2017 WL 3138003
Only the Westlaw citation is currently available.

UNPUBLISHED OPINION. CHECK COURT RULES BEFORE CITING.

Superior Court of New Jersey, Appellate Division.

IN RE: ACCUTANE LITIGATION

Argued May 16, 2017
|
Decided July 25, 2017

On appeal from the Superior Court of New Jersey, Law Division, Atlantic County, Case No. 271 (MCL).

Attorneys and Law Firms

Bruce D. Greenberg argued the cause for appellants in A–4760–14 (*Seeger Weiss, LLP*, *Lite, DePalma, Greenberg, LLC*, and *Weitz & Luxenberg, PC*, attorneys; *David R. Buchanan* and *Peter Samberg*, on the brief).

Mary Jane Bass (*Beggs & Lane*) of the Florida bar, admitted pro hac vice, argued the cause for appellants in A–0164–15 (*Seeger Weiss, LLP*, *Lite, DePalma, Greenberg, LLC*, *Weitz & Luxenberg, P.C.*, and *Ms. Bass*, attorneys; *David R. Buchanan* and *Peter Samberg*, on the brief).

Paul W. Schmidt (*Covington & Burling LLP*) of the District of Columbia bar, admitted pro hac vice, argued the cause for respondents (in A–4760–14) and respondents/cross-appellants (in A–0164–15) *Hoffmann–La Roche Inc.* and *Roche Laboratories Inc.* (*Gibbons P.C.*, *Dughi Hewit & Domalewski, P.C.* and *Mr. Schmidt*, attorneys; *Michelle M. Bufano*, *Natalie H. Mantell*, *Russell L. Hewit*, *Mr. Schmidt*, and *Michael X. Imbroscio* (*Covington & Burling LLP*) of the District of Columbia bar, admitted pro hac vice, on the brief).

Edward J. Fanning, Jr., argued the cause for amicus curiae The HealthCare Institute of New Jersey in A–4760–14 (*McCarter and English, LLP*, attorneys; *Mr. Fanning* and *David R. Kott*, of counsel and on the brief; *Gary R. Tulp*, on the brief).

Before Judges Fisher, Ostrer and Moynihan.

Opinion

PER CURIAM

***1** These two appeals, calendared back-to-back, stem from orders entered in this multicounty litigation (MCL). The first (A–4760–14) concerns eighteen cases in which plaintiffs alleged that, on various dates after April 10, 2002, they were prescribed and ingested Accutane, a prescription acne drug manufactured by defendants Hoffman–La Roche Inc. and Roche Laboratories Inc. (collectively "defendants") in New Jersey. By that time, the Accutane package insert or label had been amended to provide that the drug had been "associated with inflammatory bowel disease." In these cases, plaintiffs allege they developed ulcerative colitis (an inflammatory bowel disease or IBD) from taking the drug; the judge determined—by way of summary judgment—that the post-2002 Accutane warnings were adequate as a matter of New Jersey law.

The second appeal (A–0164–15) concerns the dismissal of 514 Accutane complaints involving plaintiffs who were prescribed and ingested Accutane in jurisdictions other than New Jersey. These plaintiffs alleged they developed ulcerative colitis from ingesting the drug and that the post-2002 warnings were inadequate. In part one of a two-part opinion, the trial judge granted defendants' omnibus motion for summary judgment by applying New Jersey law. The judge did not conduct a choice-of-law analysis in this part of his decision; instead he found New Jersey law applied because of counsel's representations in the 2005 MCL petition. In part two of his opinion, the judge held that if the law of other jurisdictions applied to these out-of-state plaintiffs, he would have granted defendants' motion for summary judgment dismissing 394 of the cases under the laws of twenty-one of the jurisdictions, denied the motion as to 101 cases under the laws of twenty other jurisdictions, and granted the motion dismissing the remaining nineteen cases because the law of the state of injury in three jurisdictions was so unclear New Jersey law should apply.

In this second appeal, plaintiffs argue the trial judge erred in applying or interpreting New Jersey law and, also, that the substantive law of the other jurisdictions required a denial of summary judgment. [1] In their cross-appeal, defendants argue the judge erred in his alternative disposition denying summary judgment in 101 of the

cases. We turn first to the issues in A–4760–14 and then to those posed in A–0164–15.

I

In considering the issues raised in the first appeal, we first (a) discuss the background of these cases, (b) the evidential materials urged in opposition to summary judgment and the trial judge's determination, (c) the general legal principles followed when applying New Jersey products liability law to a claim based on the use of a pharmaceutical drug, and (d) the application of New Jersey law to these eighteen suits. In addition, even though unnecessary to our determination, we briefly discuss (e) plaintiffs' argument that the law-of-the-case doctrine barred the trial judge's summary judgment ruling.

A

(1)

***2** By way of background, we briefly observe that, in 2005, the Supreme Court designated all pending and future statewide actions involving Accutane as a mass tort pursuant to *Rule* 4:38A; all cases were transferred to Atlantic County to be heard on a coordinated basis. From 2007 to 2008, trials were conducted in the three bellwether cases; those juries found the 1984 warning, which warned that Accutane had been "temporally associated" with IBD, was inadequate. *McCarrell v. Hoffman–La Roche, Inc. (McCarrell I)*, No. A–3280–07 (App. Div. 2009), *certif. denied*, 199 *N.J.* 518 (2009); *Kendall I*, *supra*, 209 *N.J.* at 182–86 (post-2000 warning received after diagnosis); *Sager v. Hoffman–La Roche, Inc.*, No. A–3427–09 (App. Div. 2012), *certif. denied*, 213 *N.J.* 568 (2012). [2]

On March 20, 2008, Judge Carol Higbee denied defendants' omnibus motion for summary judgment on the adequacy of the post-2000 package insert warning in seventy-eight MCL cases, including *Tanna v. Hoffman–La Roche Inc.*, No. ATL–L–3366–04 (applying California law), *Alfano v. Hoffman–La Roche Inc.*, No. ATL–L–2650–07, and *Phillips v. Hoffman–La Roche Inc.*, No. ATL–L–1909–07 (a subject of this appeal). We denied defendants' motion for leave to appeal.

On December 10, 2008, Judge Higbee denied defendants' omnibus motion for summary judgment on the adequacy of the post-2001 warnings in eighty-four MCL cases, including *Alfano*, *Tanna*, and *Phillips*. We denied defendants' motion for leave to appeal.

On January 16, 2009, Judge Higbee denied defendants' omnibus motion for summary judgment in twenty-four cases filed by New Jersey plaintiffs, including *Phillips*, on the adequacy of some of the pre- and post-2000 warnings. And, in June 2010, Judge Higbee denied defendants' motion for summary judgment based on federal preemption in *Weathersbee v. Hoffman–La Roche, Inc.*, No. ATL–L–3260–04 and *Falco v. Hoffman–La Roche, Inc.*, No. ATL–L–2646–08 (applying North Carolina law), where the plaintiffs received post-2001 warnings.

Juries found the 1984 warning inadequate in four subsequently tried cases. *McCarrell v. Hoffman–La Roche, Inc. (McCarrell II)*, No. A–4481–12 (App. Div. 2015), *rev'd and remanded*, 227 *N.J.* 569 (2017); *Kendall v. Hoffman–La Roche, Inc. (Kendall II)*, No. A–0301–14 (App. Div. 2016); *Gaghan v. Hoffman–La Roche*, Nos. A–2717–11, A–3211–11, A–3217–11 (App. Div. 2014); and *Rossitto v. Hoffman–La Roche, Inc.*, No. A–1236–13 (App. Div. 2016), *certif. denied*, 228 *N.J.* 419 (2016).

Meanwhile, on various dates from 2007 to 2013, the eighteen plaintiffs in the first appeal at hand—plaintiffs who ingested Accutane in New Jersey after April 10, 2002—filed MCL complaints against defendants seeking damages for, among other things, a failure to warn under the New Jersey Product Liability Act (PLA), *N.J.S.A.* 2A:58C–1 to -11.

***3** In January 2015, defendants moved for summary judgment in *Alfano* on the adequacy of the post-2002 warnings under either New Jersey or Washington law. Alfano, however, dismissed her case with prejudice for unrelated reasons, prompting defendants to file an amended notice of motion for summary judgment (the subject of this appeal) based on the adequacy of the warnings in all MCL cases where plaintiffs first ingested Accutane after April 10, 2002.

On April 2, 2015, the newly-designated Accutane trial judge issued a written opinion finding the post-April 10,

2002 Accutane warnings were adequate as a matter of law under the PLA. An order dismissing those eighteen cases was entered on May 11, 2015.

(2)

In light of the familiar *Brill* standard,[3] which applies with equal vigor in our review of summary judgment determinations, *Templo Fuente De Vida Corp. v. Nat'l Union Fire Ins. Co. of Pittsburgh*, 224 *N.J.* 189, 199 (2016), we consider the following facts and circumstances in the light most favorable to plaintiffs. *Brill*, *supra*, 142 *N.J.* at 540.

In 1982, the Food and Drug Administration (FDA) approved defendants' new drug application (NDA) to market Accutane, "known generically as isotretinoin, for the treatment of recalcitrant nodular acne." *McCarrell II*, *supra*, 227 *N.J.* at 577. The drug is a retinoid, derived from vitamin A, and is highly effective in treating severe acne. *Kendall I*, *supra*, 209 *N.J.* at 180.

There is no dispute that Accutane "has a number of known side effects, including dry lips, skin and eyes; conjunctivitis; decreased night vision; muscle and joint aches; elevated triglycerides; and a high risk of birth defects if a woman ingests the drug while pregnant." *Ibid.* There is also evidence that Accutane, originally studied for use in treating cancer, has an effect on the gastrointestinal tract, *McCarrell I*, *supra*, slip op. at 6, 23–26, as acknowledged in the Accutane patent applications, *Rossitto*, *supra*, slip op. at 8. Pre-approval studies using dogs also "revealed instances of dose-related gastrointestinal bleeding." *Id.* at 6. Similarly, in defendants' Accutane clinical study of 523 patients, 21.6% suffered gastrointestinal side effects—primarily effects on mucous membranes—including such minor effects as increased thirst and appetite, nausea, and anorexia, as well as more serious gastrointestinal bleeding. *Ibid.* Gastrointestinal symptoms were also reported in 34% of the clinical trial patients who took a chemically-similar drug (Vesanoid, the brand name for tretinoin), manufactured by defendants to treat leukemia. *Ibid.*

These Accutane cases concern the alleged propensity of the drug to cause IBD, a chronic disease that primarily manifests as one of two diseases: Crohn's disease or ulcerative colitis. *Kendall I*, *supra*, 209 *N.J.* at 181.[4] Ulcerative colitis—plaintiffs' diagnosed condition—primarily involves inflammation of the lining of the colon (large intestine), while Crohn's disease can occur in any part of the digestive tract from the mouth to the anus, although it primarily manifests in the small intestine (the ileum) and the colon. *Rossitto*, *supra*, slip op. at 7. Both IBD forms share the same core symptoms: abdominal pain, frequent and often bloody bowel movements, and rectal bleeding. *Kendall I*, *supra*, 209 *N.J.* at 181.

***4** IBD's cause remains largely unknown; several triggers, however, are associated with a statistically increased rate of IBD, including family history, infections, some antibiotics, smoking, and possibly the use of oral contraceptives and nonsteroidal anti-inflammatory drugs. *Ibid.* IBD's peak onset occurs during adolescence, the same period individuals are likely to take Accutane. *Ibid.*

(3)

Defendants "designed, manufactured, and labeled Accutane in New Jersey and distributed the product from this State." *McCarrell II*, *supra*, 227 *N.J.* at 577. The FDA did not require a warning about IBD on the 1982 Accutane launch label, even though defendants, "as the sponsoring pharmaceutical company, had included information in its NDA indicating that the drug had an effect on the gastrointestinal tract." *Rossitto*, *supra*, slip op. at 8. Upon obtaining FDA approval, defendants began receiving reports of IBD in Accutane patients. *Id.* at 9. Defendants amended the "Adverse Reactions" section of the label in August 1983 to provide that "IBD and mild gastrointestinal bleeding had been reported in 'less than 1% of patients and may bear no relationship to therapy.' " *Ibid.*

By letter dated September 8, 1983, Public Citizen, a nonprofit consumer advocacy group, "petitioned the FDA for enhanced warnings on Accutane about a variety of serious adverse reactions, including IBD." *Ibid.* "Public Citizen expressed concern that the 'potential toxicity' of Accutane had been 'seriously under-emphasized' because the drug had been approved on limited data, had received 'fast track' approval, and had been overprescribed by physicians." *Id.* at 9–10. Public Citizen cited reports of patients developing IBD, noting that because of underreporting the reported cases underestimated IBD's actual occurrence, and recommended defendants'

inclusion of a warning about the risk of developing the disease. *Id.* at 10.

Defendants amended the "Warnings" section of the Accutane package insert provided to physicians in March 1984[5]; that warning remained in effect until 2000. It provided that "Accutane has been temporally associated with [IBD] in patients without a prior history of intestinal disorders" and that patients "experiencing abdominal pain, rectal bleeding or severe diarrhea should discontinue Accutane immediately." *Ibid.* At that same time, defendants issued a "Dear Doctor" letter to prescribing physicians, which explained that ten Accutane patients:

> have experienced gastrointestinal disorders characteristic of inflammatory bowel disease (including 4 ileitis and 6 colitis). While these disorders have been temporally associated with Accutane administration, i.e., they occurred while patients were taking the drug, a precise cause and effect relationship has not been shown. [Defendants are] ... continuing to monitor adverse experiences in an effort to determine the relationship between Accutane ... and these disorders.
>
> [*McCarrell I*, *supra*, slip op. at 7.]

As compelled by law, 21 *C.F.R.* §§ 314.80–81 (2017), defendants continued to: monitor the safety of Accutane; report to the FDA any adverse drug experiences and any new information that might affect the "safety, effectiveness or labeling of the drug product"; review the scientific literature; and review the data for evidence of signals, that is, "potential safety issues that should be included on the product label." *Rossitto*, *supra*, slip op. at 13.[6] "From 1992 to 1998, defendants recorded several positive rechallenge reports of IBD." *Id.* at 14. Dr. Alan Bess, defendants' former Director of Drug Safety, admitted that a single positive rechallenge could be significant enough to warrant inclusion of the event on the label. *Ibid.* Dr. Martin Huber, another former Director of Drug Safety, however, "stated it was 'very difficult to interpret' positive rechallenge data for IBD, because it is a permanent disease in which the symptoms wax and wane." *Ibid.*

***5** Defendants also inputted data from reports of adverse drug experiences (ADE) into their internal ADVENT database, which contained a field reflecting defendants' assessment of relatedness. *Id.* at 15. Defendants prepared periodic internal causality reports, which were not required to be submitted to the FDA, that evaluated the ADE reports. *Ibid.* In one internal causality assessment, defendants set forth that from 1982 to 1994, 104 cases of IBD and related syndromes were reported in Accutane users, "of which thirty-three were given a causality rating of 'possibly or probably related to the administration of the drug.' " *Ibid.* Based on that information, Dr. Henry Lefrancq, a Roche physician, stated in a February 24, 1994 internal memo—which was not submitted to the FDA—that "[i]t is reasonable to conclude from this data, that in rare cases, ROACCUTANE[7] may induce or aggravate a preexisting colitis." *Id.* at 16. He explained "it was reasonable to assume Accutane has the same effect on the intestinal mucosa as on the other mucosae in the body such as the oral or nasal mucosae" and that "these reactions have always been reversible, the colitis which may develop in a relatively limited number of patients can as well be regarded as reversible." In their June 1994 "general data" report, defendants stated that "[c]olitis appears as a possible Side [E]ffect of ROACCUTANE" and that inflammation of the small intestine and colon "is a possible side effect of ROACCUTANE in very rare cases, possibly in patients predisposed to inflammatory gastro-intestinal diseases."

