The 'Newly Acquired Information' Shift In Pharma Litigation

By **Richard Dean**

There has been a sea change in pharmaceutical litigation over the last four years. Before 2015, the key issue on which most pharmaceutical litigation generally turned was the adequacy of the warning given the prescribing physician; litigation was characterized by testimony about the physician's subjective knowledge of drug-related risks, experience with the drug in question and prescribing habits.

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Those issues remain central to the ultimate outcome in these lawsuits (indeed, a failure-to-warn plaintiff cannot meet his or her burden of proof without it). But a survey of pharmaceutical litigation reveals that many of these cases now turn on a more narrow preliminary question: whether there is "newly acquired information," within the meaning of 21 CFR 314.3(b), which would permit the pharmaceutical manufacturer to change its label through the "Changes Being Effected," or "CBE" regulatory process, defined in 21 CFR 314.70 (c)(6)iii).

If a manufacturer cannot make a CBE change, then federal law requires it to seek permission from the FDA before doing so. When this happens, the result is preemption of the failure-to-warn claim. The CBE regulation is not new, but what gives this argument its power is courts' increasing familiarity with its importance as a dispositive issue, and corresponding willingness to treat it as a threshold requirement for failure-to-warn cases.

The best example comes from the Eliquis litigation, where an entire MDL was dismissed at the pleading stage as a result of the plaintiff's failure to plead "newly acquired information," which would have permitted a CBE, with sufficient particularity. As the court explained, the plaintiffs were required to "plausibly allege the existence of newly acquired information that could have justified Defendants' revising the Eliquis label through the CBE regulation."[1]

The plaintiffs attempted to meet this threshold requirement by alleging that "[b]efore and after marketing Eliquis, defendants became aware of many reports of serious hemorrhaging in users of [their] drugs" and that "[n]umerous studies published after Eliquis' approval in 2012 confirm the problematic bleeding events associated with Eliquis."[2]

Yet the Second Circuit reasoned that for those "reports" and "studies" to constitute newly acquired information, as the term is defined in 21 C.F.R. § 314.3(b), they must have "reveal[ed] risks of a different type or greater severity or frequency than previously included in submissions to the FDA."[3]

The court examined the relevant scientific studies in incredible detail, but nevertheless concluded that "the complaint provides no basis upon which the court could conclude that the bleeding events covered by the alleged 'reports' and 'studies' presented a different type of risk than those the company had discussed with the FDA, or were more severe or more

frequent than the bleeding events that the government already knew about."[4]

There are multiple decisions from the MDL court, all of which are contained in the Second Circuit's recent decision affirming the dismissal.[5]

A similar example of this issue resolving a litigation at an early stage is In re Celexa and Lexapro Marketing and Sales Practices Litigation.[6] There, the allegations in the complaint were based on a claim that the warning approved by the FDA was inadequate.

The plaintiffs conceded — as they had to — that there was no new scientific information between the time of drug approval and the time the plaintiff took the drug. That concession left the plaintiff unable to show any "newly acquired information."[7]

And it is not just the lapse between the time of drug approval and the time of a plaintiff's exposure that is important. The interval is more appropriately judged as the time period between the last prelitigation label change and the plaintiff's exposure. For if the FDA took a full look at this issue and approved a label change, then there must be new information thereafter for the manufacturer to be able to submit a CBE.

Newly acquired information is not just an issue for the pleadings stage; it has also been addressed after discovery and as part of the parties' motions in limine practice. In the In re Lipitor (Atorvastin Calcium) Marketing Sales Practices and Products Liability Litigation,[8] the plaintiffs' claims of new information were based on two separate studies done post approval.

