In re: ACCUTANE LITIGATION	:	SUPERIOR COURT OF NEW JERSEY APPELLATE DIVISION CONSOLIDATED APPEALS: DOCKET NO. A-2832-15 T1 DOCKET No. A-2833-15 T1 DOCKET NO. A-2834-15 T1 DOCKET No. A-2835-15 T1 Civil Action On Appeal From: Superior Court of New Jersey Law Division, Atlantic County Case No. 271 Sat Below: Hon. Nelson C. Johnson, J.S.C.

AMICUS CURIAE BRIEF OF NEW JERSEY DEFENSE ASSOCIATION

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PRELIMINARY STATEMENT

The New Jersey Defense Association (NJDA) respectfully submits this brief as amicus curiae in support of Defendants-Respondents Hoffmann-La Roche Inc. and Roche Laboratories Inc. (collectively, "Roche").

Under the laws of each state at issue in this appeal, proximate cause in a pharmaceutical warnings case hinges on whether different warnings would have changed the prescribing decision. This formulation of the proximate cause standard flows directly from the learned intermediary doctrine. Because this doctrine measures a company's duty through the adequacy of warnings to the prescribing doctor, the related proximate cause question naturally depends on whether different warnings would have changed the doctor's prescribing decision.

Plaintiffs and their amicus, New Jersey Association for Justice (NJAJ), ask this Court to depart from that clear standard by hinging proximate cause on whether (1) a doctor might have warned the patient differently had the doctor received a different warning and (2) the patient might have decided not to take the medicine if given a different warning. Both Plaintiffs and NJAJ invoke the informed consent doctrine to justify this facially speculative rule. But this argument conflates two distinct doctrines. Whereas the learned intermediary doctrine focuses on the interactions between the

company and the doctor, and thus the doctor's decision to prescribe, the informed consent doctrine focuses on interactions between the doctor and the patient. Informed consent has no applicability in cases where no physician has been joined as a party and no complaint has been lodged against the physician, and where the question instead is whether the doctor has been adequately warned.

Accordingly, this Court should adhere to treating the proximate cause question as distinct from the informed consent question, by hinging proximate cause on whether different warnings would have changed the prescribing decision.

STATEMENT OF AMICUS CURIAE

NJDA is a non-profit organization established in 1966, whose membership consists of approximately 650 New Jersey attorneys. NJDA members devote a substantial portion of their practices to representing private companies and public entities in the defense of civil lawsuits and claims in a wide variety of contexts, including personal injury, products liability, and professional negligence litigation.

The overarching purposes of NJDA are to encourage the prompt, fair, and just disposition of lawsuits, promote improvements in the administration of justice and the service of the legal profession to the public, support the improvement of the adversarial system of jurisprudence and operation of the

courts, work for the elimination of court congestion and delays in civil litigation, and sponsor continuing legal education through a series of educational seminars and its quarterly publication, New Jersey Defense.

NJDA submits this brief to address the serious public interests at stake in this appeal. In particular, NJDA asks this Court to consider its views on the harm that would be visited on defendants, especially members of New Jersey's vital pharmaceutical industry, if they were subjected to the unfair and unworkable proximate-cause standard advocated by Plaintiffs and NJAJ here.

NJDA is uniquely suited to address the important issues at stake in this appeal. As an organization devoted to improvements in the administration of justice and ensuring fairness in civil litigation, NJDA can provide this Court with a valuable perspective on the real-world deleterious implications of the standard advocated by Plaintiffs and NJAJ here.

FACTUAL & PROCEDURAL HISTORY

Amicus curiae NJDA adopts and incorporates by reference the Procedural History and Statement of Facts set forth in the Defendants-Respondents' Brief filed in connection with this appeal on August 12, 2016.

LEGAL ARGUMENT

I. Plaintiffs' Proposed Proximate Cause Standard Improperly Conflates the Learned Intermediary Doctrine and the Informed Consent Doctrine.

The learned intermediary doctrine and the informed consent doctrine are distinct legal doctrines. The former governs the provision of warnings from the manufacturer to the physician, and the latter focuses on the transmission of warnings from the physician to the patient.