Meanwhile, defendants prepared periodic safety update reports (PSUR) for the European market. In an August 17, 1988 report, Dr. Peter Schifferdecker, a physician and product specialist, reviewed the ADE reports received from patients using Accutane from January 1 to June 30, 1988, and reported that "[s]ince introduction, R[oche] Drug Safety received [thirty-eight] case reports of colitis and proctitis[8] in association with [Accutane] treatment." *Kendall I*, *supra*, slip op. at 10. Schifferdecker wrote that:

> [u]lcerative colitis and proctitis has an incidence rate of approximately 6–8 cases per 100,000 population per year (U.S.A. and western Europe)....
>
> It appears that cases of colitis and proctitis reported to R[oche] Drug Safety are within the spontaneous incidence rates of the background population, although underreporting of such cases may occur. It should be stressed that approximately one half of the patients were at a certain risk for the development of colitis prior to [Accutane] treatment. Although there is evidence from

> in vitro and animal experiments that [Accutane] may protect the organism from experimental colitis,[9] [ ] R[oche] Drug Safety will further monitor closely cases of colitis and proctitis reported in association with [Accutane] treatment.
>
> [*Id.* at 10–11.]

In a November 16, 2000 PSUR, which they also did not submit to the FDA, defendants reviewed ADEs from September 1, 1999, to August 31, 2000, and concluded that "[i]sotretinoin has been found to be causally associated with [IBD], including colitis."

(4)

In December 1997, as sales of Accutane were "escalating sharply," there arose differences of opinion between defendants' drug safety department and defendants' marketing department about adopting a label change to warn about a different side effect (depression) of Accutane. *Rossitto*, *supra*, slip op. at 17. Bess testified that Frank Condella, defendants' vice-president of marketing, "felt very strongly that any label change would hurt U.S. sales." *Ibid.* "The marketing department's 'philosophy was to protect the franchise' and 'build the product,' and thus Condella, during a 'very loud disagreement,' 'made it very clear that he wouldn't tolerate any action that would hurt the product.' " *Ibid.* "Mike Carter, [a drug safety officer] who reported to Bess, agreed that '[m]arketing was calling the shots.' " *Id.* at 17–18.

Russell Ellison, defendants' former chief medical officer, who testified in *Rossitto*, *Gaghan*, and *Kendall II*, admitted defendants "made a significant investment in marketing Accutane, and that its investment strategy was to '[f]eed the goose that lays the golden egg.' " *Rossitto*, *supra*, slip op. at 18. Ellison acknowledged there were "disagreements" between marketing and drug safety, and that safety-related label changes can hurt sales, but he disputed that marketing "called the shots" and claimed that marketing concerns "did not prevail because in February 1998 the Accutane label was changed to include a stronger warning about depression." *Ibid.*

***6** In any event, in March 1998, the FDA warned defendants that their advertising and promotional materials for Accutane were "false or misleading" and promoted "Accutane for an unapproved use." The FDA found that Roche had failed to disclose "that depression may be associated with the use of Accutane," and had "misleadingly" suggested "that Accutane therapy will minimize or improve the patient's psychosocial status, including depression," even though Roche had "not systematically studied" the ability of Accutane to modify or prevent depression. According to the FDA, Roche's claim was "particularly troublesome in light of information recently presented in a Dear Doctor letter, that Accutane may cause depression[.]" The FDA required Roche to cease this promotional activity and to instruct its sales personnel to stop disseminating the materials.

[*Id.* at 18–19.]

As our record reflects, in February 1999, the FDA asked defendants whether they had "enough data to observe" Accutane-associated IBD "reversibility." This inquiry generated some internal "confusion" because defendants understood IBD was a permanent, irreversible condition. In considering defendants' response, Carter observed that the Accutane label "says nothing" about reversibility "particularly, therefore one would assume ... [FDA may feel wrongly] the event is reversible." In a series of internal emails captioned "urgent," Huber sought help on the "reversibility" issue.

In January 2000—eleven months later—while then engaged in negotiations with the FDA regarding finalizing a new Accutane label—defendants responded to the FDA's inquiry by relying on a report by Dr. John LaFlore, a Roche physician, and by proposing no changes to the IBD label. In his October 1999 report, LaFlore had stated that, from 1992 to 1999, there had been 206 "case reports" "with IBD as a preferred term," but claimed there had been only one "positive rechallenge," explaining:

> [t]he onset of these events during isotretinoin use and the positive dechallenge reports are sufficient to justify the current warning in the label that IBD and regional ileitis may temporally arise during therapy and anyone with appropriate symptoms should discontinue therapy. However, the

> reports do not have the quality to revise this warning.

He concluded there was insufficient information

> to recommend additional label changes related to [IBD]. Some patients with known active symptoms and diagnosis of ... (IBD) are treated with Accutane for their severe recalcitrant acne without clinical sequel to their IBD symptoms.... There is no additional information to suggest an association of isotretinoin use with recurrence or prolongation of the symptoms of the disease based on the etiology and epidemiology of the disease.

Nonetheless, in May 2000, the FDA approved an amendment to the "WARNINGS" section of the package insert or label—warnings at issue in this appeal. These amendments, which were provided to physicians but not patients, removed the word "temporally," and this time warned that:

> Accutane has been associated with inflammatory bowel disease (including regional iletis) in patients without a prior history of intestinal disorders. In some instances, symptoms have been reported to persist after Accutane treatment has been stopped. Patients experiencing abdominal pain, rectal bleeding or severe diarrhea should discontinue Accutane immediately (see ADVERSE REACTIONS: Gastrointestinal).

***7** The "ADVERSE REACTIONS" section asserted that the "relationship of some" of the listed events "to Accutane therapy"

> is unknown. Many of the side effects and adverse reactions seen in patients receiving Accutane are similar to those described in patients taking very high doses of vitamin A (dryness of the skin and mucous membranes, e.g. of the lips, nasal passage, and eyes).
>
> ....
>
> Gastrointestinal inflammatory bowel disease (see WARNINGS: inflammatory bowel disease) ... bleeding and inflammation of the gums, colitis, ileitis, nausea, and other nonspecific gastrointestinal symptoms.

Bess admitted that "[t]he term 'association' is susceptible of different meanings within a package insert or label." Eileen Leach, defendants' former Medical Director of Dermatology, testified that "associated" does not mean "cause," and that if defendants had concluded that Accutane caused IBD, it should have included that finding on the label. Huber agreed there was a difference between "association" and "causation." Huber similarly admitted it would be inappropriate to state that a drug is "associated with" an adverse event (such as birth defects) if defendants knew there was a causal relationship. And he recognized that, if defendants believed that an event was caused by a drug, they "had an obligation to include that in [the] label."

(5)

Beginning in January 2002, defendants implemented a new pregnancy prevention program entitled "System to Manage Accutane Related Tetatogenicity," or "S.M.A.R.T." Under that program, a physician could only prescribe Accutane after obtaining a supply of yellow Accutane stickers. To receive the stickers the physician had to "[r]ead" the S.M.A.R.T. Guide to Best Practices, and "[s]ign and return" a letter of understanding that stated:

- I know the risk and severity of fetal injury/birth defects from Accutane.
- I know how to diagnose and treat the various presentations of acne.
- I know the risk factors for unplanned pregnancy and the effective measures for avoidance of an unplanned pregnancy.
- ... I will refer [the patient] for expert, detailed pregnancy prevention counseling and prescribing, reimbursed by the manufacturer, OR I have the expertise to perform this function and elect to do so.

- I understand and will properly use throughout the Accutane treatment course, the S.M.A.R.T. procedures for Accutane including monthly pregnancy avoidance counseling, pregnancy testing and use of the yellow self-adhesive Accutane Qualification stickers.

This S.M.A.R.T. Guide to Best Practices provided to physicians, however, focused almost exclusively on birth control and pregnancy and only briefly warned about IBD in a section entitled "About Accutane," prefaced with a statement that "Accutane is teratogenic and must not be used by pregnant women," following which it acknowledged that

> Accutane use is associated with other potentially serious adverse effects, as well as more frequent, but less serious side effects. More frequent, less serious side effects include cheilitis, dry skin, skin fragility, pruritus, epistaxis, dry nose and dry mouth and conjunctivitis.
>
> Adverse Event Warnings include psychiatric disorders ... ; pseudotumor cerebri; pancreatitis; hyperlipidemia; hearing impairment; hepatotoxicity; inflammatory bowel disease; skeletal changes ... ; [and] visual impairment.

***8** These paragraphs were followed by a statement that "[p]atients should be reminded to read the Medication Guide, distributed by the pharmacist at the time Accutane is dispensed." Pharmacists gave the "Medication Guide," published in January 2001, directly to patients. In alerting of the "possible serious side effects" of Accutane, the Guide described some of the symptoms of IBD but did not refer to the disease by name:

> Abdomen (stomach area) problems. Certain symptoms may mean that your internal organs are being damaged. These organs include the liver, pancreas, bowel (intestines), and esophagus .... If your organs are damaged, they may not get better even after you stop taking Accutane. Stop taking Accutane and call your prescriber if you get severe stomach, chest or bowel pain; have trouble swallowing or painful swallowing; get new or worsening heartburn, diarrhea, rectal bleeding, yellowing of your skin or eyes, or dark urine.
>
> ....
>
> Serious permanent problems do not happen often. However, because the symptoms listed above may be signs of serious problems, if you get these symptoms, stop taking Accutane and call your prescriber. If not treated, they could lead to serious health problems. Even if these problems are treated, they may not clear up even after you stop taking Accutane.

Beginning in January 2002, physicians were also required to provide patients with a patient brochure: a bright pink-colored, metal-ring binder entitled "Be Smart/Be Safe/Be Sure." *Kendall I*, *supra*, 209 *N.J.* at 183. As with the other materials referred to above, the "binder materials primarily focused on the dangers of becoming pregnant while taking Accutane." *Ibid.* The first section of the Eighth and Ninth Edition warned of "serious side effects," without specifically referring to IBD. These editions also included consent forms to be removed and signed by the patients, one of which stated that the patient had read and understood the provided written materials, and listed several side effects of Accutane, including birth defects and the risk of depression and suicide, but not IBD. [10]

Similar warnings to patients were included on the blister packaging, which again primarily warned about birth defects and depression, but also warned of "other serious side effects to watch for," without specifically referring to IBD:

> Stop taking Accutane and call your prescriber if you develop any of the problems on this list or any other unusual or severe problems. If not treated they could lead to serious health problems. Serious permanent problems do not happen often.
>
> **....**
>
> Severe stomach pain, diarrhea, rectal bleeding, or trouble swallowing **....**

In September 1999, the American Journal of Gastroenterology published a letter to the editor in which the mother of an Accutane patient raised concerns about the latent onset of IBD. The writer suggested defendants, who had not conducted any post-marketing clinical or epidemiological studies to investigate a link between Accutane and IBD, should conduct such a study. Defendants internally expressed concern that they should look at this issue "with some dispatch," and that "a letter

in a fairly widely-read journal ... might add fuel to fires which are already set."

***9** Ten years later (after trials in the first two Accutane cases, *McCarrell I* and *Kendall I*), the first Accutane observational epidemiological studies [11] were conducted by researchers, not defendants; these studies yielded mixed results. Only one study found a statistically-significant positive association between Accutane and ulcerative colitis, although four studies found a positive association between the drug and ulcerative colitis (but not Crohn's disease).

(6)

Cheryl Blume, a pharmacologist and vice-president of a pharmaceutical consulting company, testified as plaintiffs' expert in regulatory affairs, pharmacovigilance, and drug labeling in all of the Accutane cases tried to date. *Rossitto*, *supra*, slip op. at 26. She opined that neither the 1984 warning, *McCarrell I*, *supra*, slip op. at 108, *Sager*, *supra*, slip op. at 21–22; *Rossitto*, *supra*, slip op. at 26, nor the amended 2000–warning, *Kendall I*, *supra*, slip op. at 31–32, accurately reflected defendants' knowledge concerning IBD.

In opposing defendants' summary judgment motion, plaintiffs cited to Blume's testimony at the *Tanna* trial; there, she opined the post-2000 warnings were inadequate because defendants failed to disclose all information they possessed at that time: information they had disclosed for other adverse events, including birth defects and psychiatric disorders. She explained the package insert was the "hub of all the information, and everything else comes out of it" like spokes on a wheel. In her view, as a general matter, the warning section of a label contains "the more serious adverse events that have been observed with a product."

Blume testified that although defendants listed IBD in the warnings section of the label, they failed to advise physicians they had internally concluded Accutane was "causally associated" with IBD, that several cases of IBD had been found to be "possibly" or "probably" related to Accutane, and that Accutane can "induce or aggravate a preexisting colitis." She testified that defendants also failed to warn that IBD is a permanent, irreversible condition that cannot be treated, that there were several reported cases of rechallenges, that there is a latent onset effect, and that the drug was contraindicated for patients with a family history or pre-existing IBD. And she asserted that Schifferdecker erroneously reported in 1988 that adverse events of IBD were "within the spontaneous incidence rates" because he failed to account for underreporting.

***10** Blume explained the difference between the term "associated," which "simply means that the event occurred in some time proximity to when the drug was taken," and "causally associated," meaning "there's information linking the drug use with the adverse event." She additionally testified that defendants, in warning about other adverse events, had included: causal language (birth defects and psychiatric disorders); a warning that the adverse event had been found to be "possibly or probably related to Accutane" (hepatotoxicity); and a warning that the event had subsided with discontinuation of therapy and recurred with reinstitution of therapy (psychiatric disorders). Consequently, she testified defendants should similarly have included more information about IBD, as they had for another rare disease (pseudotumor cerebri), because the prescribing physicians were generally dermatologists who may not have been familiar with the permanence and severity of this gastrointestinal disease.

Blume concluded that the amended 2000 label had not been effective in warning physicians about IBD's severity and permanence because defendants continued to receive reports of rechallenges; that is, physicians continued to prescribe Accutane even after patients developed gastrointestinal side effects. And she opined that the other warning materials, including the Medication Guide and the S.M.A.R.T. binders, did not make sufficiently clear that IBD was a permanent disease that cannot be cured with treatment. In fact, Blume found the risk of IBD was minimized in both the Medication Guide and the S.M.A.R.T. binders because the symptoms of the disease were grouped with other non-relevant gastrointestinal problems such as painful swallowing and dark urine.

B

Despite this evidence, the trial judge granted defendants' motion for summary judgment, finding the post-2002 warnings contained in the written literature were adequate

as a matter of law to alert prescribing physicians that IBD was a risk associated with the ingestion of Accutane. In revisiting these issues, which Judge Higbee had already considered and rejected, the judge alluded to "new controlling authority," namely, *Bailey v. Wyeth, Inc.*, 424 *N.J. Super.* 278, 314 (Law Div. 2008), *aff'd*, 422 *N.J. Super.* 360 (App. Div. 2011), *certif. denied*, 211 *N.J.* 274 (2012), and concluded plaintiffs failed to present "the type and quality of evidence" required to "overcome the rebuttable presumption of adequacy under the NJPLA afforded to the FDA-approved labeling utilized by these [d]efendants in the marketing of Accutane." Citing to the written warnings, and not to the testimony of Leach, Bess, Huber or Blume, or defendants' internal documents, the judge concluded that:

> Both the substance and form of the warning literature issued to prescribing physicians by [d]efendants emanates a very forceful seriousness of purpose; driving home the message to physicians of ordinary skill, care and diligence that is clear, accurate and unambiguous, namely, You are about to prescribe a medication that is associated with risk of serious side effects. You are responsible for counseling your patients of these risks.
>
> Taken as a whole, the warning system crafted by [d]efendants conveys a meaning as to potential risks and consequences that is unmistakable. It is inconceivable to this court that the reasonable dermatologist (or any physician, generally) of ordinary education, training and experience could examine the materials comprising the warning literature and not immediately conclude that Accutane has been associated with life-altering side effects, including IBD. At multiple points, IBD is explicitly communicated to the prescribing physician as a potential risk of Accutane ingestion.
>
> [T]he labeling and all the warning literature issued to physicians by the manufacturer very ably disclose with ample detail and intensity the risks associated with taking Accutane. Viewed objectively, it is a striking package of information for introducing a medication to a prescribing physician. Any physician of ordinary skill, care and diligence who ignored the [d]efendants' warning system did [ ] patients a disservice. Such warnings are entitled to the benefit of our state's rebuttable presumption of adequacy and are deemed adequate as a matter of law.