The court examined each study carefully and concluded that one met the definition of "newly acquired information," and thus a CBE would have been permitted.[9] As a result, failure-to-warn claims arising from an alleged failure to disclose that information were not preempted.[10] The court, however, concluded that the other study did not include newly acquired information, and so claims based on an alleged failure to disclose that information were preempted.[11]

The doctrine has even been invoked to reverse a jury verdict on appeal. In Dolin v. GlaxoSmithKline LLC,[12] a 2011 article was advanced as new information supporting the plaintiff's failure-to-warn claim. The plaintiff's expert, however, conceded that study was based on an earlier analysis, and also contained the same data as the 2006 analysis. Because "the undisputed evidence shows that the FDA was aware of the nature of the data it received from" the manufacturer, the court vacated the judgment on which it was based.[13]

In all of these cases, the courts decided the "newly acquired information" issue as a matter of law without even considering whether the issue was a legal question or factual one. Whether scientific studies meet a regulatory definition would appear at first blush to be a legal issue; juries don't usually answer questions of regulatory interpretation.

Yet, one court has denied a summary judgment motion on the grounds that the issue before it was disputed and for the jury — the District of Massachusetts in the In re Zofran (Ondansetron) Products Liability Litigation.[14] In doing so, it specifically relied on the Third Circuit's decision in In re Fosamax Product Liability Litigation.[15]

But Fosamax dealt with the issue of "clear evidence," not "newly acquired information."[16] These are different issues; even if a plaintiff can show "newly acquired information," a defendant can still advance the argument that there is "clear evidence" that

the FDA would not have approved a label change. Moreover, the Third Circuit's decision in Fosamax was recently reversed by the U.S. Supreme Court, which concluded that preemption was a legal issue to be decided by the court.[17]

The Zofran court will presumably have to reconsider its decision, since it was so clearly premised on Fosamax. If "clear evidence" is an issue for the court to resolve, so is "newly acquired evidence."

So what has changed? Why are all there these "newly acquired information" decisions from 2015 to the current time? The short answer is the decisions in PLIVA Inc. v. Mensing[18] and Mutual Pharmaceutical Co. Inc. v. Bartlett[19].

Those cases established that if an entity has to ask the federal government for permission to be in compliance with state law, the claim is preempted. This effectively linked preemption to the "newly acquired information" issue. Prior to that time, the "newly acquired information" regulation impacted only regulatory law with no tort liability consequences.

The decision in In re Celexa was the first explicit recognition of this linkage. Now, this explosion of law within the last four years, with significant decisions from the First, Second and Seventh Circuits, leaves little doubt that this issue will be a huge battlefield in pharmaceutical litigation in the immediate future.

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[1] Gibbons v. Bristol-Myers Squibb Co., 919 F.3d 699, 708 (2d Cir. 2019).

[2] Id.

[3] Id.

[4] Id.

[5] See generally 919 F.3d 699 (2d Cir. 2019).

[6] In re Celexa and Lexapro Marketing and Sales Practices Litigation, 779 F.3d 34 (1st Cir. 2015).

[7] Id. at 43.

[8] In re Lipitor (Atorvastin Calcium) Marketing Sales Practices and Products Liability Litigation, 185 F. Supp. 3d 761 (D.S.C. 2016).

[9] Id. at 770.

[10] Id. ("Any claims that Defendant should have changed its label based on the CASHMERE

study are not preempted, as the study would be "newly acquired information").

[11] Id. at 770-71 ("[T]o the extent that Plaintiffs claim that a state law duty required Defendant to include different statements on Lipitor's label regarding Lipitor's efficacy for primary prevention in women, based on the ASCOT data or information solely related to the risk of diabetes, those claims are preempted").

[12] Dolin v. GlaxoSmithKline LLC, 901 F.3d 803 (7th Cir. 2018).

[13] Id. at 815.

[14] In re Zofran (Ondansetron) Products Liability Litigation, ---F. Supp. 3d ---, 2019 WL 454593 (D. Mass. Feb. 5, 2019)

[15] In re Fosamax Product Liability Litigation, 852 F.3d 268 (3rd Cir. 2017).

[16] Id. at 280.

[17] Merck Sharp & Dohme Corp. v. Albrecht, No. 17-290, slip op. (U.S. May 20, 2019).

[18] PLIVA Inc. v. Mensing, 564 U.S. 604 (2011).

[19] Mutual Pharmaceutical Co. Inc. v.Bartlett, 570 U.S. 472 (2013).