medtronic, Inc.*, the United States Supreme Court was asked to decide whether the premarket approval (PMA) process for Class III medical devices enacted under the Medical Device Amendments to the FDCA constituted a federal requirement for express preemption purposes.[15] The Court first noted that the FDA's regulations provide that "[s]tate or local requirements are preempted only when the Food and Drug Administration has established specific counterpart regulations or there are other specific requirements applicable to a particular device under the act ..."[16] Thus, the critical inquiry was whether the PMA process imposed device-specific requirements.

The Court then looked to its prior decision in *Medtronic, Inc. v. Lohr*, in which it had held that the "substantially equivalent" standard enacted in 21 U.S.C. § 510(k) did not constitute a federal requirement and instead reflected "entirely generic concerns about device regulation generally."[17] The *Riegel* Court distinguished the PMA process from the substantial equivalency standard, reasoning that premarket approval imposes specific requirements on individual devices and is focused on safety, not just equivalence.[18] In other words, while devices that enter the market after substantial equivalency review have not been formally tested for safety or efficacy, the FDA may approve a device under the PMA process only after it determines that the device offers "reasonable assurances of safety and effectiveness."[19] Once PMA is granted, a device must be made with almost no deviations from the specification in its approval application.[20] Accordingly, the *Riegel* Court concluded that the PMA process for Class III devices constitutes a federal requirement that expressly preempts any conflicting state requirements.[21]

The court in *Mills v. Warner-Lambert, Inc.* relied on *Riegel's* analysis of the PMA process for medical devices in concluding that the New Drug Application (NDA) process and monograph systems used to approve non-prescription drugs also constitute federal requirements for preemption purposes.[22] The plaintiffs in *Mills* filed suit under Texas' CPA alleging that the defendants' over-the-counter lice treatments amounted to "snake oil" and did not actually kill lice.[23] In reviewing the defendants' preemption argument under the FDCA, the court first noted that one of the products in question originally was approved through the NDA process.[24] The other two drugs, on the other hand, had been approved through the FDA's monograph system.[25] To determine whether these regulatory processes amounted to "federal requirements" for the purposes of preemption, the court looked to cases interpreting the FDCA's Medical Device Amendments for guidance.[26]

First, the *Mills* court acknowledged that the premarket approval process for Class III medical devices had been deemed a "federal requirement" in *Riegel*.[27] Due to the striking similarities to the premarket approval process, the court held that the NDA process constituted a federal requirement.[28] The court further found that the monograph system was comparable to the FDCA's regulations for Class II medical devices, which have also been deemed to be federal requirements for preemption purposes.[29] Because the approved monograph for pediculicides contains specific labeling requirements applicable to the defendants' products, the court held that the monograph process also constituted a federal requirement.[30]

The defendants in *Riegel* and *Mills* successfully identified the federal statutes and regulations that would be impacted by the plaintiff's civil claims. On the

other hand, the defendant in *Canale v. Colgate-Palmolive Co.* was unable to identify any applicable federal requirement that would subject the plaintiffs' consumer protection claims to preemption, despite offering several options to the court.[31] The plaintiffs in *Canale* brought suit under New York's consumer protection statutes, arguing that the defendant had made false and misleading claims concerning the whitening capabilities of its Optic White toothpastes.[32] The defendant moved to dismiss the plaintiffs' claims, arguing they were expressly preempted by the FDCA.[33] The defendant relied on three purported federal law requirements as the basis for its preemption argument. First, the defendant pointed to the final FDA monograph regulating other-the-counter (OTC) anticaries drugs, which establishes "conditions under which OTC anticaries drug products ... are generally recognized as safe and effective and not misbranded."[34] The District Court found that the final monograph made no mention of whitening toothpastes or related products.[35] While the monograph permits the sale, without a new drug application, of products with certain active ingredients, "[i]t does not purport to address the issue raised by Plaintiff's claims here, or otherwise immunize any other representation made by the product's manufacturer."[36]

Next, the defendant in *Canale* argued that the FDA had specifically addressed the whitening effects of toothpaste in a non-final version of the anticaries monograph.[37] However, this version of the monograph discussed only whether a warning was appropriate regarding temporary surface teeth *staining* caused by products containing stannous fluoride.[38] Accordingly, the court found that the non-final monograph did not impose a federal requirement that applied to the plaintiffs' claims.[39]