***11** In our de novo review of this determination, we start with certain general principles.

C

As a general matter, the adequacy of a warning presents a jury question. *Kendall I*, *supra*, 209 *N.J.* at 195. At the same time, we recognize that when a plaintiff fails to overcome the PLA's rebuttable presumption of adequacy in pharmaceutical cases, *Bailey*, *supra*, 424 *N.J. Super.* at 314, or where a warning is accurate, clear and unambiguous, *Banner v. Hoffmann–La Roche Inc.*, 383 *N.J. Super.* 364, 378–80 (App. Div. 2006), *certif. denied*, 190 *N.J.* 393 (2007), a court may conclude that warnings are adequate as a matter of law.

We also observe that the PLA was enacted "as a remedial measure to limit the liability of manufacturers by establishing 'clear rules with respect to certain matters relating to actions for damages for harm caused by products,' " and "[i]n particular," to "reduce the burden on manufacturers of FDA-approved products resulting from products liability litigation." *Kendall I*, *supra*, 209 *N.J.* at 194 (quoting *N.J.S.A.* 2A:58C–1(a)). In accordance with common law principles, *Feldman v. Lederle Labs.*, 125 *N.J.* 117, 144 (1991), *cert. denied*, 505 *U.S.* 1219, 112 *S. Ct.* 3027, 120 *L.Ed.* 2d 898 (1992), the PLA provides that a manufacturer shall be rendered liable for harm caused by a product "not reasonably fit, suitable or safe for its intended purpose" when the product "fail[s] to contain adequate warnings." *N.J.S.A.* 2A:58C–2. The PLA represents "an expression of New Jersey's strong public policy of ensuring that manufacturers attach adequate warnings and instructions to prescription drugs so that consumers, ultimately, will be made aware of the relevant risks, dangers, and precautions in taking such medications." *In re Reglan Litig.*, 226 *N.J.* 315, 335 (2016).

In addition, we take note that the Supreme Court of the United States has "articulated an overarching federal policy for permitting state-law [failure-to-warn] suits," *id.* at 334, by recognizing that the FDA:

> has limited resources to monitor the 11,000 drugs on the market, and manufacturers have superior access to information about their drugs, especially in the postmarketing phase as new risks emerge. State tort suits uncover unknown drug hazards and provide

> incentives for drug manufacturers to disclose safety risks promptly. They also serve a distinct compensatory function that may motivate injured persons to come forward with information. Failure-to-warn actions, in particular, lend force to the [Federal Food, Drug, and Cosmetic Act's] premise that manufacturers, not the FDA, bear primary responsibility for their drug labeling at all times.
>
> [*Wyeth v. Levine*, 555 *U.S.* 555, 578–79, 129 *S. Ct.* 1187, 1202, 173 *L.Ed.* 2d 51, 68–69 (2009).]

Of additional importance, the PLA incorporates the "learned intermediary" doctrine by which a manufacturer's duty to warn about the dangers of prescription drugs runs to the physician, not the patient. *N.J.S.A.* 2A:58C–4; *Perez v. Wyeth Labs., Inc.*, 161 *N.J.* 1, 10 (1999); *Niemiera by Niemiera v. Schneider*, 114 *N.J.* 550, 559 (1989). Significantly, the PLA recognizes "the important role of the federal regulatory system over prescription drugs," *Reglan Litig.*, *supra*, 226 *N.J.* at 335, and provides that an FDA-approved drug warning constitutes "a rebuttable presumption" that the warning is adequate, *N.J.S.A.* 2A:58C–4. In other words, "an FDA-approved label is presumably adequate to inform a reasonable person of the dangers of a product." *Kendall I*, *supra*, 209 *N.J.* at 197. The Court also expressed an expectation that the presumption would be overcome only in "rare cases." *Perez*, *supra*, 161 *N.J.* at 25.

***12** We also recognize that, in accordance with the Federal Food, Drug, and Cosmetic Act (FDCA), 21 *U.S.C.A.* §§ 301–399f, all pharmaceutical drugs must be FDA-approved before being marketed in the United States. *Reglan Litig.*, *supra*, 226 *N.J.* at 329. The FDA, which regulates the manufacturing, packaging, and labeling of drugs under the FDCA, approved all of the warnings at issue here, including: the May 2000 package insert; the January 2001 Medication Guide; the January 2002 S.M.A.R.T. Guide to Best Practices; the January 2002 "Be Smart/Be Safe/Be Sure" patient brochure; and the blister packaging. *See* 21 *U.S.C.A.* § 355(a).

The FDCA requires a pharmaceutical manufacturer to prove, prior to marketing, that a new drug "is safe and effective and that the proposed label is accurate and adequate." *PLIVA, Inc. v. Mensing*, 564 *U.S.* 604, 612, 131 *S. Ct.* 2567, 2574, 180 *L.Ed.* 2d 580, 588 (2011). These federal statutes and regulations are based on the central premise that "the manufacturer bears responsibility for the content of its label at all times [and] is charged both with crafting an adequate label and with ensuring that its warnings remain adequate as long as the drug is on the market." *Wyeth*, *supra*, 555 *U.S.* at 570–71, 129 *S. Ct.* at 1197–98, 173 *L.Ed.* 2d at 63. The FDCA renders a manufacturer responsible for "the accuracy and adequacy" of a label "not only when it files a new drug application, but also when it seeks FDA approval for updated labeling to inform the public of previously unknown adverse side effects caused by a drug, 21 *U.S.C.A.* §§ 355(b)(1),(d),(j)(2)(A)." *Reglan Litig.*, *supra*, 226 *N.J.* at 330 (quoting *Mensing*, *supra*, 564 *U.S.* at 612, 131 *S. Ct.* at 2574, 180 *L.Ed.* 2d at 588).

In failure-to-warn claims involving pharmaceutical drugs, our Legislature has acknowledged "the preeminent role of federal regulation," *Cornett v. Johnson & Johnson*, 211 *N.J.* 362, 387 (2012), by affording manufacturers a "rebuttable presumption" that FDA-approved warnings will be assumed "adequate." *N.J.S.A.* 2A:58C–4. This presumption helps "to ensure that manufacturers are not made guarantors against remotely possible, but not scientifically-verifiable, side-effects of prescription drugs, a result that could have 'a significant anti-utilitarian effect.' " *Perez*, *supra*, 161 *N.J.* at 25.

D

Notwithstanding, the PLA recognizes that compliance with FDA regulations provides only "compelling"—"not absolute"—evidence that "a manufacturer satisfied its duty to warn about the dangers of its product." *Kendall I*, *supra*, 209 *N.J.* at 195; *Perez*, *supra*, 161 *N.J.* at 24. It was anticipated that this "virtually dispositive" presumption would be difficult to overcome. *Kendall I*, *supra*, 209 *N.J.* at 195–97; *see* Dreier, Keefe & Katz, *Current N.J. Products Liability & Toxic Torts Law* 468–69 (2017). Yet the parties acknowledge the statutory presumption can be overcome. They disagree, however, as to the precise effect and force of the presumption. Plaintiffs argue that, "on its face, the statute does not appear to require anything more than that necessary to overcome a standard *N.J.R.E.* 301 presumption." We reject this view.

N.J.R.E. 301 provides that "[i]f evidence is introduced tending to disprove the presumed fact, the issue shall be submitted to the trier of fact for determination unless the evidence is such that reasonable persons

would not differ as to the existence or nonexistence of the presumed fact." Latching on to this approach, plaintiff argues the PLA created, in their words, only "a garden variety rebuttable presumption" that should be viewed in the manner prescribed by *N.J.R.E.* 301. But, when considering the PLA's intent to limit the liability of drug manufacturers, it seems clear the garden-variety presumption of *N.J.R.E.* 301 was discarded in favor of what *Perez* described as something that "[f]or all practical purposes," will not be overcome "absent deliberate concealment or nondisclosure of after-acquired knowledge of harmful effects, compliance with FDA standards should be virtually dispositive of [failure-to-warn claims]." 161 *N.J.* at 25.

***13** The Court confirmed that interpretation in *Rowe v. Hoffman–La Roche, Inc.*, 189 *N.J.* 615, 626 (2007). And, in *Kendall I*, *supra*, 209 *N.J.* at 195, the Court referred to its holding in *Perez* as having created "a super-presumption." Consequently, we reject plaintiff's argument that the statutory presumption should be approached in the manner described in *N.J.R.E.* 301. We recognized as much when we affirmed the trial court's explanation in *Bailey*, *supra*, 424 *N.J. Super.* at 314, that "the presumption of adequacy afforded to a manufacturer's compliance with FDA requirements is stronger and of greater evidentiary weight than the customary presumption referenced in *N.J.R.E.* 301." *See also* Dreier, Keefe & Katz, *supra*, at 468–69 (observing that the statutory presumption described in *Perez* is much stronger than the typical presumption).

Consequently, this view of the presumption poses a question relevant to this appeal: what type and degree of proof will rebut the *N.J.S.A.* 2A:58C–4 "super presumption?" In *Kendall I*, *supra*, slip op. at 53, we said the "strength of the statutory presumption may be lessened ... if the warning at issue is not the initial warning approved by the FDA for the drug," as in these cases, "but rather is a modified warning that was negotiated post-market between the manufacturer and the FDA." And we recognized in *McDarby v. Merck & Co.*, 401 *N.J. Super.* 10, 65 (App. Div. 2008), *appeal dismissed*, 200 *N.J.* 267 (2009), that, prior to 2007, the FDA did not have the "authority to compel labeling changes, but instead had to negotiate changes with the drug's sponsor." And, given the manufacturers' "common resistance to such labeling changes, a revised label may be the result of a compromise, rather than a unilateral expression of the FDA's preferred regulatory approach." *Kendall I*, *supra*, slip op. at 54. In light of the ongoing regulatory dynamics between drug companies and the FDA, the PLA's presumption of adequacy is easier to overcome for a negotiated, post-market label than for the original warning accompanying the drug, which was not, to the same extent, the result of "conciliatory processes." *McDarby*, *supra*, 401 *N.J. Super.* at 69. *See Wyeth*, *supra*, 555 *U.S.* at 578–79, 129 *S. Ct.* at 1202, 173 *L.Ed.* 2d at 68 (recognizing FDA's "limited" monitoring resources).

The presumption may also be overcome with: (1) evidence of a deliberate concealment or nondisclosure of after-acquired knowledge of harmful effects, *Perez*, *supra*, 161 *N.J.* at 25; *Rowe*, *supra*, 189 *N.J.* at 626; or (2) substantial evidence of economically-driven manipulation of the post-market regulatory process, *McDarby*, *supra*, 401 *N.J. Super.* at 63, 66.

As to this first aspect, we note that the Court in *Cornett*, *supra*, 211 *N.J.* at 390, upheld our reversal of a dismissal on the grounds of federal preemption, because:

> defendants withheld information from the general public and the medical community about the limitations of the device or safe use of the device, including information that instructions for post-implantation therapy were not part of the [premarket approval (PMA)] process, and misrepresented to the general public and medical community that the [device] was non-thrombogenic. As stated, this claim overcomes the PLA rebuttable presumption of adequacy. *Perez*, *supra*, 161 *N.J.* at 25. Such a claim falls within a traditional area of state concern and regulation because fraud on the FDA is not an element of the claim and it can be proved by evidence other than by evidence of fraud on the FDA.

On the other hand, *Bailey* presents an example of a plaintiff's failure to overcome the presumption regarding a revised label.[12] Applying the *Perez*/*Rowe* exceptions here, we must consider—through the *Brill*

prism—whether plaintiffs presented sufficient evidence of deliberate concealment or nondisclosure of after-acquired knowledge of harmful effects to suggest that a genuine dispute as to whether the PLA's "super" presumption may be overcome.

***14** Plaintiffs contend, as in other Accutane cases involving the 1984 warning, that they can overcome the presumption because of evidence that defendants "failed to disclose information it had on the risk of IBD with Accutane use, that economics drove its decisions on drug safety and warnings, and that it withheld information on the risk of the drug from the medical community and the public." We commence our consideration of the evidential materials by observing that in all other cases tried to date [13] within this MLC matter, juries have found the 1984 FDA-approved warning that Accutane had been temporally associated with IBD was inadequate.

For example, in *McCarrell II*, *supra*, 227 *N.J.* at 577–78, the plaintiff claimed that

> the Accutane label and other warnings conveyed the impression that the listed adverse reactions to Accutane would arise while the patient was taking the medication and that discontinuing its use would resolve such problems. Plaintiff also contends that the warnings did not suggest that he could develop an irreversible case of [IBD] after completion of the Accutane regimen. He asserts that, during the period he took Accutane, Roche knew or should have known that Accutane not only could trigger [IBD] after its use, but that it also could cause irreversible damage to his organs, and that Roche failed to provide adequate warnings to him and his physician about those risks.

We affirmed those findings in all of the cases raising the issue of the adequacy of the 1984 warning. In fact, in *McCarrell I*, *supra*, slip op. at 108, we rejected defendants' argument that the 1984 Accutane label warning was adequate as a matter of law under the PLA. In *Kendall I*, *supra*, slip op. at 88–89, we determined that Blume's testimony was sufficiently persuasive to overcome the statutory presumption. And, in *Rossitto*, *supra*, slip op. at 55–57, we were satisfied plaintiff presented sufficient evidence to overcome the presumption, stating:

> As in *McCarrell I* and *Kendall I*, here there was evidence that the 1984 warning, as it existed when plaintiffs took the drug from 1992 to 1998, was inadequate even though it specifically referred to IBD, because it did not accurately reflect the knowledge the company allegedly had. As we have noted, Dr. Blume testified that during the sixteen years that the label had remained unchanged (from 1984 to 2000), Roche had received information through ADE reports that indicated both a causal relationship between Accutane and IBD and a latency effect, which she asserted was critically important information for a physician to have in making a risk/benefit analysis. Dr. Blume also criticized Roche's use of the term "temporally associated," which was subject to differing definitions by the company's own employees, and which she said meant while a patient was taking the drug. The labeling expert opined that the use of the term "temporally" falsely suggested that the disease was reversible, and that there was no latent effect.
>
> We recognize that the FDA approved the 1984 version of the label. Nevertheless, plaintiffs marshalled sufficient competing evidence upon which a jury reasonably could rely to overcome the rebuttable statutory presumption of adequacy. At a minimum, viewing the record from this trial, as we must, in a light most favorable to the respondents ... there was potentially credible proof of the company's "deliberate concealment or nondisclosure of after-acquired knowledge of [Accutane's] harmful effects[.]" *Perez*, *supra*, 161 *N.J.* at 25 (emphasis added); *see also Rowe*, *supra*, 189 *N.J.* at 626. On a retrial, the parties are free to continue to litigate the general causation issues bearing upon Accutane's actual "harmful effects" and the adequacy of the 1984 label, with the opportunity to expand the proofs to include more recent scientific studies further addressing those questions.

***15** We have yet to directly address whether plaintiffs overcame the presumption of adequacy as to the post-2000 warnings. In *Kendall I*, *supra*, 209 *N.J.* at 182–84, the Court only considered the post-2000 warnings as it related to the tolling of the statute of limitations. In that case, the plaintiff was first prescribed Accutane in 1997 (when the 1984 warning was in effect), was diagnosed with IBD in April 1999, received her fifth course of Accutane

in December 2000, and her sixth course from 2003 to 2004 (when the 2000 warnings at issue here were in effect). *Id.* at 184–86. The jury considered only the earlier warnings and found defendants failed to provide an adequate warning to the treating physician of the risks of IBD from Accutane that it either knew or should have known prior to April 1999. We reversed and remanded on other grounds but found Kendall had presented sufficient evidence, regarding its pre-1999 warnings, to overcome the presumption:

> There is ample factual proof in the present record to justify the jury's determination that the warnings supplied with Accutane, even though they had been approved by the FDA, were inadequate to have reasonably alerted plaintiff and her physicians to the risks that plaintiff would contract IBD from using the drug.
>
> ....
>
> Among other things, the expert testimony of plaintiff's labeling expert, Dr. Blume (who was not countered by an equivalent defense expert specifically called to opine exclusively on labeling issues) was sufficiently persuasive and tied to the proofs that a reasonable juror could have found the statutory presumptions were overcome.
>
> [*Kendall I*, *supra*, slip op. at 88–89.]

