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THE 2015 AMENDMENTS TO THE FEDERAL RULES OF CIVIL PROCEDURE:

What You Need To Know

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DEAR CLIENT

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Coming to a court near you (and soon): In our first article, "*The 2015 Amendments to the Federal Rules of Civil Procedure: What You Need to Know*," we highlight upcoming changes that will impact discovery practice and document production, including preservation of electronic information. The new rules will apply to all federal cases, including those currently pending, so we've taken this opportunity to emphasize some features that may affect your litigation – present and future.

Our next article is a sequel with a happy (at least happier) ending. In "*Alabama No Longer an Outlier State: Legislature Says "No" To Innovator Liability*," we look at how the Alabama legislature (finally!) nullified that state's minority position regarding "innovator liability." Long-time readers of *Pro Te Solutio*, and those following the tortured case law on innovator liability, will recall that *Wyeth, Inc. v. Weeks* cast Alabama as one of only three states to allow a brand manufacturer to be held responsible for damages caused by a generic drug (which it did not manufacture). The legislative process moved quickly to put Alabama back in the vast majority of states that prohibit such a recovery.

Third, we offer something a little different in this issue: think of this article as our indie film option. In "*Legal Process Management: A Value-Driven Approach*," we provide a birds-eye view of procedures to eliminate or reduce what clients spend on legal services. Butler Snow is employing these techniques to provide continued value to our clients with streamlined service.

Finally, we introduce our "*New and Noteworthy*" section, which will be used to provide a quick preview of developing trends or interesting cases. In this edition, we look at two recent opinions: one concerns the "apex doctrine," discussing what a plaintiff must establish to depose a high-ranking corporate executive. We also address a troubling incident of an appellate judge going outside the record on appeal to conduct independent research regarding drug dosing that related to an issue on appeal.

As always, we hope that this issue provides information that is both pertinent to your business and helpful to you. Take a seat and enjoy!

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THE 2015 AMENDMENTS TO THE FEDERAL RULES OF CIVIL PROCEDURE:

WHAT YOU NEED TO KNOW

The 2015 Amendments to the Federal Rules of Civil Procedure have been years in the making and will finally take effect on December 1. The amendments include changes that redefine the scope of relevant discovery and provide for sanctions for failure to provide electronically stored information. The amendments also are intended to speed up the early stages of litigation. Here we provide a summary of what you need to know to stay on top of the changing landscape for federal practice.

WHEN DO THE AMENDMENTS GO INTO EFFECT?

The amendments take effect on December 1, 2015.[1]

WHAT CASES FALL UNDER THE REVISED RULES?

The amendments apply to all proceedings commenced after December 1, 2015, as well as all proceedings then pending "insofar as just and practicable."

WHICH RULES ARE AMENDED?

The amendments affect Rules 1, 4, 16, 26, 30, 31, 33, 34, 37, 55 and 84.

WHAT ARE THE CHANGES?

1. SCOPE OF DISCOVERY

Arguably, the changes that have generated the most buzz in the legal community are to the scope of discovery under Rule 26(b). The new Rule 26(b)(1) language is quite different from the former Rule:

OLD RULE 26(B)

(1) *Scope in General.* Parties may obtain discovery regarding any nonprivileged matter that is relevant to any party's claim or defense – including the existence, description, nature, custody, condition, and location of any documents or other tangible things and the identity and location of persons who know of any discoverable matter. For good cause, the court may order discovery of any matter relevant to the subject matter involved in the action. Relevant information need not be admissible at the trial if the discovery appears reasonably calculated to lead to the discovery of admissible evidence. All discovery is subject to the limitations imposed by Rule 26(b)(2)(C)

(2) *Limitations on Frequency and Extent.*

. . .

(C) *When Required.* On motion or on its own, the court must limit the frequency or extent of discovery otherwise allowed by these rules or by local rule if it determines that:

. . .

(iii) the burden or expense of proposed discovery outweighs its likely benefit, considering the needs of the case, the amount in controversy, the parties' resources, the importance of the issues at stake in the action, and the importance of the discovery in resolving the issues.

NEW RULE 26(B) *(CHANGES IN* **BOLD***)*

(1) *Scope in General.* Parties may obtain discovery regarding any nonprivileged matter that is relevant to any party's claim or defense **and proportional to the needs of the case, considering the importance of the issues at stake in the action, the amount in controversy, the parties' relative access to relevant information, the parties' resources, the importance of the discovery in resolving the issues, and whether the burden or expense of the proposed discovery outweighs its likely benefit. Information within this scope of discovery need not be admissible in evidence to be discoverable.**

(2) *Limitations on Frequency and Extent.*

. . .

(C) *When Required.* On motion or on its own, the court must limit the frequency or extent of discovery otherwise allowed by these rules or by local rule if it determines that:

. . .

(iii) the proposed discovery is outside the scope permitted by Rule 26(b)(1).

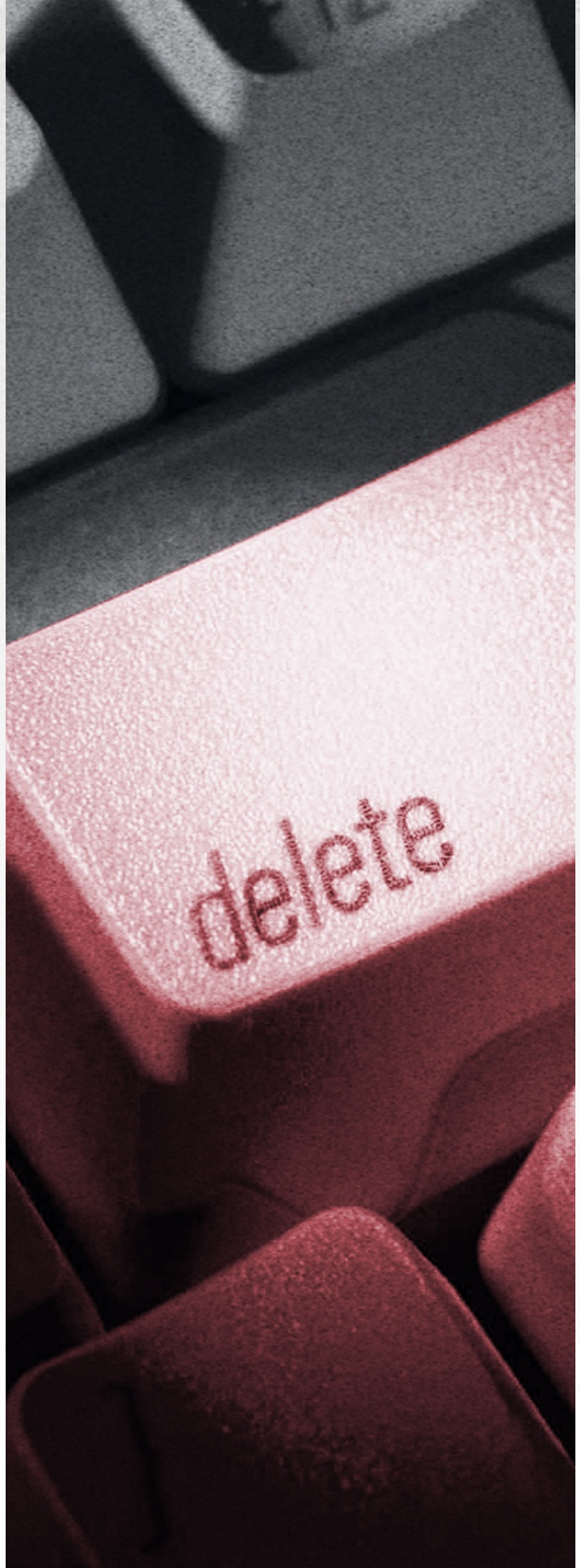
SEVERAL KEY CHANGES ARE IMMEDIATELY APPARENT:

• ADDITION OF PROPORTIONALITY

The Amendment restores proportionality as an express component to Rule 26's scope of discovery. The factors that were previously to be considered on a motion to limit to discovery under Rule 26(b)(2)(C) are now part of the proportionality inquiry under Rule 26(b)(1). Parallel changes are made in Rules 31, 31 and 33 to reflect Rule 26(b)(1)'s recognition of proportionality.