Finally, the defendant in *Canale* pointed to the FDA's denial of a citizen petition filed by the American Dental Association, which requested that certain peroxide-containing tooth whiteners be subjected to regulatory classification as over-the-counter drugs.[40] Reviewing this document, the court determined that the FDA found insufficient evidence to determine whether they should be regulated as drugs.[41] The court then found that the FDA had not endeavored to regulate representations about peroxide-containing tooth whiteners at all when it rejected the citizen petition.[42] Because the defendant was unable to identify any federal requirements applicable to its products beyond the FDCA's general prohibition against false and misleading labeling, the court found that the plaintiff's state law claims were not expressly preempted.[43]

Riegel, *Mills* and *Canale* instruct that the existence of express preemption statutes within the FDCA, by itself, does not make for a successful preemption defense. Courts must still "identify the domain expressly preempted" by the statute in question.[44] It is also insufficient simply to point to the FDCA's general regulations governing drugs, medical devices and cosmetics. Manufacturers must dig deeper into the plaintiff's allegations to identify the specific federal regulations that touch on the plaintiff's specific allegations.[45] Otherwise, it will be difficult to prove that a plaintiff's consumer protection claim imposes a requirement that is different from federal law.

Riegel, Mills, and Canale instruct that the existence of express preemption statutes within the FDCA, by itself, does not make for a successful preemption defense.

The distinction between the holdings in *Mills* and *Canale* is also instructive. While the defendants in both cases relied on the FDA's monographs for their respective categories of products, only the monograph in *Mills* contained regulations that specifically applied to the subject matter of the plaintiffs' claims. Thus, the existence of a regulatory regime like a monograph may not be sufficient to preempt a state law claim.

2. Consumer Protection Actions Are State Law "Requirements" Under the FDCA

In *Bates v. Dow Agrosciences, Inc.*, the United States Supreme Court reasoned that a state law cause of action did not necessarily constitute a "requirement" for purposes of the express preemption provision found in the Federal Insecticide, Fungicide and Rodenticide Act because "[a]n occurrence that merely motivates an optional decision does not qualify as a requirement."[46] However, in reviewing the FDCA's preemption provisions, the Court more recently clarified in *Riegel* that "Congress is entitled to know what meaning this Court will assign to terms regularly used in its enactments. Absent other indication, reference to a state's 'requirements' includes its common-law duties."[47] Indeed, "[state] regulation can be as effectively exerted through an award of damages as through some form of preventive relief. The obligation to pay compensation can be, indeed is designed to be, a potent method of governing conduct and controlling policy."[48] Because the FDA is best equipped to balance the competing concerns of safety and effectiveness, state law liability that is premised on those same concerns can upset the balance. Thus, federal preemption can prevent a plaintiff from bringing *any* state law cause of action that would impose a requirement on the defendant that differs from the requirements imposed on it by federal law.[49]

Other courts have relied on *Riegel* to hold that the FDCA's preemption provisions apply to both statutory and common law causes of action, including consumer protection claims. In *Mills*, for example, the court found that there is no substantive difference between state law claims founded on common law duties and those founded on statutory duties. They also found that the FDCA's preemption provisions were drafted broadly enough to encompass any

cause of action that does not meet the definition of a "product liability claim."[50] The court in *Carter v. Novartis Consumer Health, Inc.* took a similar approach, finding that *Riegel* had adopted a particularly broad definition of "requirements."[51] The *Carter* court found that "*Riegel* held that *any* state law liability imposed upon a Class III device manufacturer who is otherwise in full compliance with FDA regulations may establish a 'requirement' that is 'different from, or in addition to' federal law."[52] The court also looked to Section 379r(c)(2), which provides that any requirements involving public "warning[s] of any type of drug" are subject to preemption.[53] The court reasoned that this provision "expands the universe of potentially preempted state law claims to include those that require additional warnings in the advertising for nonprescription drugs, and not only on the labeling."[54] The court concluded that, "[t]aken together, *Riegel* and § 379r(c)(2) suggest that virtually any state requirement that relates to the regulation of nonprescription drugs can be preempted, regardless of the common law theory under which it is brought."[55]

In light of *Riegel's* broad definition of "requirements," it is clear that state consumer protection claims qualify as state law requirements and fall within the scope of the FDCA's preemption provisions. Therefore, the next step in the analysis is to compare the requirements imposed by the plaintiff's state law claims to determine whether they conflict with federal law.