The Supreme Court affirmed, holding that "Kendall's suit may proceed because the evidence not only overcame the presumption, but established that under all the circumstances, Kendall reasonably was unaware that defendants caused her injury until after December 21, 2003." *Kendall I*, *supra*, 209 *N.J.* at 198. The Court wrote:

> Although we can conceive of circumstances in which the 2003 warning might have been sufficient to alert a plaintiff of the connection between Accutane and her disease, it was certainly not sufficient, in these circumstances, to cause Kendall to doubt her physicians or to disregard the advice and information that had been imparted to her by them for the prior six years. That is particularly so in light of the lack of a discernable link between Kendall's symptoms and the ingestion of the drug.
>
> [*Id.* at 199.]

The Accutane MCL trial judges have addressed this issue, but with conflicting results on the adequacy of the post-2000 warnings.

In considering the adequacy of the post-April 10, 2002 warnings, it may be true that the warnings to physicians (May 2000 package insert and S.M.A.R.T. Guide to Best Practices), and to patients (2001 Medication Guide, Be Smart/Be Safe/Be Sure binder, and blister packaging) possess greater clarity than the 1984 warnings at issue in *McCarrell I and II*, *Kendall I and II*, *Sager*, *Gaghan*, and *Rossitto*. "[T]emporally" was removed; without the connotation conveyed by that word, physicians were warned that Accutane is "associated" with IBD. Warnings were also added that IBD symptoms had persisted in some cases after Accutane was discontinued, thus coming closer to conveying that symptoms may be permanent. In *Rossitto*, *supra*, slip op. at 45, we said "it is manifestly clear that the 2000 warning ... strengthen[ed] the label's warning relating to IBD and gastrointestinal disorders by removing the 'temporally associated' phrasing."

But the post-2002 warnings like the 1984 warnings still lack causal language—what Blume said was "critically important" information for physicians. *Id.* at 56. In fact, many of the treating physicians in the Accutane MCL cases have testified they would have wanted to know if there was a causal relationship, and if warned, they would have conveyed that warning to their patients. *Id.* at 58–61. The warnings also lack information as to a latency effect, and lack any statement that the disease is not reversible. Indeed, the materials provided to patients, which were also available to physicians, implied that if "treated" a patient would not suffer "serious health problems." As Judge Higbee found in denying defendants' previous motion for summary judgment, the Medication Guide compounded the confusion as to causation by failing to refer to IBD and by listing the symptoms of IBD along with other non-relevant symptoms such as yellowing of the eyes and dark urine.

***16** The record also contains evidence that defendants had after-acquired knowledge of these harmful effects that they failed to disclose. For example, there was evidence that defendants had internally concluded, based on information contained in ADE reports, that in some cases there was a causal effect between the drug and IBD, but defendants did not disclose that information to the FDA or include it in the Accutane label. And there

was evidence that defendants included that information for other adverse events, including strong warnings that "there is an extremely high risk that a deformed infant can result if pregnancy occurs while taking Accutane," and warnings that Accutane "may cause" psychiatric disorders."

The record also contains evidence that defendants received several positive rechallenge reports, which they did not include in the label as they had for psychiatric disorders. Consequently, plaintiffs argue defendants may have misrepresented the number of rechallenge events in responding to the FDA's inquiry. In addition, defendants did not respond to the FDA's inquiry regarding whether Accutane-induced IBD was reversible. Despite this after-acquired knowledge of harmful effects, and the confusion as to whether the disease was reversible, no changes to the 1984 label were proposed by defendants in 2000.

In applying our familiar standard of review on summary judgment dispositions, we conclude from this record that plaintiffs presented sufficient evidence of defendants' nondisclosure of after-acquired knowledge of Accutane's harmful effects to overcome the rebuttable statutory presumption of adequacy and to present a jury question as to the adequacy of the warning. Although defendants specifically mentioned IBD in their warnings, there is evidence from which a finder of fact could conclude that, after FDA-approval, defendants internally concluded there was a causal effect between Accutane and IBD and received reports of rechallenges and a latency effect—critical information that defendants did not disclose in their post-2002 warnings.

Even though unnecessary to our disposition of this appeal—because we conclude that plaintiffs overcame the statutory presumption by presenting sufficient evidence under the first prong—we briefly discuss the second prong, i.e., whether plaintiffs presented substantial evidence of economically-driven manipulation of the post-market regulatory process.

To give context to this argument we briefly discuss our experiences with this second prong. In *McDarby*, *supra*, 401 *N.J. Super.* at 50, the plaintiffs brought claims under the PLA against a manufacturer of Vioxx for failure to warn of cardiovascular risks. At the time of FDA approval, the defendant was aware of a possible, but unconfirmed, risk of increased cardiovascular events. *Id.* at 67. Defendant's post-approval study unintentionally confirmed the increased risk. *Ibid.* The defendants, however, sought "to dilute the labeling required as a result of [this] study" and "to ensure" the results "were not communicated to prescribing physicians by sales persons." *Id.* at 68. We concluded this type of conduct can overcome the presumption, finding that given the

> admitted flaws in the FDA's control over postmarket labeling in the years that Vioxx was on the market, we are unwilling to accept Merck's position that the presumption of adequacy of a prescription drug's label can be overcome only upon proof of deliberate concealment or nondisclosure. Facts unavailable to the Supreme Court at the time of the *Perez* decision demonstrate that such a restriction is too narrow.
>
> [*Id.* at 66.]

A similar approach was taken by the trial judge in *Bailey*, *supra*, 424 *N.J. Super.* at 315–19.

***17** Although the evidence here might not appear as strong as that in *McDarby*, we conclude that for present purposes—requiring that evidence be viewed in plaintiffs' favor—that this evidence also required a denial of summary judgment.

In support of their arguments on this second prong of the *Perez*/*Rowe* exception, plaintiffs refer to: (1) the "marketing trumps safety" discussions regarding Accutane and depression; (2) Ellison's comments that defendants' investment strategy was to "feed the goose that lays the golden egg"; and (3) defendants' failure to respond to the FDA's query regarding IBD reversibility. Because the significance or weight of this evidence is a matter for the trier of fact, we conclude that it was sufficient to preclude summary judgment.

In granting summary judgment, the trial judge adopted a view similar to defendants' conclusory assertion that "no reasonable jury could conclude that Accutane's 2002 warnings failed to adequately warn prescribers of the risk of IBD." The judge similarly concluded that the warnings are "clear, accurate and unambiguous," and that the facts demonstrate

> the labeling and all the warning literature issued to physicians by the manufacturer very ably disclose

> with ample detail and intensity the risks associated with taking Accutane. Viewed objectively, it is a striking package of information for introducing a medication to a prescribing physician. Any physician of ordinary skill, care and diligence who ignored [d]efendants' warning system did his/her patients a disservice. Such warnings are entitled to the benefit of our state's rebuttable presumption of adequacy and are deemed adequate as a matter of law.

We reject the judge's determination that the warning was clear enough to negate a trial on the issue. The PLA provides that a manufacturer shall be liable for harm caused by a product that was "not reasonably fit, suitable or safe for its intended purpose" because it "failed to contain adequate warnings." *N.J.S.A.* 2A:58C–2. A manufacturer "shall not be liable for harm caused by a failure to warn if the product contains an adequate warning," which is defined as

> one that a reasonably prudent person in the same or similar circumstances would have provided with respect to the danger and that communicates adequate information on the dangers and safe use of the product, taking into account ... in the case of prescription drugs ... the characteristics of, and the ordinary knowledge common to, the prescribing physician....
>
> [*N.J.S.A.* 2A:58C–4.]

The PLA thereby incorporates the "learned intermediary" doctrine under which a pharmaceutical manufacturer's duty to warn about the dangers of prescription drugs runs to the physician, not the patient. *Perez*, *supra*, 161 *N.J.* at 10; *Niemiera*, *supra*, 114 *N.J.* at 559. "A product warning or instruction that does not comport with" *N.J.S.A.* 2A:58C–4 is "defective." *Banner*, *supra*, 383 *N.J. Super.* at 375.

Consequently, we reverse because we substantially agree with the views expressed by Judge Higbee when she denied summary judgment on this same issue. Judge Higbee emphasized, as do we, that the summary-judgment procedure required a consideration of the evidence in the light most favorable to plaintiffs:

> Looking at the facts in [the] light most favorable to plaintiff, the question is does the warning convey in a clear, concise, and sufficiently forceful way the risk of the patient developing IBD which is a severe life changing condition that is permanent even after the drug is discontinued?
>
> ***18** It may be that the facts about the disease are not as represented by plaintiff's expert, but for purposes of this motion the Court must assume that Accutane causes IBD which is very different from transient gastrointestinal problems associated with many medications. Even if the jury finds that plaintiff's allegations about Accutane and IBD are all true, they still can find this warning is adequate. The jury can accept that even if Accutane probably "causes" IBD, the words "associated with" are sufficient. A warning can be adequate without using the word "causes," but it can also be inadequate depending on all the facts.
>
> The jury may conclude this warning adequately conveys to doctors the nature of the risk because all doctors should understand IBD is permanent and serious, but plaintiffs point out that doctors who prescribe Accutane are usually dermatologists, not gastroenterologists. A jury could decide the second and third sentence [in the warning] suggests to a doctor the lesser more transient conditions of diarrhea and gastrointestinal pain that may persist after removal from the drug, but which eventually resolves especially by saying the drug should be discontinued if there are these common GI symptoms. This may be found to imply to the physicians that stopping the treatment would prevent the development of IBD.
>
> A drug label does not have to have the best possible warning, but it must be sufficient to adequately convey the nature, extent, and seriousness of the risk in a clear unambiguous way to the prescribers of the drug. In this case, as in most cases, the sufficiency of the warning is for the jury.
>
> The bottom line is this [c]ourt cannot find as a matter of law that this warning was inadequate, but also cannot find it was adequate as a matter of law.

In addition, in denying defendants' omnibus motion for summary judgment on the post-2000 package insert and the January 2001 Medication Guide warnings, Judge Higbee found that:

> The question now is does the language in the patient guide strengthen the 2000 warning and make it so clear that the issue of adequacy [ ] should be taken from the jury. As the plaintiffs point out, the new language itself does not mention IBD. In fact, the new language generally refers to "the liver, pancreas, and bowel (intestines)." It is so general it could be found to weaken the information in the label, not strengthen it. There is no direct reference to IBD.
>
> The Medication Guide also states "[the symptoms] may not get better even after you stop taking Accutane." (emphasis added). It is not disputed that if you have IBD, you will not get "better," in the sense you will ever be cured.
>
> Additionally, the plaintiffs point out (and the defendants ignore) additional language in the Medication Guide in a paragraph at the bottom of the "serious side effects" listings. The language states that "[i]f [the symptoms are] not treated, they could lead to serious health problems. Even if these problems are treated, they may not clear up after you stop taking Accutane." (emphasis added). The "could lead" and "may not" language are ambiguous. The ambiguity of the warnings reflects the defendants' position that there is no proof of causation. Since the [c]ourt must accept all facts in favor of the plaintiff, including causation, which four juries have found does exist, "could lead" and "may not" are just not direct enough to render the warning adequate as a matter of law even if they directly discussed IBD which they do not. Again, it may be adequate, but it clearly is a jury question.

To be sure, defendants' arguments are colorable. We have discussed the legal standards, which saddle plaintiffs with the obligation to demonstrate that a reasonably prudent manufacturer would have provided a stronger warning than the 2000 warning: "Accutane has been associated with inflammatory bowel disease." The post-2000 warnings may be clearer than the 1984 warnings but we are satisfied, substantially for the reasons expressed by Judge Higbee quoted above, that plaintiffs have presented a sufficient issue of material fact about the warning's adequacy. Defendants still failed to use any causal language, warning instead that IBD was "associated" with Accutane use, even though there was evidence from which a jury could find that defendants had internally concluded there was a causative effect. The word "associated" is susceptible of different meanings and, when viewed in the light most favorable to plaintiffs, would appear not to be sufficiently "intens[e]" or "striking"—words used by the judge to describe the warning—to suggest to a reasonably prudent reader that the drug being "associated" with IBD was the same as the drug causing IBD. [14]

***19** For these reasons, we reverse the entry of summary judgment in favor of defendants.

E

Plaintiffs also argue that the trial judge erred in rejecting Judge Higbee's prior rulings on the same subject matter. Although not necessary to our disposition—since we reverse on the merits—we briefly observe that we find no particular error in the judge's revisiting of these issues.

The so-called law-of-the-case doctrine is a non-binding, discretionary rule designed to prevent litigation of a previously resolved issue. *Lombardi v. Masso*, 207 *N.J.* 517, 538 (2011). The doctrine requires "judges to respect unreversed decisions made during the trial by the same court or a higher court regarding questions of law." *Sisler v. Gannett Co.*, 222 *N.J. Super.* 153, 159 (App. Div. 1987), *certif. denied*, 110 *N.J.* 304 (1988). "Prior decisions on legal issues should be followed unless there is substantially different evidence at a subsequent trial, new controlling authority, or the prior decision was clearly erroneous." *Ibid.*

An order denying summary judgment, however, "is not subject to the law of the case doctrine because it decides nothing and merely reserves issues for future disposition." *Gonzalez v. Ideal Tile Importing Co.*, 371 *N.J. Super.* 349, 356 (App. Div. 2004), *aff'd*, 184 *N.J.* 415 (2005), *cert. denied*, 546 *U.S.* 1092, 126 *S. Ct.* 1042, 163 *L.Ed.* 2d 857 (2006). The denial of summary judgment "is always interlocutory, and never precludes the entry of judgment for the moving party later in the case ...." *Hart v. City of Jersey City*, 308 *N.J. Super.* 487, 498 (App. Div. 1998).

Because the prior ruling represented a denial of summary judgment, the doctrine had no application. The trial judge was entitled to revisit—in a sound exercise of discretion—that interlocutory disposition at any time prior to entry of final judgment in the interests of justice. *R.* 4:42–2. [15]

II

The 514 plaintiffs involved in the second appeal filed MCL Accutane complaints against defendants on various dates between 2005 and 2013. The long-form complaint, designated for use in these MCL cases, contains their claim of defendants' failure to warn under New Jersey's PLA, "and/or [sic] the analogous law of plaintiff's state(s) of ingestion and/or [sic] prescription."

In January 2015, defendants moved for summary judgment in a case scheduled for trial a few months later on the adequacy of the post-2002 warnings under either New Jersey or Washington law; that plaintiff, however, dismissed her case for unrelated reasons. Defendants then amended their motion for summary judgment based on the adequacy of the warnings in all MCL cases where plaintiffs first ingested Accutane after April 10, 2002.

In deciding that motion, the judge issued a written opinion explaining that, in his view, the warnings given by defendants on or after April 10, 2002, were adequate as a matter of law under the PLA. The judge also sought supplementation of the parties' submissions to allow for a determination as to which states plaintiffs had ingested Accutane other than New Jersey during the same time period.

***20** The judge heard additional argument regarding any choice-of-law determinations necessary in claims in which it was alleged Accutane was ingested in places other than New Jersey. He also sought the parties' views about the significance of counsel's initial request for MCL treatment of these cases.[16] At that time, the judge provided a preliminary view:

> an objective reading of [counsel's] representations to the court indicates that [p]laintiffs wished to consolidate the sixty-eight cases in order that a determination may be made regarding "whether defendant violated the New Jersey Products Liability Act in its marketing and sale of Accutane."
>
> This preliminary opinion is deduced from the fact that of the sixty-eight cases referenced in the letter, only two were brought by New Jersey residents. There is nothing in [the letter]—nor [a] follow-up letter of March 15, 2005, referencing "95 cases pending in New Jersey"—which advises ... the [p]laintiffs from "around the country ... in geographically disperse areas" wish to bring the law of their states with them to New Jersey.
>
> There are now 4,600(+) cases pending in the Accutane litigation. Of these, 35 are known to be [pursued by] New Jersey residents. The need for a state-by-state, choice-of-law analyses, and a [p]laintiff-by-[p]laintiff fact discovery deposition of every prescribing physician of the remaining [p]laintiffs was neither requested, advised of, nor alluded to by [counsel] in his letters [seeking MCL].
>
> Regardless of what may have transpired in prior proceedings in the Accutane MCL, I have serious concerns as to this court's obligation to consider [p]laintiffs' claims under any legal standards but those of the New Jersey Products Liability Act, as requested [in the] January 25, 2005 letter.

