Morris v. Biomet, Inc., Ebert v. C.R. Bard, Inc., and Zitney v. Wyeth LLC

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WHY THEY MADE THE LIST

These cases[1] made the list together because of their shared impact on the evolution of failure to warn claims during 2020 in the prescription drug and device arena. Two of these add to the growing body of law expanding the type of prescribing physician testimony that breaks the proximate causal chain in a failure to warn context and the third rejects an expansion of the legal duty owed by manufacturers to those prescribing physicians in terms of how warnings are conveyed—no duty to send "dear doctor" letters about label changes. In short, the adequacy of a warning becomes moot in a failure to warn claim where the physician does not recall having reviewed it and/or does not routinely rely on such things. And, under normal circumstances, a manufacturer need not go beyond including the labeling of its product in the usual way.

FRAMEWORK FOR DISCUSSION— FAILURE TO WARN AND THE LEARNED INTERMEDIARY

Failure to warn claims in a prescription product context are almost universally dictated by the learned intermediary doctrine. Adequacy of product labeling is most often judged by reference to the impact on the prescriber as opposed to the patient. While it is true that many failure to warn claims are simply barred by the application of other dispositive legal defenses (primarily preemption), when prescription product cases do get to the point of evaluation, the key is often the testimony of the prescribing physician.

The Restatement (Second) of Torts expresses the basic requirements for a plaintiff to plead and prove a failure to warn claim. A plaintiff must allege and establish (1) the manufacturer either knew, or should have known, of dangers inherent in the use of the product, yet adequate warnings were not given; and (2) if adequate warnings had been provided, the harm would have been avoided.[2] Thus, the first point of dispute is almost always whether the product is "properly prepared, and accompanied by proper

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1 Morris v. Biomet, Inc., —F.Supp.3d—, 2020 WL 5849482 (D. Md. Sept. 30, 2020); Ebert v. C.R. Bard, Inc., 459 F. Supp. 3d 637, 641 (E.D. Pa. 2020); Zitney v. Wyeth LLC, 2020 PA Super 278, 243 A.3d 241, 243 (2020).

2 Restatement (Second) of Torts § 402A cmt. j.

directions and warnings."[3] As noted, in the prescription product context, the manufacturer must make adequate warnings available to the patient's doctor—not to the patient—since physicians are in a better position to understand the risks and also initiate the decision for the patient to use the prescription product.[4] In this context, the physician is the *learned intermediary*.[5]

The second part is the causation element, asking whether different warnings would have resulted in a different outcome. Proximate cause is essential for the survival of failure to warn claims. If the learned intermediary does not read the label, plaintiff cannot show proximate cause and the warning claim fails.[6] For example, a claim was brought by a patient's widow alleging that her husband's prescription antidepressants did not adequately warn his physician of the associated side-effects. But she failed to show that the alleged inadequate warnings proximately caused her husband's death when his physician admitted that he had not read the label.[7] So ended the failure to warn claim regardless of the contents of the warning.

It has also been established that even an allegedly inadequate label does not proximately cause injury if a treating physician has independent knowledge of the risk (from his/her own practice, medical journals, etc.). What was less established was how a court might treat testimony from a treating doctor that was more equivocal about reading the labeling—the "does not recall" versus "never reviewed." This less defined treating physician testimony informs the decisions in two of the three selected cases. The third case discusses the question of how warnings are disseminated and what is required when an undisputedly adequate warning is placed in the box accompanying the product as opposed to disseminated otherwise.

DISCUSSION

Failure to "Recall" Reviewing the Labeling—Ebert v. C.R. Bard, Inc. *and* Morris v. Biomet, Inc.

Ebert v. C.R. Bard Inc. and *Morris v. Biomet, Inc*. examine to what end the learned intermediary must read the prescription product labeling for proximate cause to survive. In *Ebert v. C.R. Bard Inc.,* plaintiff Melissa Ebert (Ms. Ebert) was implanted with Bard's G2 inferior vena cava (IVC) filter that she alleged failed several years later.[8] In her action against Bard, Ms. Ebert brought a failure to warn claim alleging that while Bard cautioned that a filter fracture is a known complication, it did not provide her physician comparative failure rates between the G2 IVC filter and other Bard filters and other non-Bard filters.[9]

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3 Restatement (Second) of Torts § 402A cmt. k.

4 Reyes v. Wyeth Labs., Inc. 498 F.2d 1264, 1276 (5th Cir. 1974) ("Prescription drugs are likely to be complex medicines, esoteric in formula and varied in effect. As a medical expert, the prescribing physician can take into account the propensities of the drug, as well as the susceptibilities of his patient. His is the task of weighing the benefits of any medication against its potential dangers[.]").

5 *See id.*

6 *E.g.*, Motus v. Pfizer Inc. (Roerig Div.), 358 F.3d 659 (9th Cir. 2004).