3. State Requirements That Do Not Mirror Federal Requirements Are Preempted

Critically, the FDCA's preemption provisions "[do] not prevent a state from providing a damages remedy for claims premised on a violation of FDA regulations; the state duties in such a case 'parallel,' rather than add to, federal requirements."[56] State requirements also need not use the exact same language as their federal counterparts.[57] Rather, the focus is on the equivalence, or lack thereof, between the requirements imposed by federal and state law. If the manufacturer cannot comply with both the FDCA and the state requirement, then the state law requirement must yield. Once a court has determined that federal law imposes requirements on the subject matter of the plaintiff's claims, this inquiry should be relatively straightforward.

The courts in *Mills* and *Carter* both made short work of determining that the plaintiffs' consumer protection claims imposed requirements that conflicted with the FDCA and therefore were preempted. The court in *Mills* reasoned that "[d]efendants can market their products in compliance with the FDA requirements or they can refrain from marketing their products in order to comply with the requirements (and avoid liability) imposed by Plaintiffs' lawsuit. They cannot do both."[58] Similarly, the court in *Carter* found that the defendants' liability for the plaintiffs' consumer protection claims was founded on the allegation that the defendants' products were not safe and effective for children under the age of six.[59] Because these claims deviated from the FDA's specific regulations establishing labeling and dosage requirements for the defendants' products, the court concluded that the plaintiffs' claims were preempted.[60]

The plaintiffs in *Carter* attempted to argue that their claims for monetary damages were not preempted because they did not force the defendants to deviate from the FDCA's labeling requirements.[61] While recognizing that a monetary judgment may induce, but not require, a manufacturer to alter its conduct, the court concluded that the United States Supreme Court's holding in *Riegel* did not suggest any distinctions between various theories of liability or categories of remedies sought: "if the defendant is in full compliance with FDA regulations, any non-parallel state law liability, including a jury verdict for damages, imposes a 'requirement' and is expressly preempted."[62] Because the plaintiffs did not allege that the defendants had violated any provision of the FDCA, their claims were not parallel.[63]

The plaintiffs' claims in *Mills* and *Carter* were preempted because they would have required the defendants to violate the FDCA in order to avoid state law liability. In *Vermont Pure Holdings, Ltd. v. Nestle Waters North America, Inc.*, however, the court found that the plaintiff's consumer protection claims were not preempted because they imposed a requirement that was identical to federal law.[64] In *Vermont Pure Holdings,* the plaintiff sued Nestle Waters North America (Nestle) under the Lanham Act and various state consumer protection acts for allegedly making false and misleading statements regarding the source, nature and purity of Poland Spring bottled water.[65] The defendant argued that the plaintiff's claims were preempted by the FDCA, which contains regulations explicitly defining "spring water."[66] The court rejected this argument, finding that the plaintiff's claims could proceed to the extent that they were based on the FDCA's definition of "spring water."[67] In other words, while the FDA's spring water regulations defined the scope of the federal requirement at issue, the mere existence of those regulations did not preempt the plaintiff's claims if those claims did not differ from the federal requirements.[68] In this regard, the plaintiff's cause of action merely sought to enforce the provisions of the FDCA.

4. Savings Clauses: What Is a Product Liability Claim?

Not all state law causes of action are preempted by the FDCA. In enacting the FDCA's preemption provisions, Congress carved out exemptions for claims brought under state product liability law, at least with respect to non-prescription drugs and cosmetics. The question of whether a consumer protection claim qualifies as a product liability claim is one that has not been heavily litigated. However, courts generally have agreed that this determination must be made by reviewing applicable state law. Courts have distinguished these two categories of claims by recognizing that injury to the plaintiff is an essential element of a product liability claim. Thus, consumer protection claims based solely on allegations of deceptive advertising or labeling, without evidence of a resulting injury to the plaintiff, do not fall within the scope of a product liability claim and are not exempted from preemption.