• DELETION OF "DESCRIPTION, NATURE," ETC.

The new rule deletes the provision for discovery of "the existence, description, nature, custody, condition and location of any documents or other tangible things and the identity and location of persons who know of any discoverable



matter." The Committee Note explains that the deletion is not meant to remove those items from the realm of discovery, but rather "[d]iscovery of such matters is so deeply entrenched in practice that it is no longer necessary to clutter the long test of Rule 26 with these examples."

• DELETION OF "RELEVANT TO THE SUBJECT MATTER"

The Amendment removes the prior language authorizing the court, *for good cause*, to order discovery of any matter relevant to the subject matter of the litigation. The Committee Note states that this language was "rarely invoked" and that proportional discovery suffices.

• DELETION OF "REASONABLY CALCULATED TO LEAD TO DISCOVERY OF ADMISSIBLE EVIDENCE"

Amendment also deletes the statement that evidence need not be admissible "if the discovery appears reasonably calculated to lead to the discovery of admissible evidence." The Committee Note states that phrase "has been used by some, incorrectly, to define the scope of discovery" and that it was "never intended to have that purpose." The new rule replaces this language with a statement that "[i]nformation within this scope of discovery need not be admissible in evidence to be discoverable." The Amendment, according to the Committee Note, eliminates this incorrect reading of the rule, but still retains the rule that inadmissibility is not a valid reason to oppose discovery of relevant information.

In addition, the Amendments also authorize under Rule 26(c)(1)(B) protective orders to include "allocation of expenses" arising from discovery. After concerns were raised in public comments, however, the Committee Note was amended to state that "[r]ecognizing the authority to shift the costs of discovery does not mean that cost-shifting should become a common practice" and that "[c]ourts and parties should continue to assume that a responding party ordinarily bears the costs of responding."

2. FAILURE TO PRESERVE ELECTRONIC INFORMATION

Another significant change to the Rules is the addition of provisions regarding sanctions for failure to preserve electronically stored information. Whereas the prior Rule 37 had very limited protection for litigants who had lost electronic information, the new Rule 37(e) provides for a more fulsome procedure in the imposition of sanctions for failure to provide electronically stored information.

OLD RULE 37(E)

(e) Failure to Provide Electronically Stored Information. Absent exceptional circumstances, a court may not impose sanctions under these rules on a party for failing to provide electronically stored information lost as a result of the routine, good-faith operation of an electronic information system.

NEW RULE 37(E) *(CHANGES IN* **BOLD***)*

(e) Failure to **Preserve** Electronically Stored Information. **If electronically stored information that should have been preserved in the anticipation or conduct of litigation is lost because a party failed to take reasonable steps to preserve it, and it cannot be restored or replaced through additional discovery, the court:**

(1) upon finding prejudice to another party from loss of the information, may order measures no greater than necessary to cure the prejudice; or

(2) only upon finding that the party acted with the intent to deprive another party of the information's use in the litigation may:

(A) presume that the lost information was unfavorable to the party;
(B) instruct the jury that it may or must presume the information was unfavorable to the party; or
(C) dismiss the action or enter a default judgment.

Per the Committee Note, the old more limited Rule "has not adequately addressed the serious problems resulting from the continued exponential growth in the volume of [electronically stored] information." Accordingly, federal courts had established ranging standards for the imposition of sanctions or other measures for failure to preserve ESI, causing litigants "to expend excessive effort and money on preservation in order to avoid the risk of severe sanctions if a court finds they did not do enough." The new Rule is intended to foreclose reliance on the court's inherent authority or state law to determine what measures a court may employ if it finds information that should have been preserved was lost and what findings are necessary to justify those measures. The Committee made clear, however, that the new Rule 37(d) does not affect independent state law claims for spoliation. The Rule also does not create a new duty to preserve – rather, it is based on the existing common-law duty.

The Committee Note provides greater detail about what a finding of "reasonable steps" or "prejudice" entails and what "measures" might be appropriate where information is lost. Finally, it should also be noted that Rule 37(e)(2) rejects the use of an adverse-inference instruction on a finding of negligence or gross negligence in failing to preserve ESI, resolving a circuit split on the issue.[2] According to the Committee Note, "[t]he better rule for the negligent or grossly negligent loss of electronically stored information is to reserve a broad range of measures to cure prejudice caused by its loss, but to limit the most severe measures to instances of intentional loss or destruction."

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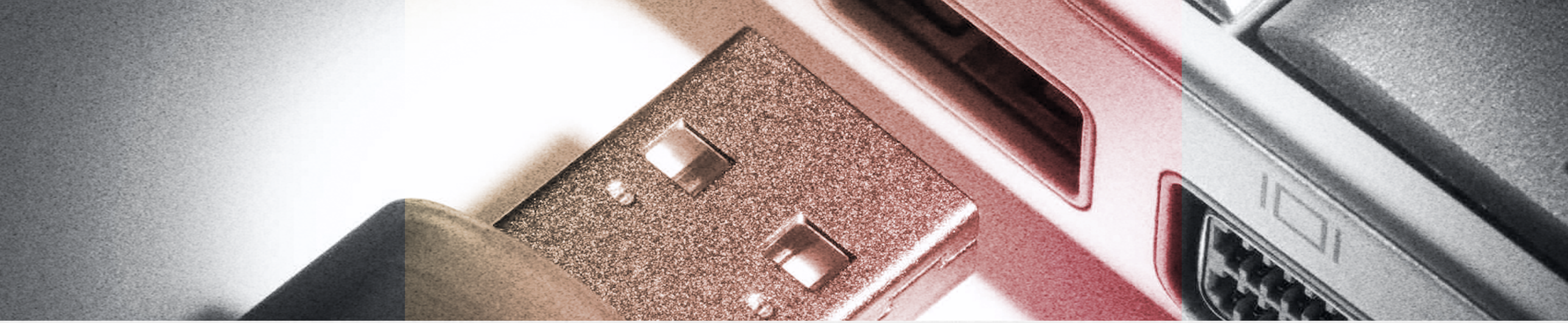


3. RESPONDING TO RFPS

There are three changes with respect to the substance of RFP responses: (1) objections to RFPs must be stated "with specificity," (2) responding parties may state they will produce copies of documents or ESI instead of permitting inspection, and should state a reasonable time for production,[3] and (3) an objection must state whether any responsive materials are being withheld on the basis of the objection.

OLD RULE 34

(B) *Responding to Each Item.* For each item or category, the response must either state that inspection and related activities will be permitted as requested or state an objection to the request, including the reasons.

(C) *Objections.* An objection to part of a request must specify the part and permit inspection of the rest.