The learned intermediary doctrine, under which a manufacturer's duty to warn runs only to the prescribing physician, focuses on the manufacturer's warning and the doctor's decision to recommend the medicine for a patient following the doctor's receipt of that warning. See Gaghan v. Hoffmann-La Roche Inc., Nos. A-2717-11, A-3211-11, & A-3217-11, 2014 WL 3798338, at *12 (App. Div. Aug. 4, 2014) (Aa1-Aa18).[1] Where a patient alleges that a manufacturer failed to meet its duty to warn the prescriber, that claim is necessarily governed by the learned intermediary doctrine.

In contrast, the informed consent doctrine, which concerns the interaction between the prescriber and the patient, is "predicated on the duty of a physician to disclose to a patient information that will enable him to 'evaluate knowledgeably the

[1] "Aa__" refers to *amicus* NJDA's appendix.

options available and the risks attendant upon each' before subjecting that patient to a course of treatment." Matthies v. Mastromonaco, 160 N.J. 26, 35 (1999).[2] Informed consent is therefore not implicated in a pharmaceutical failure-to-warn case, where, as here, a plaintiff does not fault her prescriber for failing to convey a direct warning about the condition at issue. See Scott v. Eli Lilly & Co., No. A-1701-14T4, 2016 WL 1741241, at *2 (App. Div. May 3, 2016) (Aa19-Aa20) (explaining that a complaint that a prescriber failed to warn of a medicine's risks is "a claim of professional malpractice based on lack of informed consent, not a products liability claim."); Gaghan, 2014 WL 3798338, at *13 (distinguishing a product liability failure-to-warn claim against the manufacturer of a prescription medicine from "the malpractice of the treating dermatologist in failing to give adequate advice about the serious side effects of Accutane and in failing to obtain [] informed consent"). Indeed, issues pertaining to prescriber-patient discussions are irrelevant to the question of whether a manufacturer had fulfilled its duty to the prescriber and, in turn, whether the manufacturer could be held liable for a plaintiff's alleged injuries.

[2] Contrary to NJAJ's suggestion, Roche does not dispute that a patient's prerogative to accept or reject a physician's prescription recommendation is relevant to the doctrine of informed consent.

Plaintiffs' proffered standard seeks to consider patient-prescriber discussions and a patient's informed consent, even when using Plaintiffs' proposed warning would have no effect on the prescriber's decision to prescribe.[3] This standard conflates the learned intermediary and informed consent doctrines.

By conflating these doctrines, Plaintiffs' standard would effectively make pharmaceutical defendants the guarantor of prescribers' duties under the informed consent doctrine. A company could, as here, directly warn by name of the relevant risk. A doctor could decide, exercising his or her judgment, not to share that risk with the patient. Under Plaintiffs' standard, the company would be at risk for that independent medical judgment, even in cases like these where the doctor is not sued or faulted by the plaintiff in any way. This completely contravenes the learned intermediary doctrine. As even its name indicates, this doctrine exists because, once a company warns a prescriber, the prescriber then uses her independent medical judgment to decide how and whether to warn

[3] The Supreme Court and this Court in Strumph, Gaghan, and Sager v. Hoffmann-La Roche, Inc., No. A-3427-09T4, 2012 WL 3166630, at *14 (App. Div. Aug. 7, 2012) (Aa1-Aa18), consistently defined proximate cause based on whether a different warning would had changed the doctor's prescribing decision. However, Plaintiffs' arguments based on language in Rossitto v. Hoffmann-La Roche Inc., Nos. A-1236-13 & A-1237-13, 2016 WL 3943335, at *17 (App. Div. July 22, 2016) (Aa36-Aa55), highlight the necessity for a clear and uniform proximate cause standard.

her patients. See Sager, 2012 WL 3166630, at *14 ("The physician's task is to 'inform himself of the qualities and characteristics of those products which he prescribes for . . . his patients, and to exercise an independent judgment, taking into account his knowledge of the patient as well as the product.'").