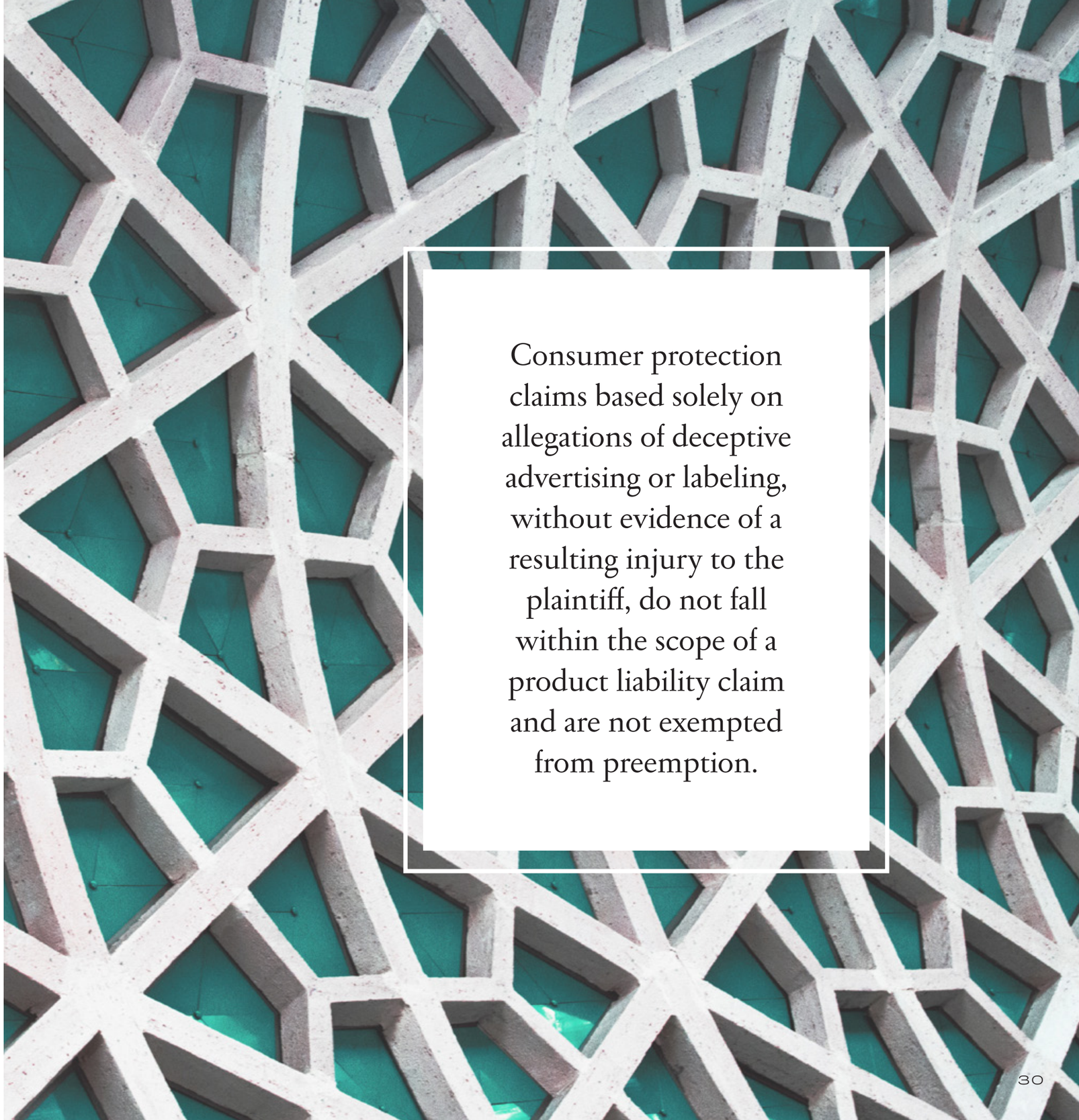
Mills and *Carter* are two examples of the rare cases in which the courts have been asked to analyze a plaintiff's consumer protection claims under the FDCA's preemption savings clause for non-prescription drugs. The plaintiffs in *Mills* argued that their claims were exempted from preemption by the savings

clause for product liability claims relating to non-prescription drugs.[69] They claimed that Congress intended Section 379r(e) to apply broadly to any action based on a defective product, regardless of its categorization under state law.[70] But the court rejected this argument, finding that "the statute's language reflects an intent to defer to each state's interpretation of 'product liability,' and thereby avoid interfering with the state's product liability regime."[71] Because the plaintiffs' claims did not meet the Texas statutory definition of a products liability claim—i.e., the plaintiffs did not allege personal injury, wrongful death or property damage—the court found that Section 379r(e) did not save their claims from preemption.[72]