NEW RULE 34 *(CHANGES IN* **BOLD***)*

(B) *Responding to Each Item.* For each item or category, the response must either state that inspection and related activities will be permitted as requested or state **with specificity the grounds for objecting to the request,** including the reasons. **The responding party may state that it will produce copies of documents or of electronically stored information instead of permitting inspection. The production must then be completed no later than the time for inspection specified in the request or another reasonable time specified in the response.**

(C) ***Objections.*** **An objection must state whether any responsive materials are being withheld on the basis of that objection.** An objection to part of a request must specify the part and permit inspection of the rest.

According to the Standing Committee Chair Report, these three amendments are intended to eliminate three frequent problems: "broad, boilerplate objections," "responses that state various objections produce some information and do not indicate whether anything else has been withheld," and responses that state responsive documents will be produced but provide no indication of when they will be produced and the documents then are not produced expeditiously.

The Note goes on to say that a conference "may be held in person, by telephone, or by more sophisticated electronic means," seemingly doing away with conferences by mail.

4. SPEEDING UP AND STREAMLINING LITIGATION

Several changes throughout the Rules have the purpose of expediting the early stages of litigation and generally streamlining litigation:

- **SERVICE OF SUMMONS**

  The Amendments change Rule 4(m) to reduce the time for serving a defendant from 120 days following the filing of a complaint to 90 days.

- **ISSUANCE OF SCHEDULING ORDER**

  Rule 16(b)(2) is amended to reduce the time for the judge to issue the scheduling order from 120 days after service to 90 days, or from 90 days after any defendant has appeared to 60 days, unless there is good cause for delay.

- **EARLY RULE 34 REQUESTS**

  Under the old Rule 26, a party could not serve discovery until after the Rule 26(f) conference. Under new Rule 26(d)(2), RFPs may be served as soon as 22 days after service of the complaint and summons and before the Rule 26(f) conference. However, the response time does not commence until after the Rule 26(f) conference. This change is also reflected in Rule 34(b)(2)(A). The purpose of the change, according to the Committee Note, is to "facilitate focused discussions [on discovery] during the Rule 26(f) Conference."

- **ALTERING SEQUENCE OF DISCOVERY**

  Whereas the prior Rule 26 allowed for discovery in any sequence unless the court orders otherwise, the new Rule 26(d)(3) allows for the parties to agree to case-specific sequences of discovery.

5. RULE 16 CONFERENCES

The new Rule 16 strikes the provision that a scheduling conference may be held "by telephone, mail, or other means." Rather, the Committee Note explains that "[a] scheduling conference is more effective if the court and parties engage in direct simultaneous communication." The Note goes on to say that a conference "may be held in person, by telephone or by more sophisticated electronic means," seemingly doing away with conferences by mail.

OLD RULE 16(B)(1)

. . . . the district judge – or a magistrate judge when authorized by local rule – must issue a scheduling order: . . .

(A) after receiving the parties' report under Rule 26(f); or

(b) after consulting with the parties' attorneys and any unrepresented parties at a scheduling conference by telephone, mail or other means.

NEW RULE 16(B)(1)

. . . the district judge – or a magistrate judge when authorized by local rule – must issue a scheduling order:

(A) after receiving the parties' report under Rule 26(f); or

(b) after consulting with the parties' attorneys and any unrepresented parties at a scheduling conference.

6. CONTENT OF SCHEDULING ORDERS AND DISCOVERY PLANS

Rules 26(f)(3) and 16(b)(3) are amended in parallel to add additional items to scheduling orders and discovery plans:

• THREE ADDITIONS TO WHAT MAY BE IN A RULE 16 SCHEDULING ORDER:

The Amendments change Rule 4(m) to reduce the time for serving a defendant from 120 days following the filing of a complaint to 90 days.

• TWO ADDITIONS TO WHAT MUST BE IN A RULE 26(F) DISCOVERY PLAN:

Under the amended Rule 26(f)(3), the discovery plan must now also state the parties' views and proposals on: (1) any issues about preservation of electronically stored information, and (2) whether to ask the court to include their agreement about attorney-client privilege or work-product protection in an order under Federal Rules of Evidence 502.

7. THE RULES ARE THE RESPONSIBILITY OF ALL PARTIES

To emphasize that the parties share in the responsibility to employ the rules, Rule 1 is amended to state that the Rules shall be "construed, and administered and employed by the court and the parties to secure the just, speedy, and inexpensive determination of every action and proceeding." (Additions underlined). The Committee Note makes clear, though, that the amendment does not create any new or independent scope of sanctions.

8. SETTING ASIDE A DEFAULT

Rule 55(c) is amended to clarify that the Rule 60(b) standards only apply when seeking relief from a final judgment. A default judgment that disposes of less than all claims among all parties is not a final judgment unless the court directs the entry of a final judgment under Rule 54(b).

9. NO MORE APPENDIX OF FORMS

The Committee found that the purpose of the Appendix was to provide illustrations for the rules, which is no longer necessary. The Appendix of Forms has therefore been abrogated. The form for a Waiver of Service has been directly incorporated into the text of Rule 4.

SO WHAT DOES THIS MEAN FOR MY PENDING CASES?

As noted above, the amendments only apply to pending cases "insofar as just and practicable." But what is just and practicable? Obviously, for any cases in the very early stages of litigation, it is plain that most changes will be applicable going forward. For cases further along, the answer will vary case to case.

Should you go back and revise your discovery responses because of the changes to the scope of discovery? As explained in the Committee Note, the changes were more intended to correct misunderstandings rather than to change the proper scope of discovery. Thus, discovery responses should not need to be revised for scope, but only if the Rules were applied correctly the first time around.

What about responses to Requests for Production? If you are served with a set of RFPs between now and December 1, the best practice would be to prepare your responses to comply with the new Rules and avoid the time, cost and expense of preparing the responses under the old Rules and then revise them to comply with the new Rules. Also, depending on the animosity level between the parties, and to avoid timely and costly discovery disputes, a review of prior discovery responses may be necessary to bring them into compliance with the new rules. For instance, if the responses stated objections but did not state those objections "with specificity" or whether any information was withheld on the basis of those objections, the best practice would probably be to revise those responses.

Should you change your document preservation policies? The amendment regarding failure to preserve ESI should not affect what you preserve in your pending cases, as the new Rule 37 does not seek to define when the duty to preserve arises but rather what should happen once ESI that should have been preserved is lost. In fact, many judges have already implemented local rules to address ESI issues as the new Rules have done. Nevertheless, the Committee Note provides an important refresher about what "reasonable steps" to preserve ESI include.