NJAJ relies on Niemiera for the proposition that informed consent factors into the proximate cause analysis. However, NJAJ fundamentally misconstrues the Supreme Court's opinion. As an initial matter, the plaintiff in Niemiera never alleged that the vaccine's manufacturer failed to adequately warn the prescriber:

> ***The question in this case is not the adequacy of Wyeth's warning.*** Rather, the question is whether the warning should have been communicated directly to the patient. It is conceded that Wyeth informed physicians through material that accompanied its product of the possible side-effects, including irreversible brain damage or death, attendant to the administration of this vaccine.

Niemiera by Niemiera v. Schneider, 114 N.J. 550, 558-59 (1989) (emphasis added). Upon holding that the learned intermediary doctrine applied and the manufacturer was not required to warn the patient directly, id. at 559-560, the Supreme Court turned to the analysis of the plaintiff's failure to warn claim against the physician under the doctrine of informed consent, id. at

562-568. Notably, the Court explained that the learned intermediary cannot be excused from providing proper warnings to her patients and that "[t]he concept of proper warning ***by*** the learned intermediary will blend in this context with the concept of informed consent." Id. at 562.

Thus, far from "requir[ing] that proximate cause under the LID accommodate the patient's [choice]," NJAJ Br. at 5, Niemiera stands for the straightforward proposition that a prescriber's failure to communicate risks to her patient may render her liable under the informed consent doctrine. Niemiera, 114 N.J. at 562. In other words, Niemiera underscores that manufacturers should not be held the guarantor of a prescriber's duty under the informed consent doctrine.

Under these rationales, the New Jersey Supreme Court, the courts from each of the jurisdictions in this appeal, and courts in numerous other jurisdictions have rejected the same arguments raised by Plaintiffs and articulated the same prescriber-focused proximate cause standard: to survive summary judgment, a "plaintiff must show that adequate warnings would have altered her doctors' decision to prescribe." Strumph v. Schering Corp., 256 N.J. Super. 309, 323 (App. Div. 1992) (Skillman, J., dissenting), rev'd on dissent, 133 N.J. at 34; see also Gaghan, 2014 WL 3798338, at *15-16 (adopting the same prescriber-focused proximate cause standard even though the prescriber had

testified that he "would have passed [revised warning] information to the patient," and explaining that because a prescription medicine's warning "is directed to the doctor, the adequacy of the warning must be measured from the doctor's point of view."); Motus v. Pfizer, Inc., 196 F. Supp. 2d 984, 995-97 (C.D. Cal. 2001) (summary judgment is appropriate unless better warning "would have changed the treating physician's decision to prescribe the product for the plaintiff"), aff'd, 358 F.3d 659 (9th Cir. 2004); Vanderwerf v. SmithKlineBeecham Corp., 529 F. Supp. 2d 1294, 1312 (D. Kan. 2008) (granting summary judgment because "[n]othing in the record discredits any testimony of the prescribing physicians that they still would have prescribed" the medicine under different warnings); Willett v. Baxter Int'l, Inc., 929 F.2d 1094, 1099 (5th Cir. 1991) ("Because the defective aspect of the product must cause the injury, the plaintiff must show that a proper warning would have changed the decision of the treating physician, *i.e.* that but for the inadequate warning, the treating physician would not have used or prescribed the product."); Centocor, Inc. v. Hamilton, 372 S.W.3d 140, 172 (Tex. 2012) (affirming summary judgment because "the [plaintiffs] failed to show that the warning's alleged inadequacies regarding lupus-like syndrome would have changed [plaintiff's] prescribing physicians' decision to prescribe Remicade"); Wyeth v. Weeks, 159 So. 3d 649, 673-74 (Ala. 2014)

("In short, the patient must show that, but for the false representation made in the warning, the prescribing physician would not have prescribed the medication to his patient."); Dietz v. Smithkline Beecham Corp., 598 F.3d 812 (11th Cir. 2010) ("The doctor provided explicit, uncontroverted testimony that, even when provided with the most current research and FDA mandated warnings, he still would have prescribed Paxil for [Appellant's] depression. Pursuant to Georgia's learned intermediary doctrine, this assertion severs any potential chain of causation through which Appellant could seek relief, and Appellant's claims thus fail."); Janssen Pharmaceutica, Inc. v. Bailey, 878 So. 2d 31, 58 (Miss. 2004) ("The Plaintiffs bear the burden of establishing that Propulsid was the cause of their injuries and that 'an adequate warning would have convinced the treating physician not to prescribe the product for the [P]laintiff[s].").