The court in *Carter* applied a similar analysis to find that the plaintiffs' claims were preempted by the FDCA. The plaintiffs in *Carter* contended that their consumer protection claims qualified as product liability actions and therefore were saved from preemption by Section 379r(e).[73] The court rebuffed this argument, finding that injury to the plaintiff is an essential element of a product liability action under California law.[74] The plaintiffs had not alleged that they or their children were injured by the defendants' products. On the contrary, they alleged in their complaints that "damages for personal injuries ... are not within the scope of this case."[75] Thus, their claims could not be considered actions for product liability.

Two important lessons can be extracted from the courts' holdings in *Mills* and *Carter*. First, it is clear that the determination of whether the plaintiff's consumer protection claim qualifies as a product liability action turns on the applicable state law definition of a product liability action. Accordingly, defendants must review the applicable CPA and any case law interpreting that statutory scheme to determine whether any or all claims brought under the CPA are considered product liability actions. Courts in some states explicitly have held that claims brought under their CPAs do *not* qualify as product liability actions, but the answer will not be this straightforward in every state.[76] Defendants must still compare the elements of a product liability claim and a consumer protection claim and be prepared to highlight any substantive differences.

Second, the courts in *Mills* and *Carter* both distinguished claims seeking solely economic damages from those in which the plaintiff alleges a personal injury arising from the defendant's allegedly deceptive conduct. Because injury to the plaintiff is typically an essential element of a product liability



Consumer protection claims based solely on allegations of deceptive advertising or labeling, without evidence of a resulting injury to the plaintiff, do not fall within the scope of a product liability claim and are not exempted from preemption.

claim, consumer protection actions that do not allege an injury cannot take advantage of the product liability savings clause. Nevertheless, it is possible that a court would reach a different result if the plaintiff *did* allege an injury, even in the absence of an express tort claim. Therefore, it is important to identify if the plaintiff (whether they be a private individual or a state attorney general) has alleged a specific injury as a result of the defendant's deceptive practices.

Conclusion

The express preemption provisions of the FDCA provide a powerful defense against state law causes of action based on deceptive marketing and labeling of products. However, manufacturers must be prepared to identify the specific federal requirements that would be affected by the plaintiff's claim before they can present a successful preemption defense. Manufacturers must also carefully define the specific requirements imposed by the plaintiff's cause of action and explain how those requirements conflict with federal law. Finally, the manufacturer must be able to determine whether a plaintiff's claim can qualify as a product liability action under applicable state law, which may save it from preemption.

Given that consumer protection actions have become more ubiquitous in recent years, the defense of preemption should be raised whenever possible to prevent these actions from creating a patchwork of inconsistent drug and device requirements in every state.