What will the return of the "proportionality" requirement do to your cases? Though the Advisory Committee has said that restoring proportionality to Rule 26 does not change the responsibilities of the court and the parties, it is likely that this amendment will renew focus on the issue to the benefit of defendants. For example, many cases involve a single plaintiff against a large corporate defendant. The cost for a plaintiff to produce ESI is far less than it costs a corporate defendant to produce ESI, especially when most plaintiffs ask for voluminous documents over a large period of time. So, if a plaintiff's damages would be $300,000, but it would cost the defendant $150,000-$200,000 to produce the ESI, is that proportional? In most cases, the answer may be clear, but there will be instances where it is not. When the cost of discovery vs. damages scenario is as the example above, is it then appropriate to ask the plaintiff to share in the cost? And is that consistent with the Committee Note that the changes to the rules are not intended to shift the cost of discovery? It is likely that the courts will see more of these types of arguments now that proportionality has been expressly returned to Rule 26. ■

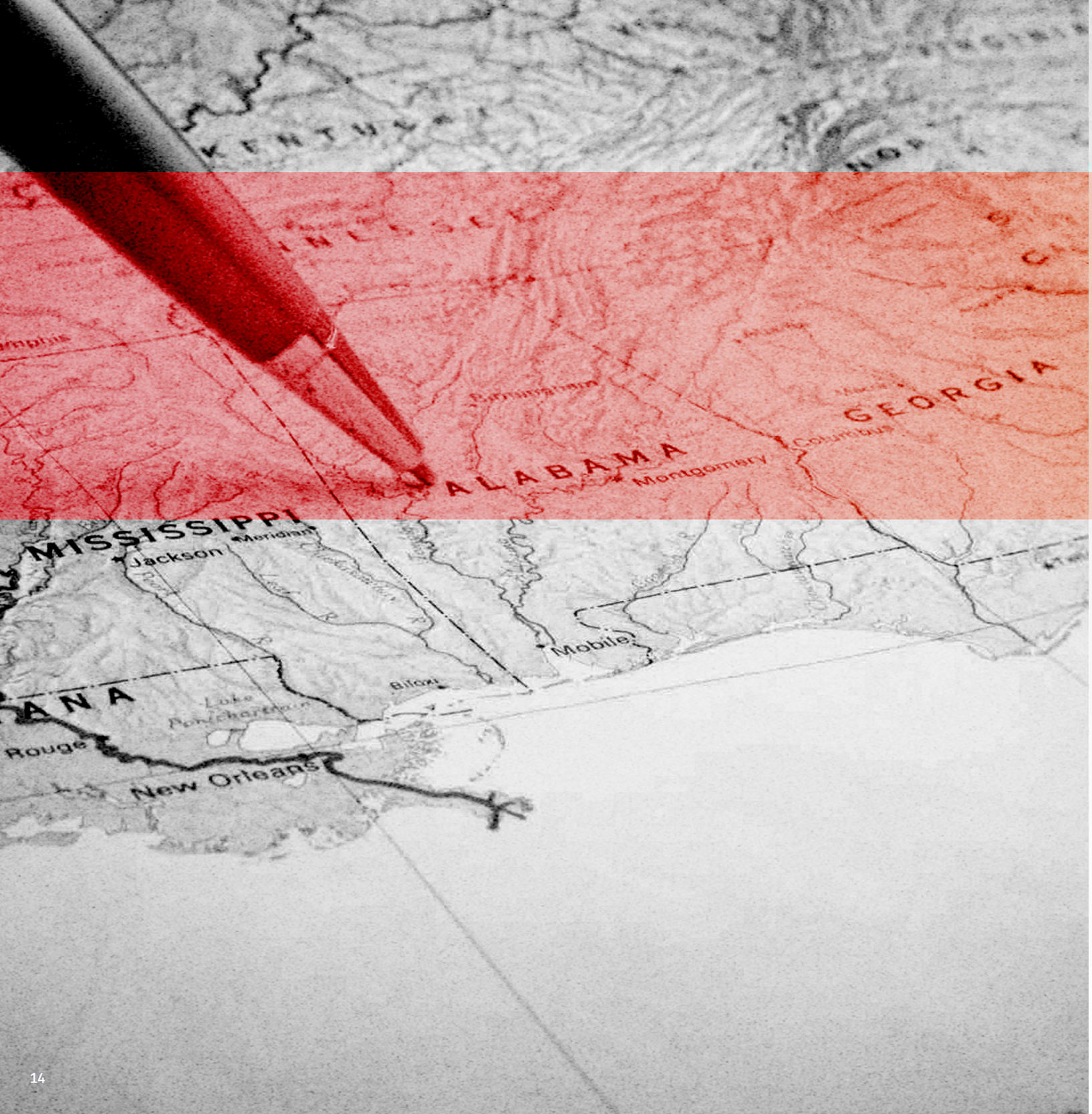
[1] *See* Order of Supreme Court adopting the rules (April 29, 2015). The entire package of materials transmitted to Congress – including the proposed rules, orders adopting the rules, Advisory Committee Note and Standing Committee Chair Report – is available at http://www.uscourts.gov/file/document/congress-materials.

[2] *Compare, e.g., Residential Funding Corp. v. DeGeorge Fin. Corp.,* 306 F.3d 99, 113 (2d Cir. 2002) ("[D]iscovery sanctions…may be imposed upon a party that has breached a discovery obligation not only through bad faith or gross negligence, but also through ordinary negligence.") with *Aramburu v. Boeing Co.,* 112 F.3d 1398, 1407 (10th Cir. 1997) ("The adverse inference must be predicated on the bad faith of the party destroying the records. Mere negligence in losing or destroying records is not enough because it does not support an inference of consciousness of a weak case.").

[3] Accordingly, Rule 37(a)(3)(B)(iv) is also amended to add authority to move for an order to compel production if "a party fails to produce documents."

By Chip Morrow

By Susanna Moldoveanu



ALABAMA NO LONGER AN OUTLIER STATE:

LEGISLATURE SAYS "NO" TO INNOVATOR LIABILITY

I. INTRODUCTION

Since the United States Supreme Court's decision in *Pliva, Inc. v. Mensing*[1], the plaintiffs' bar has been feverishly searching for an alternate theory of recovery when the claimant took a generic prescription drug. One of those alternate theories is "innovator liability," which posits that the brand manufacturer should be liable for injuries caused by the generic equivalent even if the claimant did not ingest the brand manufacturer's product. Plaintiffs rationalize that because the FDA requires the generic manufacturer to copy the brand's label and warnings, the brand manufacturer should be liable.

The innovator theory contravenes a principal foundation of product liability law: that a manufacturer is not liable for injuries resulting from use of another manufacturer's product. Indeed, the logic is undeniable – if a manufacturer did not make the product, it cannot be liable for damages allegedly caused by its use.

In the context of pharmaceutical litigation, this foundational rule was set forth in *Foster v. American Home Products*,[2] which required product identification – a direct evidentiary link between the allegedly harmful product and the allegedly liable defendant-manufacturer.[3] The Foster court reasoned that making brand-name drug manufacturers liable for generic manufacturers' activities was unfair and stretched the boundaries of legal foreseeability in product liability law.[4]

The innovator theory contravenes a principal foundation of product liability law: that a brand-name manufacturer is not liable for injuries resulting from use of another manufacturer's product.