Eventually, the judge determined the PLA applied to claims asserted by out-of-state plaintiffs because of counsel's statement in the *Rule* 4:38A petition for MCL. And, because the judge had determined that application of the PLA warranted entry of summary judgment as to the post-2002 warnings were adequate as a matter of law, he granted summary judgment in those matters. For reasons set forth in our disposition of A–4760–14, we have determined that the judge's application of the PLA and New Jersey law was erroneous and that the adequacy of the warnings could not be resolved as a matter of law in any case in which New Jersey law applied. Consequently, if we were to agree with the propriety of applying New Jersey law to claims asserted by out-of-state plaintiffs, we would reverse the summary judgments entered against those out-of-state plaintiffs.

***21** The judge, however, also provided an alternative basis for granting summary judgment in many of the cases commenced by out-of-state plaintiffs. Invoking the interests of "judicial economy," the judge conducted a choice-of-law analysis and found that, upon applying the law of the jurisdictions in which these out-of-state plaintiffs resided and ingested Accutane, defendants were entitled to summary judgment. The judge granted summary judgment against plaintiffs who resided in and ingested Accutane in twenty-one other jurisdictions (Alabama, California, Colorado, Florida, Georgia, Illinois, Indiana, Kentucky,

Maryland, Mississippi, Missouri, New Hampshire, New York, North Dakota, Puerto Rico, Tennessee, Texas, Virginia, Washington, Wisconsin, and Wyoming). He denied summary judgment under the laws of twenty other jurisdictions (Arkansas, Connecticut, Delaware, District of Columbia, Idaho, Iowa, Kansas, Maine, Massachusetts, Minnesota, Montana, Nevada, Ohio, Oklahoma, Oregon, Pennsylvania, Rhode Island, South Carolina, Utah and Vermont). With regard to plaintiffs residing in three other jurisdictions (Louisiana, Nebraska, and South Dakota), the judge deemed it appropriate to apply New Jersey law. On July 24, 2015, the judge entered an order dismissing 514 Accutane cases with prejudice.

Plaintiffs appeal, and defendants cross-appeal from that order. In examining the issues posed in this appeal, we (a) consider—and reject—the judge's determination that statements made by the attorney who sought mass tort designation constituted a waiver of the out-of-state plaintiffs' right to an appropriate choice-of-law analyses. We then (b) consider—and conclude—that application of New Jersey's choice-of-law rules requires adoption of the substantive law of the jurisdictions in which plaintiffs resided and ingested Accutane. And, we lastly examine (c) the judge's specific determinations about the law of the other applicable jurisdictions and whether or to what extent the law of those other jurisdictions support the judge's rulings on defendants' summary judgment motion in those cases.

A

Given the language of counsel's representations in seeking the Supreme Court's May 2, 2005 order that granted MCL treatment of these cases—which we have already partially quoted in footnote 16, *supra*—the judge held that he was required to consider

> all of the remaining claims and issues —in this instance, warning adequacy —under New Jersey law. This is so because it was the [p]laintiffs who framed the limits of the MCL jurisdiction by asking the court to consolidate all claims on the question of whether [d]efendants violated the [PLA] in its marketing and sale of Accutane. By invoking New Jersey law, [counsel's] letter highlights why New Jersey law should control this MCL. Plaintiffs wanted the benefit of having their claims heard under the [PLA]. How this court's predecessor handled this issue or the fact that cases were tried under California and Florida law is of no moment. The representations of [p]laintiffs' petition for MCL designation are unambiguous, and request [ ] determination[s] under the [PLA].

Citing *P.V. ex rel. T.V. v. Camp Jaycee*, 197 *N.J.* 132, 154 (2008), where the Court recognized that "[t]he interests of judicial administration" require "consider[ation] [of] practicality and ease of application, [which] further the values of uniformity and predictability," the judge chose not to perform a choice-of-law analysis in this part of his opinion, stating instead that such analyses would not promote "the values of uniform and predictability" but instead would:

> (a) place Atlantic County jurors in the incongruous position of hearing claims under another state's law; (b) likely generate inconsistent rulings; (c) as illustrated by the decision in *Sager* ... likely generate a multiplicity of appeals for which there are no binding precedents; and (d) impose an unreasonable burden upon the resources of the judiciary.

And, relying on *Veazey v. Doremus*, 103 *N.J.* 244, 248 (1986), where the Court observed that choice-of-law questions are "to be determined on an issue-by-issue basis," the judge declared that a choice-of-law analysis in those cases that might arguably be governed by the law of forty-four other jurisdictions would impose an undue burden on "the resources of the judiciary," which he rhetorically enumerated:

> ***22** First, is it likely that at the time of entering its [o]rder of May 2, 2005, our Supreme Court contemplated such an imbroglio being thrust upon our trial courts?

> Second, is it reasonable for the New Jersey [c]ourt [s]ystem to assume responsibility for resolving the claims of thousands of parties from scores of foreign jurisdictions on litigation involving cutting edge issues of science and law, all the while applying the law of other states, many of which express standards incompatible with the [PLA]?
>
> Third, in ten years there has been little to no progress toward resolving this MCL. Is there any reason to believe that this MCL will be resolved within the next ten years by applying choice-of-law analyses to each matter that is selected for trial?
>
> Fourth, is there another state court system in the United States which has welcomed such a flood of litigation against a corporate citizen of that state wherein each of the [p]laintiffs get to bring the law of their home state with them?

The judge responded that, from his "perspective," the answers to all these question was: "not likely." He consequently found that:

> As framed by plaintiffs' counsel, the choice-of-law analysis for label adequacy would have to be considered plaintiff-by-plaintiff, doctor-by-doctor, totally dependent upon the testimony of a prescribing physician. Such a subjective standard militates against [a] philosophy of creating a MCL proceeding. As can be readily deduced, the choice-of-law considerations raised by the Accutane MCL are not those of a discrete and solitary claim such as that in *Camp Jaycee* involving a single claimant and a conflict regarding the competing public policy interests over charitable immunity. Here, there are thousands of claimants from scores of states; the conflicting interests and equitable considerations are far more complex, or one might say, muddled.

The judge concluded, with an additional emphasis on the age and status of this MCL litigation, that "[a]pplying New Jersey law to all the outstanding failure to warn cases will inject uniformity and predictability which are sorely lacking." We reject the judge's reasoning.

We turn first to the judge's determination that statements made by an attorney—who had yet to be designated liaison counsel—were binding on all out-of-state plaintiffs in this MCL. To be sure, we would agree that a statement regarding the substantive law to be applied to a claim may, at times, be binding upon parties and, also, that parties may stipulate to the application of the substantive law even if a proper choice-of-law analysis would generate a different result. *See Fairfax Fin. Holdings Ltd. v. S.A.C. Capital Mgmt.*, —— *N.J. Super.* ——, —— (App. Div. 2017) (slip op. at 36–40). But the judge's reliance on the 2005 request by counsel for MCL treatment of these and other Accutane cases is, at best, only a factor in the choice-of-law analysis, not its alpha and omega.

In explaining, we start by rejecting the relevance or accuracy of the judge's enumerated rhetorical concerns. As to the first, only the Supreme Court can say, but we would think a future need to conduct multiple or many choice-of-law analyses was contemplated. The second rhetorical question seems to have no bearing on the propriety of choice-of-law analyses in the cases commenced by out-of-state plaintiffs. Although additional legal questions may be presented for the courts, as they are here, those questions are hardly so difficult as to represent an undue burden. Nor has it been shown —as the judge suggests in his third rhetorical question— that these choice-of-law questions have been the cause of any perceived delay during the pendency of the MCL. The fourth rhetorical—in which the judge questioned whether any other state would undertake an MCL like this—seems irrelevant in considering whether the court should take the easy way out and simply apply New Jersey law in all cases because those plaintiffs chose to sue in defendants' home state.

***23** Second, we find no evidence other than counsel's loose statement in a letter written more than a decade ago to support a waiver of all appropriate choice-of-law issues. *Rule* 4:38A recognizes the authority of the Supreme Court to "designate a case or category of cases as Multicounty Litigation [MCL] to receive centralized management in accordance with criteria and procedures

promulgated by the Administrative Director of the Courts upon approval by the Court." Here, in applying for MCL, counsel represented in 2005 that the Accutane claims shared common issues of law and fact, including "whether defendant violated the New Jersey Products Liability Act in its marketing and sale of Accutane." Counsel submitted that application before the selection of liaison counsel and before the filing of the complaints at issue on appeal; he did not have the authority to, nor did he, stipulate to the choice of law for these plaintiffs. *See*, *e.g.*, *Banner v. Hoffmann–La Roche Inc.*, 383 *N.J. Super.* 364, 373 (App. Div. 2006), *certif. denied*, 190 *N.J.* 393 (2007). For that reason alone, we think it inimical to a just determination of the many pending Accutane cases to interpret the 2005 letter as a waiver of a choice-of-law analysis for out-of-state plaintiffs. Moreover, this matter has long proceeded as if choice-of-law analyses would occur. For example, after entry of the MCL order, plaintiffs filed long-form complaints alleging claims for failure-to-warn under New Jersey's PLA "and/or [sic] the analogous law of plaintiff's state(s) of ingestion and/or [sic] prescription." Our courts have also addressed choice-of-law issues in cases contained in this MCL matter without concerns for the so-called administrative problems cited by the trial judge. *See*, *e.g.*, *McCarrell II*, *supra*, 227 *N.J.* at 582–99 (considering whether New Jersey's or Alabama's statute of limitations applied). And, although no section of the Second Restatement specifically addresses mass torts, we deem it inappropriate to conclude that by participating in mass tort litigation plaintiffs waive their right to a choice-of-law analysis when the court is presented with a potential conflict regarding the application of state law. [17]

We, thus, reject this procedural bar to otherwise required choice-of-law analyses in these matters.

B

As a result of the judge's erroneous finding of a waiver, we must consider whether a choice-of-law analysis nevertheless requires application of New Jersey law or whether the law of other jurisdictions should apply.

As the forum state, we apply New Jersey choice-of-law rules. *McCarrell II*, *supra*, 227 *N.J.* at 584. When a conflict of substantive law arises—regardless of whether it happens to occur in MCL litigation—our courts apply the principles set forth in sections 146, 145, and 6 of the *Restatement (Second) of Conflicts of Law*. *McCarrell II*, *supra*, 227 *N.J.* at 591. "Multi-faceted choice-of-law principles, such as those expressed in the Second Restatement, have been developed to assist judges in resolving such conflicts." *Ginsberg ex rel. Ginsberg v. Quest Diagnostics, Inc.*, 441 *N.J. Super.* 198, 223 (App. Div. 2015), *aff'd*, 227 *N.J.* 7 (2016). *See* Kramer, *supra*, 71 *N.Y.U. L.Rev.* at 549 (recognizing that "[b]ecause choice of law is part of the process of defining the parties' rights, it should not change simply because, as a matter of administrative convenience and efficiency, we have combined many claims in one proceeding; whatever choice-of-law rules we use to define substantive rights should be the same for ordinary and complex cases"). Our courts will also render, when necessary, multiple individualized choice-of-law determinations within the same suit. At times that choice may vary from one defendant to another, *Ginsberg*, *supra*, 227 *N.J.* at 18, or from one plaintiff to another, *Fairfax*, *supra*, —— *N.J. Super.* at —— (slip op. at 35–36). That said, there may be times when an individualized, party-by-party determination is not feasible. The *Ginsberg* Court explained that in

> ***24** very complex cases with many defendants and multiple claims, a defendant-specific choice-of-law analysis may generate a jury charge that is unwieldy and unclear.... In a complex case with many parties from different states, the trial court retains the discretion to decline a defendant-by-defendant approach and, utilizing a *Restatement* [sections] 146, 145 and 6 analysis as described above, apply the law of a single state to claims asserted against all defendants.
>
> [*Ginsberg*, *supra*, 227 *N.J.* at 20.]

Here, in contrast, although plaintiffs' claims were coordinated for administrative purposes, each plaintiff filed a separate complaint. Some cases have been tried individually and others were tried with plaintiffs from the same state, thereby alleviating any jury confusion about the applicable law that could compromise the trial in the manner of concern to the Court in *Ginsberg*. Clearly, the MCL claims pursued by numerous plaintiffs in separate proceedings does not pose the same potential for jury confusion as in *Ginsberg*, where plaintiffs pursued claims against numerous defendants of different jurisdictions in the same proceeding. We therefore reject the argument that simplification of procedures and uniformity of results should govern the choice-of-law questions presented

because plaintiffs in the cases involved in this appeal reside and ingested Accutane elsewhere.

In the alternative, the trial judge conducted a choice-of-law analysis utilizing sections 146, 145, and 6 of the Second Restatement. He found the law of the state of injury applied in forty-one of the forty-four jurisdictions. We agree with that analysis, with the exception that we conclude the law of the jurisdiction of the injury applied in all these cases, not just forty-one of forty-four.

"The analytical framework for deciding how to resolve a choice-of-law issue is a matter of law." *McCarrell II*, *supra*, 227 *N.J.* at 583; *see also Mastondrea v. Occidental Hotels Mgmt. S.A.*, 391 *N.J. Super.* 261, 283 (App. Div. 2007). Review of the trial judge's choice-of-law determination is thus de novo. *McCarrell*, *supra*, 227 *N.J.* at 583–84.

New Jersey's "choice-of-law jurisprudence has striven to structure rules that will lead to predictable and uniform results that are fair and just and that will meet the reasonable expectations of the parties." *McCarrell II*, *supra*, 227 *N.J.* at 573. The first inquiry is "whether the laws of the states with interests in the litigation are in conflict." *Id.* at 584. If there is no actual distinction, there is no choice-of-law issue to be resolved, and the forum state applies its own substantive law. *Rowe v. Hoffman–La Roche, Inc.*, 189 *N.J.* 615, 621 (2007); *see also DeMarco v. Stoddard*, 223 *N.J.* 363, 383 (2015), *cert. denied*, —— U.S. ——, 137 *S. Ct.* 44, 196 *L.Ed.* 2d 28 (2016). The trial judge did not make any specific findings as to how the laws conflict but simply proceeded on an assumption of a conflict.

As we have already said here, the PLA, in combination with common law principles, provides that a manufacturer shall be liable for harm caused by a product that was "not reasonably fit, suitable or safe for its intended purpose" because it "failed to contain adequate warnings." *N.J.S.A.* 2A:58C–2. The PLA incorporates the "learned intermediary" doctrine by which a manufacturer's duty to warn about the dangers of prescription drugs runs to the physician, not the patient. *N.J.S.A.* 2A:58C–4; *Perez*, *supra*, 161 *N.J.* at 10; *Niemiera*, *supra*, 114 *N.J.* at 559. Significantly, the PLA also provides that:

> ***25** If the warning or instruction given in connection with a drug or device or food or food additive has been approved or prescribed by the federal Food and Drug Administration under the "Federal Food, Drug, and Cosmetic Act," ... a rebuttable presumption shall arise that the warning or instruction is adequate....
>
> [*N.J.S.A.* 2A:58C–4.]

In *Perez*, *supra*, 161 *N.J.* at 25, the Court held that "[f]or all practical purposes, absent deliberate concealment or nondisclosure of after-acquired knowledge of harmful effects, compliance with FDA standards should be virtually dispositive of [failure-to-warn claims]." *See Kendall I*, *supra*, 209 *N.J.* at 195 (where the Court recognized that "in *Perez* we created what can be denominated as a super-presumption").