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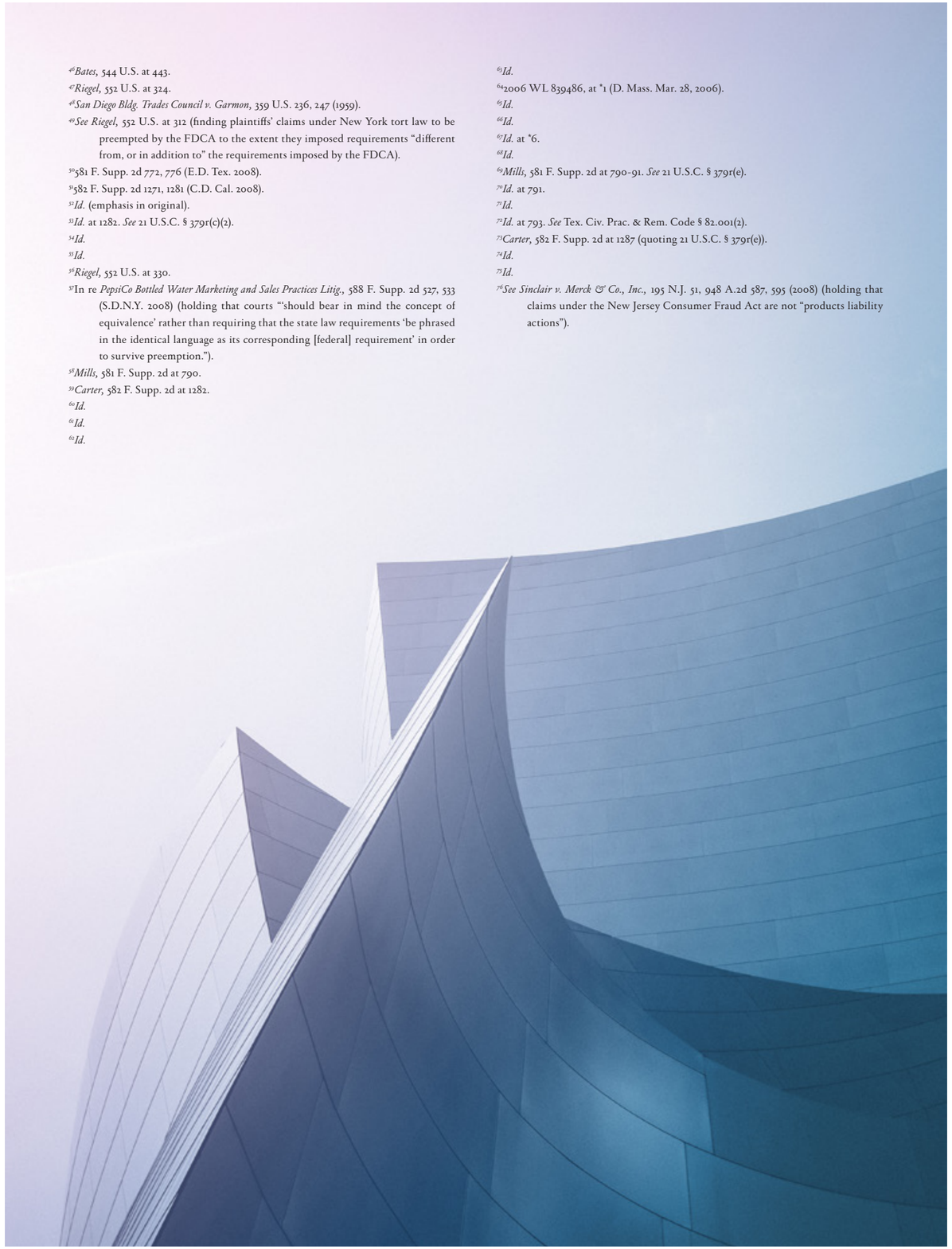
[1]U.S. Const. Art. VI, cl. 2.
[2]*See Maryland v. Louisiana*, 451 U.S. 725, 746 (1981) ("[W]e have long recognized that state laws that conflict with federal law are 'without effect.'").
[3]*See*, e.g., 21 U.S.C. §§ 343-1, 360k, 379r, 379s.
[4]*See Medtronic, Inc. v. Lohr*, 518 U.S. 470, 475 (1996).
[5]*Id.* at 494.
[6]*Altria Group, Inc. v. Good*, 555 U.S. 70, 77 (2008).
[7]*See Puerto Rico v. Franklin Cal. Tax-Free Trust*, 136 S. Ct. 1938 (2016).
[8]*English v. Gen. Electric Co.*, 496 U.S. 72, 79 (1990).
[9]21 U.S.C. § 343-1.
[10]21 U.S.C. § 360k.
[11]21 U.S.C. § 379r. No preemption provision exists for prescription drugs.
[12]21 U.S.C. § 379s.
[13]*Bowling v. Johnson & Johnson*, 65 F. Supp. 3d 371, 377 (S.D.N.Y. Nov. 4, 2014).
[14]*See*, e.g., 21 U.S.C. § 379r.
[15]552 U.S. 312 (2008).
[16]*Id.* at 322 (quoting 21 C.F.R. § 808.1(d)).
[17]*Lohr*, 418 U.S. at 501.
[18]*Riegel*, 552 U.S. at 323.
[19]*Id. See* 21 U.S.C. 360e(d).
[20]*Id.*
[21]*Id.*
[22]581 *F. Supp.* 2d 772, 776 (E.D. Tex. 2008).
[23]*Id.*
[24]*Id.* at 783.
[25]*Id.* at 783.
[26]*Id.* at 785-86.
[27]*Id.* at 785 (citing *Riegel, Inc.*, 552 *U.S.* 312; *Gomez v. St. Jude Medical Daig Division Inc.*, 442 F.3d 919 (5th Cir. 2006); *Martin v. Medtronic, Inc.*, 254 F.3d 573 (5th Cir. 2001) and *Stamps v. Collagen Corp.*, 984 F.2d 1416, 1420-22 (5th Cir. 1993)).
[28]*Id.*
[29]*Id.* at 787.
[30]*Id.* at 788.
[31]258 F. Supp. 3d 312, 316 (S.D.N.Y. 2017).
[32]*Id.*
[33]*Id.* at 318.
[34]*Id.* at 321.
[35]*Id.*
[36]*Id.*
[37]*Id.*
[38]*Id.*
[39]*Id.*
[40]*Id.* at 322.
[41]*Id.*
[42]*Id.*
[43]*Id.* at 323.
[44]*Cippollone v. Liggett Group, Inc.*, 518 U.S. 470, 484 (1996).