This established law took a step backward with the first mention of innovator liability in *Conte v. Wyeth, Inc.*[5] In *Conte*, the court concluded that *Foster*'s analysis was flawed because it did not consider concurrent liability, rationalizing that it was reasonable to require brand-name manufacturers to put correct information on their labels or be held liable for its failure to warn.[6] The *Conte* court held that it would not protect the brand-name manufacturer from foreseeable injuries caused by its allegedly inadequate warnings that the generic manufacturers are required to replicate.[7]

In addition to California, Alabama and Vermont are the only other jurisdictions to apply the innovator liability theory to hold a brand-name manufacturer liable for misstatement or omission for an injury caused by a generic drug manufactured by a different company.[8] However, Alabama recently took swift action to curtail the potential Pandora's box of litigation created by the *Wyeth v. Weeks* decision. In doing so, the Alabama legislature reduced the number of innovator liability states to just two, a considerable minority to the number of states addressing the issue and holding otherwise.[9]

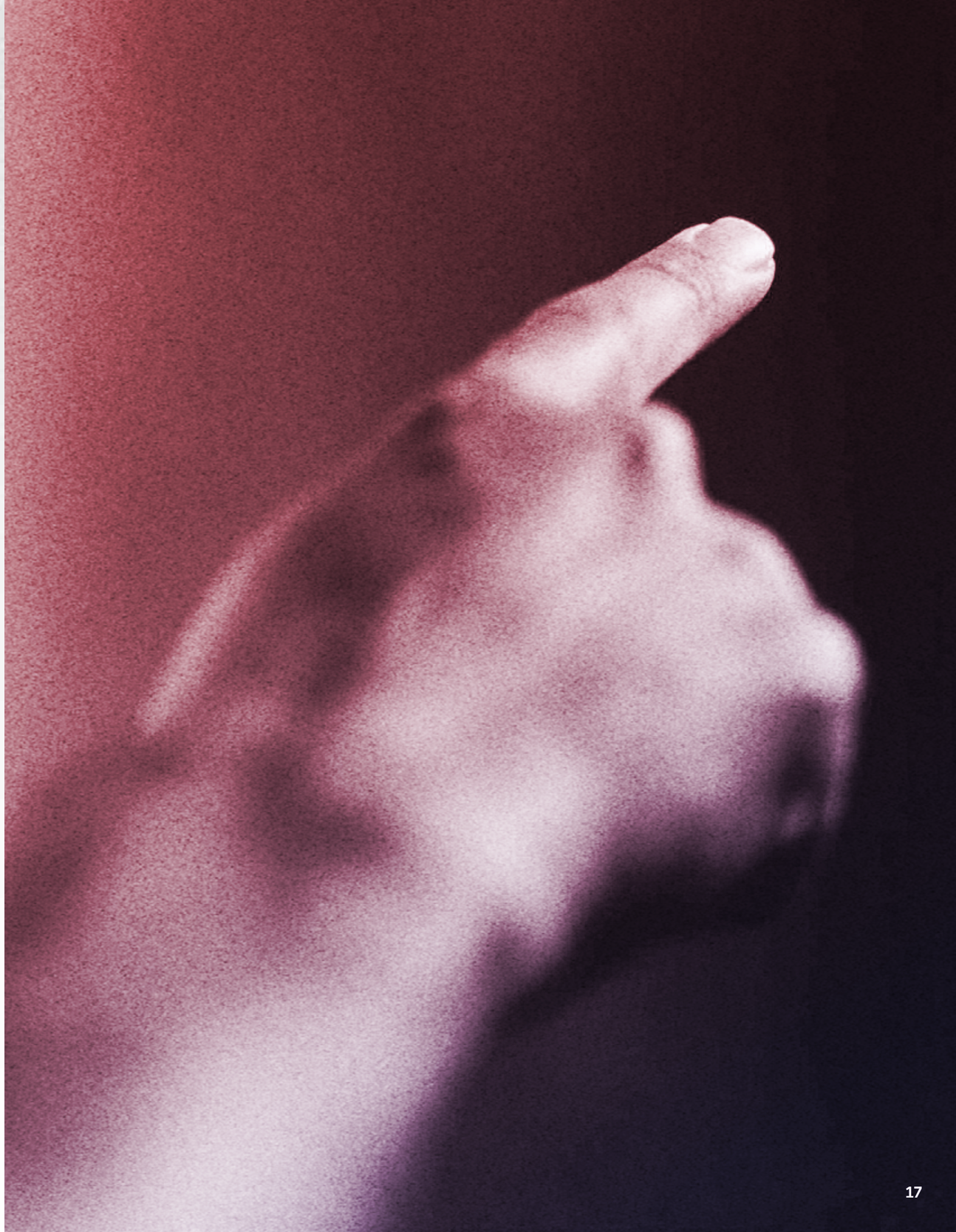
II. WEEKS: THE "WORST PRESCRIPTION DRUG/MEDICAL DEVICE DECISION OF 2014"

In our July 2013 *Pro Te* article, "*What Do California, Vermont and Alabama Have In Common*?,"[10] we reported on what had been deemed the "worst prescription drug/medical device decision of 2014."[11] To recap, in *Wyeth, Inc. v. Weeks*, the Alabama Supreme Court allowed a plaintiff claiming injury from a generic product to maintain a misrepresentation claim against the brand manufacturer. The original *Weeks* decision garnered widespread negative press, thus causing the Alabama Supreme Court to reconsider its original opinion, *en banc*.

At rehearing, Wyeth argued – supported by the majority of states – that it had no relationship with the Weeks plaintiffs and, thus, it owed them no duty to warn. However, the Alabama Supreme Court emphatically rejected this notion and admonished Wyeth's argument, holding:

> Wyeth's argument completely ignores the nature of prescription medication. The Weekses cannot obtain Reglan or any other prescription medication directly from a prescription-drug manufacturer. The only way for a consumer to obtain a prescription medication is for a physician or other medical professional authorized to write prescriptions (i.e. a learned intermediary) to prescribe the medication to his or her patient. When the warning to the prescribing health-care professional is inadequate, however, the manufacturer is directly liable to the patient for damage resulting from that failure. [12]

Although one would think – as the majority of states have previously held – that the above rationale would prevent brand-name manufacturer liability in the case of generic ingestion, the Supreme Court rejected such a conclusion, rationalizing:



> The substitution of a generic drug for its brand-name equivalent is not fatal to Weekses' claim because the Weekses are not claiming that the drug Danny ingested was defective; instead, the Weekses' claim is that Wyeth fraudulently misrepresented or suppressed information concerning the way the drug was to be taken and, as discussed, the FDA mandates that the warning on a generic-drug label be the same as the warning on the brand-name-drug label and only the brand-name manufacturer may make unilateral changes to the label.[13]

The Alabama Supreme Court again relied heavily on the United States Supreme Court's holding in *Mensing*, noting that "the Supreme Court in PLIVA held that it would have been impossible for the generic manufacturers to change their warning labels without violating the federal requirement that the warning on the generic drug must match the warning on the brand-name version, preempting failure-to-warn claims against generic manufacturers."[14] The *Weeks* Court thus emphasized the FDA's role in drug labeling and restrictions placed upon generic manufacturers, remarking "FDA regulations require that a generic manufacturer's labeling[15] for a prescription drug be exactly the same as the brand-name manufacturer's labeling." In further justification of its holding, the Alabama Supreme Court rationalized that:

> it is not fundamentally unfair to hold the brand-name manufacturer liable for warnings on a product it did not produce because the manufacturing process is irrelevant to misrepresentation theories based, not on manufacturing defects in the product itself, but on information and warning deficiencies, when those alleged misrepresentations were drafted by the brand-name manufacturer and merely repeated, as allowed by the FDA, by the generic manufacturer. [16]

Justice Parker, relying on Justice Murdock's 2013 dissent in *Weeks*, stressed the potentially grave consequences of the court's dissolution of bedrock legal principles of duty and privity, noting:

> [n]othing in federal legislation or regulations at issue here requires this Court to ignore, modify, or override our bedrock legal principles of duty and privity with regard to the originator of a pharmaceutical drug and a consumer who has not consumed a drug manufactured by the originator of the drug. [17]

As recognized by the United States Supreme Court, while a consumer may be left without a remedy absent a legislative change, "it is not this Court's task to decide whether the statutory scheme established by Congress is unusual or even bizarre."[18]

The *Conte* court held that it would not protect the brand-name manufacturer from foreseeable injuries caused by its allegedly inadequate warnings that the generic manufacturers are required to replicate.