Although the other forty-four jurisdictions recognize products liability claims based on a failure to adequately warn, and the majority of those jurisdictions have adopted the learned intermediary doctrine, there is a conflict between the laws of most of the other implicated jurisdictions because only three of the forty-four implicated jurisdictions have adopted statutory rebuttable presumptions of adequacy for FDA-approved warnings (Utah, Tennessee, and Texas).[18] Those presumptions, however, appear different from New Jersey's because courts in those states have not applied their rebuttable presumptions in precisely the same way as the PLA's statutory presumption or determined in the same way whether or to what extent the presumption may be overcome. That is, in New Jersey it has been recognized that the PLA's statutory presumption may be overcome by a showing of deliberate concealment or nondisclosure of after-acquired knowledge of harmful effects, *Perez*, *supra*, 161 *N.J.* at 25, or substantial evidence of economically driven manipulation of the post-market regulatory process, *McDarby*, *supra*, 401 *N.J. Super.* at 63–66. Other states with a statutorily-created rebuttable presumption do not appear to either recognize those exceptions or in quite the same way.

Rather than analyze and compare each jurisdiction looking for a conflict—or the absence of a conflict—we view our PLA as sufficiently different from most, if not all, the other competing jurisdictions as to warrant an assumption that all forty-four jurisdictions are in conflict with (or at least different from) New Jersey law on the particular questions posed by defendants' motion for summary judgment.

Next, a court must identify "the state that is the place of injury and presume [ ] that the law of that state governs the action." *Ginsberg*, *supra*, 227 *N.J.* at 12. Section 146 of the Second Restatement states that in an action for personal injury,

> the local law of the state where the injury occurred determines the rights and liabilities of the parties, unless, with respect to the particular issue, some other state has a more significant relationship under the principles stated in [section] 6 to the occurrence and the parties, in which event the local law of the other state will be applied.

***26** It is undisputed that in the Accutane cases before us there are plaintiffs who resided—and ingested Accutane—in forty-four other jurisdictions. Section 146 recognizes those forty-four jurisdictions as "likely to have the predominant, if not exclusive, relationship to the parties and issues in the litigation." *Camp Jaycee*, *supra*, 197 *N.J.* at 144. That presumption is then "tested against the contacts detailed in section 145 and the general principles outlined in section 6 of the Second Restatement." *Id.* at 136. A court must decide "whether the presumption in favor of the law of the place of injury has been overcome by virtue of a competing state's 'more significant relationship to the parties and issues.' " *Ginsberg*, *supra*, 227 *N.J.* at 12 (quoting *Camp Jaycee*, *supra*, 197 *N.J.* at 143). When "another state has a more significant relationship to the parties or issues," the presumption has been overcome. *Camp Jaycee*, *supra*, 197 *N.J.* at 136.

Section 145(2) of the Second Restatement lists several factors to be weighed in identifying the state with the most significant interests:

> (a) the place where the injury occurred,
>
> (b) the place where the conduct causing the injury occurred,
>
> (c) the domicil, residence, nationality, place of incorporation and place of business of the parties, and
>
> (d) the place where the relationship, if any, between the parties is centered.

Application of those contacts supports a finding that the other jurisdictions have a more significant relationship to these lawsuits than New Jersey. Plaintiffs' injuries occurred in the other jurisdictions, plaintiffs resided there, and plaintiffs were prescribed and ingested the drug there. *See Cornett v. Johnson & Johnson*, 414 *N.J. Super.* 365, 378–80 (App. Div. 2010), *aff'd as modified*, 211 *N.J.* 362 (2012); *Yocham v. Novartis Pharms. Corp.*, 736 *F. Supp.* 2d 875, 882 (D.N.J. 2010).

It bears further mention that these contacts with plaintiffs' home states were not fortuitous. Defendants deliberately marketed and sold their product in those jurisdictions with the intention that physicians prescribe and patients take the drug in those jurisdictions. The locus of the parties' relationship does not compel a different result because, although defendants are located and issued its warnings from New Jersey, plaintiffs and their physicians received them and suffered from their omission in the other jurisdictions.

Next, in measuring the significance of the section 145 contacts, courts look to section 6's cornerstone principles "to determine whether the presumption has been overcome." *Camp Jaycee*, *supra*, 197 *N.J.* at 143. In tort cases, the section 6 factors may be grouped into five categories: "(1) the interests of interstate comity; (2) the interests of the parties; (3) the interests underlying the field of tort law; (4) the interests of judicial administration; and (5) the competing interests of the states." *Fu v. Fu*, 160 *N.J.* 108, 122 (1999). These factors "are not exclusive," and their weight may vary "depending upon the circumstances presented." *Ginsberg*, *supra*, 441 *N.J. Super.* at 239.

Here, as in *Camp Jaycee*, *supra*, 197 *N.J.* at 148, the competing interest of the state and relevant tort law principles overlap. New Jersey and all the other relevant jurisdictions have established failure-to-warn laws intended to compensate injured plaintiffs while deterring the manufacture and distribution of unsafe products. *See Reglan Litig.*, *supra*, 226 *N.J.* at 335; *Gantes v. Kason Corp.*, 145 *N.J.* 478, 490 (1996). "[O]f the two policy goals, the first is more important." Dreier, Keefe & Katz, *supra*, at 563. Consequently, the state where the injured person resides "is generally considered paramount." *Ibid.*

Our Legislature enacted the PLA "as a remedial measure to limit the liability of manufacturers by establishing 'clear

rules with respect to certain matters' " relating to actions for damages for harm caused by products, and "[i]n particular," to "reduce the burden on manufacturers of FDA-approved products resulting from products liability litigation." *Kendall I*, *supra*, 209 *N.J.* at 194 (quoting *N.J.S.A.* 2A:58C–1(a)). The PLA "impliedly accepts that the presumption of adequacy will not be rebutted in all cases" and "accepts FDA regulation as sufficient, at least in part, to deter New Jersey pharmaceutical companies from manufacturing unsafe prescription drugs." *Rowe*, *supra*, 189 *N.J.* at 625.

***27** Arguably, there are conflicting policies—New Jersey's interest in the uniform application of its limitation of a manufacturers' liability and in deterring unsafe products—and the competing interests of the other jurisdictions in regulating the adequacy of warnings and in compensating injured victims. At best, those interests are in equipoise. As we have already observed, the fact that plaintiffs suffered injuries in other jurisdictions was not fortuitous; defendants chose to market and sell their product there. If the other jurisdictions' products liability laws are to have any deterrent effect it must apply in the state where the plaintiff was injured. New Jersey's "interest in deterring local manufacturing corporations from providing inadequate product warnings, within the context of an FDA approved drug," does not clearly outweigh the laws of the other jurisdictions who have an interest in protecting their citizens from harm and in compensating their citizens for injuries. *See id.* at 629–30.

Interstate comity seeks to "further harmonious relations between the states and to facilitate commercial intercourse between them," *Restatement*, *supra*, § 6 cmt. d; *see Camp Jaycee*, *supra*, 197 *N.J.* at 152, by ascertaining "whether application of a competing state's law would frustrate the policies of other interested states," *Fu*, *supra*, 160 *N.J.* at 122. By the same token, this factor "must not be overemphasized," because, to some extent, "every tort rule is designed both to deter other wrongdoers and to compensate the injured person." *Restatement*, *supra*, § 145 cmt. c.

Similarly, application of New Jersey law that limits liability for FDA-approved warnings might frustrate the other states' policies in deterring a broader scope of inadequate warnings and would limit their ability to regulate the conduct of manufacturers who sell products in their states. *See Camp Jaycee*, *supra*, 197 *N.J.* at 153. Moreover, New Jersey can continue to protect its pharmaceutical manufacturers when they sell products in this state.

In considering the interests-of-the-parties factor, it would, generally speaking, "be unfair and improper to hold a person liable under the local law of one state when he had justifiably molded his conduct to conform to the requirements of another state." *Ginsberg*, *supra*, 441 *N.J. Super.* at 243 (quoting *Restatement*, *supra*, § 6 cmt. g). Defendants argue that New Jersey pharmaceutical manufacturers are justified in expecting that a New Jersey law designed to "re-balance the law in [their] favor," *Rowe*, *supra*, 189 *N.J.* at 623, would apply if they were sued in New Jersey. In *Camp Jaycee*, *supra*, 197 *N.J.* at 154, the Court explained that in *Fu*, *supra*, 160 *N.J.* at 135, it "dismissed the notion that a corporation could reasonably expect automatic immunization when conducting affairs outside the state" and observed that "however reasonable may be a rental agency's reliance on New Jersey's vicarious liability laws for purposes of an accident in this State, any blanket reliance on this State's law as a defense to conduct occurring in a foreign jurisdiction could not be justified."

Although defendants might legitimately have expected protection under the PLA's presumption, they could not reasonably expect that protection to apply in other states with no interest in reducing the liability burden on New Jersey pharmaceutical manufacturers. Thus, the application of the laws of other jurisdictions to these out-of-state claims is consistent with the reasonable interests of the parties.

The interests of judicial administration obligate courts to consider "practicality and ease of application, factors that in turn further the values of uniformity and predictability." *Camp Jaycee*, *supra*, 197 *N.J.* at 154. The comments to the Second Restatement illuminate these interests:

> To the extent that [these values] are attained in choice of law, forum shopping will be discouraged. These values can, however, be purchased at too great a price. In a rapidly developing area, such as choice of law, it is often more important that good rules be developed than that predictability and uniformity of result should be assured through continued adherence to existing rules. Predictability and uniformity of result are of particular importance in areas where the parties are likely to

give advance thought to the legal consequences of their transactions.

***28** [*Restatement*, *supra*, § 6 cmt. i.]

Interests of judicial administration should not be accorded undue weight; they "are of lesser importance and must yield to a strong state interest implicated by the [other] factors." *Fu*, *supra*, 160 *N.J.* at 124; *see also Erny v. Estate of Merola*, 171 *N.J.* 86, 102 (2002). Ultimately, as we observed in *Ginsberg*, *supra*, 441 *N.J. Super.* at 245, applying one state's law indiscriminately to all of the claims against out-of-state defendants would be "pragmatic" but would not promote "a sound or fair result."

To be sure, as the trial judge observed, MCL litigation poses unique challenges to judicial administration and efficiency. And we agree New Jersey's judicial-administration interest should be given greater weight in an MCL case than in a standard tort case. Certainly, application of New Jersey's substantive law to the adequacy of pharmaceutical warnings would, to some degree, present more efficient results. But this factor should yield to the other jurisdictions' strong state interests for a number of reasons.

First, a multistate analysis is feasible in this MCL case. *See Ginsberg*, *supra*, 227 *N.J.* at 12. As one commentator pointed out, resolving choice-of-law questions in complex mass tort cases "may not be fun, but it is far from impossible." Kramer, *supra*, 71 *N.Y.U. L. Rev.* at 584. One solution to efficiently resolve MCL cases is to group cases involving states with similar laws, thereby reducing the number of conflicts to a manageable number. Such grouping has, in fact, has already occurred in this MCL litigation. And modern means of research—Lexis and Westlaw—reduce the burden of conducting a fifty-state search that would have proved daunting in former times.

Second, there is no reason to believe the parties anticipated that this MCL case would become an "imbroglio being thrust upon" the court, as viewed by the trial judge. It is likely plaintiffs expected to try a few "bellwether" cases, thereby "enhancing prospects of settlement or for resolving common issues or claims." *Perez*, *supra*, 161 *N.J.* at 7 n.2 (quoting *In re Chevron, U.S.A., Inc.*, 109 *F.*3d 1016, 1019–20 (5th Cir. 1997)). The fact that only one Accutane MCL case has settled does not weigh in favor of applying New Jersey's law to all of the pending out-of-state claims.

We also reject the notion that application of the substantive laws of the jurisdiction in which a plaintiff's injury occurred will encourage a "flood of litigation" against defendants in this state. Plaintiffs have filed claims in New Jersey because defendants' business is located here and because the Court approved the MCL application. Moreover, application of out-of-state law has resulted in the dismissal of some of the Accutane cases. And we affirm the dismissal of others here.

Lastly, the fact that application of other jurisdictions' laws may lead to inconsistent results does not weigh in favor of the application of New Jersey law; such results are entirely fair and appropriate in products liability actions brought by plaintiffs from different states. *See* Kramer, *supra*, 71 *N.Y.U. L. Rev.* at 579 (recognizing "[s]ome differences in outcome reflect the fact that different states with legitimate interests have made different judgments about how to handle tort problems").

***29** For these reasons, we are satisfied the presumption in favor of the law of the state of the injury was not overcome, and we conclude the trial judge erred in part one of his opinion in applying New Jersey law to these claims.

C

The judge also examined the law of forty-four jurisdictions. Because we have determined that New Jersey law doesn't provide the substantive law applicable to claims asserted by plaintiffs who resided and ingested Accutane in other jurisdictions, the judge's alternative rulings about the law of those other jurisdictions has taken on greater relevance.

We start with the fact that, of the forty-four jurisdictions, the judge found application of the law of eighteen—Arkansas, Connecticut, Delaware, District of Columbia, Idaho, Iowa, Kansas, Maine, Massachusetts, Minnesota, Montana, Nebraska, Oregon, Pennsylvania, Rhode Island, South Carolina, Utah, and Vermont—required the denial of summary judgment. The judge also denied summary judgment in cases governed by the law of two states—Ohio and Oklahoma—because those states

recognize an exception to the learned intermediary doctrine for materials disseminated directly to patients. Defendants' cross-appeal seeks reversal of the denial of summary judgment in those cases governed by the law of those twenty jurisdictions. We find insufficient merit in defendants' arguments regarding those cases to warrant further discussion in a written opinion. *R.* 2:11–3(e)(1)(E).

Consequently, we turn to the other twenty-four jurisdictions—as to which the judge granted summary judgment in defendants' favor—and separately examine the judge's determinations as they relate to: (1) three jurisdictions, which espouse, in the trial judge's view, substantive law that is either "irrational" or "unclear"; (2) fourteen jurisdictions in which the learned intermediary doctrine had been adopted in a manner that, in the judge's view, permitted a determination of a drug label's adequacy as a matter of law; and (3) seven jurisdictions in which the adequacy of the warning was viewed as determinable as a matter of law for other reasons.

(1) The First Group

In cases where it was alleged plaintiffs resided and ingested Accutane in Louisiana, Nevada and South Dakota, the judge applied New Jersey law for reasons other than those discussed earlier. We reject those reasons and conclude, for the following reasons, the judge was obligated to ascertain the law of those jurisdictions and determine whether it permitted a disposition of the issues presented as a matter of law.

a. Louisiana

We first consider Louisiana law, which the judge disregarded because he found it "irrational."

Courts that have applied the "Louisiana Products Liability Act," *La. Rev. Stat. Ann.* § 9:2800.51–.60 (2016), have understood that a drug manufacturer has "satisfied its duty to warn under the learned intermediary doctrine," *Stahl v. Novartis Pharms. Corp.*, 283 *F.*3d 254, 268 (5th Cir.), *cert. denied*, 537 *U.S.* 824, 123 *S. Ct.* 111, 154 *L.Ed.* 2d 34 (2002)—a circumstance that can be decided in an appropriate case as a matter of law, *Anderson v. McNeilab, Inc.*, 831 *F.*2d 92, 93 (5th Cir. 1987)—when "a particular adverse effect is clearly and unambiguously mentioned in a warning label and the prescribing physician unequivocally states that he or she was adequately informed of that risk by the warning," *Stahl*, *supra*, 283 *F.*3d at 268.

***30** Here, the trial judge observed that "the net result" of such a standard

> grants the prescribing physician what amounts to a veto on the adequacy of a drug label. If a competent physician read and understood the manufacturer's warnings, then the warning is adequate; if another physician is unable to "unequivocally state[ ] that he or she was inadequately informed of that risk by the warning" then the warning is inadequate. Such a subjective standard is incompatible with how New Jersey courts strive to adjudicate disputes.
>
> When the Legislature adopted the [PLA] it sought to level the courtroom floors and respect the rights of both consumers and manufacturers. When balancing the competing interests of Louisiana's apparent policy of protecting consumers by accepting or rejecting the adequacy of a drug label based on the observations of the prescribing physicians, anyone of whom may be more or less conscientious, informed or attentive than another, with New Jersey's interests in insuring that all its litigants be accorded a trial based upon predictable and rational standards, New Jersey's public policy interests prevail.

The judge concluded he would "not subject a New Jersey corporate resident to such an irrational standard" and chose, instead, to apply New Jersey law.