7 *Id.* at 661.

8 Ebert v. C.R. Bard, Inc., 459 F. Supp. 3d 637, 642 (E.D. Pa. 2020).

9 *Id.* at 646.

Ms. Ebert's physician testified that while he would not have used the G2 IVC filter had he known that the filter carried a significant risk of fracturing, he independently knew that IVC filters could fracture, and, even more notably, he admitted never reading the full G2 IVC's instructions for use (IFU) and could not remember reading any of the IFU before Ms. Ebert's surgery.[10] Additionally, the physician could not testify that he relied on the IFU in deciding whether to use the G2 IVC filter over another filter.[11] Accordingly, the court dismissed the failure to warn claim, reasoning that since the physician did not rely on the IFU, it would have made no difference to the physician's decision to implant the G2 IVC filter in Ms. Ebert.[12]

While *Ebert* was more akin to other cases where the physician admitted to not reading the prescription product's labeling altogether, the court in *Morris v. Biomet, Inc.* dismissed the plaintiff's failure to warn claim as a matter of law, despite there being a scintilla of evidence that remained potentially supporting the existence of proximate cause.[13] In *Morris*, plaintiff Charlotte Morris (Ms. Morris) was diagnosed with a pseudotumor allegedly from Biomet's metal-on-metal hip joint replacement.[14] Ms. Morris' failure to warn claim alleged that Biomet's metal-on-metal hip joint replacement failed to adequately warn her of the *severity and prevalence of the risks* of metal hips and the secondary consequences of long-term exposure to toxic metals in the blood.[15]

Ms. Morris' physician testified that he was already aware that that metal-on-metal devices could cause pseudotumors related to metal-metal hypersensitivity.[16] The physician further testified that he made his own decisions based on peer-reviewed literature.[17] But he also testified that, though he could not recall whether he read the IFU prior to Ms. Morris' surgery, it was his standard practice to familiarize himself with the indications received from the manufacturer.[18] For the sake of ruling on summary judgment, the court seemed to assume that Ms. Morris' physician read the IFU.[19] Yet it still dismissed the failure to warn claim reasoning that "the evidence overwhelmingly shows that [the physician (i.e., the learned intermediary)] placed little weight on Biomet's warnings, indicating the different warnings would not have altered his decision-making."

In both *Ebert* and *Morris,* plaintiffs alleged that the IFUs needed more than merely the risks associated with their respective devices. But their inadequate warnings allegations were almost totally disregarded when it came to light that the respective learned intermediaries *placed little to no weight on the prescription products' labeling.*

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[10] *Id.* at 647.

[11] *Id.* at 648.

[12] *Id.*

[13] Morris v. Biomet, Inc., No. GJH-18-2440, 2020 WL 5849482, at *8, 10 (D. Md. Sept. 30, 2020) (A scintilla of proof that the physician may have read the label is not enough to defeat a motion for summary judgment, but in any event, the physician strongly favored his own research and knowledge over the label information anyway.).

[14] *Id.* at *3.

[15] *Id.* at *10.

[16] *Id.*

[17] *Id.*

[18] *Id.*

[19] *Id.*

It follows—from these cases—that neither plaintiff could show their injuries were proximately caused by the alleged inadequate warnings.[20]

Failure to Send Warnings by "Dear Doctor" Letter—Zitney v. Wyeth LLC

Zitney v. Wyeth LLC dismissed arguments that reasonable care in warning prescribing physicians must go beyond a drug's labeling and requires sending a "dear healthcare provider" (aka "dear doctor") letter.[21] In the end, the court in Pennsylvania put a ceiling on the manufacturer's standard of care.[22] The court found the manufacturer's satisfaction of its responsibility to warn of dangers in the FDA-reviewed label and labeling was enough.[23]

Years earlier, the U.S. Supreme Court in *Pliva, Inc. v. Mensing* (*Mensing*) held that generic manufacturers owe a "duty of sameness" under federal law requiring their labels to be the same as the reference listed drug (RLD) the generic drug follows, and therefore any state law claim imposing a duty on generic drug manufacturers to deviate from the RLD label is preempted.[24] A prior Pennsylvania Superior Court decision addressing preemption seemed to leave the door open with respect to similar—but not the same—duties of generic drug manufacturers in the *In re Reglan/Metoclopramide Litigation* decision.[25] *Zitney* managed to avoid any discussion of preemption, which is atypical in a failure to warn case relating to the duties of a generic drug manufacturer.[26] In doing so, the outcome in *Zitney* simplifies the analysis, particularly with prior Pennsylvania authority diverging on the question of what warning activity might be subject to preemption in the wake of *Mensing*.[27]

The plaintiff in *Zitney*, Janine Zitney, was diagnosed with tardive dyskinesia and brought claims against manufacturers of metoclopramide, the generic versions of Reglan, alleging the manufacturers knew but failed to warn her physician that tardive

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[20] The court in *Ebert* provided a footnote that even if her physician had read the IFU, no legal authority supported Ms. Ebert's allegation that Bard's duty to warn extended to providing comparative failure rates. But in *Morris*, the court was not prepared to review whether Biomet had a duty to warn of the magnitude of the risks associated with its metal-on-metal hip joint replacement. Nonetheless, the plaintiffs' inadequate warnings were papered over.