III. THE ALABAMA LEGISLATURE TO THE RESCUE

Despite the Alabama Supreme Court's refusal to alter the Weeks decision, innovator liability will not stand in the State of Alabama. Less than one year after Weeks, the Alabama Legislature passed Act No. 2015-106 (S.B. 80), effectively abolishing innovator liability in the State of Alabama. Originally introduced in the Alabama Senate, Act No. 2015-106 passed the Alabama House of Representatives on April 28, 2015. With Governor Robert Bentley signing the bill into law on May 1, 2015, Act No. 2015-106 returned Alabama to the majority of states disallowing innovator liability in cases involving generic ingestion.

While the statute will not take effect until November 1, 2015, it states in part:

> Section 1. In any civil action for personal injury, death, or property damage caused by a product, regardless of the type of claims alleged or the theory of liability asserted, the *plaintiff must prove, among other elements, that the defendant designed, manufactured, sold, or leased the particular product the use of which is alleged to have caused the injury on which the claim is based, and not a similar or equivalent product.* Designers, manufacturers, sellers, or lessors of products not identified as having been used, ingested, or encountered by an allegedly injured party may not be held liable for any alleged injury. A person, firm, corporation, association, partnership, or other legal or business entity whose design is copied or otherwise used by a manufacturer without the designer's express authorization is not subject to liability for personal injury, death, or property damage caused by the manufacturer's product, even if use of the design is foreseeable. [19] (emphasis added).

Theoretically, under this statutory approach, liability is limited to entities that "manufactured, sold, or leased" the product at issue, and may not be imposed on those whose original product design is later copied.

Theoretically, under this statutory approach, liability is limited to entities that "manufactured, sold, or leased" the product at issue, and may not be imposed on those whose original product design is later copied.

On its face, Act No. 2015-106 makes no mention of pharmaceutical drug products or brand versus generic manufacturers. Instead, the statute applies more broadly to "[d]esigners, manufacturers, sellers, or lessors of products." Regardless, brand-name pharmaceutical manufacturers will likely sleep easier knowing innovator liability is no longer a viable claim in Alabama.

I. CONCLUSION

Under Alabama Act No. 2015-106, brand-name drug manufacturers may no longer be held liable under Alabama law for misrepresentations in cases where the plaintiff never ingested the brand drug product. Alabama legislatively re-joined the majority of states disallowing innovator liability. Only time will tell if California and Vermont will follow suit.

APPENDIX OF CASES DECLINING INNOVATOR LIABILITY

ARKANSAS LAW

- *Fullington v. Pfizer, Inc.*, 720 F.3d 739 (8th Cir. 2013).
- *Bell v. Pfizer, Inc.*, 716 F.3d 1087 (8th Cir. 2013).
- *Neal v. Teva Pharm. USA, Inc.*, No. 09-CV-1027, 2010 WL 2640170 (W.D. Ark. July 1, 2010).
- *Fields v. Wyeth, Inc.*, 613 F. Supp. 2d 1056 (W.D. Ark. 2009).

COLORADO LAW

- *Sheeks v. Am. Home Prods. Corp.*, No. 02CV337, 2004 WL 4056060 (Colo. Dist. Ct. Oct. 15, 2004).

FLORIDA LAW

- *Metz v. Wyeth, L.L.C.*, 525 F. App'x 893 (11th Cir. 2013).
- *Guarino v. Wyeth, L.L.C.*, 719 F.3d 1245 (11th Cir. 2013).
- *Howe v. Wyeth, Inc.*, No. 8:09-CV-610, 2010 WL 1708857 (M.D. Fla. Apr. 26, 2010).
- *Levine v. Wyeth Inc.*, 684 F. Supp. 2d 1338 (M.D. Fla. 2010).
- *Dietrich v. Wyeth, Inc.*, No. 50-2009-CA-021586, 2009 WL 4924722 (Fla. Cir. Ct. Dec. 21, 2009).
- *Sharp v. Leichus*, 952 So. 2d 555 (Fla. Dist. Ct. App. 2007).

GEORGIA LAW

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1. *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567, *reh'g denied*, 132 S. Ct. 55 (2011).
2. 29 F.3d 165 (4th Cir. 1994).
3. *Id.*
4. *Id.* at 170-71.
5. 168 Cal. App. 4th 89 (2008).
6. *Id.* at 109.
7. *Id.* at 110.
8. *Wyeth, Inc. v. Weeks*, 2013 Ala. Lexis 2, *59 (Ala. Jan. 17, 2013); *Kellogg v. Wyeth*, 762 F. Supp. 2d 694 (D. Vt. 2010).
9. The appendix lists 102 judicial decisions, applying the law of 30 states, holding that a brand-name drug manufacturer is not liable for injuries caused by a competitor's generic equivalent.
10. "What Do California, Vermont and Alabama Have In Common?" Pro Te: Solutio, Vol. 6 No. 3 (September 2013).
11. http://druganddevicelaw.blogspot.com/2014/12/thumbs-down-worst-prescription.html.
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16. *Id.*
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By Chris Berdy

By John Dollarhide

By Ashley Nader Stubbs

LEGAL PROCESS MANAGEMENT:

A VALUE-DRIVEN APPROACH

WHAT IS LEGAL PROCESS MANAGEMENT?

Legal Process Management applies continuous improvement and change management principles to legal processes, maximizing both the micro- and macro-effects of those changes with the end goal of providing greater value to the client.

Articles written on this topic typically skip across the surface loaded with textbook definitions and illustrations of continuous improvement concepts, but lack substantive examples and practical applications in the legal industry. No fault to those early submittals as they build an understanding and continue the conversation, but absence of specific implementation and results leaves room for doubt.

This article, however, goes beyond the high-level platitudes to provide an example of solving real challenges that are driving inefficiencies in everyday legal processes. Inefficiencies, if you are not careful, can result in large costs absorbed either by the client or by the law firm.

You are invited to explore deeper an environment where the status quo is no longer accepted and where legal service providers work in conjunction with their clients to eliminate waste and reduce legal spending: ***LEGAL PROCESS MANAGEMENT.***

REAL WORLD JOURNEY

Processing high volumes of incoming documents by law firms (or third-party vendors), like plaintiff fact sheets or complaints in the mass tort setting, provides a nice platform to show how easily poor process design can drive inefficiencies.

IN THIS PARTICULAR EXAMPLE, THE LEGAL TEAM IS RESPONSIBLE FOR:

- Acknowledging and recording receipt of the incoming complaint and supporting documents (e.g. medical records, fact sheet, etc.)
- Extracting key information into databases for statistical reporting and status updates
- Forwarding documents to the client, co-counsel and third-party vendors
- Filing documents into a document management system

At face value, the process appears linear and straightforward. However, when litigation expands and it becomes necessary to process more complaints, details of the process design become extremely important. Adding to the strain, court orders place demands on the legal team and increase the complexity of processing these documents. And as the litigation progresses, attorneys start requesting more and more statistical information about the population of complaints. The legal team becomes increasingly stressed and overwhelmed as the initial system design can no longer handle the demand.