This was erroneous. In conducting a choice-of-law analysis, "it is the forum state's duty to disregard its own substantive preference." *Fu*, *supra*, 160 *N.J.* at 131 (quoting *O'Connor v. Busch Gardens*, 255 *N.J. Super.* 545, 550 (App. Div. 1992). The inquiry does not concern whether Louisiana or New Jersey "passed the better law; that is a normative judgment best suited for the legislative process." *Rowe*, *supra*, 189 *N.J.* at 629. Louisiana law must apply because New Jersey does not have a more significant relationship under the principles stated in section 6 to the occurrence and the parties.

We conclude that summary judgment was not appropriate when applying Louisiana law to cases in which Accutane was either prescribed or ingested in Louisiana because

defendants did not demonstrate that the prescribing physicians had unequivocally acknowledged receipt of an adequate warning.

b. Nebraska and South Dakota

The judge also applied New Jersey law in cases where plaintiffs were injured in Nebraska and South Dakota, finding the law of those states too sparse to apply.

We suppose that, in a vacuum—if it could ever be concluded there is "no law" on a subject—choice-of-law principles would not apply because the absence of law would not conflict with a forum's existing law. But, the mere fact that a state's courts and legislature have not spoken on a particular topic doesn't mean that state lacks legal principles that would illuminate the disposition of a dispute. For example, even if it could be shown the courts or legislature of a particular state never uttered any product-liability principles, that state's view on the subject could conceivably be extrapolated from other common-law principles recognized by that jurisdiction. On the other hand, we don't disagree that a state with sparse law on a subject may possess a lesser interest in governing a dispute than another interested state possessing well-established legal principles. This circumstance, however, is merely a factor to be considered; it is not conclusive. *McCarrell II*, *supra*, 227 *N.J.* at 596.

***31** Having said all that, we reject the trial judge's determination that not enough has been said by the legislatures or the courts of Nebraska and South Dakota to allow an accurate understanding of their substantive law on the subject. To the contrary, Nebraska's highest court has observed that failure-to-warn claims sound in negligence and strict liability and has also recognized and applied the learned intermediary doctrine in a claim based on the ingestion of Accutane. *Freeman v. Hoffman–La Roche, Inc.*, 618 *N.W.*2d 827, 842 (Neb. 2000).

Similarly, in South Dakota, *S.D. Codified Laws* § 20–9–10.1 (2016) provides that:

> In any product liability action based upon negligence or strict liability, whether the design, manufacture, inspection, testing, packaging, warning, or labeling was in conformity with the generally recognized and prevailing state of the art existing at the time the specific product involved was first sold to any person not engaged in the business of selling such a product, may be considered in determining the standard of care, whether the standard of care was breached or whether the product was in a defective condition or unreasonably dangerous to the user.

In South Dakota, a manufacturer has "a duty to warn based on what it knew or should have known at the time the drug was administered to plaintiff." *McElhaney v. Eli Lilly & Co.*, 575 *F. Supp.* 228, 231 (D.S.D. 1983), *aff'd*, 739 *F.*2d 340 (8th Cir. 1984). And federal courts applying South Dakota law have utilized the learned intermediary doctrine. *Ibid.*; *Yarrow v. Sterling Drug, Inc.*, 263 *F. Supp.* 159, 162 (D.S.D. 1967), *aff'd*, 408 *F.*2d 978 (8th Cir. 1969).

From these principles, we conclude that, under both Nebraska and South Dakota law, plaintiffs presented sufficient evidence to demonstrate a genuine dispute about whether the warnings were accurate, clear and unambiguous and that those plaintiffs presented evidence that defendants knew but failed to warn of a causal and latency effect. We conclude the judge erred in dismissing the cases governed by Nebraska or South Dakota law.

(2) The Second Group

We find reasons to distinguish among the fourteen jurisdictions that adopted the learned intermediary doctrine [19] as to which the trial judge granted summary judgment. Consequently, we break this group into two smaller groups: (a) one group that requires reversal, and (b) a second that requires affirmance.

a. Alabama, Florida, Georgia, Illinois, Kentucky, Puerto Rico, Tennessee, and Washington

***32** Products liability law in Alabama is governed by the judicially-created Alabama Extended Manufacturer's Liability Doctrine (AEMLD). *Atkins v. Am. Motors Corp.*, 335 *So.* 2d 134, 137 (Ala. 1976); *Casrell v. Altec*

Indus., Inc., 335 *So.* 2d 128, 130 (Ala. 1976). Here, the trial judge relied on *Morguson v. 3M Co.*, 857 *So.* 2d 796, 802 (Ala. 2003), where the court held in a medical device case that the warning was adequate as a matter of law because it warned "against the exact acts and errors committed" by the hospital staff in assembling the device; we find this circumstance to be distinguishable. We also observe that our Supreme Court has rejected defendants' argument under either New Jersey or Alabama law that the 1984 label, which specifically referred to IBD, was adequate as a matter of law. *McCarrell I*, *supra*, slip op. at 108. These same principles require a reversal of the summary judgment entered in the thirteen cases governed by Alabama law.

In this setting, Florida law requires that a plaintiff prove a manufacturer "did not adequately warn of a particular risk that was known or knowable in light of the generally recognized and prevailing best scientific and medical knowledge available at the time of the manufacture and distribution." *Thomas v. Bombardier Rec. Prods. Inc.*, 682 *F. Supp.* 2d 1297, 1300 (M.D. Fla. 2010). In determining the adequacy of the warning under Florida law, the critical inquiry is whether it was adequate to warn the physician of the possibility that the drug caused the plaintiff's injury. *Upjohn Co. v. MacMurdo*, 562 *So.* 2d 680, 683 (Fla. 1990). "The sufficiency and reasonableness of the warnings are questions of fact best left for the jury unless the warnings are accurate, clear, and unambiguous." *Thomas*, *supra*, 682 *F. Supp.* 2d at 1300. Consequently, the judge erred in dismissing thirty-nine cases under Florida law because, as discussed earlier in this opinion, plaintiffs presented evidence that the warnings were not accurate, clear and unambiguous.

In Georgia, the "manufacturer's duty to warn is limited to an obligation to advise the prescribing physician of any potential dangers that may result from the drug's use." *Bryant v. Hoffmann–La Roche, Inc.*, 585 *S.E.*2d 723, 730 (Ga. Ct. App. 2003) (quoting *Hawkins v. Richardson–Merrell, Inc.*, 249 *S.E.*2d 286, 288 (Ga. Ct. App. 1978)). Georgia law also recognizes that "[t]he adequacy of drug warnings is generally a question of fact, but it can 'become a question of law where the warning is accurate, clear and unambiguous.' " *Weilbrenner v. Teva Pharms. USA, Inc.*, 696 *F. Supp.* 2d 1329, 1339 (M.D. Ga. 2010) (quoting *Thom v. Bristol–Meyers Squibb Co.*, 353 *F.*3d 848, 853 (10th Cir. 2003). Nevertheless, we conclude the judge erred in dismissing twenty-four claims governed by Georgia law because plaintiffs presented sufficient evidence that the warnings were not accurate, clear and unambiguous.

In Illinois, "[t]he duty to warn of the dangers of prescription drugs is owed to the physician, and therefore, the adequacy of the warning must be judged by whether it sufficiently apprises physicians of the risks associated with the use of the drug." *Hernandez v. Schering Corp.*, 958 *N.E.*2d 447, 455 (Ill. App. Ct. 2011). Although "[t]he sufficiency of the warning can become a question of law where the warning is clear, accurate and unambiguous," *ibid.*, for the reasons already outlined regarding the other jurisdictions in this group, we conclude that the judge erred in dismissing twenty-six cases under Illinois law; plaintiffs presented sufficient evidence that the warnings were not accurate, clear and unambiguous.

In *Larkin v. Pfizer, Inc.*, 153 *S.W.*3d 758, 764 (Ky. 2004), Kentucky's highest court has recognized that an adequate warning is that which "sufficient [ly] [ ] apprise[s] the general practitioner as well as the 'unusually sophisticated medical man' of the dangerous propensities of the drug," *McEwen v. Ortho Pharm. Corp.*, 528 *P.*2d 522, 529 (Or. 1974) (quoting *Parke–Davis & Co. v. Stromsodt*, 411 *F.*2d 1390, 1400 (9th Cir. 1969)). It is, the Court held, "incumbent upon the manufacturer to bring the warning home to the doctor." *Larkin*, *supra*, 153 *S.W.*3d at 764. The judge erred in dismissing twelve cases under Kentucky law because plaintiffs presented sufficient evidence that defendants did not "bring the warning home" to the prescribing physician as to Accutane's causative effect.

***33** In Puerto Rico, a plaintiff must prove in a products liability case that "(1) the manufacturer knew, or should have known of the risk inherent in the product; (2) there were no warnings or instructions, or those provided were inadequate; (3) the absence of warnings made the product inherently dangerous; (4) the absence of adequate warnings or instructions was the proximate cause of plaintiff's injury." *Cruz–Vargas v. R.J. Reynolds Tobacco Co.*, 348 *F.*3d 271, 276 (1st Cir. 2003), *cert. denied*, 543 *U.S.* 959, 125 *S. Ct.* 413, 160 *L.Ed.* 2d 323 (2004).

"If the warning should suffice to alert the general practitioner as well as the specialist, it is adequate, and the manufacturer is not liable for the injuries caused by the drug." *Guevara v. Dorsey Labs., Div. of Sandoz, Inc.*, 845 *F.*2d 364, 367 (1st Cir. 1988).

The judge erred in dismissing one case under the law of Puerto Rico because there was sufficient evidence, including expert and other testimony, that the warnings were not accurate, clear and unambiguous to submit the question to the jury.

In Tennessee, products liability is governed by statute. *Tenn. Code Ann.* § 29–28–104 (2016) provides:

> Compliance by a manufacturer or seller with any federal or state statute or administrative regulation existing at the time a product was manufactured and prescribing standards for design, inspection, testing, manufacture, labeling, warning or instructions for use of a product, shall raise a rebuttable presumption that the product is not in an unreasonably dangerous condition in regard to matters covered by these standards.

"Warnings concerning prescription drugs generally are adequate when they contain a full and complete disclosure of the potential adverse reactions to the drug." *Pittman*, *supra*, 579 *F. Supp.* 2d at 429. The adequacy of a drug manufacturer's warnings is usually a question of fact. *Ibid.* "It becomes a question of law only when the instructions are accurate and unambiguous." *Ibid.* "[A]ll causation issues, are 'ordinarily jury questions, unless the uncontroverted facts and inferences to be drawn from them make it so clear that all reasonable persons must agree on the proper outcome.' " *Payne v. Novartis Pharms. Corp.*, 767 *F.*3d 526, 528 (6th Cir. 2014) (quoting *Haynes v. Hamilton Cty.*, 883 *S.W.*2d 606, 612 (Tenn. 1994)). The judge erred in dismissing eighteen cases under Tennessee law because there was enough evidence to support the contention that the warnings were not sufficiently accurate or clear to require disposition of that question by the factfinder.

In Washington, products liability is governed by *Wash. Rev. Code Ann.* § 7.72 to 7.72.070 (2016). "A warning for a prescription drug may be adequate as a matter of law if it provides specific and detailed information about the risks of using the drug." *Estate of LaMontagne*, *supra*, 111 *P.*3d at 862. But "[b]ecause the FDA regulations provide only the minimum requirements for drug manufacturers, compliance with those regulations does not necessarily establish warnings were adequate." *Ibid.* Instead, "[t]o determine whether a warning is adequate requires an analysis of the warnings as a whole and the language used in the package insert." *Laisure–Radke v. PAR Pharm., Inc.*, 426 *F. Supp.* 2d 1163, 1172 (W.D. Wash. 2006). A court "must examine the meaning and context of the language and the manner of expression to determine if the warning is accurate, clear and consistent and whether the warning portrays the risks involved in taking the prescription drug." *Ibid.* In light of this fact-sensitive issue, we conclude that the judge erred in dismissing nineteen cases governed by Washington law.

b. California, Colorado, Indiana, Maryland, Mississippi, New York, Texas, and Virginia

***34** With the exception of Texas, which we discuss separately, these other jurisdictions all possess similar legal principles. And each applies the learned intermediary doctrine. *See* cases cited in footnote 17, *supra*. For the reasons that follow, we affirm the summary judgment entered in favor of defendants in the cases governed by the law of these jurisdictions.

Under California law, prescription-drug manufacturers are strictly liable for injuries caused by a failure to warn of a product's known or reasonably, scientifically-knowable, dangerous propensities available when manufactured and distributed. *Johnson v. Am. Standard, Inc.*, 179 *P.*3d 905, 910 (Cal. 2008). This obligation has been interpreted, as a matter of California law, to require a determination that a drug warning is adequate as a matter of law if it directly warns "in plain and explicit terms" of the specific risk that has caused injury. *Kearl v. Lederle Labs.*, 218 *Cal. Rptr.* 453, 467 (Cal. Ct. App. 1985), *disapproved on other grounds*, *Brown v. Superior Court*, 751 *P.*2d 470, 482 (Cal. 1988).

Notably, in the MDL Accutane case, the federal district court granted defendants' motion for summary judgment under California law on the adequacy of later IBD warnings, *In re Accutane Prods. Liab.*, No. MDL 1626, 2014 U.S. Dist. LEXIS 155313, at *15, 2014 WL 7896548 (M.D. Fla. Sep. 23, 2014), finding:

> The Physician Package Insert plainly and prominently identified inflammatory bowel disease by name as

> a possible consequence of taking isotretinoin. This risk information appeared in the "WARNINGS" and "ADVERSE REACTIONS" sections of the insert. It also identified the common symptoms of IBD and instructed what should be done if those symptoms appeared. Likewise, the Medication Guide warned that isotretinoin may result in permanent damage to the bowels. The Medication Guide and patient brochures also broadly communicated that isotretinoin "can cause" serious side effects and proceeded to list permanent damage to various organs, including the bowels, among such potential serious side effects. This language tracked the WARNINGS section of the Physician Package Insert, which notified physicians that isotretinoin "has been associated with" IBD. Both independently and taken together, these formulations communicated the same essential message to prescribing physicians: IBD is a potential risk of isotretinoin. Accordingly, under California law, summary judgment is appropriate as a matter of law under these circumstances.
>
> [*Id.* at *14–15.]

We view the law of the other jurisdictions in this group—Colorado, *Caveny v. Ciba–Geigy Corp.*, 818 *F. Supp.* 1404, 1406 (D. Colo. 1992); Indiana, *Tucker*, *supra*, 701 *F. Supp.* 2d at 1066; Maryland, *Nolan v. Dillon*, 276 *A.*2d 36, 40 (Md. 1971); Mississippi, *Austin v. Will–Burt Co.*, 361 *F.*3d 862, 868 (5th Cir. 2004); New York, *Martin*, *supra*, 628 *N.E.*2d at 1312–13; and Virginia, *Ball v. Takeda Pharms. Am., Inc.*, 963 *F. Supp.* 2d 497, 504 (E.D. Va. 2013)—to require the same result. It is enough in these jurisdictions that IBD was referenced to render the warning adequate as a matter of law.

In Texas, the adequacy of a product's warning generally presents a fact question. *Murthy v. Abbott Labs.*, 847 *F. Supp.* 2d 958, 968 (S.D. Tex. 2012) (citing *McNeil v. Wyeth*, 462 *F.*3d 364, 368 (5th Cir. 2006)). "In prescription drug cases involving the learned intermediary doctrine," however, a warning that "specifically mentions the circumstances complained of" is adequate as a matter of law, *ibid.*, as in the other jurisdictions contained in this particular grouping. But Texas also has a statutory rebuttable presumption of adequacy for prescription drugs, *Tex. Civ. Prac. & Rem.* § 82.007 (2015), which can be rebutted only if a plaintiff can show: (1) the defendant "withheld from or misrepresented to" the FDA "required information that was material and relevant to the performance of the product and was causally related to the claimant's injury"; (2) the product was sold or prescribed "after the effective date of an order" to remove it from the market; (3) the defendant engaged in off-label promotion that was causally related to the plaintiff's injury; and (4) the defendant engaged in criminal violation of federal anti-bribery law. So heavy is this burden, that even if a plaintiff could show a defendant withheld information about causation, permanency, and latency from the FDA, the action could proceed only if the FDA itself found fraud. *Lofton v. McNeil Consumer & Specialty Pharms.*, 672 *F.*3d 372, 381 (5th Cir. 2012); *Willis v. Alaven Pharm. LLC*, 62 *F. Supp.* 3d 560, 563 (E.D. Tex. 2014). There is no evidence in this record that would support a principled basis for overcoming Texas's unique statutory presumption.