[21] Zitney v. Wyeth LLC, 2020 PA Super 278, 243 A.3d 241, 244 (2020).

[22] *Id.* at 246.

[23] *Id.*

[24] In *Mensing*, the plaintiffs brought failure to warn claims against generic drug manufacturers alleging, in part, that they had a duty to ensure that the plaintiffs' physicians were aware of the dangers associated with the prescription generic drugs by sending out "Dear Doctor" letters. PLIVA, Inc. v. Mensing, 564 U.S. 604, 615, 131 S. Ct. 2567, 2576, 180 L. Ed. 2d 580 (2011). However, federal law mandates that the generic drugs' labeling must mirror the branded drug's label, and the plaintiffs' proposed "Dear Doctor" letters would be considered labeling that the brand did not have. *Id.* at 624. Thus, if the manufacturers acted in accordance with the duty proposed by the plaintiffs, they would be violating the Federal Food, Drug & Cosmetic Act. *Id.* Thus, the U.S. Supreme Court dismissed the plaintiffs' failure to warn claims on the basis of implied preemption. *Id.*

[25] In re Reglan/Metoclopramide Litig., 2013 PA Super 214, 81 A.3d 80, 95 (2013) (finding that there is not a state law claim for plaintiffs' failure-to-communicate theory alleging the defendants' failure to unilaterally update their generic drug labeling, and accordingly, the claim could not be preempted by federal law).

[26] *Zitney*, 243 A.3d at 244.

[27] *Id.* at 246.

dyskinesia was a side effect of using the drug long-term.[28] But for purposes of the specific issue at hand, Mrs. Zitney did not allege that the IFU was inadequate.[29] Instead, her theory was that the manufacturers should have directly conveyed the required safety information to Mrs. Zitney's physician—as her learned intermediary[30]—in an additional "Dear Health Care Provider" letter reiterating the warnings found in the IFU.[31]

The *Zitney* court recognized that there is a reasonable limit to how manufacturers must inform the learned intermediary.[32] That limit coincides with years of FDA rules and enforcement. There was no reason for the court to impose additional requirements to labels that have already been reviewed and approved/cleared by the FDA.[33] As such, the court dismissed Mrs. Zitney's failure to warn claim.[34]

The importance of *Zitney* is in its approach to the issue of duty and warnings. Whereas the Supreme Court's decision in *Mensing* is farther-reaching in terms of its ability to bind other courts, it is directed fundamentally at generic drug manufacturers as it relied on impossibility preemption to dismiss warning claims.[35] The court in *Zitney*, however, did not consider or distinguish between prescription generic and branded drugs. [36] Instead, the court set the ceiling for the manufacturer's duty to notify as no higher than "provid[ing] content-appropriate warning labels in their [prescription product] packaging."[37]

IMPACT AND CONCLUSION

Though there are differences among them, the *Morris*, *Ebert*, and *Zitney* cases intersect in their approach to a learned intermediary's understanding of the risks from the labels at the time of the surgery. There is a general presumption that proximate cause cannot be shown if the physician never reviewed the prescription product's label. And *Ebert* and *Morris* likely expanded that presumption to account for the absence of weight the physician placed on the label compared to his or her own knowledge of the risks. In an effort to mitigate the risk that a plaintiff's physician neglected to read the warnings, the plaintiff in *Zitney* sought to bolster her failure to warn claims by asserting a manufacturer's duty to provide additional communication that ensured the physicians were alerted to and understood the risks. Yet *Zitney* rebuffed this view, setting the ceiling no higher than what is already required under the Federal Food, Drug and Cosmetic Act. Though *Zitney* needs to be tested against a failure to warn claim involving a prescription branded product, the fact that the subject of the suit was a generic drug did not seem to play a role in the court's reasoning. The

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28 *Id.* at 244.

29 *Id.* at 246.

30 Simon v. Wyeth Pharm., Inc., 2009 PA Super 263, ¶ 31, 989 A.2d 356, 368.

31 *Zitney*, 243 A.3d at 244.

32 *Id.* at 246.

33 *Id.*

34 *Id.*

35 *PLIVA, Inc.,* 564 U.S. at 615.

36 *Zitney*, 243 A.3d at 246.

37 *Id.*

fact that *Zitney* was not a preemption decision provides a fresh take on the issue where the adequacy of the label is not challenged. All three are thus important cases in the ongoing evolution of warning claims.