RECOGNIZING SYMPTOMS
- BACKLOGS
- OVERTIME
- QUALITY
- REPORTING
- STRESS

SYMPTOMS OF A PROBLEM

SYMPTOMS OF AN INEFFICIENT PROCESS BEGIN TO EMERGE:

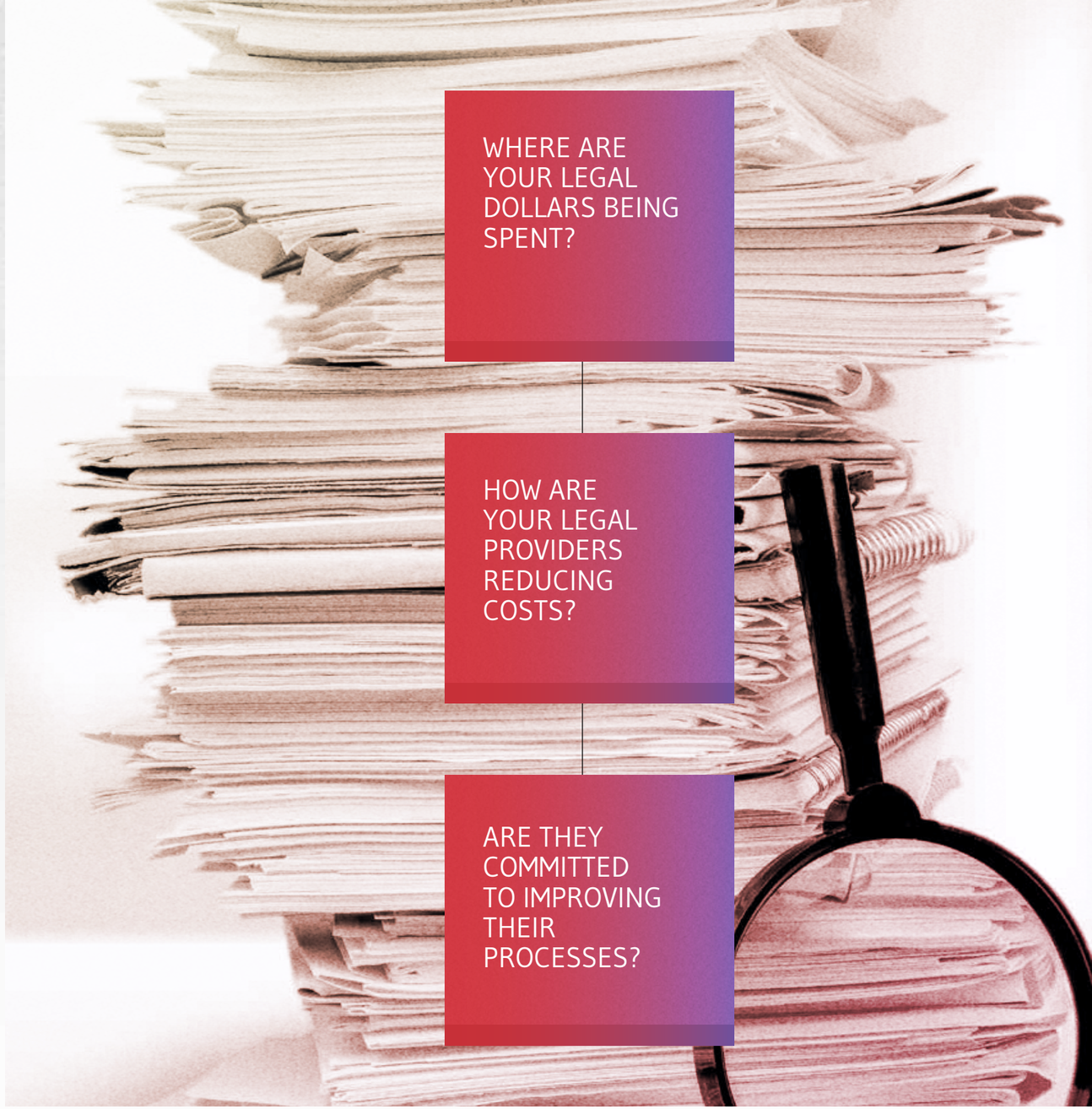
- Unprocessed document backlogs grow
- Timekeeper hours spike, and overtime becomes the new norm
- Quality begins to suffer
- Reporting is no longer real-time and reflective of the current status
- Ability to "catch up" falls out of reach
- Fatigue, stress and frustration permeate the mood of the team

IN RESPONSE TO THE CURRENT STATE OF AFFAIRS BUT LACKING THE PROPER TRAINING OR TIME TO EVALUATE THE SITUATION, THE LEGAL TEAM DEFAULTS TO TRADITIONAL, REACTIVE RESPONSES:

1. Increase Staff = More Cost
2. Increase Quality Inspections = More Bottlenecks
3. Increase Controls = More Complexity

The request for additional manpower under the same inadequate process design expedites the cost curve as more timekeepers bill more hours to the client. As quality issues emerge, likely through an embarrassing moment with an attorney – or even worse, with the client – the team adds quality-control checks, sometimes 100 percent of the work product. If not employed effectively, these quality checks create more bottlenecks and backlog issues, again driving up costs. And finally, in an attempt to control the process, more rules are introduced to try to prevent mistakes, but in many cases the rules just create more complexity and confusion. The vicious cycle continues, but now with more steps and more resources churning away hours in the attempt to keep up.

At this point, the legal team begins to question, "Why is the situation not improving?"



Legal teams are typically motivated and open to ideas when the situation is dire, and legal process managers are equipped to take advantage of this mindset.

BUILDING TRUST

- HERE TO HELP; NO HIDDEN AGENDAS OR NEGATIVE RECOURSE
- PROVIDE THE TEAM A VOICE
- MAKE IT THEIR IDEA
- GIVE ALL THE GLORY TO TEAM

A CONTINUOUS IMPROVEMENT APPROACH

Although a more proactive effort on the front end is preferred, legal process managers are accustomed to entering into high-stress situations. Legal teams are typically motivated and open to ideas when the situation is dire, and legal process managers are equipped to take advantage of this mindset.

However, there is still the all-important *TRUST* factor, so how do legal process managers, "invite themselves to the party"?

MOST RELY ON THE FOLLOWING PRINCIPLES IN ORDER TO BUILD TRUST WITH THE TEAM:

- Establish the motive: Here to HELP the team with no hidden agendas
- Assure the team that no person will be penalized or reprimanded as a result of the project
- Listen, listen and listen while refraining from initial suggestions or assumptions
- Convert team concerns into their ideas for solutions
- Guarantee the glory goes to the team, not the legal process manager

Once the legal process manager engages with the team, the first step is to define the current state, and the most effective approach is process mapping. Although the concept is simple, a trained legal project manager can steer the team to provide the right amount of detail and to highlight issues along the way.

In this example of document and data intake for new cases, the process is initially designed for lower volumes with minimum data requirements. As the litigation grows, steps are added to the process to address additional requests, but those steps are not evaluated against their effect on the entire system.

FORTUNATELY, THE PROCESS MAP QUICKLY IDENTIFIES THE MAJOR PROBLEM AREAS:

- ***Waiting.*** Due to process sequencing, multiple choke-points exist, preventing team members from completing their responsibility, which results in large quantities of work-in-process (WIP). Constant start/stop activities drive inefficiency as team members expend time to refamiliarize themselves with the document. In legal process management terms, this step is referred to as "setup time."
- ***Inventory.*** High levels of WIP require additional management burden until the work is complete. Team members are forced to find creative ways to maintain multiple statuses of each document based on what work has been performed. This type of activity is often referred to as the "hidden factory."
- ***Over-processing.*** The process flow diagram also reveals that documents are touched by various paralegals and attorneys multiple times. In some cases, as many as 10 different occasions before the processing is complete. Instead, the goal is to process incoming documentation as quickly and efficiently as possible with a minimum amount of touches. With multiple individuals picking up and putting down the same documents, the document management system (DMS) and statistical databases reflect duplicative instances of the same information. Again, unnecessary redundant work.