Indeed, even NJAJ cites numerous cases that support the prescriber-focused proximate cause inquiry. For example, in Gove v. Eli Lilly & Co., 394 F. App'x 817, 819 (2d Cir. 2010), the Second Circuit, applying Arizona law, affirmed summary judgment for lack of proximate cause upon concluding "that there is no evidence that [plaintiff's] treating practitioners would have ***altered their decision to prescribe*** Zyprexa had a different warning been provided by Eli Lilly." Id. (emphasis added). The

court emphasized that "[b]ecause [plaintiff's] practitioners were aware of the risks associated with Zyprexa but ***would not have made different clinical treatment decisions had alternative warnings been provided,*** [plaintiff] has failed to establish that Eli Lilly's allegedly inadequate warnings regarding the potential risks associated with Zyprexa were the proximate cause of her diabetic condition." Id. (emphasis added).

Similarly, NJAJ cites McNeil v. Wyeth, 462 F.3d 364, 372 (5th Cir. 2006), which frames the proximate cause inquiry under Texas law as hinging on "whether [the prescriber] would have prescribed the drug had the label's warning been adequate." To the extent there is any doubt regarding the relevant standard, the Texas Supreme Court recently emphasized that, in light of the learned intermediary doctrine, the proximate cause analysis focuses on the physician's decision to prescribe. Centocor, Inc. v. Hamilton, 372 S.W.3d 140, 154 (Tex. 2012) (finding no proximate cause because plaintiffs "failed to present any evidence that including additional post-approval reports in the warning would have caused [plaintiff's] physicians to change their prescription").

Finally, NJAJ's citation of Sanchez v. Boston Scientific Corp., 38 F. Supp. 3d 727, 736 (S.D.W. Va. 2014), which denied summary judgment under California law because prescriber testified a different warning "would affect her 'risk/benefit

analysis' in ***prescribing*** the Pinnacle device," (emphasis added), further underscores the prescriber-focused proximate cause standard.

II. Plaintiffs' Proposed Proximate Cause Standard Improperly Exceeds the Scope of the Relevant Inquiry.

All parties to pharmaceutical product liability actions benefit from clear tort standards. Recognizing that pharmaceutical companies are required by law to tailor their medicines' warnings only to physicians, the trial court's ruling properly focused on the relationship between the warnings provided by pharmaceutical manufacturers and the medical judgment of the learned intermediaries receiving those warnings. This standard provides the courts and all parties with a clear test with respect to warning adequacy and the related proximate cause standard, leaving intact a plaintiff's right to pursue an informed consent claim against her prescriber for failing to pass along the warning.

In contrast, Plaintiffs' alternative proximate cause standard improperly hinges the proximate cause inquiry on two layers of speculation: first, that a differently-worded version of a warning already in the label might have altered a physician's risk discussion with her patient, and second, that having had a possibly different discussion, the patient would have refused the medicine. Plaintiffs' request for such a

standard, which turns on a plaintiff's after-the-fact testimony about what he might have done years ago, is simply another way of plaintiffs asking this Court to eliminate proximate cause as a basis for summary judgment. See In Re: Accutane Litigation, 2016 WL 355843, at *4 (Law Div. Jan. 29, 2016) ("Human nature is what it is, the common law acknowledges that, after the fact, upon diagnosis of a condition said to be associated with a medication, that the patient is likely to testify that she/he would never have taken the medication had they known then, what they know now.") (Ja15).