[45]*Lohr*, 518 U.S. at 500 (holding that federal requirements must be "'applicable to the device' in question, and, according to the regulations, preempt state law only if they are 'specific counterpart regulations' or 'specific' to a 'particular device.'"
[46]*Bates*, 544 U.S. at 443.
[47]*Riegel*, 552 U.S. at 324.
[48]*San Diego Bldg. Trades Council v. Garmon*, 359 U.S. 236, 247 (1959).
[49]*See Riegel*, 552 U.S. at 312 (finding plaintiffs' claims under New York tort law to be preempted by the FDCA to the extent they imposed requirements "different from, or in addition to" the requirements imposed by the FDCA).
[50]581 F. Supp. 2d 772, 776 (E.D. Tex. 2008).
[51]582 F. Supp. 2d 1271, 1281 (C.D. Cal. 2008).
[52]*Id.* (emphasis in original).
[53]*Id.* at 1282. *See* 21 U.S.C. § 379r(c)(2).
[54]*Id.*
[55]*Id.*
[56]*Riegel*, 552 U.S. at 330.
[57]In re *PepsiCo Bottled Water Marketing and Sales Practices Litig.*, 588 F. Supp. 2d 527, 533 (S.D.N.Y. 2008) (holding that courts "'should bear in mind the concept of equivalence' rather than requiring that the state law requirements 'be phrased in the identical language as its corresponding [federal] requirement' in order to survive preemption.").
[58]*Mills*, 581 F. Supp. 2d at 790.
[59]*Carter*, 582 F. Supp. 2d at 1282.
[60]*Id.*
[61]*Id.*
[62]*Id.*
[63]*Id.*
[64]2006 WL 839486, at *1 (D. Mass. Mar. 28, 2006).
[65]*Id.*
[66]*Id.*
[67]*Id.* at *6.
[68]*Id.*
[69]*Mills*, 581 F. Supp. 2d at 790-91. *See* 21 U.S.C. § 379r(e).
[70]*Id.* at 791.
[71]*Id.*
[72]*Id.* at 793. *See* Tex. Civ. Prac. & Rem. Code § 82.001(2).
[73]*Carter*, 582 F. Supp. 2d at 1287 (quoting 21 U.S.C. § 379r(e)).
[74]*Id.*
[75]*Id.*
[76]*See Sinclair v. Merck & Co., Inc.*, 195 N.J. 51, 948 A.2d 587, 595 (2008) (holding that claims under the New Jersey Consumer Fraud Act are not "products liability actions").



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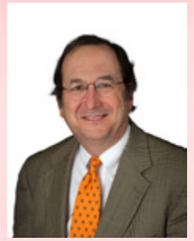

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