***35** We, thus, affirm the summary judgment entered in favor of defendants insofar as it dismissed the cases governed by the substantive law of this subgroup.

(3) The Third Group

The trial judge granted summary judgment under the laws of the seven states that make up our third and final group.[20] We find the substantive law of this group—Missouri, New Hampshire, North Dakota, Wisconsin and Wyoming—to be similar and, for the reasons that follow, conclude for the reasons that briefly follow that the judge erred in granting summary judgment in cases governed by the law of those jurisdictions.

In Missouri, the focus in a failure-to-warn case rests "on what the manufacturer knew rather than on the product." *Moore v. Ford Motor Co.*, 332 *S.W.*3d 749, 764 (Mo. 2011). In addition, "Missouri courts have held that in cases involving manufacturers of prescription drugs, the manufacturer has 'a duty to properly warn the doctor of the dangers involved and it is incumbent upon the manufacturer to bring the warning home to the doctor.' " *Doe*, *supra*, 3 *S.W.*3d at 419 (quoting *Krug v. Sterling Drug, Inc.*, 416 *S.W.*2d 143, 146 (Mo. 1967)). Our discussion of the factual record in the earlier part of this opinion demonstrates plaintiffs presented evidence that the warning failed to "bring home to the doctor" latency, permanency and causation.

In New Hampshire, "[t]he duty to warn is concomitant with the general duty of the manufacturer, which 'is limited to foreseeing the probable results of the normal use of the product or a use that can reasonably be anticipated.' " *Thibault v. Sears, Roebuck & Co.*, 395 *A.*2d 843, 847 (N.H. 1978) (quoting *McLaughlin v. Sears, Roebuck & Co.*, 281 *A.*2d 587, 588 (1971)). "An adequate warning is one reasonable under the circumstances." *Brochu*, *supra*, 642 *F.*2d at 657. "A warning may be inadequate in factual content, in expression of the facts, or in the method by which it is conveyed." *Ibid.* So stated, we view the application of New Hampshire law to the warnings in question as generated a question of fact for a jury to determine.

North Dakota law holds that "in order to be adequate the warning must satisfactorily convey the seriousness of the danger such that a reasonable physician would be alerted to the danger." *Ehlis*, *supra*, 233 *F. Supp.* 2d at 1196. Again, plaintiffs presented evidence that the warning failed to convey the seriousness of the danger.

Wisconsin has adopted comments g and i to *Restatement (Second) of Torts* § 402A (1965), which explain "that a product is defective if it is 'in a condition not contemplated by the ultimate consumer, which will be unreasonably dangerous to him [or her]'; and that for a product to be considered 'unreasonably dangerous,' it must be 'dangerous to an extent beyond that which would be contemplated by the ordinary consumer who purchases it, with the ordinary knowledge common to the community as to its characteristics.' " *Mohr v. St. Paul Fire & Marine Ins. Co.*, 674 *N.W.*2d 576, 589 (Wis. Ct. App. 2003).

***36** "Although compliance with FDA standards generally will foreclose negligence per se, ... such compliance ... does not preclude a finding of negligence." *Kurer v. Parke, Davis & Co.*, 679 *N.W.*2d 867, 876 (Wis. Ct. App. 2004). And, "[w]hether a warning is adequate is generally an issue of fact to be determined by the jury." *Mohr*, *supra*, 674 *N.W.*2d at 589. A warning may be found adequate as a matter of law only when the warning "[c]learly and repeatedly" warns of the risks associated with the drug. *See Kurer*, *supra*, 679 *N.W.*2d at 878 (emphasis added). Here, plaintiffs presented sufficient evidence that the warnings did not clearly or repeatedly warn of the causal and latency effect.

In Wyoming, "a plaintiff may show a 'defect' by establishing that the manufacturer failed to warn about dangers associated with the product." *Rohde v. Smiths Med.*, 165 *P.*3d 433, 441 (Wyo. 2007). "[A] drug manufacturer is required to warn only of those adverse effects of which it knows or reasonably should know." *Jacobs v. Dista Prob. Co.*, 693 *F. Supp.* 1029, 1033 (D. Wyo. 1988). But "[i]mplicit in this holding is a continuing duty of drug manufacturers to provide notification of side effects subsequently discovered." *Id.* at 1034.

"Although the adequacy of warnings concerning drugs is generally a question of fact, it can 'become a question of law where the warning is accurate, clear and unambiguous.' " *Thom*, *supra*, 353 *F.*3d at 853 (quoting *Felix*, *supra*, 540 *So.* 2d at 105). For the reasons expressed regarding other jurisdictions with a similar approach, we find the judge erred in granting summary judgment on cases governed by Wyoming law.

III

To briefly summarize our holdings in both appeals, we reverse the summary judgment entered in A–4760–14, and we reverse in part and affirm in part the order granting summary judgment in A–0164–15.

All Citations

Not Reported in A.3d, 2017 WL 3138003

Footnotes

1 All of the cases reviewed to date, except *Kendall v. Hoffman–La Roche, Inc. (Kendall I)*, No. A–2633–08 (App. Div. Aug. 5, 2010), *aff'd*, 209 *N.J.* 173 (2012), involved the 1984 Accutane warning. In *Kendall*, which has settled, the plaintiff received the 1984 warning when she began taking Accutane in 1997, and received the amended post-2002 warning after her diagnoses with ulcerative colitis. 209 *N.J.* at 182–86. Only one post-2000 warning case, *Tanna v. Hoffman–La Roche, Inc.*, ATL–L–3366–04, was tried; that case resulted in a hung jury and has not been retried.

2 We recognize that, as a general matter, Rule 1:36–3 precludes the citation of unpublished opinions by our courts. That *Rule*, however, provides an exception for the citation of unpublished opinions when necessary for, among other things,

res judicata and collateral estoppel purposes. Although the *Rule* may not have contemplated the use of an unpublished opinion in one or more cases within a larger group of collectively-managed cases, such as in this MCL litigation, we deem it appropriate not only to refer to some of our unpublished opinions for reasons expressed in the *Rule*'s exceptions, but also to point out that the trial judge remains bound to those unpublished opinions because they arose out of the same MCL litigation.

3 *Brill v. Guardian Life Ins. Co. of Am.*, 142 *N.J.* 520 (1995).

4 We note that an appeal is pending in *In re Accutane Litigation*, A–4698–14, from the trial judge's May 8, 2016 order that dismissed MCL cases in which the plaintiffs alleged they developed Crohn's disease as a result of taking Accutane.

5 The insert contained a "black box" warning about the risk of birth defects and of developing pseudotumor cerebri (intercranial hypertension), but not IBD.

6 "As part of that monitoring process, defendants collected data on adverse drug experiences ... or events through its call center and through MedWatch, the FDA's voluntary reporting system." *Ibid.* As required by 21 *C.F.R.* § 314.80(f) (2017), defendants "recorded the reports on an FDA form, listing among other information, a description of the event and whether it abated after the patient stopped using Accutane and returned after reintroduction (referred to as 'challenge'/'dechallenge'/'rechallenge')." *Id.* at 13–14.

7 Roaccutane, also spelled Roaccutan, is Accutane's European brand name.

8 Proctitis is an inflammation of the lining of the rectum.

9 Scientists have attempted to produce colitis in laboratory animals through vascular impairment and immunological methods.

10 Female patients also were required to sign a second "patient information/consent" form, which stated that the patient had read and understood the written material and had watched a video on contraception.

11 There are two types of epidemiological studies: experimental and observational. *Reference Manual on Sci. Evidence* 549, 555 (3d ed. 2011), which may be found at the following location: http://www.supremecourt.ohio.gov/LegalResources/LawLibrary/resources/scientificEvidence.pdf. Experimental studies, or double-blind randomized control trials, in which one group is exposed to an agent and the other is not, are "considered the gold standard for determining the relationship of an agent to a health outcome or adverse side effect." *Ibid.* There are no Accutane experimental studies because even though such studies have the potential to provide higher quality evidence, they cannot ethically be conducted if researchers suspect that a drug's side effects are harmful. *Id.* at 555–56. Instead, all Accutane epidemiological studies to date have been less rigorous observational studies. Unlike experimental studies in which risk factors can be controlled, observational studies generally focus on individuals living in a community, "for whom characteristics other than the one of interest, such as diet, exercise, exposure to other environmental agents, and genetic background, may distort a study's results." *Id.* at 556. "[T]he Achilles' heel of observational studies is the possibility of differences in the two populations being studied with regard to risk factors other than exposure to the agent." *Ibid.*

12 In *Bailey*, a trial judge found the plaintiffs failed to overcome the rebuttable presumption of adequacy afforded FDA-approved labeling even though the label had been significantly revised on multiple occasions since initial approval. 424 *N.J. Super.* at 304, 336. The *Bailey* trial judge found the plaintiffs "failed to present any evidence of deliberate concealment or nondisclosure of after-acquired knowledge" because there was no proof that defendants withheld any information on safety, including adverse event reports, prior to approval by the FDA. *Id.* at 315.

13 *McCarrell I and II*, *Kendall I and II*, *Sager*, *Gaghan*, and *Rossitto*.

14 We are not persuaded that our decision in *Spinden v. Johnson & Johnson*, 177 *N.J. Super.* 605, 606 (App. Div.), *certif. denied*, 87 *N.J.* 376 (1981) requires a different result. There, the plaintiff alleged warnings contained on packages of Ortho–Novum (birth control pills) which referred to the risk of developing thromboembolic disease were inadequate. The package insert provided in relevant part that:

> An increased risk of thrombo-embolic disease associated with the use of hormonal contraceptives has now been shown in studies conducted in both Great Britain and the United States.
>
> Retrospective studies of morbidity in Great Britain and studies of morbidity in the United States have shown a statistically significant association between thrombophlebitis, pulmonary embolism and cerebral thrombosis and the use of oral contraceptives....
>
> [*Id.* at 607.]

The trial judge in *Spinden* found these warnings were adequate as a matter of law and granted an involuntary dismissal. *Ibid.* In affirming, we found the "trial judge's reasoning that the phrase 'a statistically significant association' means a cause and effect relationship seems correct," mainly because it was expressed in the context of a clearer and more elaborate warning about " 'an increased risk of thromboembolic disease associated with the use of hormonal contraceptives ....'

" *Id.* at 608 (quoting *Goodson v. Searle Labs*, 471 *F. Supp.* 546, 547 (D. Conn. 1978)). This case is distinguishable because here the label warns only that Accutane has been "associated" with IBD—a term which, when used in a label, even defendants' own employees conceded could be susceptible to different meanings.

15 Even if it were otherwise, the law-of-the-case doctrine is not immutable; it is always to be balanced against "factors that bear on the pursuit of justice," and should never "be used to justify an incorrect substantive result." *Hart*, *supra*, 308 *N.J. Super.* at 498; *see State v. K.P.S.*, 221 *N.J.* 266, 276 (2015); *Toto v. Princeton Twp.*, 404 *N.J. Super.* 604, 618 (App. Div. 2009).

16 The judge referred to a January 25, 2005 letter, submitted by plaintiffs' counsel, pursuant to *Rule* 4:38A, for classification of Accutane cases as "a mass tort" (now known as "multicounty litigation" or "MCL") and centralized case management. In that letter, counsel advised of the sixty-eight Accutane cases pending in New Jersey (sixty-two were venued in Atlantic County) and the expectation of many more; he also asserted:

> These claims share common issues of law and fact, including whether Accutane causes the injuries alleged by plaintiffs, whether defendant adequately warned of the risks of ingesting Accutane, and whether defendant violated the New Jersey Products Liability Act in its marketing and sale of Accutane.
>
> [Emphasis added.]

17 As the popularity of mass torts at both the federal and state levels gained in popularity, commentators have argued in favor of modification to the choice-of-law practices to allow application of a single state's law in complex litigation. *See* Larry Kramer, *Choice of Law in Complex Litigation*, 71 *N.Y.U. L. Rev.* 547 (1996) (challenging the "consensus, at least, that ordinary choice-of-law practices should yield in suits consolidating large numbers of claims and that courts should apply a single law in such cases"). In 1993, the American Law Institute adopted and submitted to Congress for enactment, statutory recommendations for mass torts. American Law Institute, *Complex Litigation Project*, Proposed Final Draft (May 13, 1993). The Project proposed a set of choice-of-law rules for "mass-tort" actions transferred to federal courts, not state courts. Under that proposal, a court would consider a list of enumerated factors modeled on the Second Restatement, "with the object of applying, to the extent feasible, a single state's law to all similar tort claims being asserted against a defendant." *Id.* at § 6.01 (emphasis added). ALI's Project, however, was not enacted.

18 *See Utah Code Ann.* § 78B–6–703 (2017) (rebuttable presumption that product is free from any defect where in conformance with government standards); *Tenn. Code Ann.* § 29–28–104 (2017) (compliance with government standards creates rebuttable presumption that the product "is not in an unreasonably dangerous condition"); *Tex.Civ. Prac. & Rem.* § 82.007 (2015) (rebuttable presumption that manufacturer is not liable for failure to provide adequate warnings if the warnings were FDA-approved).

19 Each of these fourteen jurisdictions has adopted the learned intermediary doctrine. *See Stone v. Smith, Kline & French Labs.*, 447 *So.* 2d 1301, 1305 (Ala. 1984); *Carlin v. Superior Court*, 920 *P.*2d 1347, 1348–54 (Cal. 1996); *O'Connell v. Biomet, Inc.*, 250 *P.*3d 1278, 1281 (Colo. App. 2010); *Felix v. Hoffmann–La Roche, Inc.*, 540 *So.*2d 102, 104 (Fla. 1989); *Presto v. Sandoz Pharms. Corp.*, 487 *S.E.*2d 70, 73 (Ga. Ct. App. 1997); *Kirk v. Michael Reese Hosp. & Med. Ctr.*, 513 *N.E.*2d 387, 393 (Ill. 1987); *Tucker v. SmithKline Beecham Corp.*, 701 *F. Supp.* 2d 1040, 1066 (S.D. Ind. 2010); *Hyman & Armstrong, P.S.C. v. Gunderson*, 279 *S.W.*3d 93, 109 (Ky. 2008); *Janssen Pharmaceutica, Inc. v. Bailey*, 878 *So.*2d 31, 58 (Miss. 2004); *Martin v. Hacker*, 628 *N.E.*2d 1308, 1311 (N.Y. 1993); *De Oca v. Adventis Pharma*, 579 *F. Supp.* 2d 222, 227 (D.P.R. 2008); *Pittman v. Upjohn Co.*, 890 *S.W.*2d 425, 429 (Tenn. 1994); *Pfizer, Inc. v. Jones*, 272 *S.E.*2d 43, 44 (Va. 1980); *Estate of LaMontagne v. Bristol Meyers Squibb*, 111 *P.*3d 857, 862 (Wash. Ct. App. 2005).

20 These jurisdictions recognize the learned intermediary doctrine. *See Doe v. Alpha Therapeutic Corp.*, 3 *S.W.*3d 404, 419 (Mo. Ct. App. 1999); *Brochu v. Ortho Pharm. Corp.*, 642 *F.*2d 652, 656 (1st Cir. 1981) (applying New Hampshire law); *Ehlis v. Shire Richwood, Inc.*, 233 *F. Supp.* 2d 1189, 1196 (D.N.D. 2002) (applying North Dakota law), *aff'd*, 367 *F.*3d 1013 (8th Cir. 2004); *Menges v. Depuy Motech, Inc.*, 61 *F. Supp.* 2d 817, 830 (N.D. Ind. 1999) (applying Wisconsin law); *Thom*, *supra*, 353 *F.*3d at 852 (applying Wyoming law).

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