It would be inconsistent with both the goal of applying clear legal standards and with the law's truth-seeking function to hinge liability on a lawyer's ability: (1) to induce a doctor to say that she might have passed along different information if it were in the warning, when the facts show that the doctor chose not to pass along the direct IBD warning she indisputably was given; and (2) to induce his client to say that information would have changed the client's decision years ago to use the medicine. Thus, this Court should confirm that the proximate cause inquiry in these cases focuses on whether a different warning would have changed a physician's decision to prescribe the medicine.

III. Adoption of Plaintiffs' Proposed Standard Would Result in Numerous Practical Problems for New Jersey Trial Judges.

This Court also should reject Plaintiffs' and NJAJ's proposed standard as impracticable and exceedingly problematic for trial courts. A standard that grafts informed consent concepts onto the proximate cause analysis in pharmaceutical product liability cases presents significant real-world problems, and is not as easy to implement as Plaintiffs and NJAJ would have this Court believe. That impracticability is yet another reason why this Court should affirm the decision under review.

If this Court accepts Plaintiffs' and NJAJ's position, then the trial court on remand in this case – and trial courts in pharmaceutical product liability cases statewide – will have to instruct juries on informed consent concepts, despite crucial differences between the purposes served by that doctrine and those served by the learned intermediary doctrine. In addition to being legally inapplicable to cases involving no claims against a doctor, informed consent concepts are of no practical value in a pharmaceutical product liability case and would have no effect beyond rendering the jury instruction exceedingly complicated and confusing.

Primarily, the objective inquiry in the informed consent context is incompatible with the subjective proximate cause

inquiry that must be answered by juries in product liability cases. Compare N.J. Model Civil Jury Charge 5.50C ("Informed Consent") at 4 (revised 3/02) ("[T]he issue to be resolved is not what this plaintiff would have done. You must decide whether a reasonably prudent person would not have consented (or chosen another course of treatment), if provided with material information which you find the doctor failed to provide in this case."), with N.J. Model Civil Jury Charge 5.40C ("Failure to Warn/Instruct") at 7 (revised 10/01) (providing that it is plaintiff's burden to prove "[t]hat the *[Plaintiff]* would have followed an adequate warning/instruction if it had been provided," and recognizing that defendant is permitted to introduce plaintiff-specific evidence that "notwithstanding the knowledge imparted by the warning, plaintiff would have proceeded voluntarily and unreasonably to subject himself or herself to the dangerous product" (citing Coffman v. Keene Corp., 133 N.J. 581, 609 (1993))).

Under Plaintiffs' and NJAJ's proposal, therefore, courts in pharmaceutical product liability cases would somehow have to instruct jurors to consider whether a "reasonably prudent patient" would consent to taking the medication based on what information the plaintiff claims the doctor should have provided, while also instructing those jurors that the causation question they must answer is the subjective inquiry of whether

this plaintiff proved that his doctor would not have prescribed the drug if the doctor had received that allegedly lacking information.

Further complicating matters, the informed consent law on which Plaintiffs and NJAJ rely requires jurors to consider not only the objective mindset of a reasonably prudent patient, but also the specific doctor's knowledge of the specific patient's position, when determining which of all possible risks should have been communicated to the particular patient. See Largey v. Rothman, 110 N.J. 204, 211-12 (1988); see also N.J. Model Civil Jury Charge 5.50C ("Informed Consent") at 2-3 ("The doctor is not required to disclose to the patient all the details of a proposed operation or treatment or all the possible risks, no matter how small or remote. The doctor is not required to communicate those dangers known to the average person or those dangers the patient has already discovered. Taking into account what the doctor knows or should know to be the patient's need for information, the doctor must disclose the medical information and risks which a reasonably prudent patient would consider material or significant in making the decision about what course of treatment, if any, to accept.").

In sum, it simply makes no sense to insert informed consent concepts into a case in which no doctor is a party and in which no party alleges wrongdoing by a doctor. To do so would

needlessly, but extensively, complicate trial courts' ability to instruct jurors and confuse jurors in their efforts to understand and apply the relevant product liability law.

CONCLUSION

For the foregoing reasons, this Court should affirm the trial court's decisions dismissing Plaintiffs' cases for lack of proximate cause.

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