TYPICAL PROBLEMS

- PROCESS CHOKE POINTS
- WIP/INVENTORIES
- OVER-PROCESSING
- REDUNDANT WORK

BEFORE

BOTTLENECKS

INEFFICIENCIES

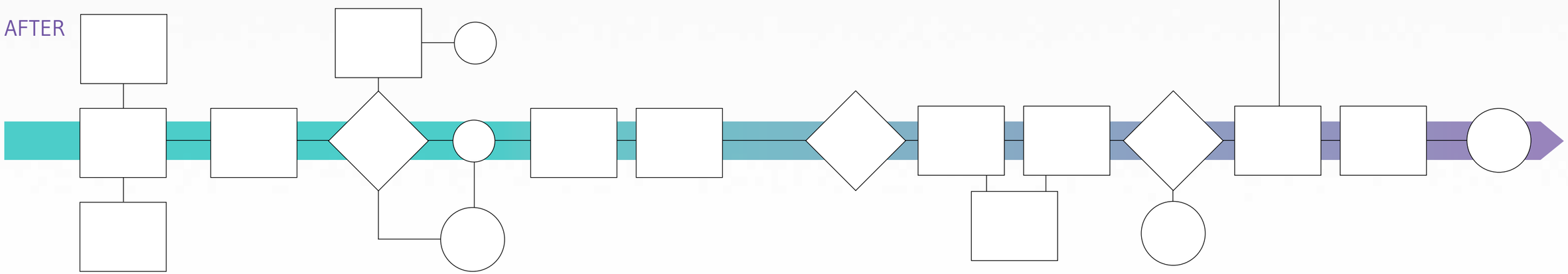
INITIAL FINDINGS

- Backlog Issues
- Process Redundancies and Unnecessary Processing
- Opportunity to Improve Standardization
- Unbalanced Allocation of Staffing
- TeamsWorking Independently
- Change Management Deficiencies

RE-ENGINEERED PROCESS

- Backlog Eliminated
- 50% Reduction in Process Steps
- Eliminated reoccurring ours of Over-processing and RedundantWork
- Developed over (15) Flow Charts and (30) Protocols for Standardization
- Created Knowledge Center for Team Training and Process Updates
- Re-allocated Resources to Address Capacity Issues and to Create a More FlexibleWorkforce with Cross-Training

AFTER



Documents are touched by various paralegals and attorneys multiple times. In some cases, as many as ten different occasions before processing is complete.

RESULTS

With a well-defined current state and a process flow diagram exposing the opportunities for improvement, the legal team in collaboration with the legal project manager devises a set of solutions.

Through implementation of their ideas utilizing a LEAN system re-engineering approach, the team is able to eliminate 50 percent of the steps from the process. Intake backlogs along with redundant processing times are also eliminated. As by-products of these changes, reporting accuracy improves, well-defined protocols are created and team members are able to cross-train, thus creating a more flexible workforce.

Although mass tort litigation provides an illustration of costs on a grand scale, opportunities exist in legal processes regardless of the area of law or the size of the practice. A continuous improvement culture is a key ingredient of *Legal Process Management,* as every day you don't do this, you pay dearly for it.

In future editions of *Pro Te Solutio*, the *LPM* conversation continues, providing an inside look at concepts and tools, such as workflow mapping and identifying waste in legal processes, which are the fabric of this client-value-driven approach. ■

By Thomas Agostinelli

NEW AND **NOTEWORTHY**

A JUDGE LOOKS TO THE INTERNET FOR DRUG INFORMATION.

Seventh Circuit Judge Richard Posner has stirred up a hornet's nest by going to the internet independently to find facts he believed to be relevant to the appeal of a grant of summary judgment.

In *Rowe v. Gibson*, 2015 WL 4934970 (7th Cir. Aug. 19, 2015), a prisoner representing himself asserted that he had been cruelly and unusually punished by the way the prison had administered ranitidine, a drug he needed to treat a painful gastroesophageal reflux disease. Ranitidine is made in prescription strength by GlaxoSmithKline and in over-the-counter form by Boehringer Ingelheim and sold under the trade name Zantac. The district court granted summary judgment based on a doctor's affidavit which said that giving a dose every 12 hours was sufficient. The prisoner said the failure to administer a dose 30 to 60 minutes before each meal needlessly inflicted pain.

The Seventh Circuit reversed the summary judgment and said the case presented fact issues that needed to be tried. Judge Posner's opinion discussed at length information he personally found on the internet – principally the Boehringer Ingelheim and Mayo Clinic websites – which he said supported the prisoner's claim. He justified his departure from the record before him by saying that he was not treating the website information as being conclusively true. Rather, he was only using it to suggest a fact dispute because it might be true.

Judge Hamilton, in dissent, decried the departure from the record that was made in the district court. Judge Posner's internet research also departs from the ABA's 2008 Model Code of Judicial Conduct Rule 2.9(c), which specifically instructs judges not to investigate the facts of cases independently. ■

By Luther Munford

GOOD RESULT UNDER APEX DOCTRINE

A request for the deposition of a high-ranking executive poses the substantial risk of gamesmanship, blustering by plaintiff's counsel and improperly burdensome discovery. The "apex doctrine" is designed to avoid such risks and protects high-level corporate officers from being deposed in certain circumstances. On August 19, 2015, United States District Court Judge Gene E.K. Pratter applied the apex doctrine to quash a subpoena to depose the former CEO of a defendant pharmaceutical manufacturer. The order provides a concise and helpful summary of the apex doctrine.

In a *qui tam* action – *USA, ex rel. Galmines v. Novartis Pharmaceuticals Corp.* (E.D. Penn., Case No. 2:06-cv-3213) – plaintiff alleged that Novartis engaged in off-label marketing for the eczema drug Elidel, resulting in alleged false claims for reimbursement under Medicare and Medicaid and also alleged violations of state anti-kickback statutes. Plaintiff sought to depose Alex Gorsky – the former CEO of Novartis and current chairman and CEO of Johnson & Johnson. Gorsky moved to quash the subpoena under the apex doctrine, among other reasons.

In an attempt to avoid application of the apex doctrine, plaintiff argued that Gorsky was involved in marketing the product, developing corporate responses to the FDA and authored emails regarding off-label sales. The court was not persuaded by these claims, finding that plaintiff failed to "articulate a specific and substantiated argument" to support the need for the deposition, thus quashing the subpoena.

In reaching its conclusion, the court noted that the burden of persuasion remained on the party seeking to quash, but that the apex doctrine provides a "rebuttable presumption that a high-level official's deposition represents a significant burden upon the deponent." This presumption is only rebutted upon proof on the apex doctrine's two critical factors: (1) whether the high-level official has personal or superior knowledge of the facts at issue; and (2) whether the information sought could be obtained in a less burdensome way or from lower-level employees.

Plaintiff was unable to show why he could not obtain the same information from lower- level employees or through less burdensome means. Important to the court's reasoning was the substantial discovery of corporate witnesses that had taken place, all without plaintiff attempting to elicit information about Gorsky's personal involvement from those sources. Thus, the burden of the deposition outweighed its likely benefit. ■

By Ben Scott

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